Cancer Vaccines - Clinical Trial Analysis

Contents

- 1 Cancer Incidence
- 2 Market Overview - Cancer Vaccines
  - 2.1 Market Size
  - 2.2 Market Segmentation
    - 2.2.1 By Vaccine Type
    - 2.2.2 By Cancer Type
  - 2.3 Market Forecast
  - 2.4 Market Analysis
    - 2.4.1 Prostate Cancer
      - 2.4.1.1 Prostate Cancer - Incidence Rate
- 3 Significant Cancer Vaccine Approvals
- 4 Clinical Trials - Cancer Vaccines
  - 4.1 Number of Clinical Trials
    - 4.1.1 By Cancer Type and Trial Phase
    - 4.1.2 By Company/University conducting the trial and Trial Phase
  - 4.2 Possible Cancer Vaccine Launches
    - 4.2.1 Number of Cancer Vaccines in each area
    - 4.2.2 Drug Details
  - 4.3 Clinical Trial Details - by Cancer Type
    - 4.3.1 Lung Cancer
    - 4.3.2 Prostate Cancer
    - 4.3.3 Colon/Rectal Cancer
    - 4.3.4 Breast Cancer
    - 4.3.5 Pancreatic Cancer
    - 4.3.6 Melanoma Cancer
    - 4.3.7 Ovarian Cancer
    - 4.3.8 Renal Cancer
    - 4.3.9 Cervical Cancer
    - 4.3.10 All other Cancer types
- 5 Challenges in Cancer vaccine development

Cancer Incidence

The following interactive chart gives the global cancer incidence, Cancer incidence by countries, Cancer incidence in USA (for every type of cancer) and agewise cancer incidence (Breakup for male and female is also depicted).

Click on the tabs to view the required information

This is supposed to be a flash animation. You'll need the flash plugin and a browser that supports it to view it.

Sources: SEER, Centers for Disease Control and Prevention, US, American Cancer Society, WHO, Cancer Research UK

Market Overview - Cancer Vaccines

The following interactive chart gives the market overview for Cancer Vaccines

Click on the relevant tab for more information

This is supposed to be a flash animation. You'll need the flash plugin and a browser that supports it to view it.

Sources: Kalorama Information Research, Press Releases

Market Size

- The global market size of Cancer vaccines has increased from **$1500 Mn in 2007** to **$1657 Mn in 2010**
- Till 2009, the Cancer Vaccine market was dominated by Cervical Cancer Vaccines, occupying more than 99% market share
- The major Cervical cancer vaccines in the cancer vaccines market were Gardasil (by Merck) and Cervarix (by Glaxo Smith Kline)
- These vaccines prevent the occurrence of human papillomavirus (HPV), the most common sexually transmitted infection (STI) in the United States, with about 6.2 million cases diagnosed annually
- Gardasil prevents infection of four strains of HPV?two strains (16, 18) that cause 70% of cervical cancer cases and two strains (6, 11) that cause 90% of genital warts cases
- The Cervarix vaccine, which is used more broadly in several countries outside the U.S., protects only against HPV strains 16 and 18
- Only after the launch of Provenge, a prostate cancer vaccine by Dendreon in April 2010, Prostate cancer vaccine market gained a market share of 10% in 2010
- The CAGR of Cancer Vaccines Market during the period 2007-2010 was 3.4%

Source: kaiseredu.org

Market Segmentation

By Vaccine Type

The Cancer Vaccines market can be segmented based on the when a particular vaccine is to be administered. Based on the Vaccine type, cancer vaccines are segmented into 2 segments:

1. **Therapeutic Cancer Vaccines** - Therapeutic cancer vaccines are designed to **treat** existing cancers. They are given to cancer patients to stimulate the immune system into recognizing and destroying their existing cancer
2. **Prophylactic Cancer Vaccines** - Prophylactic cancer vaccines are designed to **prevent** the development of cancer. They are given to healthy subjects to prevent infection with cancer-causing viruses

By Cancer Type

Cancer Vaccine market can also be segmented based which type of cancer, the vaccine caters to. According to this classification, cancer vaccine market has **7 major segments**:

1. Prostate Cancer Vaccine
2. Renal Cancer Vaccine
3. Bladder Cancer Vaccine
4. Cervical Cancer Vaccine
5. Colon/Rectal/Colorectal Cancer Vaccine
6. Lymphoma Cancer Vaccine
7. Melanoma Cancer Vaccine

Other minor segments in the cancer vaccine market are almost non existent. But there are many clinical trials going on in these segments by various companies and universities. These segments include Lung Cancer, Breast Cancer, Pancreatic Cancer, Ovarian Cancer, Brain Cancer, Metastate Cancer etc

Market Forecast

- The Cancer Vaccine market is forecasted to generate a revenue of **$2198 Mn in 2011**
- It is expected to grow at a CAGR of 35.9% and reach the market size of **$7690 Mn by 2015**
- Therapeutic cancer vaccines are expected to occupy a market share of 76.1% whereas Prophylactic cancer vaccines occupy only 23.9% of the market
- Prostate cancer is expected to gain 58.39% of the cancer vaccines market by 2015 and Cervical Cancer Vaccines are expected to occupy 25.49% of the market
- The other types of cancer vaccines, mainly being Renal, Bladder, Colon/Rectal, Lymphoma and Melanoma, are expected to occupy 15.67% of the market share

Market Analysis

Prostate Cancer

- The **Prostate Vaccine Segment** is expected to be the **most lucrative** in the cancer vaccine market by 2015
- Provenge, the only prostate cancer vaccine, is expected to generate a lot of revenue for Dendreon
- Within 9 months of its launch, Provenge generated a revenue of **$48Mn** in 2010 (Source: Dendreon Annual Report 2010)
- Provenge is expected to generate revenues of **$350-400 Mn** in 2011 (Source:WSJ)
- Prostate Cancer vaccine market is expected to grow with a **CAGR of 90.3% by 2015** (The CAGR calculated is for the period 2010 - 2015)
- Prostate Cancer is seeing high activity with **21 clinical trials** in this segment

Prostate Cancer - Incidence Rate

The following chart illustrates Delay-adjusted SEER Incidence Rates by Year, for Prostate Cancer:

This is supposed to be a flash animation. You'll need the flash plugin and a browser that supports it to view it.

Source: SEER

To know more about Prostate Cancer, click here

Cervical Cancer

- Cervical cancer is expected to be the second most lucrative segment in the cancer vaccines market by 2015
- Cervical cancer vaccines **Gardasil and Cervaix** will be among the top three **bestselling vaccines**
- Cervical Cancer vaccine market is expected to grow with a **CAGR of 5.8% by 2015** (The CAGR calculated is for the period 2010 - 2015)

Apart from the cervical cancer segment - **Melanoma and Lung Lymphoma cancer vaccine segments** are also seeing high activity with a number of products in late stage of development (Source)

Significant Cancer Vaccine Approvals

In April 2010, the cancer vaccine market experienced one of the biggest achievements in the therapeutic vaccine treatment of cancer-the approval of the prostate cancer vaccine PROVENGE (TM). This, in addition to the success of cervical cancer vaccine products, has created a viable market for what was merely a speculative area just one decade ago. Even with achievements for some companies, numerous vaccines with apparently strong prospects have been hit by developmental delays and failures. These include CancerVax's Canvaxin, Aphton's Insegia, Progenics' GMK vaccine, and Biomira's Theratope. Despite setbacks many developers are hopeful of a turnaround. With a couple prophylactic vaccines for cervical cancer on the market, a few select therapeutic vaccine approvals and several therapeutic vaccines on a promising path to commercialization, the market could see a surge of regulatory activity and an influx of market opportunities.

The following table lists down the significant Cancer Vaccines that have been approved in 2000-2010

Product Approved	Company	Region	Approval Year	Cancer Type Treated	Vaccine Type
Cervarix	GlaxoSmithKline	European Union	2007	Cervical	Prophylactic
Cervarix	GlaxoSmithKline	United States	2009 (October)	Cervical	Prophylactic
DCVax-Brain	Northwest Biotherapeutics	Switzerland	2007 (November)	Brain	Therapeutic

Gardasil	Merck	United States	2006 (June)	Cervical	Prophylactic
Gardasil	Merck	European Union	2006 (September)	Cervical	Prophylactic
Melacine (disc.)	Corixa Corp	Canada	2001	Melanoma	Therapeutic
MVAX	AVAX Technologies	Switzerland	2005	Melanoma	Therapeutic
MVAX (disc.)	AVAX Technologies	Australia	2000	Melanoma	Therapeutic
Oncophage	Antigenics	Russia	2008 (April)	Renal	Therapeutic
Onco VAX	Vaccinogen	Netherlands	2008 (May)	Colon	Therapeutic
Provenge	Dendreon	United States	2010 (April)	Prostate	Therapeutic

Sources: Kalorama Information Research, Press Releases

Clinical Trials - Cancer Vaccines

This section presents detailed information on all the clinical trials, by companies and universities, that are going on in the Cancer Vaccines area in United States.

Source for all the clinical trials: Clinicaltrials.gov

Number of Clinical Trials

By Cancer Type and Trial Phase

Click on the cells below to get the corresponding number of clinical trials in that area, by companies/universities

This is supposed to be a flash animation. You'll need the flash plugin and a browser that supports it to view it.

Source: Clinicaltrials.gov

By Company/University conducting the trial and Trial Phase

Click on the cells below to get the corresponding number of clinical trials in that area, by cancer type

This is supposed to be a flash animation. You'll need the flash plugin and a browser that supports it to view it.

Source: Clinicaltrials.gov

Possible Cancer Vaccine Launches

Number of Cancer Vaccines in each area

There are **28 clinical trials going on in Phase III** in the cancer vaccines area, which could be a potential launch in the next 5 years.

The following table shows the number of clinical trials, in Phase III, going on in each cancer area

Cancer Type	No. of Vaccines under Clinical Trial
Prostate	6
Lung	4
Melanoma	3
Renal	3
Cervical	2
Breast	1
Colon/Rectal	1
Genital Warts	1
Lymphoma	1
Vaginal	1
Vulvar	1

Drug Details

The areas expected to display the highest competition include melanoma, lymphoma, cervical, renal and prostate cancer. These areas have a wide range of research and development activities brewing from preclinical trials to Phase III. Many of the products already in Phase III development have orphan drug status, SPA status, or Fast Track status. This provides a promising future for many of these products.

The following Cancer Vaccines are in their last stages of the clinical trials (Phase III). The table gives details of every possible Cancer Vaccine, to be launched by 2013-2015.

S.No.	Cancer Vaccine Type	Drug Name	Biological Name	Developer	Current Development Phase	Additional Information	Start Date	Completion Date	Source
1	Breast	-	Stimuvax	Oncothyreon	III	Suspended	-	-	-
2	Cervical	-	HPV-16/18 vaccine (Cervarix) Aimmugen?	GlaxoSmithKline	III	Approval in more than 70 countries including European Union countries, Mexico, Singapore, Australia; Received approval in the U.S. in October 2009	2006	2009	Source
3	Cervical	-	V503	Merck	III	Expected results in late 2011	2010	2011	Source
4	Colon/Rectal	-	OncoVAX autologous vaccine	Vaccinogen	III	Available in Netherlands/Switzerland Possible U.S. and E.U. approvals in 2014	-	-	-
5	Genital Warts	-	V503	Merck	III	Expected results in late 2011	2010	2011	Source
6	Lung	-	Lucanix	NovaRx	III	Earliest approval - late 2013	2008	2012	Source
7	Lung	-	Stimuvax, Placebo	EMD Serono, Merck KGaA	III	**Active**: The purpose of this study is to determine whether the cancer vaccine Stimuvax in addition to best supportive care is effective in prolonging the lives of patients with unresectable stage III non-small cell lung cancer, compared to best supportive care alone.	2006	2014	Source
8	Lung	-	TG 4010	Transgene	II/III	TG4010 is a suspension of recombinant Modified Vaccinia virus strain Ankara (MVA strain) carrying coding sequences for human MUC1 antigen and human interleukin-2 (IL2). TG4010 has been developed for use as an immunotherapy in cancer patients whose tumors express the MUC1 antigen.	2011	2016	Source
9	Lung	-	L-BLP25 or BLP25 liposome vaccine (Stimuvax), Placebo	Merck KGaA	III	Darmstadt, Germany, June 17 2010 - Merck Serono, a division of Merck KGaA, and its U.S. affiliate, EMD Serono, Inc. today announced that they are resuming their Stimuvax® (BLP25 liposome vaccine)* clinical program in patients with non-small cell lung cancer (NSCLC) which includes the Phase III studies, START and INSPIRE.	2009	2018	Source
10	Lung	-	MAGE-A3	GlaxoSmithKline	III	Beyond 2015	-	-	-
11	Lung	-	EGF Cancer Vaccine/ TGF Cancer Vaccine	Biovest International	II/III	-	-	-	-

12	Lymphoma	-	tumor specific immune response, control vaccine	Biovest International	III	Fast-Track Phase III completed; Pending U.S. and European regulatory applications	2000	2009	Source
13	Lymphoma	-	MyVax	Genitope Corporation	II/III	This is a multi-center, open-label, single arm Phase 1/2 study evaluating the feasibility, safety, and tolerability of a series of 16 immunizations of Id-KLH with GM-CSF in patients with previously untreated B-CLL.	2006	Ongoing	Source
14	Melanoma	-	MDX-010 (anti-CTLA4) monoclonal antibody	Bristol-Myers	III	Fastrack Approval possibly by 2013	2004	2009	Source
15	Melanoma	-	Dacarbazine (DTIC), Temozolomide (TMZ)	Vical/AnGes	III	Approval possibly by 2013	2006	2012	Source
16	Melanoma	-	MVax autologous cell vaccine	AVAX Technologies	III	Study suspended pending capitalization in US	-	-	-
17	Ovarian	-	Abagovomab	Menarini Group	II/III	The purpose of this study is to evaluate the benefit of vaccination with Abagovomab, an experimental immunotherapy in ovarian cancer patients. The benefit will be evaluated in terms of time the remission status is kept as well as prolongation of life expectancy.	2006	2015	Source
18	Prostate	-	sipuleucel-T, APC-Placebo	Dendreon	III	Completed. This is a randomized, double blind, placebo controlled trial of immunotherapy with autologous antigen-loaded dendritic cells (Provenge, APC8015) for asymptomatic, metastatic, hormone-refractory prostate cancer.	2000	2005	Source
19	Prostate	-	Provenge	Dendreon	III	The Protect-Provenge Treatment and Early Cancer Treatment trial is a Phase IIIB trial for patients with hormone sensitive prostate cancer.	2001	2006	Source
20	Prostate	-	Provenge	Dendreon	III	The PROTECT-PROvenge Treatment and Early Cancer Treatment trial is a Phase IIIB trial for patients with hormone sensitive prostate cancer	2001	2006	Source
21	Prostate	Provenge	Sipuleucel-T, APC-Placebo	Dendreon	III	Provenge is an investigational product designed to activate a man?s own antigen presenting cells, a type of immune cell, so that they can detect prostate cancer cells and initiate an immune response against them. Having completed Phase 1 and Phase 2 clinical trials, Provenge is now at the Phase 3 level. One	2003	2010	Source

						important Phase 3 trial of Provenge has been completed; the current trial is also a Phase 3 study.			
22	Prostate	ProstAtak	AdV-tk + valacyclovir; Placebo + valacyclovir	Advantagene	III	This is a double-blinded, randomized, placebo-controlled Phase 3 trial of ProstAtak?(AdV-tk + valacyclovir) in combination with standard external beam radiation therapy with or without androgen deprivation therapy (ADT) for intermediate-high risk localized prostate cancer. ProstAtak? is an investigational product that kills tumor cells and elicits an anti-tumor vaccine effect. The hypothesis is that this combination therapy can lead to improvement in the clinical outcome for patients with newly diagnosed prostate cancer. Patients will be randomized to the ProstAtak? or control arm at a 2:1 ratio.	2011	2015	Source
23	Prostate	-	DCVax-Prostate	Northwest Biotherapeutics	III	Earliest Approval -2011	-	-	-
24	Renal	Sunitinib, Cyclophosphamide	IMA901 plus GM-CSF	Immatics Biotechnologies GmbH	III	The primary objective of the phase III study is to investigate whether IMA901 can prolong overall survival in patients with metastatic and/or locally advanced renal cell carcinoma (RCC) when added to standard first-line therapy with sunitinib. Secondary objectives include a subgroup analysis of overall survival in patients defined by a certain biomarker signature, the investigation of progression-free survival, best tumor response, safety, and immunological parameters	2010	2011	Source
25	Renal	-	-	Antigenics	III	Terminated due to lack of enrollment	2002	-	Source
26	Renal	-	Reniale	FBM-Pharma	III	Approval in select regions outside the U.S. by 2013	-	-	-
27	Vaginal	-	V503	Merck	III	Expected results in late 2011	2010	2011	Source
28	Vulvar	-	V503	Merck	III	Expected results in late 2011	2010	2011	-

Source: Clinicaltrials.gov

Clinical Trial Details - by Cancer Type

Lung Cancer

There are 44 clinical trials for cancer vaccines going on in the Lung Cancer area.

The following table gives all the details on clinical trials going on in the field of Lung Cancer for Vaccines

S.No		Biological Name	Developer		Additional Information			Source

	Drug Name			Current Development Phase		Start Date	Completion Date	
1	-	AVX701	AlphaVax	I/II	The primary objective of this protocol is to determine the safety of immunization with CEA(6D) VRP in patients with advanced or metastatic CEA expressing malignancies.	2007	2010	Source
2	-	V934/V935	Merck	I	Completed. This is a two-part study to test the safety, tolerability, and immune response for V934/V935 vaccine using a new prime-boost regimen in participants with selected solid tumors.	2008	2011	Source
3	-	Lucanix	NovaRx	III	Earliest approval - late 2013	2008	2012	Source
4	-	MAGE-A3	GlaxoSmithKline	III	Beyond 2015	-	-	-
5	-	BLP25 Liposome Vaccine plus best supportive care	Oncothyreon/ Merck	II	NDA submission 2011-2012	2000	2006	Source
6	-	EGF Cancer Vaccine/ TGF Cancer Vaccine	Biovest International	II/III	-	-	-	-
7	-	GI-4000 Vaccine + Activated T Cells, Surgical Evaluation after Vaccine 4	University of Pennsylvania	I	The purpose of this study is to determine if it is safe to add multiple immunotherapies to standard chemotherapy and radiation for treating pancreatic cancer tumors that cannot be completely removed by surgery	2008	2009	Source
8	-	HyperAcute-Lung Cancer Vaccine	NewLink Genetics	II	Terminated. Purpose was: To determine the response rate of the administration of HyperAcute-Lung Cancer Vaccine for subjects with stage IIIB or stage IV non-small cell lung cancer who have been treated with first line platinum-doublet therapy and have responded or are considered to have stable disease.	2007	2011	Source
9	-	TG 4010	Transgene	II/III	TG4010 is a suspension of recombinant Modified Vaccinia virus strain Ankara (MVA strain) carrying coding sequences for human MUC1 antigen and human interleukin-2 (IL2). TG4010 has been developed for use as an immunotherapy in cancer patients whose tumors express the MUC1 antigen.	2011	2016	Source
10	-	LungVax	AVAX Technologies	II	-	-	-	-

For more clinical trials in the Lung Cancer area, click here

Prostate Cancer

There are 21 clinical trials for cancer vaccines going on in the Prostate Cancer area.
The following table gives all the details on clinical trials going on in the field of Prostate Cancer for Vaccines

S.No.	Drug Name	Biological Name	Developer	Current Development Phase	Additional Information	Start Date	Completion Date	Source
1	GVAX Pancreas, Cyclophosphamide and CRS-207	-	Aduro BioTech	I	This clinical trial will evaluate the safety, immune response and overall survival of the sequential administration of two cancer vaccines, GVAX Pancreas Vaccine and CRS-207. GVAX vaccines are composed of cancer cells	2011	2014	Source

					that have been genetically-modified to secrete granulocyte-macrophage colony-stimulating factor (GM-CSF) to stimulate the immune system and that have been irradiated to prevent further cell division. GVAX Pancreas is administered with cyclophosphamide, which has been shown to increase effectiveness of GVAX by inhibiting T regulatory cells			
2	GVAX Pancreas, Cyclophosphamide and CRS-207	-	Aduro BioTech	II	This clinical trial will evaluate the safety, immune response and overall survival of the sequential administration of two cancer vaccines, GVAX Pancreas Vaccine and CRS-207. GVAX vaccines are composed of cancer cells that have been genetically-modified to secrete granulocyte-macrophage colony-stimulating factor (GM-CSF) to stimulate the immune system and that have been irradiated to prevent further cell division. GVAX Pancreas is administered with cyclophosphamide.	2011	2014	Source
3	-	AVX701	AlphaVax	I/II	The primary objective of this protocol is to determine the safety of immunization with CEA(6D) VRP in patients with advanced or metastatic CEA expressing malignancies.	2007	2010	Source
4	-	AVX704	AlphaVax	I/II	The primary objective of this protocol is to determine the safety of immunization with CEA(6D) VRP in patients with advanced or metastatic CEA expressing malignancies.	2007	2010	Source
5	-	OncoVEX GM-CSF modified herpes-simplex 1 virus	BioVex	I	The purpose of the study is to assess the safety of injections of OncoVEX GM-CSF into patients with pancreatic cancer that cannot be removed by surgery. The study will also test whether the injections are effective in treating the tumor.	2006	2010	Source
6	-	CDX-1309	Celldex Therapeutics	I	Celldex Therapeutics, Inc. is testing a form of immune therapy (vaccine) to see if it can be used to make the immune system attack the cancer	2006	2009	Source
7	-	carcinoembryonic antigen RNA-pulsed DC cancer vaccine	Duke University, National Cancer Institute (NCI)	I	Phase I trial to study the effectiveness of biological therapy in treating patients who have metastatic cancer that has not responded to previous treatment.	2000	2009	Source
8	-	QS22	Fox Chase Cancer Center, National Cancer Institute (NCI)	I	Phase I trial to study the effectiveness of vaccine therapy plus QS21 in treating patients who have advanced pancreatic or colorectal cancer.	-	-	-
9	-	PSMA/PRAME	MannKind Corporation	I	Completed The present clinical trial is a dose comparison of a	2007	2009	Source

					multi-component active immunotherapy designed to stimulate an immune reaction to specific tumor associated antigens which are highly expressed on a large number of solid cancers.			
10	-	Interleukin-2	National Cancer Institute (NCI)	II	Phase II trial to study the effectiveness of a vaccine made with the patients? white blood cells mixed with tumor proteins in treating patients who have advanced cancer.	-	-	-

For more clinical trials in the Prostate Cancer area, click here

Colon/Rectal Cancer

There are 31 clinical trials for cancer vaccines going on in the Colon/Rectal Cancer area.

The following table gives all the details on clinical trials going on in the field of Colon/Rectal Cancer for Vaccines

S.No	Drug Name	Biological Name	Developer	Current Development Phase	Additional Information	Start Date	Completion Date	Source
1	GVAX Pancreas, Cyclophosphamide and CRS-207	-	Aduro Biotech	I	Terminated This clinical trial will evaluate the safety, immune response and overall survival of the sequential administration of two cancer vaccines, GVAX Pancreas Vaccine and CRS-207	2011	2014	Source
2	-	AVX705	AlphaVax	I/II	The primary objective of this protocol is to determine the safety of immunization with CEA(6D) VRP in patients with advanced or metastatic CEA expressing malignancies.	2007	2010	Source
3	-	AVX701	AlphaVax	I/II	The primary objective of this protocol is to determine the safety of immunization with CEA(6D) VRP in patients with advanced or metastatic CEA expressing malignancies.	2007	2010	Source
4	-	AVX702	AlphaVax	I/II	The primary objective of this protocol is to determine the safety of immunization with CEA(6D) VRP in patients with advanced or metastatic CEA expressing malignancies.	2007	2010	Source
5	-	Oncophage	Antigenics	Preclinical	-	-	-	-
6	-	GVAX	BioSante Pharmaceuticals	I	The present clinical trial is a dose comparison of a multi-component active immunotherapy designed to stimulate an immune reaction to specific tumor associated antigens which are highly expressed on a large number of solid cancers.	2007	2009	-
7	-	CDX-1308	Celldex Therapeutics	I	Celldex Therapeutics, Inc. is testing a form of immune therapy (vaccine) to see if it can be used to make the immune system attack the cancer	2006	2009	Source
8	-	CDX-307	Celldex Therapeutics	II	-	-	-	-
9	-	CA-9	Dendreon	Preclinical	-	-	-	-

10	-	Lapuleucel-T	Dendreon	Preclinical	-	-	-	-

For more clinical trials in the Colon/Rectal Cancer area, click here

Breast Cancer

There are 28 clinical trials for cancer vaccines going on in the Breast Cancer area.

The following table gives all the details on clinical trials going on in the field of Breast Cancer for Vaccines

S.No	Drug Name	Biological Name	Developer	Current Development Phase	Additional Information	Start Date	Completion Date	Source
1	-	ADXS31-164	Advaxis	I	-	-	-	-
2	-	AVX701	AlphaVax	I/II	The primary objective of this protocol is to determine the safety of immunization with CEA(6D) VRP in patients with advanced or metastatic CEA expressing malignancies.	2007	2010	Source
3	-	AVX701	AlphaVax	I/II	The primary objective of this protocol is to determine the safety of immunization with CEA(6D) VRP in patients with advanced or metastatic CEA expressing malignancies.	2007	2010	Source
4	-	NeuVax	Apthera	II	-	-	-	-
5	-	MVA-BN HER2 vaccine	Bavarian Nordic ImmunoTherapeutics	I/II	To evaluate the safety of MVA-BN-HER2 in women with HER-2-positive breast cancer.	2010	2011	Source
6	-	GVAX	BioSante Pharmaceuticals	II	-	-	-	-
7	-	CDX-1307	Celldex Therapeutics	I	Celldex Therapeutics, Inc. is testing a form of immune therapy (vaccine) to see if it can be used to make the immune system attack the cancer	2006	2009	Source
8	-	CEA	Dendreon	Preclinical	-	-	-	-
9	-	Lapuleucel-T	Dendreon	I	-	-	-	-
10	Lapatinib	dHER2 + AS15 ASCI	Duke University, GlaxoSmithKline	I/II	This is a phase I/II study to determine the safety and gain insight into the immune response of the immunologic agent dHER2+AS15 ASCI when administered in combination with lapatinib. This study is for patients with metastatic breast cancer (invasive breast cancer with stage IV disease) that overexpresses HER2 and is resistant to trastuzumab (Herceptin).	2009	2011	Source

For more clinical trials in the Breast Cancer area, click here

Pancreatic Cancer

There are 21 clinical trials for cancer vaccines going on in the Pancreatic Cancer area.

The following table gives all the details on clinical trials going on in the field of Pancreatic Cancer for Vaccines

S.No.	Drug Name	Biological Name	Developer	Current Development Phase	Additional Information	Start Date	Completion Date	Source
1	GVAX Pancreas, Cyclophosphamide and CRS-207	-	Aduro BioTech	I	This clinical trial will evaluate the safety, immune response and overall survival of the sequential administration of two cancer vaccines, GVAX Pancreas Vaccine and CRS-207. GVAX vaccines are composed of cancer cells that have been	2011	2014	Source

					genetically-modified to secrete granulocyte-macrophage colony-stimulating factor (GM-CSF) to stimulate the immune system and that have been irradiated to prevent further cell division. GVAX Pancreas is administered with cyclophosphamide, which has been shown to increase effectiveness of GVAX by inhibiting T regulatory cells			
2	GVAX Pancreas, Cyclophosphamide and CRS-207	-	Aduro BioTech	II	This clinical trial will evaluate the safety, immune response and overall survival of the sequential administration of two cancer vaccines, GVAX Pancreas Vaccine and CRS-207. GVAX vaccines are composed of cancer cells that have been genetically-modified to secrete granulocyte-macrophage colony-stimulating factor (GM-CSF) to stimulate the immune system and that have been irradiated to prevent further cell division. GVAX Pancreas is administered with cyclophosphamide.	2011	2014	Source
3	-	AVX701	AlphaVax	I/II	The primary objective of this protocol is to determine the safety of immunization with CEA(6D) VRP in patients with advanced or metastatic CEA expressing malignancies.	2007	2010	Source
4	-	AVX704	AlphaVax	I/II	The primary objective of this protocol is to determine the safety of immunization with CEA(6D) VRP in patients with advanced or metastatic CEA expressing malignancies.	2007	2010	Source
5	-	OncoVEX GM-CSF modified herpes-simplex 1 virus	BioVex	I	The purpose of the study is to assess the safety of injections of OncoVEX GM-CSF into patients with pancreatic cancer that cannot be removed by surgery. The study will also test whether the injections are effective in treating the tumor.	2006	2010	Source
6	-	CDX-1309	Celldex Therapeutics	I	Celldex Therapeutics, Inc. is testing a form of immune therapy (vaccine) to see if it can be used to make the immune system attack the cancer	2006	2009	Source
7	-	carcinoembryonic antigen RNA-pulsed DC cancer vaccine	Duke University, National Cancer Institute (NCI)	I	Phase I trial to study the effectiveness of biological therapy in treating patients who have metastatic cancer that has not responded to previous treatment.	2000	2009	Source
8	-	QS22	Fox Chase Cancer Center, National Cancer Institute (NCI)	I	Phase I trial to study the effectiveness of vaccine therapy plus QS21 in treating patients who have advanced pancreatic or colorectal cancer.	-	-	-
9	-	PSMA/PRAME	MannKind Corporation	I	Completed The present clinical trial is a dose comparison of a multi-component active	2007	2009	Source

					immunotherapy designed to stimulate an immune reaction to specific tumor associated antigens which are highly expressed on a large number of solid cancers.			
10	-	Interleukin-2	National Cancer Institute (NCI)	II	Phase II trial to study the effectiveness of a vaccine made with the patients? white blood cells mixed with tumor proteins in treating patients who have advanced cancer.	-	-	-

For more clinical trials in the Pancreatic Cancer area, click here

Melanoma Cancer

There are 20 clinical trials for cancer vaccines going on in the Melanoma Cancer area.

The following table gives all the details on clinical trials going on in the field of Melanoma Cancer for Vaccines

S.No.	Drug Name	Biological Name	Developer	Current Development Phase	Additional Information	Start Date	Completion Date	Source
1	-	aldesleukin, incomplete Freund?s adjuvant, recombinant tyrosinase-related protein-2	Alphavax	II	To compare the effectiveness of vaccine therapy plus interleukin-2 to that of vaccine therapy alone in treating patients who have metastatic melanoma that has not responded to previous treatment.	2001	Ongoing	Source
2	-	MVax autologous cell vaccine	AVAX Technologies	III	Study suspended pending capitalization in US	-	-	-
3	-	GVAX	BioSante Pharmaceuticals	I	-	-	-	-
4	-	MDX-010 (anti-CTLA4) monoclonal antibody	Bristol-Myers	III	Fastrack Approval possibly by 2013	2004	2009	Source
5	-	BMS-936558 (MDX-1106)	Bristol-Myers Squibb	I	The purpose of this study is to determine the safety and effectiveness of MDX-1106 in patients with certain types of cancer.	2008	2015	Source
6	-	CDX-1401	Celldex Therapeutics	I/II	The main purpose of this study is to examine the safety and tolerability of CDX-1401 when given in combination with an immune stimulant (resiquimod) to patients with advanced cancers that are known to express the NY-ESO-1 protein.	2009	2013	Source
7	-	2401502 (domain antibody targeted multicomponent vaccine)	GlaxoSmithKline	I	-	-	-	-
8	-	PG13-MAGE-A3 TCR9W11 (anti-MAGE-A3/12 TCR) Transduced Autologous Peripheral Blood Lymphocytes, Aldesleukin, Cyclophosphamide, Fludarabine	GlaxoSmithKline/NCI	II	To evaluate the safety and effectiveness of anti-MAGE-A3/12 lymphocytes as a treatment for metastatic cancers that have not responded to standard treatment	2010	2012	Source
9	-			I/II		2008	2009	Source

		Melaxin (autologous dendritoma vaccine) and BCG	Greenville Hospital System University Medical Center, Oncolix		The purpose of this study is to determine if treatment with the autologous cellular vaccine, Melaxin, in combination with Bacillus Calmette-Guerin (BCG) injections is effective in Stage IV malignant melanoma.			
10	-	TDS/DNA Cancer Vaccine	Ichor Medical Systems	I	-	-	-	-

For more clinical trials in the Melanoma Cancer area, click here

Ovarian Cancer

There are 19 clinical trials for cancer vaccines going on in the Ovarian Cancer area.

The following table gives all the details on clinical trials going on in the field of Ovarian Cancer for Vaccines

S.No.	Drug Name	Biological Name	Developer	Current Development Phase	Additional Information	Start Date	Completion Date	Source
1	-	OVax: Autologous, DNP-Modified Ovarian Cancer Vaccine	AVAX Technologies	I/II	To determine if a vaccine made from the patient?s own tumor tissue can stimulate an immune response against the patient?s tumor cells. To determine the safety of the vaccine.	2008	2011	Source
2	-	OVax: Autologous, DNP-Modified Ovarian Cancer Vaccine	Avax Technologies	I/II	To determine if a vaccine made from the patient?s own tumor tissue can stimulate an immune response against the patient?s tumor cells. To determine the safety of the vaccine.	2008	2012	Source
3	-	CDX-1311	Celldex Therapeutics	I	Celldex Therapeutics, Inc. is testing a form of immune therapy (vaccine) to see if it can be used to make the immune system attack the cancer	2006	2009	Source
4	-	Lapuleucel-T	Dendreon	I	completed	-	-	-
5	-	carcinoembryonic antigen RNA-pulsed DC cancer vaccine	Duke University, National Cancer Institute (NCI)	I	Phase I trial to study the effectiveness of biological therapy in treating patients who have metastatic cancer that has not responded to previous treatment.	2000	2009	Source
6	standard of care observational follow-up	FANG	Gradalis, Inc.	II	This is a Phase II 2:1 randomized study of adjuvant intradermal autologous FANG? cancer vaccine (1.0 x 10^7 cells/injection; maximum of 12 vaccinations) in women with stage IIIC epithelial ovarian cancer who attain a clinical or pathologic complete response (including a post-treatment, prevaccination baseline serum CA-125 level of ? 20 units/ml) after primary surgical cytoreduction and a total of six courses of front-line	2011	2015	Source

					(pre- and post- or post-surgical) chemotherapy.			
7	-	oregovomab; cyclophosphamide	Gynecologic Oncology Group, NCI	I/II	This randomized clinical trial is studying the side effects of oregovomab and to see how well it works with or without cyclophosphamide in treating patients with stage III or stage IV ovarian epithelial cancer, fallopian tube cancer, or primary peritoneal cancer that responded to second-line chemotherapy.	-	-	-
8	carboplatin, cisplatin, cyclophosphamide, paclitaxel, dinitrophenyl	BCG vaccine, autologous tumor cell vaccine	Gynecologic Oncology Group, NCI	II	Phase II trial to study the effectiveness of vaccine therapy in treating patients who have stage III or stage IV ovarian epithelial cancer.	1999	2009	Source
9	-	Allogeneic whole epithelial tumor cells, DNP-conjugated and irradiated	Hadassah Medical Organization	I/II	This study is based on the finding that tumor cells that are grown in the laboratory can be modified in such a way that, when injected to the patient, they will stimulate his/her immune response. This approach will be evaluated in patients with colorectal, gastric, ovarian, breast or lung epithelial cancer	-	-	Source
10	low dose cyclophosphamide (oral)	DPX-Survivac with low dose cyclophosphamide	ImmunoVaccine Technologies, Inc.	I/II	This is a phase 1-2 study to determine the safety and immunogenicity profiles of DPX-Survivac, a therapeutic vaccine co-administered with a regimen of low dose oral cyclophosphamide. DPX-Survivac is for the treatment of ovarian, fallopian tube, and peritoneal cancers.	-	-	Source

For more clinical trials in the Ovarian Cancer area, click here

Renal Cancer

There are 17 clinical trials for cancer vaccines going on in the Renal Cancer area.

The following table gives all the details on clinical trials going on in the field of Renal Cancer for Vaccines

S.No	Drug Name	Biological Name	Developer	Current Development Phase	Additional Information	Start Date	Completion Date	Source
1	-	Cancer vaccine	Advantagene	Preclinical	-	-	-	-
2	-	HSPPC-96	Antigenics	I/II	Renal cell carcinoma patients? blood will be monitored over a period of 15 weeks to evaluate their level of immune response to multiple administration of HSPPC-96	2010	2012	Source
3	-	-	Antigenics	III	Terminated due to lack of enrollment	2002	-	Source

4	-	Dendritic cell vaccine	Argos Therapeutics	I/II	The purpose of this trial is to examine the safety, feasibility, immunological response, and clinical antitumor activity of administering a dendritic cell vaccine to patients with metastatic renal cell carcinoma.	2004	2008	Source
5	-	AGS-003+sunitinib	Argos Therapeutics/ Kirin Brewery	II	Study to investigate an anticancer cellular immunotherapeutic, AGS-003, when used in combination with sunitinib in subjects with previously untreated advanced stage RCC.	2008	2011	Source
6	-	BMS-936558 (MDX-1106)	Bristol-Myers Squibb	I	The purpose of this study is to determine the safety and effectiveness of MDX-1106 in patients with certain types of cancer.	2008	2015	Source
7	-	Serum and urinary CA9 level	Centre Hospitalier Universitaire de Saint Etienne	Preclinical	It was demonstrated that the level of expression of CA9 in tumor tissue can be used as a predictive marker of response to immunotherapy.	2009	2013	Source
8	-	Reniale	FBM-Pharma	III	Approval in select regions outside the U.S. by 2013	-	-	-
9	-	PG13-MAGE-A3 TCR9W11 (anti-MAGE-A3/12 TCR) Transduced Autologous Peripheral Blood Lymphocytes, Aldesleukin, Cyclophosphamide, Fludarabine	GlaxoSmithKline/NCI	II	To evaluate the safety and effectiveness of anti-MAGE-A3/12 lymphocytes as a treatment for metastatic cancers that have not responded to standard treatment	2010	2012	Source
10	Endoxana, IMA901, Leukine	-	Immatics Biotechnologies GmbH	II	This study was conducted in order to evaluate the efficacy and safety of the cancer vaccine IMA901 and GM-CSF as adjuvant in the treatment of advanced renal cell carcinoma.	2007	2009	Source

For more clinical trials in the Renal Cancer area, click here

Cervical Cancer

There are 13 clinical trials for cancer vaccines going on in the Cervical Cancer area.

The following table gives all the details on clinical trials going on in the field of Cervical Cancer for Vaccines

S.No.	Drug Name	Biological Name	Developer	Current Development Phase	Additional Information	Start Date	Completion Date	Source
1	-	Lorvaxin C	Advaxis	I	completed	-	-	-
2	-	CA-9	Dendreon	Preclinical	-	-	-	-
3	-	HPV-16/18 vaccine (Cervarix) Aimmugen?	GlaxoSmithKline	III	Approval in more than 70 countries including European Union countries, Mexico, Singapore, Australia; Received approval in the U.S. in October 2009	2006	2009	Source
4	-	Listeria monocytogenes	Gynecologic Oncology Group,	II	This phase II clinical trial is studying the side effects and	2010	2011	Source

		cancer vaccine ADXS11-001	NCI		how well vaccine therapy works in treating patients with persistent or recurrent cervical cancer.			
5	-	VGX-3100	Inovio Pharmaceuticals	I	The investigators have developed a DNA vaccine, VGX-3100, to include plasmids targeting E6 and E7 proteins of both HPV subtypes 16 and 18	2010	Ongoing	Source
6	-	PSMA/PRAME	MannKind Corporation	I	Completed The present clinical trial is a dose comparison of a multi-component active immunotherapy designed to stimulate an immune reaction to specific tumor associated antigens which are highly expressed on a large number of solid cancers.	2007	2009	Source
7	-	Gardasil, Placebo	Merck	Approved	Approved more than 100 countries including U.S., European Union, Mexico and others	2005	2006	Source
8	-	V503	Merck	III	Expected results in late 2011	2010	2011	Source
9	-	-	National Cancer Institute (NCI)	II	PV701 may be able to kill tumor cells while leaving normal cells undamaged.	2003	Ongoing	Source
10	-	Interleukin-2	National Cancer Institute (NCI)	II	Phase II trial to study the effectiveness of a vaccine made with the patients? white blood cells mixed with tumor proteins in treating patients who have advanced cancer.	-	-	-

For more clinical trials in the Cervical Cancer area, click here

All other Cancer types

There are 80 clinical trials for cancer vaccines going on in all other areas of Cancer.

For complete information on other clinical trials, click **here**

Challenges in Cancer vaccine development

Cancer vaccines are promising, emerging therapeutic options. The global cancer vaccine market is faced with numerous challenges.

Cancer Vaccine market is subjected to the following roadblocks:

- Clarity on how best to use cancer vaccines with respect to disease stage and in combination with other therapies
- Regulatory hurdles
- High cost involved in producing an oncology product
- Government cost containment measures
- Fear over the efficacy and side effects of cancer vaccine
- The expected cost of cancer vaccines would be around $15,000 to $20,000 per patient per year.
- This augments the reimbursement issues and it is likely to reduce the penetration rate of cancer vaccines

But it is a timely reminder for developers that the path to market for therapeutic cancer vaccines is not going to be an easy one. Companies must focus on conducting well-designed trials with achievable but robust endpoints in suitable patient populations, and perhaps even consider combination trials with other therapies.