PATENT ASSIGNMENT

Electronic Version v1.1
Stylesheet Version v1.1

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	Patent's Purchase Agreement

CONVEYING PARTY DATA

Name	Execution Date
GENOVAX S.R.L.	08/27/2012

RECEIVING PARTY DATA

Name:	MEDIOLANUM FARMACEUTICI S.P.A.
Street Address:	Via S.G. Cottolengo, 15
City:	Milano
State/Country:	ITALY
Postal Code:	20143

PROPERTY NUMBERS Total: 1

Property Type	Number
Application Number:	12997630

OP $40.00 12997630

CORRESPONDENCE DATA

Fax Number: 2126618002
Correspondence will be sent via US Mail when the fax attempt is unsuccessful.
Phone: 212-661-8000
Email: ssalvadori@lmiplaw.com
Correspondent Name: Lucas & Mercanti, LLP
Address Line 1: 475 Park Avenue South
Address Line 2: 15th Floor
Address Line 4: New York, NEW YORK 10016

ATTORNEY DOCKET NUMBER:	907-1005
NAME OF SUBMITTER:	Silvia Salvadori

Total Attachments: 42
source=Patent's Purchase Agreement (Assignment)#page1.tif
source=Patent's Purchase Agreement (Assignment)#page2.tif
source=Patent's Purchase Agreement (Assignment)#page3.tif
source=Patent's Purchase Agreement (Assignment)#page4.tif

source=Patent's Purchase Agreement (Assignment)#page5.tif
source=Patent's Purchase Agreement (Assignment)#page6.tif
source=Patent's Purchase Agreement (Assignment)#page7.tif
source=Patent's Purchase Agreement (Assignment)#page8.tif
source=Patent's Purchase Agreement (Assignment)#page9.tif
source=Patent's Purchase Agreement (Assignment)#page10.tif
source=Patent's Purchase Agreement (Assignment)#page11.tif
source=Patent's Purchase Agreement (Assignment)#page12.tif
source=Patent's Purchase Agreement (Assignment)#page13.tif
source=Patent's Purchase Agreement (Assignment)#page14.tif
source=Patent's Purchase Agreement (Assignment)#page15.tif
source=Patent's Purchase Agreement (Assignment)#page16.tif
source=Patent's Purchase Agreement (Assignment)#page17.tif
source=Patent's Purchase Agreement (Assignment)#page18.tif
source=Patent's Purchase Agreement (Assignment)#page19.tif
source=Patent's Purchase Agreement (Assignment)#page20.tif
source=Patent's Purchase Agreement (Assignment)#page21.tif
source=Patent's Purchase Agreement (Assignment)#page22.tif
source=Patent's Purchase Agreement (Assignment)#page23.tif
source=Patent's Purchase Agreement (Assignment)#page24.tif
source=Patent's Purchase Agreement (Assignment)#page25.tif
source=Patent's Purchase Agreement (Assignment)#page26.tif
source=Patent's Purchase Agreement (Assignment)#page27.tif
source=Patent's Purchase Agreement (Assignment)#page28.tif
source=Patent's Purchase Agreement (Assignment)#page29.tif
source=Patent's Purchase Agreement (Assignment)#page30.tif
source=Patent's Purchase Agreement (Assignment)#page31.tif
source=Patent's Purchase Agreement (Assignment)#page32.tif
source=Patent's Purchase Agreement (Assignment)#page33.tif
source=Patent's Purchase Agreement (Assignment)#page34.tif
source=Patent's Purchase Agreement (Assignment)#page35.tif
source=Patent's Purchase Agreement (Assignment)#page36.tif
source=Patent's Purchase Agreement (Assignment)#page37.tif
source=Patent's Purchase Agreement (Assignment)#page38.tif
source=Patent's Purchase Agreement (Assignment)#page39.tif
source=Patent's Purchase Agreement (Assignment)#page40.tif
source=Patent's Purchase Agreement (Assignment)#page41.tif
source=Patent's Purchase Agreement (Assignment)#page42.tif

MEDIOLANUM FARMACEUTICI S.p.A.

-and-

GENOVAX S.r.l.

PATENT's PURCHASE AGREEMENT

THIS AGREEMENT is made the 14th day of September, 2012

BETWEEN

(1) **Mediolanum farmaceutici S.p.A.**, having its principal place of business at Via S.G. Cottolengo 15, 20143 Milan, Italy ("Mediolanum");

AND

(2) **Genovax S.r.l.**, having its principal place of business at Via Ribes 5 c/o Bioindustry Park SilvanoFumero, 10010 Colleretto Giacosa (Turin), Italy ("Genovax");

WHEREAS:

(A) Genovax possesses and holds certain proprietary information, Patent Rights (as thereafter defined) and Genovax Know-How (as thereafter defined) regarding a Compound (as thereafter defined) to be developed;

(B) Mediolanum wishes to purchase the Patent Rights and Genovax Know-How relevant to the Compound for the Territory (as thereafter defined) with the aim to develop or have developed, register or have registered, manufacture or have manufactured and commercialise or have commercialised the Compound and the Products (as thereafter defined) in the Territory;

(C) Genovax wishes to sell the Patent Rights and Genovax Know-How relevant to the Compound for the Territory; and

(D) Genovax and Mediolanum are willing to enter into an agreement for the sale and purchase of the Patent Rights and Genovax Know-How relevant to the Compound in accordance with the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the foregoing premises and the following mutual covenants and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged,

THE PARTIES HEREBY AGREE AS FOLLOWS:

1. **Definitions and Interpretation**

1.1 In this Agreement the following words and phrases shall have the following meanings unless the context requires otherwise:

- **"Affiliate"** shall mean any company, partnership, joint venture or other business entity which Controls, is Controlled by or is under common Control with, either Party. Mediolanum's Affiliates shall also include a Mediolanum shareholders' controlled company.

- **"Agreement"** shall mean this document and any and all annexes, appendices and other addenda to it, as may be amended from time to time in accordance with the provisions of this Agreement.

- **"Chemical Class"** shall mean therapeutic vaccines targeting telomerase.

- **"Compound"** shall mean the compound currently defined as GX301 and covered by the Patent Rights, which is described in **Schedule 1** attached hereto.

- **"Competent Authority"** shall mean any national or local agency, authority, department, inspectorate, minister, ministry official, parliament or public or statutory person (whether autonomous or not) of any government of any country having jurisdiction over any of the activities contemplated by this Agreement or the Parties.

- **"Confidential Information"** shall mean any non-public information disclosed by one Party to the other, including but not limited to samples, data, know-how, technical and non-technical materials, test results and specifications, sensitive business or financial information, disclosed orally or in writing or otherwise made available to the other Party in relation to the performance of this Agreement, irrespectively of having such information been marked as confidential. For greater clarity, (i) Genovax's Confidential Information shall include the Compound, all Genovax Know-How and any New IP Rights in the Field (as applicable) as defined under Section 6.3, and (ii) Mediolanum's Confidential Information shall include Mediolanum's Know-How.

- **"Control"**, for the purpose of Affiliate definition,shall mean the direct or indirect ownership of fifty percent (50%) or more of the issued share capital or any comparable equity or ownership interest with respect to a business entity or the legal power to direct or cause the direction of the general management and policies of the Party in question.

- **"Development Milestones"** shall mean the milestones defined under the Development Plan.

- **"Development Monitoring Committee"** or **"DMC"** shall mean the committee formed of representatives from both Parties, established under Section 4 hereto as an overseeing body.

- **"Development Plan"** shall mean the program of activities, such as but not limited to researches, studies and Marketing Authorisation procedures, needed to develop the Compound in order to obtain the Product and better described in Section 4.2 hereto. An initial and tentative Development Plan is already set forth in **Schedule 2** hereto and it will be revised and amended as needed.

- **"Development Study/ies"** shall mean any activity regarding the Compound which is foreseen by the Development Plan and to be financed and managed by Mediolanum in accordance with Section 4.5 hereto and in line with the Development Plan.

- **"Disclosing Party"** shall mean the Party which discloses Confidential Information to the other Party.

- **"Documents"** shall mean any reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, paper, notebooks, books, files, ledgers, records, tapes, discs, diskettes, CD-ROM, computer programs and documents thereof, computer information storage means, samples of material, other graphic or written data and including any other media.

- **"Effective Date"** shall mean the date first above written.

- **"Field of Use"** shall mean any and all therapeutic, prophylactic or other indications for the Products in the treatment of cancer in humans.

- **"First Commercial Sale"** shall mean, in relation to each country where the Product is marketed, the date of first sale of a Product by Mediolanum, its Affiliates or a Licensee in said country.

- **"Genovax Know-How"** shall mean any and all technical and other information relating to the Compound, obtained by Genovax prior to the Effective Date and described under Schedule 4, including, but not limited to, full information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, assays, plans, procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), processes (including manufacturing processes, specifications and techniques), laboratory records, chemical, pharmacological, toxicological, clinical, analytical and quality control data, trial data, case report forms, data analyses, reports, manufacturing data or summaries and information contained in submissions to and information from ethical committees and Regulatory Authorities. Genovax Know-How includes Documents containing Genovax Know-How, including trade secrets, copyright, database or design rights protecting such Genovax Know-How but excludes the Results and the Improvements.

- "**Mediolanum Know-How**" means any and all information relating to the Compound and the Product obtained from the Effective Date, including but not limited to, Results, Improvements and Improvement Patents.

- "**Improvement(s)**" means any improvement in or modification to or new application of the Compound; and any new know-how or invention (whether patented or the subject of patent applications or otherwise) whereby the Compound or Product may be manufactured or used more advantageously or more economically or more extensively and which is identified or developed in the performance of the Development Plan and during the Term of this Agreement.

- "**Improvement Patents**" means any patents, patent applications and patents granted on such applications claiming an Improvement and any amendments, extensions, re-examinations (including Supplementary Protection Certificates granted in the EU or equivalent rights elsewhere in the Territory), divisional applications, continuations, continuations-in-part, re-issues or patents of addition based on any of them.

- "**Legal Requirements**" shall mean any and all applicable current or future law, regulation, directive, instruction, direction or rule of any Competent Authority including any amendment extension or replacement thereof, which is in force.

- "**Licensee**" shall mean any Third Party to which Mediolanum has granted a license under the Patent Rights and/or the Genovax Know How and/or the Mediolanum Know-How.

- "**License Income**" shall mean all amounts received by Mediolanum from any Licensee, including (but not limited to) any entry fee, milestone payments, royalty payments, profit share payments or other amounts linked to or calculated based upon the Net Sales of Products but excluding amounts possibly paid by such Licensee to co-finance the Development Plan.

- "**Major Country**" shall mean Top 5 European Countries, US and Japan.

- "**Marketing Authorisation**" means all approvals (including pricing and reimbursement approvals) licences, registrations or authorisations of any Regulatory Authority, necessary for the manufacture and sale of a Product in a regulatory jurisdiction.

- "**Net Sales**" shall mean the gross amounts deriving from the sale of each Product(s), less the following deductions:

  - transportation charges, and other charges, such as insurance, relating thereto,

  - sales and excise taxes or customs duties paid by the seller and any other governmental charges imposed upon the sale of such Product(s),

- distributors' fees, commissions, rebates, retroactive price reductions, or allowances actually granted or allowed, including government and managed care rebates,
- quantity discounts, cash discounts or charge-backs granted, allowed or incurred in the ordinary course of business in connection with the sale of the such Product(s), and
- allowances or credits given to customers and not in excess of the selling price of such Product, on account of rejection, recalls or return of such Product(s).

For clarity, Net Sales shall further exclude any amount received from sale or transfer of Product(s): (i) among Mediolanum and its Affiliates, or (ii) at or below costs of goods for compassionate use or in connection with research and development activities, including performing clinical trials.

- **"Party(-ies)"** shall mean Genovax and Mediolanum.

- **"Patent Rights"** shall mean the patents and patent applications listed in Schedule 3, together with all inventions disclosed or claimed therein or covered thereby, any patents which may be granted on such application(s), including without limitation, the related process of manufacture and any divisional applications and patents, filings, renewals, continuations, continuations-in-part, patents of addition, amendments, extensions (including patent term extensions), reissues, substitutions, confirmations, registrations, revalidation and additions of or to any of them, as well as any supplementary protection certificates and equivalent protection rights in respect of any of them.

- **"Product"** shall mean each finished product which (i) exploits a Patent Right and/or (ii) contains the Compound, inserted in a ready-to-use package, ready for commercialisation and consumption which has obtained the marketing authorization by a Regulatory Authority.

- **"Receiving Party"** shall mean the Party which receives Confidential Information from the other Party.

- **"Regulatory Authority (-ies)"** shall mean any national, supranational (e.g., the European Commission, the European Agency for the Evaluation of Medicinal Products or the Food and Drug Administration), regional, federal, state or local regulatory agency, department, bureau, commission, council or other governmental entity in any country involved in the granting of Marketing Authorisation for pharmaceutical products.

- **"Results"** shall mean all results, including inventions, Improvements, data, Document, patent rights, Improvement Patents, know-how (whether patentable or not), developed or conceived in the performance of the Development Plan or arising pursuant to it.

- "**Royalty Bearing Product**" shall mean Products being covered by a Valid Patent in a country, said Valid Patent being maintained in such country.

- "**Term**" shall have the meaning set forth in Clause 10.1.

- "**Territory**" shall mean all the countries of the World.

- "**Third Party(-ies)**" shall mean any person or entity other than Mediolanum, Genovax and their respective employees or Affiliates.

- "**Valid Patent**" shall mean a Patent Right that has been officially granted the status of patent in a country by the patent office of that country and has obtained a formal number of patent with relevant expiration date.

1.2 **In this Agreement:**

- headings are inserted for convenience only and shall not affect the interpretation of any provision of this Agreement;
- unless the contrary intention appears, reference to the words "include" or "including" are to be construed without the limitation to the generality of the preceding words; and
- reference to any statute or regulation includes any modification to or re-enactment of that statute or regulation.

2. Object of the Agreement

2.1 Genovax herewith sells to Mediolanum, and Mediolanum herewith buys any and all existing rights, data and information on the Compound, the Patents Rights and Genovax Know-How, such assignment being effective upon the Effective Date.

2.2 Immediately upon the Effective Date, the Parties shall sign and execute all necessary documents to formalise the transfer of the Patents Rights in Mediolanum's name and thereafter Mediolanum shall have the obligation to maintain and keep in force the Patents Rights at its own costs and expenses.

2.3 It is understood and agreed that, should Mediolanum at any time prior to the commercialisation of the Product, intend to abandon the Patent Rights in one or more countries in which a Valid Patent exist, it shall provide Genovax with a written communication in that respect at least 90 days prior to the date in which the abandonment would occur. Genovax shall have the right to obtain, under no consideration, the assignment of the Patent Rights in such Countries, provided that Genovax will support all relevant

administrative costs and expenses. It is furthermore understood and agreed that, should Mediolanum intend to abandon the Patent Rights in all the countries where such Patent Rights exist and should Genovax exercise the right to be assigned such Patent Rights according to this Section 2.3, the provisions set out under following Section 11.3 shall apply.

2.4 Mediolanum shall apply its reasonable best efforts to develop and/or have developed the Compound with the aim of obtaining and registering the Product(s) for using, selling, offering for sale, importing, exporting, distributing and commercialising, and/or for having used, offered for sale, imported, exported, distributed and commercialised, the Product(s) in the Field of Use in the Territory.

2.5 Development program and strategy will be jointly discussed by the Development Monitoring Committee in order to set up a Development Plan and ultimately decided by Mediolanum in accordance with Section 4 hereto. For the sake of clarity, it is agreed that Mediolanum shall have final say in all decisions relating to development, expenses, regulatory, marketing, reimbursement approval and commercialisation matters of the Compound and the Product(s).

2.6 It is understood and agreed that this Agreement shall not limit, in any manner whatsoever, Genovax's right to conduct research activities (also under a research agreement possibly executed with a Third Party) inside the Field of Use and/or the Chemical Class, provided however that: Mediolanum shall be granted a right of first negotiation, in accordance with following Section 6.3, in relation to the possible results deriving thereof.

2.7 Notwithstanding the above, Genovax shall not investigate or research or use in any way whatsoever the Compound, the Genovax Know-How, the Mediolanum Know-How and the Patent Rights other than as necessary to perform its obligations under this Agreement. For the sake of clarity, it is understood and agreed by the Parties that any and all derivatives or progeny of the Compound or of the Product or Improvement or Improvement Patent discovered or identified by Genovax shall not be part of the New IP Rights in the Field referred to at Section 6.3 hereto as they will, instead, automatically fall within the scope of the Patent Rights object of this Agreement.

2.8 **Assignment.** It is understood and agreed between the Parties that, should Mediolanum wish or intend to assign the Patent Rights and the Genovax Know-How to a Third Party ("**Assignee**"):

(i) Mediolanum shall obtain Genovax's prior consent, in accordance with Section 13.1 hereto, such consent not to be unreasonably withheld or delayed by Genovax subject to following Section 2.8(ii); and

(ii) This Agreement shall be as well assigned to the Assignee, on even date of the assignment of the Patent Rights and Genovax's Know-How, so that the Assignee irrevocably and immediately assumes all duties, responsibilities, rights and obligations of Mediolanum as set forth in this Agreement.

3. Payments and Royalties

3.1 **Payments.** For the acquisition of the Patent Rights and the Genovax Know-How, Mediolanum shall pay to Genovax the following amounts:

3.1.1 if any, on the Effective Date;

3.1.2 if any, after 24 months from the Effective Date;

3.1.3 if any, after 36 months from the Effective Date.

3.1.4 The Parties expressly agree that, should the Agreement be earlier terminated, or any of the Discontinuation Events or of the Other Event, as defined, respectively, under Sections 5.3 and 5.4 below, occur:

- after the Effective Date and prior to the expiration of a 24 months period from the Effective Date, payments under Sections 3.1.2 and 3.1.3 shall not be due to Genovax;
- after 24 months from the Effective Date and prior to the expiration of a 36 months period from the Effective Date, payment under Section 3.1.3 shall not be due to Genovax.

Unless otherwise stated in this Agreement, it is understood and agreed between the Parties that in no case Mediolanum shall be refunded of any of the amounts already paid under Sections 3.1.1, 3.1.2 and 3.1.3.

3.1.5 The Parties agree that the amount referred to at Section 3.1.1 above shall be paid by Mediolanum at 10 (ten) days from the date of the relevant Genovax's invoice, while the amounts referred to at Sections 3.1.2 and 3.1.3 above shall be paid by Mediolanum at 60 (sixty) days from the date of the relevant Genovax's invoices.

3.2 **Royalties.** Mediolanum further agrees to pay to Genovax, during the Royalty Term:

3.2.1 royalty rate of the Net Sales for all Royalty Bearing Products directly commercialised by Mediolanum and its Affiliates; and

3.2.2 royalty rate of the License Incomes that Mediolanum receives from Licensees; in such a case, Genovax's royalty shall be calculated based on the invoices issued by Mediolanum to Licensees.

3.3 It is agreed and understood that in case a Valid Patent is not granted in a certain country then the royalty to be paid by Mediolanum to Genovax shall be:

(i) of the Royalties set forth in Section 3.2.1 above for a period of ten years from the date of the First Commercial Sale in said country; and

(ii) of the License Incomes, if any, that Mediolanum receives from a Licensee for a period of ten years from the date of the First Commercial Sale in said country.

3.4 Within forty-five (45) days after the end of each calendar quarter, Mediolanum shall send to Genovax (i) a statement of the amount of Net Sales for all Royalty Bearing Products generated by Mediolanum or an Affiliate; (ii) a statement of the License Incomes, if any, received by Licensees during the applicable calendar quarter and (iii) a statement of the amount of Net Sales of Products and of License Income, if any, received by a Licensee during the applicable calendar quarter in such country in which a Valid Patent is not granted for the purposes of previous Section 3.3. Such statements shall contain reasonable detail regarding the calculation of the Net Sales and/or License Income, as applicable, and the payment owed.

3.5 Following receipt of the statements mentioned under previous Section 3.4, Genovax shall issue its invoice to Mediolanum. Royalties shall be paid by Mediolanum to Genovax within 60 days from relevant Genovax's invoice date. All amounts payable to Genovax under this Agreement shall be paid in Euros by wire transfer to a bank account specified in writing by Genovax. The Parties agree that such Royalty payments are out of VAT.

3.6 On a country-by-country basis, Royalties shall be paid by Mediolanum to Genovax from the First Commercial Sale until the Product(s) is(are) covered by a Valid Patent in such country (the "Royalty Term"), unless an earlier termination of this Agreement occurs prior to the expiration of the Royalty Term.

3.7 Mediolanum shall keep accurate books and accounts of record in connection with Net Sales and receipt of License Income in sufficient detail to permit verification of Mediolanum's payments under Sections 3.2 and 3.3 (as applicable). Mediolanum shall obtain that its

Affiliates and Licensees keep accurate books and accounts of records in connection with their sales of Products for which a royalty is due hereunder. Mediolanum shall maintain its records for a period of three (3) years from the end of the calendar quarter in which sales occurred.

3.8 Genovax, at its expense, through an independent and certified public accountant reasonably acceptable to Mediolanum, shall have the right to access Mediolanum's relevant books and records for the sole purpose of verifying Mediolanum's payments to Genovax under Sections 3.2 and 3.3 (as applicable) during any portion or all of the preceding three (3) years from the day in which the payment accrued; such access shall be conducted after reasonable prior written notice by Genovax to Mediolanum, during Mediolanum ordinary business hours and without a major involvement of Mediolanum's personnel, it shall not be more frequent than once during any calendar year and shall not include any books and records that were previously accessed pursuant to this Section 3.8. Such accountant shall execute a confidentiality agreement with Mediolanum and shall only disclose to Genovax whether Mediolanum paid Genovax the correct amounts pursuant to Sections 3.2 and 3.3 (as applicable) during the audited period and if not, any information necessary to explain the source of the discrepancy. If such audit determines that Mediolanum paid Genovax less than the amount due, then Mediolanum shall promptly pay Genovax an amount equal to such underpayment, and if the amount of underpaid exceeds ten percent (10%) of the amount due over the audited period, Mediolanum shall also reimburse Genovax for the reasonable costs of such audit (including the reasonable fees and expenses of the certified public accountant). In the event such audit determines that Mediolanum paid Genovax more than the amount due in respect of the audited period, then Genovax shall promptly issue a refund to Mediolanum of such overpayment.

4 Conduct of Development

4.1 Both Parties shall carry out their respective obligations as set out in this Agreement and its Schedules.

4.2 Development Monitoring Committee (DMC). Within fifteen (15) days of the Effective Date Genovax and Mediolanum shall establish the Development Monitoring Committee, which shall have overall responsibility for monitoring progress and facilitating the success of the Parties' efforts under this Agreement towards the development of the Product(s). The purposes of the DMC shall be to evaluate and discuss the development program and strategy in order to amend and revise the Development Plan, to coordinate the Parties' activities

hereunder and to resolve possible issues arising during the Development Studies. Role, composition and tasks of DMC will be agreed upon in good faith by the Parties taking into consideration Mediolanum's leading role and final decision authority.

4.3 The DMC shall be composed by a pair of primary technical contact persons (the "**Primary Contacts**"), one to be appointed by each Party. As of the Effective Date, Mediolanum' Primary Contact shall be Dr. Francesco Gianese and Genovax's Primary Contact shall be Prof. Franco Indiveri. Either Party may change its designated Primary Contact at any time, upon written notice to the other Party. The DMC shall, among other things, have responsibility (i) for setting up a precise plan of Development Studies, with relevant estimates of costs, timing and clearly defined Development Milestones (the "**Development Plan**") within 10 (ten) days after the Effective Date and, (ii) for key operational matters highlighted in the Development Plan and Development Studies. The Development Plan may be revised and amended by the DMC as needed, in order to ensure the fast and successful development of the Compound. The Primary Contacts will communicate regularly and when necessary hold meetings or conferences in order to review progress and timelines.

4.4 Meetings. The DMC shall hold meetings at such reasonable times as it elects to do so. Mediolanum shall be responsible for both Parties' reasonable travel expenses of participating in the Development Monitoring Committee, being it agreed and understood that Genovax's reasonable travel expenses shall be previously approved in writing by Mediolanum. The Primary Contacts will alternate responsibility for preparing minutes of each meeting of the DMC, which minutes will not be finalized until Mediolanum's Primary Contact has not reviewed and confirmed the accuracy of such minutes in writing.

4.5 Mediolanum's Specific Responsibilities. Mediolanum, with the support of the DMC, shall:

a) Design the protocols and relevant estimate of costs and of timing necessary to conduct the Development Studies;

b) Produce interim reports at the end of each Development Study (the "**Interim Report**");

c) Review progress and Results against the Development Plan and against Sections 5, 6 and 7 of **Schedule 2** (Timelines, Estimate of Costs and Development Milestones);

d) Decide, upon completion of each Development Milestone of the Development Plan, if and in which way to move forward;

e) Review and comment upon and approve modifications to the Development Plan;

f) Perform such other functions as appropriate to further the purposes of the Agreement.

4.6 The conduct of each Development Study shall be performed by Mediolanum with the support of Genovax at the DMC level. Both Parties shall carry out their duties:

a) as agreed in the Development Plan;

b) in a timely manner according to the timelines specified in the Development Plan;

c) in good scientific manner and with all reasonable due diligence;

d) in accordance with all relevant Legal Requirements (Mediolanum shall be responsible for obtaining all necessary approvals therefor from any Regulatory Authority or applicable Competent Authority).

Notwithstanding Genovax's general advice, support and involvement in the DMC as described, Mediolanum may execute separate agreements with Domenico Criscuolo and Gilberto Filaci for the purpose of obtaining their more devoted support in relation to the design and execution of the Development Plan or of single a Development Studies.

4.7 Genovax hereby agrees that:

4.7.1 It shall limit its use of the Compound, the Patent Rights, the Genovax Know-How and the Mediolanum Know-How solely to perform its obligations under this Agreement.

4.7.2 It shall not perform any research or study on the Compound without the previous written approval of Mediolanum;

4.7.3 it shall not administer the Compound to any humans;

4.7.4 It shall not analyse or modify the Compound other than as necessary to perform its obligations under this Agreement;

4.7.5 It shall not make any derivatives or progeny of the Compound under the Patent Rights;

4.7.6 It shall not transfer to any Third Party the Compound, the Patent Rights, the Genovax Know-How and the Mediolanum Know-How and shall only make the Compound available to its employees who are bound by obligations at least as strict than those set out in this Agreement, and only then to the extent necessary for Genovax to perform its obligations under this Agreement;

4.7.7 It shall give Mediolanum access to all Compound that Genovax has in its possession, at any reasonable time to be arranged in advance;

4.7.8 It shall keep or cause to be kept in a secure location all information relevant to the Development Plan and the Development Studies, including but not limited to: detailed written laboratory notebooks, analytical data, records, and reports useful for the purpose of patenting, processing, and/or for any further potential development;

4.7.9 Upon termination of this Agreement, it shall destroy any unused Compound in accordance with all Legal Requirements unless otherwise agreed in writing between the Parties.

5 Completion of the Development plan

5.1 The Development Plan shall be deemed completed once Mediolanum's Primary Contact has generated a final report which will include all the Interim Reports data as well as all the Results obtained during the Development Studies with full data listing and data analysis, and the interpretation of the Results, (the "**Final Report**"). Mediolanum's Primary Contact shall use its best endeavors to prepare the Final Report within one (1) month of the completion of the last Development Study.

5.2 Notwithstanding the above, the Development Plan and/or Development Studies may be terminated immediately, at Mediolanum's sole discretion, in the event of a Discontinuation Event or of an Other Event (as defined, respectively, at Sections 5.3 and 5.4 below). A Final Report detailing the cause of such termination shall be generated by Mediolanum's Primary Contact within one (1) month from the occurrence of such Discontinuation or Other Event.

5.3 Discontinuation Event. For the purposes of this Agreement any of the following occurrences shall be considered as a Discontinuation Event:

(i) the occurrence of a serious and unexpected major adverse reaction caused by the Compound during a Development Study, which results in the discontinuation of the development of the Compound; or

(ii) the non-obtainment of a Valid Patent for the Patent Rights in one (or more) Major Country;

(iii) a strong limitation of the Patent Rights claims (provided that it is hereby agreed that in no case the limitation of the Patent Rights claims, which prevents the development of the Product(s) in accordance with the intentions of the Development Plan herewith attached, shall be considered as a Discontinuation Event for the purposes of this Agreement); or

(iv) a sensible delay, in any case over 12 months, of the Development Plan's initial timelines, provided that such delay is not caused by a lack of effort of Mediolanum; or

(v) a sensible deviation from the Development Plan's initial estimate of costs.

5.4 Other Event. If Mediolanum determines, in the exercise of its reasonable judgment at any time after the Effective Date, that there are issues concerning the safety, efficacy, manufacturing, registration, supply or commercialisation of the Compound and/or the Product which may materially and adversely affect its medical or competitive commercial viability, including, without limitation, a clinical hold or other adverse regulatory action, then Mediolanum may decide to discontinue the Development Plan. In such a case, it shall immediately inform of its decision the Primary Contacts and the DMC in order to speed up the procedures necessary to stop the development with no delay.

5.5 Upon the occurrence of any such Discontinuation Events or Other Event, the DMC shall immediately provide Mediolanum and Genovax with a written communication ("Discontinuation Event Notice" or "Other Event Notice", as the case might be), to be followed by the Final Report within one (1) month from the occurrence of such Discontinuation Event or Other Event, in accordance with Section 5.2 above.

5.6 The Parties agree and acknowledge that in case of a Discontinuation Event or of an Other Event, this Agreement will be automatically terminated in accordance with Sections 10.2 and 11.

6. Intellectual Property Rights

6.1 Mediolanum shall be the sole owner of all such Results and relevant intellectual property rights (including Improvement Patents) arising out of the Development Plan and the Development Studies. Mediolanum shall be entitled to use and exploit such Results commercially and to file patent applications relating thereto. Should Mediolanum decide to apply for patent protection for any of those inventions in its own name and at its expense, Genovax agrees to assist Mediolanum by executing any documents reasonably required to obtain patent protection for such inventions.

6.2 Both Parties shall do all such acts and things and shall execute all such deeds and Documents as are necessary to give full effect to the provisions of Section 6.1 above. Each Party shall promptly disclose to the other Party any invention or Improvement arising from the Development Plan and the Development Studies and forming part of the Results.

6.3 In case, during a 20 years period from the Effective Date, patentable results in the Field of Use are obtained by Genovax in the performance of the research activities mentioned under previous Section 2.6 ("**New IP Rights in the Field**"), Mediolanum shall be granted a right of first negotiation ("ROFN") according to the following terms. For the sake of clarity, New IP Rights in the Field shall exclude Improvements and Improvement Patents which, in accordance with Section 2.7, shall automatically become part of the Patent Rights.

In the event that Genovax intends to enter into a license arrangement with respect to such New IP Rights in the Field, Genovax, before disclosing the relevant information and/or proposing such license to any Third Party, shall first contact Mediolanum by notifying it in writing the offer of the ROFN for such New IP Rights in the Field (the "**ROFN Notice**"). The ROFN Notice shall be followed by the execution of a confidentiality agreement by Mediolanum and, immediately after its execution, by a comprehensive, confidential package of information relevant to such New IP Rights in the Field as well as information regarding the scope and type of agreement that Genovax is seeking such New IP Rights in the Field for it (the "**ROFN Package**").

Thereafter, for a period of 60 days (the "**Evaluation Period**") from Mediolanum's receipt of the ROFN Package, Genovax shall promptly provide Mediolanum with any additional information in the possession of Genovax that Mediolanum might reasonably request on the New IP Rights in the Field subject of such license. If possible and necessary, such exchange of information will also be made through meetings and phone calls.

If Mediolanum, within the end of such Evaluation Period:

a) does not give any answer to Genovax or notifies Genovax in writing of its election not to exercise the ROFN, then Genovax shall be free to propose the New IP Rights in the Field to any Third Party and shall be entitled to negotiate with such any Third Party a license with no further obligations towards Mediolanum;

b) exercises in writing its ROFN, Genovax and Mediolanum shall enter into good faith negotiations with respect to such license ("**Mediolanum License**") for a period of 60 days following Genovax's receipt of such election from Mediolanum (the "**Negotiation Period**"). If Genovax and Mediolanum cannot reach an agreement in principle with respect to a term sheet related to such Mediolanum License within the end of the Negotiation Period, Genovax will then be free to enter into an agreement and a license with any Third Party for the New IP Rights in the Field that were the subject of the ROFN Notice delivered to Mediolanum. If, instead, Genovax and

Mediolanum reach an agreement in principle with respect to a term sheet related to such Mediolanum License but are not able to finalise the relevant agreement during the Negotiation Period, such Negotiation Period shall be extended by an additional 60 days (the "**Extended Negotiation Period**"). If Genovax and Mediolanum, despite their best efforts and good faith negotiations, do not conclude an agreement with respect to such Mediolanum License within the end of the Extended Negotiation Period, then Genovax will be free to enter into an agreement and a license with any Third Party regarding the New IP Rights in the Field that were the subject of the ROFN Notice delivered to Mediolanum.

7 Confidentiality

7.1 Each Party shall treat as strictly confidential all Confidential Information received from the other Party, any of its Affiliates or any employee or representative of any of the foregoing.

7.2 All the Results shall automatically be deemed Confidential Information of Mediolanum in accordance with Section 6.1.

7.3 The Receiving Party shall:

7.3.1 not directly or indirectly disclose any Confidential Information of the Disclosing Party to any Third Party without the Disclosing Party's prior written consent; and

7.3.2 not use any Confidential Information of the Disclosing Party except for the purpose of this Agreement; and

7.3.3 ensure that only those of its officers, employees and consultants who are directly concerned with the performance of this Agreement have access to the Confidential Information of the Disclosing Party on a "need to know" basis, are informed of the secret and confidential nature of it and are bound by confidential obligations no less strict than those provided herein.

7.4 Confidential Information shall not include any information which:

7.4.1 at the time of first disclosure was already in the Receiving Party's possession, and was not received from Disclosing Party as shown by written evidence; or

7.4.2 at the time of first disclosure is in the public domain or subsequently enters the public domain through no fault of the Receiving Party and no breach of the confidentiality obligations by the Receiving Party; or

7.4.3 is independently developed by or for the Receiving Party without the benefit of the Confidential Information supplied hereunder, as evidenced by such Party's written records;

7.4.4 is disclosed to the Receiving Party by a Third Party having a legal right to make such disclosure.

7.5 The Receiving Party may disclose Confidential Information if compelled to do so by a court, administrative agency or other tribunal of competent jurisdiction, provided however, that Receiving Party: (i) promptly gives written notice by facsimile and overnight mail to Disclosing Party to enable it to seek a protective order or other remedy; (ii) shall disclose only that portion of the Confidential Information that, in the opinion of its legal counsel, is legally required to be disclosed; and (iii) continues to maintain the obligations set forth herein with respect to all other Third Parties.

7.6 All Confidential Information disclosed by the Disclosing Party to the Receiving Party, either in oral or written form, shall remain the property of the Disclosing Party, except for the Genovax Know-How and the Patent Rights which under this Agreement becomes the property of Mediolanum.

7.7 The Receiving Party will only make limited copy of any Documents containing the Confidential Information which are strictly necessary for the performance of the Development Plan and the Development Studies, and shall refrain from preparing any extracts from such Documents unless necessary for the performance of the Development Plan and the Development Studies.

7.8 Upon completion of the Development Plan or termination of this Agreement, the Parties shall return to each other or destroy (as requested by the Disclosing Party) all copies of the Confidential Information of the other Party, provided however, the Receiving Party may retain one copy of any such Confidential Information in a confidential file for record purposes only and unless otherwise stated in this Agreement.

7.9 Genovax shall not be permitted to publish any of the Results without the prior written consent of Mediolanum.

7.10 The obligations of the Parties under this Section 7 shall remain in force for the longer within (i) twenty (20) years after the Effective Date, or (ii) the expiration of the last to expire of the Patent Rights.

8 Warranties

8.1 During the term of this Agreement, each Party represents and warrants to the other Party that it has the legal power, authority and right to enter into this Agreement and is free from any conflicting right owed to a Third Party and to perform its obligations hereunder.

8.2 Genovax warrants and represents to Mediolanum that, to the best of its knowledge, as of the Effective Date, the Compound, the Genovax Know-How and the Patent Rights do not infringe any Third Party patents or rights in the Territory and that it has not received written notice of any claim by a Third Party that the Compound, the Genovax Know-How and the Patent Rights infringe or may infringe the patents or intellectual property rights of any Third Party in the Territory. In the event that Mediolanum, its Affiliate, Licensee or distributor is required to pay royalties to a Third Party for the use of the Patent Rights in order to develop, have developed, manufacture, have manufactured, offer to sale, sale and distribution, and to use, sell, offer for sale, import, export, distribute and commercialise any Product in the Territory in the Field of Use, then Mediolanum shall be entitled to deduct 100% of any such royalty from the Royalties due to Genovax, if any.

8.3 Professional Standards. In carrying out their responsibilities under this Agreement, both Parties warrant and represent that they shall conduct their duties and obligations under this Agreement, maintain records and data and prepare all reports and Results during and after the term of this Agreement in compliance with all Legal Requirements, this Agreement and the Development Plan.

9 Liability Limitation

9.1 Each Party recognises that the Development Studies are experimental in nature and that each Party shall be liable to the other Party only in the event that negligence, breach of contract or wilful default of such Party causes loss, damages, fees, or expenses to the other Party. In particular, neither Mediolanum nor Genovax makes any representation, express or implied, as to the quality or fitness for purpose of the Compound. In no case Genovax shall be held liable for the failure to achieve any of the Development Milestones and/or for the occurrence of any Discontinuation and/or Other Event except if such failure is caused by a misinformation or misconduct of Genovax. Neither Party shall be liable to the other Party for consequential, purely financial or indirect loss including loss of profits.

10 Term; Termination

10.1 This Agreement shall become effective on the Effective Date and, unless sooner terminated pursuant to the provisions of Sections 10.2, 10.3 and 10.4 below, it shall remain valid and in full in force until the last day of the Royalty Term set forth in Clause 3.6 (the "Term").

10.2 Should the Development Study and the Development Plan be earlier terminated in accordance with Sections 5.3 (Discontinuation Event) and 5.4 (Other Event), this Agreement shall be terminated accordingly and Section 11 below shall apply.

10.3 Mediolanum may terminate this Agreement, upon written notice with immediate effect in the following cases:

c) in case of breach of Genovax of Sections 2.7 and 4.7 hereto;

d) in the event of insolvency of, assignment for the benefit of creditors by, or the initiation of bankruptcy proceedings by or against Genovax.

11 Consequences of Termination

11.1 Termination of this Agreement for whatever reason shall not affect the duty of Mediolanum's Primary Contact to generate a Final Report under Sections 5.1 and 5.2.

11.2 Unless otherwise stated under this Agreement, termination of this Agreement for whatever reason shall not affect the accrued rights of the Parties arising in any way out of this Agreement as at the date of termination and all provisions which are expressed or are implied to survive this Agreement shall remain in full force and effect. In particular, and without limiting the foregoing, the provisions of Clause 6 (Intellectual Property Rights,), Clause 7 (Confidentiality), Clause 8 (Warranties), Clause 9 (Liability Limitation), Clause 14 (Publication and Publicity) hereof shall survive the expiry or termination hereof, with no prejudice –however, to the provisions set out under this Clause 11.

11.3 **Termination for Discontinuation Event.** Upon the occurrence of a Discontinuation Event:

11.3.1 the provision set out under previous Section 3.1.4 shall apply;

11.3.2 Mediolanum obligation to pay royalties to Genovax under Sections 3.2.1, 3.2.2 and 3.3 (as applicable) shall terminate;

11.3.3 Patent Rights and Genovax Know How shall be automatically assigned back to Genovax under no consideration but subject to Section 11.3.5 below, provided that: (i)Genovax shall support any and all administrative costs related to such assignment;

and, (ii)Mediolanum shall fully cooperate with Genovax for the purposes of such assignment by signing and executing any and all documents required to formalize the transfer;

11.3.4 Genovax shall also be granted a worldwide, exclusive, royalty free and sub-licensable license on Mediolanum's Know-How, including any and all intellectual property rights related to the Results obtained until the assignment under Section 11.3.3 is executed.

11.3.5 The Parties agree that the license referred to at Section 11.3.4 here above, to be executed in good faith by the Parties upon termination for Discontinuation Event, shall at least provide that in case Genovax, at any time after the assignment under Section 11.3.3, successfully develops or have developed, sells or have sold, assigns and/or licenses to Third Parties and/or directly or indirectly commercialises the Product(s) , then Mediolanum shall be entitled to be paid:

(a) if the Discontinuation Event occurs prior to the starting of the phase 3 clinical study related to the Compound, 2,5% of the Net Sales possibly generated by Genovax and 10% of any amount paid to Genovax by a possible Third Party to which Genovax may have granted a license under the Patent Rights; or

(b) if the Discontinuation Event occurs after the starting of the phase 3 clinical study related to the Compound, 5% of the Net Sales possibly generated by Genovax and 20% of any amount paid to Genovax by a possible Third Party to which Genovax may have granted a license under the Patent Rights;

(c) if the Discontinuation Event occurs after the commercialisation of the Product, an amount equal to the double of the then existing annual turnover directly generated by Mediolanum and/or its Affiliates, plus 5% of the Net Sales possibly generated by Genovax and 20% of any amount paid to Genovax by a possible Third Party to which Genovax may have granted a license under the Patent Rights (provided that the amount mentioned under this point (c) shall be paid in instalments to be agreed upon in good faith by the Parties)

and it shall also provide audit's sections similar to Sections 3.8 and 3.9 of this Agreement .

11.4 **Termination for Other Event.** Upon the occurrence of an Other Event:

11.4.1 Patent Rights and Genovax Know How shall be automatically assigned back to Genovax under no initial consideration but subject to Section 11.4.3 below, provided that: (i)Genovax shall support any and all administrative costs related to such assignment; and, (ii) Mediolanum shall fully cooperate with Genovax for the purposes of such assignment by signing and executing any and all documents required to formalize the transfer.

11.4.2 Mediolanum shall assign to Genovax the Mediolanum's Know-How , including any and all intellectual property rights related to the Results obtained until the termination of the Development Plan for Other Event, providing its full cooperation to Genovax for the purposes of such assignment by signing and executing any and all documents required to formalize the transfer, whose costs shall entirely be borne by Genovax.

11.4.3 The Parties agree that, in case Genovax, at any time thereafter, successfully develops or have developed, sells or have sold, assigns or licenses to any Third Party and/or directly or indirectly commercialises the Product(s), then Mediolanum shall be entitled to be paid a royalty equal to 10% of the Net Sales possibly generated by Genovax and/or of the amounts paid by a possible licensee to Genovax either as a consideration for the granting of the license and/or in the form or royalties for so long as such payment achieve to entirely cover any and all amounts directly spent by Mediolanum (as documented by the minutes of the DMC) under this Agreement until the occurrence of the Other Event, including the payments made to Genovax under Section 3 hereto and any all expenses sustained by Mediolanum under and during the Development Plan. Such payments shall constitute the sole amount that Mediolanum will be entitled to receive.

12. Applicable Law and Venue

This Agreement, and the legal relations between the Parties in connection herewith, shall be governed by, and construed in accordance with, the laws of Italy, without regard to the conflict of law principles thereof. For any disputes, which cannot be settled amicably, the Parties hereby irrevocably agree to submit to the exclusive competence of the Milan Court, Italy, without restricting any rights of appeal.

13. Assignment and Change in Control

13.1 Unless otherwise provided for herein, this Agreement and the rights and obligations hereunder may not be assigned or transferred by either Party hereto without the prior written consent of the other Party, provided however that each Party may assign this Agreement - upon prior written notice to, but without prior approval of, the other Party- to an Affiliate of such Party; and that Mediolanum may assign this Agreement without the consent of Genovax in connection with the transfer or sale of all or substantially all of its assets or business or its merger or consolidation with another company.

13.2 Change in Control. In the event of a Change in Control of either Party, proper provision shall be made so that the successors of such Party shall assume the obligations set forth in this Agreement.

14. Publication and Publicity

14.1 Except as may be required by Legal Requirements, neither Party shall under no circumstances make any publicity, publication or announcement, either in written or oral form, relating the other Party or the existence, scope, or content of this Agreement, without the other Party's prior written consent.

14.2 Neither Party shall use the other Party's name or any trademarks in any press release, advertisement or other promotional material, library index or other communication directed to or readily accessible to Third Parties or the general public, without the express prior written consent of the other Party.

14.3 During the Term of this Agreement, Genovax shall not make any written or oral publication ("Publication") concerning the Development Plan, Development Studies, the Results, Mediolanum Know-How, the Genovax Know-How,, the Patent Rights, the Compound and the Product(s) without the prior written consent of Mediolanum.

15. Miscellaneous

15.1 Independent Contractor. For the purposes of this Agreement, each Party shall be an independent contractor and not an agent or employee of the other Party. Neither Party shall have authority or power to make any statements, representations or commitments of any kind, or to take any action which is binding on the other Party, except as may be explicitly provided for herein or authorized by the other Party in writing.

15.2 Notices. Any notices, which either Party may be required or shall desire to give under this Agreement, shall be deemed to be duly given when in writing and delivered personally, mailed by registered mail, courier service or sent by telefax (provided that such telefax shall be confirmed by registered mail or courier service) to the Party to whom notice is to be given, at the address specified below (or such other address designated by Party upon seven (7) days prior written notice). Notices shall be given to the following address for each Party:

If to Mediolanum:

Mediolanum farmaceutici S.p.A.
Via S.G. Cottolengo, 15
20143 Milan, Italy
Attention: CEO
Facsimile: + 39 02 89132 202

If to Genovax:

Genovax S.r.l.
Via Ribes, 5
c/o Bioindustry Park Silvano Fumero
10010 Colleretto Giacosa (Turin), Italy
Attention: CEO
Facsimile : +39 0125538791

15.3 Amendments. Any amendments to or modifications of this Agreement shall be valid only if made in writing and signed by both Parties.

15.4 Force Majeure. Failure of any Party to perform its obligations under this Agreement (other than of the obligations to make any payments or of confidentiality) shall not subject such Party to any liability or place them in breach of any term or condition of this Agreement to the other Party if such failure is caused by Force Majeure. "Force Majeure" shall mean any unforeseen act beyond the reasonable control of such non-performing Party, including acts of God, fire, explosion, flood, earthquake, drought, war, terrorism, hostility, revolution, riot,

civil disturbance, national emergency, sabotage, embargo, strikes or other labour trouble; provided however, that the Party affected by the Force Majeure shall promptly notify the other Party of the condition constituting Force Majeure, as defined herein, and shall exert reasonable efforts to eliminate, cure and overcome any such causes and to resume performance of its obligations with all possible speed.

15.5 Subcontractors. Genovax shall not delegate or subcontract any services to be performed under this Agreement without the prior written approval of Mediolanum and shall remain solely and fully liable for the performance hereunder.

15.6 Entire Agreement. This Agreement, including the Schedules hereto constitutes the entire agreement between the Parties, shall supersede and prevail over any other prior or contemporaneous arrangements, whether written or oral, and is binding upon the Parties hereto and their successors. In the event of any conflict between the terms of this Agreement and its Annexes, the terms of this Agreement will prevail.

15.7 Enforceability. If any of the provisions of this Agreement is held to be void, invalid or unenforceable by or as a result of a determination of any court, tribunal, commission or agency of competent jurisdiction in any country or community or association of countries in which this Agreement is to be performed or take effect, the Parties agree that such determination shall not result in the nullity, invalidity or unenforceability of the remaining portions of this Agreement. The Parties further agree to replace such void, invalid or unenforceable provisions by valid and enforceable provisions that will achieve as far as possible the Parties' original intent and commercial objectives. The provisions so determined to be void, invalid or unenforceable shall, however, remain in full force and effect with regard to all other countries covered by this Agreement.

15.8 Waiver. Nothing contained in this Agreement shall cause the failure of either Party hereto to insist upon strict compliance with any other provision hereof by the other Party to operate as a waiver with respect to such provision, unless such waiver is in writing and delivered to such other Party hereto.

IN WITNESS WHEREOF the Parties have executed this document in 2 (two) originals on the day, month and year first above written.

Mediolanum farmaceutici S.p.A.	Genovax S.r.l.
Name: Rinaldo Del Bono	Name: Domenico Criscuolo
Title: President	Title: President

Attachments:

- **Schedule 1 – Compounds' characteristic, description & state of the art of development**
- **Schedule 2 – Development Plan**
- **Schedule 3 – List of Patents**
- **Schedule 4 – Genovax Know How**
- *Enclosure 1*
- *Enclosure 2*

SCHEDULE 1

Compounds' Characteristic,
Description & State of the Art
of development

GX301 is composed by:

a) four telomerase peptides: Peptide hTERT540-548 (sequence: ILAKFLHWL); Peptide hTERT611-626 (sequence: EARPALLTSRLRFIPK); Peptide hTERT672-686 (sequence: RPGLLGASVLGLDDI); Peptide hTERT766-780 (sequence: LTDLQPYMRQFVAHL).

b) two adjuvants: Montanide-ISA51 (manufactured by Seppic); Imiquimod (Aldara) commercially available (Meda Pharma).

Ways of preparation and administration are described in *Enclosure 1*.

The acute toxicology of the four peptides were studied by RTC (Pomezia-Italy) in four separate experiments of "abnormal toxicity/general safety": the results of these studies show that the peptides are safe and well tolerated when administered intravenously in mice (data on file).

GX301 vaccination received the authorization to the clinical application in advanced stage prostate and renal cancer patients by the local Ethic Committee at the IRCCS - Azienda Ospedaliero Universitaria San Martino di Genova – IST Istituto Nazionale per la ricerca sul cancro (codice n.1/2007) and by the Istituto Superiore di Sanità (Prot. N. 25230(09)-PRE21-884). GX301 effects were studied in a phase I/II clinical trial (Eudract number 2009-011330-10) on patients with stage IV prostate or renal cancer multi-refractory to conventional treatments. The clinical trial demonstrated the safety of GX301 and its capacity to induce both vaccine-specific immunological reactions and clinical improvements mainly in treated patients showing full immunological response to the vaccine.

SCHEDULE 2

Development Plan

1. OBJECTIVES
2. BACKGROUND
3. STUDY DESIGN
4. Manufacturing activities
5. TIMELINES
6. ESTIMATE OF COSTS
7. DEVELOPMENT MILESTONES
8. THE DEVELOPMENT STUDY TEAM AND CONTACT PERSONS

GX 301 DEVELOPMENT PLAN

1. OBJECTIVES

The objective of this plan is to perform the necessary activities that will allow the successful registration and commercialisation of GX301 worldwide for the treatment of prostate and renal cancers. We have also indicated the option to move into other types of cancer, thus maximising the value of the product.

2. BACKGROUND

GX301 is an innovative therapeutic vaccine based on telomerase that has successfully completed a first clinical trial in prostate and renal cancer patients. The results of this study were very encouraging as they showed excellent tolerability of the vaccine and signs of immunological and clinical response; further clinical development of GX301 is therefore warranted. As telomerase is present in all cancer cells, it is anticipated that GX301 will eventually be useful in a very broad number of oncology indications. The intention is to eventually commercialise GX301 globally, exploiting initial registrations of the product in Europe and in the US.

The further clinical development of GX301 is based on a three-pronged strategy: confirm the safety and efficacy of GX301 in prostate cancer patients, while in parallel the safety and efficacy of the vaccine is explored in other types of cancer and orphan status is sought for the treatment of renal cancer. The selection of other types of cancer to be explored will be driven by considerations related to the likelihood of clinical success, the feasibility of the studies and the availability of biomarkers that will facilitate the development. This strategy will allow the fast development and early registration of GX301 for the treatment of renal cancer, which will be complemented by subsequent expansion of the registration to other types of cancer, that include prostate cancer, and maximise the value of the product. It is envisaged that GX301 will be used initially in patients at late stages of the diseases, but progressively (as further clinical experience with GX301 is gathered) the use of GX301 will be expanded to earlier stages of the disease. Key elements for the successful implementation of the strategy is a close collaboration with regulatory authorities (AIFA, EMA and FDA) from the start of the clinical development activities and the support of the Scientific Advisory Board (SAB), which Genovax already formed and which will guide the development of the compound. The SAB is composed by international (EU and US) Key Opinion Leaders in the areas of therapeutic vaccines and oncology. The tentative clinical development plan that is currently proposed will be validated by the SAB during the 4Q2012 and confirmed through the interactions with regulatory authorities, in particular the EMA/FDA by 1Q2013. Recently EMA and FDA

supported the consultation process via the so-called "parallel scientific advice", which may represent an important strategic approach, as this joint meeting will speed up the regulatory process at both EMA and FDA.

3. STUDIES DESIGN

a) The first study of the development plan will be a Phase II study in prostate cancer patients. The aim of this study will be to test the efficacy and safety of GX301 in a larger patients population and at an earlier stage of the disease. The study will be conducted in approximately 10 centres in Italy and will recruit over a two years period 90 patients with prostate cancer, surgically treated and castration resistant: so vaccinations will be performed in a patients population with a better chance of an immune response than the previously performed study with GX301, as these patients are not exposed to chemotherapy. Recently issued FDA guidelines ask for a demonstration of the selection of the vaccination schedule, so this study will evaluate three different vaccination schedules, aiming at the selection of the best regimen, to be used in future Phase III studies.

b) During 2013 it is planned to file the orphan drug status for the renal cancer indication, based on the data from the Phase I/II study. This filing may be of strategic importance, as the free EMA/FDA protocol advice will streamline the preparation of the Ph II/III clinical study protocol and speed up the NDA submission. So, the Phase II/III clinical study in renal cancer will be implemented after the EMA/FDA protocol advice, aiming at a fast track NDA submission. This study will be multicentre (EU+US), with a total number of about 150 patients (to be confirmed by EMA/FDA), and will need three years.

c) The completed Phase II study in prostate cancer will indicate the best schedule of vaccinations, and will provide new efficacy and safety data to better plan the new study. In the Phase III pivotal study, 300 patients will be treated, from 30 clinical sites (some in Europe and some in USA), at an earlier stage of the disease. This study will be a comparative one, with patients randomized to GX301 or to the comparative treatment (to be selected at the time of protocol design). It will be completed by year end 2017.

d) Phase I clinical study in other cancer(s) = Since telomerase is a universal tumor associated antigen, it is reasonable to apply GX301 vaccination to other histological forms or cancers. Melanoma could be an option due to its demonstrated immunogenicity (and eventually the possibility to associate to GX301 another peptide coming from a melanoma associated antigen). Ovarian cancer is of interest due to the lack of effective therapies, and the same

applies to pancreatic and NSCL cancers, the latter being the most frequent cancer type in the world. Haematological diseases (leukemias, lymphomas, myeloma) can also be interesting targets because chemotherapy and bone marrow or stem cell transplantation have great limitations. It is to be noted that these studies represent an opportunity to widen the market value of GX301, but must be considered as an additional effort.

e) Phase I clinical study in association = There is an international consensus that the future of anti-cancer therapy will be a combined approach. GX301 should be projected into this scenario performing studies of association with other therapies which should allow the decrease of tumor mass (i.e., bone marrow transplantation after ablative therapy) or with treatments aimed at inhibiting the activity of regulatory T lymphocytes (that are the cells that could antagonize the immunizing, anti-cancer effects of anti-telomerase vaccination). Also these studies can be an opportunity for the future of GX301, but must be considered as an additional effort. On this basis, it could be explored the possibility to perform a combination study with GX301 and bone marrow allo-trasplantation in prostate cancer (as proposed by a group from San Raffaele Hospital in Milan) or with ipilimumab in prostate cancer or melanoma.

4. MANUFACTURING ACTIVITIES

Peptides: Bachem produced the initial GMP supply of the four peptides, used for the Phase I/II study, so they have the know-how. Other offers should be requested to other companies, to compare costs. The new batch (if immediately ordered) should be available by 2Q2013, in time for the Ph II study in prostate cancer: supply will be sufficient also for the optional and additional Ph I studies in other cancer types. A new batch of peptides should be produced later, for the performance of the Phase III study. The indicated costs include also costs for stability tests.

Imiquimod and Aldara: The vaccines administration is combined with the use of these two agents, which are commercially available.

5. TIMELINES

(Note : NDA filing can be either US or EU, market launch can be either USA or any EU country)

1Q2013	Meeting of the Scientific Advisory Board; Approval of Phase II prostate ca study protocol by the Italian Authorities
2Q2013	First patient in Phase II prostate cancer study - Pre-IND meeting with EMA/FDA
3Q2013	Orphan drug application for renal cancer. Approval of exploratory study protocol in other types of cancer by Italian Authorities
4Q2013	First patient in exploratory study (studies) in other types of cancer
1Q2014	EMA/FDA approval of orphan status and protocol assistance in renal Phase II/III study
3Q2014	First patient in Phase II/III renal cancer study
1Q2015	Complete Phase II in prostate cancer
3Q2015	Start Phase III in prostate cancer – Complete exploratory study (studies) in other cancer types - Consider to activate Phase II/III in other cancer types
4Q2016	Complete Phase II/III in renal cancer
4Q2017	Complete Phase III in prostate cancer – NDA filing in renal (accelerated approval)
4Q2018	Market launch in renal cancer – NDA filing in prostate cancer
4Q2019	Market launch in prostate cancer

GX301 – Initial activities to be started in September 2012

The indicated timelines are ambitious, but realistic ones. In order to keep them, it is mandatory to activate some preliminary tasks as soon as possible: here are indicated activities to be started immediately, in order to keep the proposed timelines.

September 2012 = Scientific Advisory Board.

Genovax established a SAB, made of 5 members (4 from Italy, 1 from USA): membership should be confirmed or modified to include KOL from EU and US, and a new meeting should be called by 1Q2013.

September 2012 = GMP preparation of four peptides for the clinical studies.

Bachem has already the know how for this task: other offers were requested to other companies, and should be evaluated to compare time and cost. The final selection and the manufacturing order should follow as the top priority.

September 2012 = Imiquimod and Aldara

Activation of contacts with two companies (Seppic for montanide and Meda for Aldara-imiquimod), in order to get an offer for the supply of these two agents. A negotiation for continuous supply over several years should also be activated.

September 2012 = Contacts with CROs for the Phase II clinical study in prostate patients.

Contact 4 clinical CROs for offers to perform and report the Phase II clinical study in prostate cancer patients. It is suggested to run this study only in Italian sites, as costs are lower, and also regulatory approval will be smoother as the EC of the University of Genova already approved the Phase I/II study. Suggested CROs to contact are 2 Italian ones (Opera, Hippocrates) and 2 International (Chiltern, Premier).

6. ESTIMATE OF COSTS

Estimates are divided into two intervals. The first part (2H2012-1H2015) is based on present knowledge of the project. The long term period (2H2015-2019) values represent a reasonable estimate, but they may change on the basis of new information made available on the project.

	Sep-Dec 2012	1H2013	2H2013	1H2014	2H2014	1H2015
Peptides from Bachem						
Imiquimod and Aldara						
Ph II study in prostate ca.						
Orphan status filing for renal						
Ph II/III study in renal						
Other costs (travel, SAB)						
Optional Ph I studies in other cancer types (ovary, melanoma, pancreas)						

	2H2015	2016	2017	2018	2019
Peptides from Bachem					
Imiquimod and Aldara					
Ph III study in prostate ca.					
Ph II/III study in renal					
NDA compilations					
Other costs (travel- adv.board)					
Optional Ph II/III in another orphan indication (ovary, pancreas)					

The cost of the project (prostate and renal) for the period 2012-2019 will be 13,295,000 euro.

The cost of the project with additional indications in the period 2012-2019 will be 18.995.000 euro, but obviously will significantly expand the market potential.

Note: in the above costs, professional fees are not included. Personal contracts with Domenico Criscuolo and Gilberto Filaci will be part of separate agreements.

7. DEVELOPMENT MILESTONES

2Q2013	First patient in Phase II prostate cancer study
4Q2013	First patient in exploratory study in other types of cancer
3Q2014	First patient in Phase II/III renal cancer study
3Q2015	First patient in Phase II/III other cancer type (ovary, melanoma, pancreas?)
4Q2017	Regulatory filing for renal cancer at EMA and FDA
4Q2018	Regulatory filing for prostate cancer at EMA and FDA

8. THE DEVELOPMENT STUDY TEAM AND CONTACT PERSONS

Mediolanum Primary Contact	
Name	**Phone and e-mail address**
Dr. Francesco Gianese	+ 39 02-89132342 F.Gianese@mediolanum-farma.com

Genovax Primary Contact	
Name	**Phone and e-mail address**
Prof. Franco Indiveri	+ 39 347-4340934 Francesco.Indiveri@unige.it

September 7, 2012

SCHEDULE 3

List of Patents

COMPOUND: "GX301"

TITLE: ANTI-TUMOR IMMUNOTHERAPY

INVENTOR(s): FILACI GILBERTO, INDIVERI FRANCESCO, TRAVERSO PAOLO

PRIORITY: – 16.06.2008 – 61/061,778P – U.S.A.

COUNTRY	Application No.	Application Date	Patent No.	Issue Date	Expiration*	Status
EUROPE**	09776746.1	16.06.2009			16.06.2029	PENDING
CANADA	20092727388	16.06.2009			16.06.2029	PENDING
JAPAN	2011-0513943	16.06.2009			16.06.2029	PENDING
U.S.A.	12/997,630	16.06.2009			16.06.2029	PENDING

* Unless extended by national patent offices or by the filing of a SPC.

** EUROPE: designated countries: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LI, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR

SCHEDULE 4

Know How

The Genovax know-how related to GX301 includes:

1. General knowledge related to the state of art of therapeutic vaccines targeting telomerase (*Enclosure 2*).
2. The procedure for preparation and administration to patients of GX301 (*Enclosure 1*)
3. Data related to pre-clinical toxicology studies consisting in 4 reports on general toxicity studies performed on each one of the four peptides (data on file).
4. Data on safety, immunological effects and clinical results coming from the phase I/II clinical trial (Eudract number 2009-011330-10).
5. Theoretical perspectives for GX301 implementation based on personal scientific relationships of Genovax's scientists with scientists working in the field (namely, association of GX301 with: agents blocking regulatory cells; stem cell transplantation; other tumor associated antigens).

Enclosure 1

Immunization Procedure:

1. Peptide preparation. Peptides must be sequentially diluted in the administration vehicles.

2. Instructions for peptide dilution. First of all, wash and disinfect your hand and all the surfaces on which vials and syringes will be put down. Then, a) Take 300 µl of sterile saline using a 1 ml syringe; b) Perforate the cap of the vial and inoculate the saline in the vial with the syringe; c) Vortex the vial until the peptide powder is completely solved; d) Take 300 ml of Montanide from its vial with another 1 ml syringe; e) Inoculate the Montanide into the peptide vial as before; f) Gently shake the vial with your finger and then draw the content with the syringe: the solution will appear milky due to the formation of a water-in-oil emulsion; g) Remove the syringe from the vial, close the needle with the cap, write on the syringe the number of the contained peptide; h) Repeat the same procedure for all the other peptides.

3. The injection must be preferentially done on the skin of the abdomen.

4. Disinfect thoroughly the site of injections.

5. On the area of injection draw a circle and divide it in four quadrants.

6. Inject one peptide per quadrant. In all the future administrations follow always the same procedure injecting the same peptide in the corresponding quadrant. This will allow monitoring separately the local response to the immunization with each single peptide.

7. If possible, change the needle of the syringe before injection in order to minimize the risks of contamination.

8. Intradermically inject the syringe content.

9. Repeat the procedure for all the four peptide emulsions.

10. At the end of the injection disinfect again the skin area of administration and wait a few minutes.

11. Put on a glove and open the little bag containing Imiquimod. Spread the cream on the injection sites until completely absorbed.

12. Cover the skin with a sterile gauze for a few hours.

Enclosure 2

Telomerase is the reverse transcriptase responsible for synthesis, elongation and stabilization of the telomeric regions of chromosomes. It is normally expressed by embryonic cells but not by adult somatic cells with few exceptions, and re-expressed by tumor cells since essential for tumor immortalization. Hence, differently from what happens with other tumor associated antigens, telomerase expression cannot be down modulated or repressed by tumor cells as immune escape mechanism. Importantly, telomerase is expressed by more than 85% of tumors, independently from the histotype, and by most of cancer stem cells. Human telomerase (hTERT) is immunogenic although it is an endogenous intranuclear molecule: indeed, hTERT-specific T cells have been identified in both healthy subjects and cancer patients. This occurs because peptides derived from hTERT are naturally processed by tumor cells and antigen presenting cells, and are presented on HLA molecules and activate effector T cells. The hTERT peptide ILAKFLHWL (in amino acid single-letter codes) binds with high affinity to HLA-A2 (present in more than 40% of Caucasian population) and can be used to activate and expand specific CD8+ T cells in vitro that lyse a wide range of hTERT+ tumor cell lines and primary tumors in a peptide-specific, HLA-restricted fashion. Multiple other HLA binding epitopes derived from hTERT have been identified that include epitopes that are restricted to HLA-A2 as well as HLA-A1, -A3, -A24, and -B7 (more than 90% of humans express at least one of these alleles). Some of these peptide epitopes represent so called "cryptic" epitopes that, although classically considered poorly immunogenic because of poor binding to MHC, can induce vigorous T cell responses after modification of certain amino acids (by molecular engineering) in the wild-type sequence to increase MHC binding. Moreover, the hTERT sequence also includes multiple epitopes restricted to HLA class II that drive CD4+ T cell responses that might potentially facilitate T-cell help during a hTERT-specific immune response. In mice in vivo, mTERT-specific vaccination generates robust immune responses that protect the animals against a variety of tumor types in the absence of toxicity. A study aimed at analyzing the frequency of telomerase-specific immune responses in cancer patients with different histological and stage of tumors showed that about 90% of patients have telomerase-specific CTL in the circulation, although the frequency of CTL precursors is variable among patients. All together these findings support the concept that telomerase may represent a universal tumor-associated antigen. For this reason, in the last decade several clinical trials have been performed using telomerase as immunogen in cancer patients. These trials, involving more than 200 patients so far, consisted in protocols of therapeutic vaccination of tumor-bearing patients, most of whom had large, treatmentrefractory neoplasms that had been clinically progressive despite standard therapy. A wide variety of vaccine formulations have been tested (peptides in adjuvant, peptides with cytokines, dendritic cells loaded with hTERT

antigen, hTERT in the form of RNA or DNA) in a variety of different tumor types (carcinomas of the breast, prostate, lung, pancreas, kidney, ovary, as well as melanoma, myeloma, hepatocarcinoma, acute myeloid leukemia). Despite the variations, a number of consistent findings have been observed in these trials:

(1) hTERT-specific cellular immune responses can be induced after vaccination in the vast majority of patients, independently from the hTERT epitope targeted.

(2) No major side effects (including autoimmunity) have been induced in treated patients

(3) Objective partial or complete clinical responses have been only rarely observed, although a few dramatic cases of tumor shrinkage have been reported. This finding has been initially attributed to a low immunogenicity of telomerase, a concept now overcome by more recent findings showing that hTERT-specific CTL are fully able to kill tumor cells.

(4) In multiple studies, overall survival has been observed to be significantly improved in those patients who respond immunologically to hTERT vaccination.

These observations make hTERT a preferred candidate for a widely applicable cancer vaccine. Indeed, specific questions must be answered concerning:

a) the long-term safety of hTERT vaccination: it remains to be determined whether prolonged or more robust hTERT immune responses may result in toxicity against normal cells expressing hTERT.

b) the optimal application of hTERT vaccination since it could be performed as an independent line of treatment as well as adjuvant therapy for other lines of treatment. Moreover, the ideal timing of application is also to be determined in terms of initial of advanced disease.

In this context GX301 is innovative because:

a) it includes four peptides covering the restriction by the majority of HLA class I and II antigens;

b) it includes two adjuvants that have a demonstrated capacity to optimally activate innate immunity.

The following is a list of references relative to published articles describing the results of trials using vaccines targeting telomerase as cancer treatment:

Brunsvig PF, Kyte JA, Kersten C, et al. Telomerase peptide vaccination in NSCLC: a phase II trial in stage III patients vaccinated after chemoradiotherapy and an 8-year update on a phase I/II trial. Clin Cancer Res 2011; 17): 6847–57.

Hunger RE, Kemland Lang K, Markowski CJ, et al. Vaccination of patients with cutaneous melanoma with telomerase-specific peptides. Cancer Immunol Immunother 2011; 60: 1553–64.

Rittig SM, Haentschel M, Weimer KJ, et al. Intradermal vaccinations with RNA coding for TAA generate CD8+ and CD4+ immune responses and induce clinical benefit in vaccinated patients. Mol Ther 2011; 19: 990–9.

Berntsen A, Trepiakas R, Wenandy, et al. Therapeutic dendritic cell vaccination of patients with metastatic renal cell carcinoma: a clinical phase 1/2 trial. J Immunother 2008; 31: 771– 80.

Cortez-Gonzalez X, Zanetti M. Telomerase immunity from bench to bedside: round one. J Transl Med 2007; 5:12.

Brunsvig PF, Aamdal S, Gjertsen MK, Kvalheim G, Markowski-Grimsrud CJ, Sve I, Dyrhaug M, Trachsel S, Møller M, Eriksen JA, Gaudernack G. Telomerase peptide vaccination: a phase I/II study in patients with non-small cell lung cancer. Cancer Immunol Immunother 2006; 55: 1553-64.

Su Z, Dannull J, Yang BK, Dahm P, Coleman D, Yancey D, Sichi S, Niedzwiecki D, Boczkowski D, Gilboa E, Vieweg J. Telomerase mRNA-transfected dendritic cells stimulate antigen-specific CD8+ and CD4+ T cell responses in patients with metastatic prostate cancer. J Immunol 2005; 174:3798-807.

Vonderheide RH, Domchek SM, Schultze JL, George DJ, Hoar KM, Chen DY, Stephans KF, Masutomi K, Loda M, Xia Z, Anderson KS, Hahn WC, Nadler LM. Vaccination of cancer patients against telomerase induces functional antitumor CD8+ T lymphocytes. Clin Cancer Res 2004; 10:828-39.

Su Z, Dannull J, Heiser A, et al. Immunological and clinical responses in metastatic renal cancer patients vaccinated with tumor RNA-transfected dendritic cells. Cancer Res 2003; 63: 2127–33.

A complete list of currently ongoing trials using vaccines targeting telomerase as cancer treatment is present on the website of clinicaltrials.gov NIH registry under the keywords "telomerase". In this list it is noteworthy that there are currently no ongoing trials in patients with prostate or renal cancer.

From publications and the clinicaltrials.gov registry it results that the most interesting (considering the results in already performed trials) telomerase vaccines at present are: GV1001 (Pharmexa, KAEL GemVax), GRNVAC1 (Geron Corporation), and Vx-001 (Vaxon Biotech).

GV1001 consists in two telomerase peptide (p540-548 and p611-626) that are identical to that present in our GX301. Moreover, GV1001 includes GM-CSF as adjuvant. It is actually in a phase 3 trial in NSCLC (not yet recruiting) and in phase 1 in pancreatic cancer (recruiting).

GRNVAC1 consists in autologous Mature Dendritic Cells Transfected With mRNA Encoding Human Telomerase Reverse Transcriptase. It is in a phase 1 trial in AML (active but not recruiting).

Vx-001 consists in two telomerase peptide (p572-580, sequence RLFFYRKSV, and its optimized variant p572Y, sequence YLFFYRKSV) and in Montanide-ISA51 as adjuvant. It is expected the beginning of a phase IIb trial in MSCLC in the first half of 2012.

27 August 2012