



Developing the Cancer Vaccine Industry

A guide to the challenges and opportunities in the promising cancer vaccine market

THE PROMISING CANCER VACCINE MARKET

Why Cancer Vaccines?

The National Cancer Institute explains:

“Cancer vaccines are designed to boost the body’s natural ability to protect itself, through the immune system, from dangers posed by damaged or abnormal cells such as cancer cells.”

Unlike chemotherapy and radiation therapy, cancer vaccines have very few side effects; traditional treatments—including surgery, radiation, and chemotherapy—are aggressive approaches that can have detrimental side effects, whereas vaccines encourage the body to heal itself. This form of treatment has many advantages, including:

High specificity, low toxicity

- Vaccination targets the tumor specifically, while similar looking and behaving normal cells are left alone (dividing cells, normal brain cells, etc.)

Long-term persistence & memory

- Anti-tumor effects persist when vaccine treatment ends
- Vaccine treatments train the immune system to distinguish a disease agent as foreign, destroy it, and “remember it”, so that it is more easily recalled and destroyed if it recurs (critical for brain tumors)

High diversity & adaptability

- Vaccine treatments facilitate ongoing immune response, which can keep up with mutating tumors that would otherwise acquire treatment resistance

In 2010 GlobalData valued the global cancer vaccines market at **\$3,483 million**, after increasing at a compound annual growth rate (CAGR) of 63.7% during 2006-2010. Due to the increasing patient population of cancer, GlobalData predicts that the global cancer vaccines market will grow at a CAGR of 12.7% from 2010 to 2018, and will reach **\$9,077.9 million** by 2018.

In order for this promising industry to flourish, the pharmaceutical and biotech companies must overcome a multitude of research and manufacturing challenges. This e-book not only examines these challenges, but also provides examples of market opportunities within the growing cancer vaccine industry.

Between 2004 and 2011 most strategic consolidations in the global cancer vaccine market took place within North America (59% of Mergers and Acquisitions, 27% of deals, and 42% of co-developments).

CANCER VACCINE INDUSTRY CHALLENGES

As previously discussed, cancer vaccines have the promising potential to assist in the fight against cancer. Currently, there are more than one hundred immunotherapy products in various stages of development—but the development and approval process is complicated, to say the least.

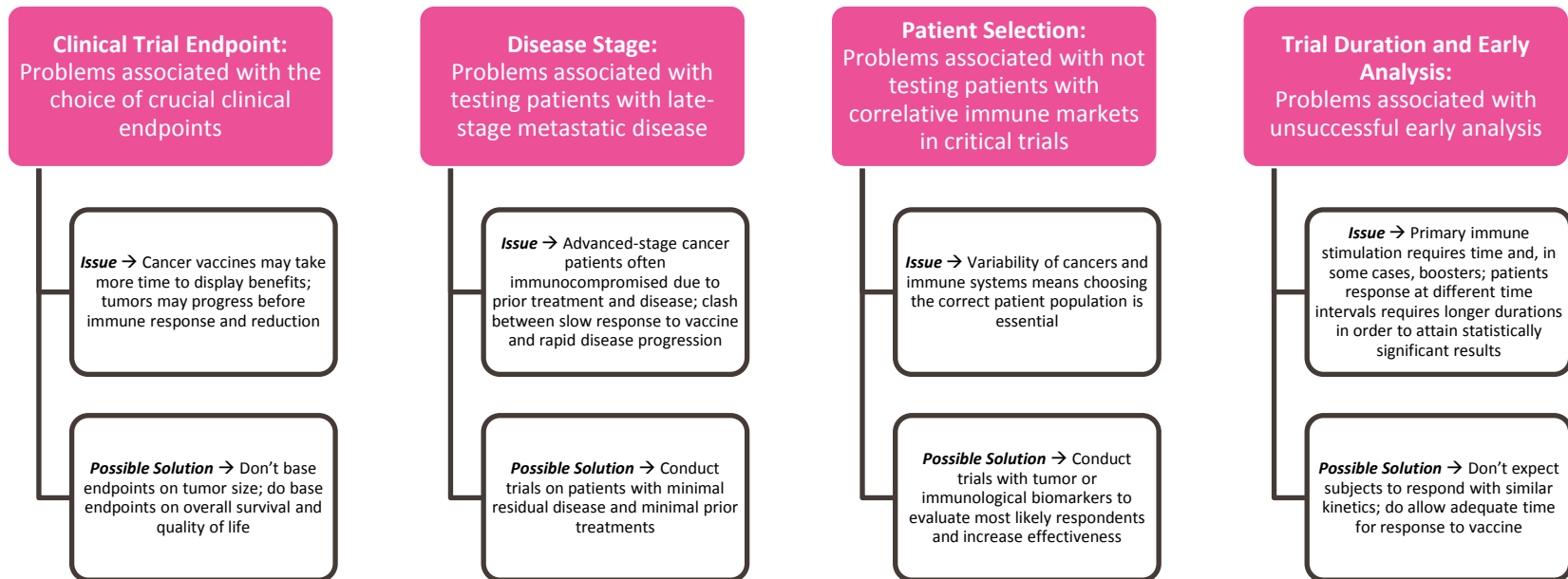
A- Research Challenges

Firstly, there are potential limitations to the cancer vaccines due to a need for thorough research and technology. A multitude of various experts are required for this field including:

- Tumor biologists & immunologists – Research and discovery
- Molecular biologist – Sequencing of proteins of peptides
- Virologists & microbiologists – Design of viral vectors, productions/manufacturing work
- Physicians, nurses, & veterinarians – Investigational New Drug (IND) process, patient treatment, developing studies
- Biochemists & researchers – Expertise in X-ray crystallography need for construction of antibodies

However, even after assembling a team of experts, additional challenges persist. For example, how does the team decide which type of cancers to target, and which method will they choose to manipulate the cells? These early choices are critical to choosing the right path towards the creation of a successful cancer vaccine.

Many companies are able to effectively complete Phase 2 studies, only to face the following **complications in Phase 3** (late clinical trials):



In addition, challenges may arise from **complicated and potentially small target markets**. For instance, a tumor antigen may be specific for limited cancer types, therefore restricting the market size, because the cancer vaccine can only benefit a subset of the population. In this case, research is imperative in finding the right target population by using biomarkers, and targeting very early stage disease.

B. Manufacturing & Commercialization Challenges

Gaining approval from regulatory agencies is not the only impediment when getting the vaccines to the market. The following table describes the other commercialization challenges, which include company size, the complicated target market, manufacturing costs, and pricing and reimbursement.

Challenges in Manufacturing and Logistics

- **Issue** → Biologics are costly to produce and manufacturing changes need to be tested for bioequivalence; personalized vaccines lack economies of scale and are difficult to distribute while maintaining sterility
- **Possible Solution** → Standardize manufacturing and logistics process early-on; use adjuvants for reduced quantity of antigen; research best logistics practices in similar industries, or seek partnerships

Challenges in Commercialization

- **Complicated and Potentially Small Target Market**
 - **Issue** → Smaller companies have limited financial resources and lack commercialization experience
 - **Possible Solution** → Partner with an established, experienced company
- **Pricing and Reimbursement**
 - **Issue** → No prior model to help establish initial market price; payers may take to accept vaccines into the current treatment landscape and, thus, resist prices and reimbursement
 - **Possible Solution** → Validate the price; establish a comprehensive value proposition and clearly communicate it to the payers

5 INDUSTRY EXAMPLES TO WATCH

1. **Aduro Biotech**
2. **Antigen Express, Inc.**
3. **Galena Biopharma**
4. **GlobeImmune**
5. **Immunocellular**

#1



Product Name: CRS-207

Indication: metastatic pancreatic cancer (combination therapy)

Development Status: Phase II

Headquarters: Berkeley, CA

Number of Employees: N/A

About Us:

“In 2002, Stephen Isaacs decided to invest in an immunotherapy program from scratch. He assembled a team, and after they completed extensive research, they chose *Listeria monocytogenes*, which has been used as a research tool for more than 50 years because of its ability to induce potent cellular immunity. *Listeria* is a common environmental pathogen, which makes its use as a vaccine somewhat counter-intuitive, but the research team engineered two distinct strains to be safe for use in humans while continuing to induce robust immune responses. These advances have been published in 20 major studies and have generated more than \$20 million in grant funding.

Listeria's unique combination of attributes makes it an ideal platform for prophylactic and therapeutic vaccines. It effectively stimulates two forms of immunity (innate and adaptive); it can be administered repeatedly without losing potency; it can increase the potency of other vaccines and treatments when used in combination; and it can be manufactured at relatively low cost.

Aduro's therapeutic vaccines have already been tested in three Phase 1 clinical safety trials in cancer and infectious disease with a total of 30 patients, and Aduro is currently planning Phase 2A and Phase 1B cancer trials with its lead therapeutic, CRS-207.

In addition to building its own proprietary pipeline, Aduro is actively seeking partnerships and contract research agreements to develop new vaccines and to boost the efficacies of other vaccines and treatments. Aduro can engineer a new vaccine strain and have it ready for clinical testing within 12 months.”

Officers and Directors:

Stephen T. Isaacs – President and CEO

Seth David Model, MBA – acting CFO

Thomas W. Dubensky, Jr., Ph.D. – Chief Scientific Officer

Dirk G. Brockstedt, Ph.D. – Senior VP of Research and Development

Aimee Murphy – Director of Clinical Operations

Justin Skoble, Ph.D. – Director, Biodefense and Process Development

Company Website: www.adurobiotech.com/

More Information: <http://www.fiercevaccines.com/special-reports/10-promising-therapeutic-vaccines/crs-207-10-promising-therapeutic-vaccines>

From 2006-2010 Gardasil from Merck, Cervarix from GlaxoSmithKline (GSK), and Provenge (sipulecel-T) from Dendreon Corporation comprised the cancer vaccine market.

#2

Antigen Express, Inc.

Setting the standard in active immunotherapy.

Product Name: AE37 (peptide vaccine)

Indication (a): breast cancer

Indication (b): ovarian cancer (combination therapy), prostate cancer

Development Status (a): Phase II

Development Status (b): Phase I

Headquarters: Worcester, MA

Number of Employees: 5-10

About Us:

"Antigen Express is a platform technology and product-based company developing proprietary vaccine formulations for active immunotherapy as well as disease prevention. In contrast to traditional therapies, the goal of active immunotherapy is to amplify the patients' ability to fight specific disease rather than targeting the diseased tissue or pathogenic agent directly. The novel technologies being developed at Antigen Express allows for robust and antigen-specific stimulation of CD4+ T cells, a cell type critical in the recognition of pathogens and modulation of the immune response. Antigen Express is developing these technologies for application to the treatment of cancer, infectious diseases, and other serious diseases. Our most advanced vaccine utilizes a self-potentiating peptide as an off-the-shelf product for active immunotherapy of breast and prostate cancer."

Officers and Directors:

Eric von Hofe, Ph.D. – President

Robert E. Humphreys, MD, Ph.D. – Founder (retired)

Catherine Blackwell – Business Operations Manager

Company Website: www.antigenexpress.com

More Information: <http://www.fiercevaccines.com/special-reports/10-promising-therapeutic-vaccines/ae37-10-promising-therapeutic-vaccine>

Today, the global cancer vaccines market is mostly made up of cervical and prostate cancer vaccines, while promising vaccines are expected to be launched in the following areas: cervical cancer, lung cancer, pancreatic cancer, and melanoma.

#3



Product Name: NeuVax (E75 cancer vaccine)

Indication (a): early-stage breast cancer (prevention of relapse)

Indication (b): prostate cancer

Development Status (a): Phase III

Development Status (b): Phase I/II

Headquarters: Lake Oswego, OR

Number of Employees: 39

About Us:

“Galena Biopharma is focused on discovering, developing and commercializing innovative therapies addressing major unmet medical needs using targeted biotherapeutics.”

Officers and Directors:

Mark J. Ahn, Ph.D. – President & CEO

Rosemary Mazanet, M.D., Ph.D. – Executive VP & CMO

Mark W. Schwartz, Ph.D. – Executive VP & COO

Hana B. Moran, Ph.D. – VP, Regulatory & Compliance

Ryan Dunlap – Director, Controller, & Principal Accounting Officer

Company Website: www.galenabiopharma.com

More Information: <http://www.fiercevaccines.com/special-reports/10-promising-therapeutic-vaccines/nexvax2-10-promising-therapeutic-vaccines>

#4



Product Name: GI-4000 (therapeutic vaccine)

Indication (a): colorectal cancer, pancreatic cancer

Indication (b): colorectal cancer (first-line therapy), colorectal cancer (second-line therapy), NSCLC

Development Status (a): Phase II

Development Status (b): Phase I

Product Name: GI-6207 (therapeutic vaccine)

Indication: metastatic cancer

Development Status: Phase I

Product Name: GI-6301 (brachyury peptide vaccine)

Indication: solid tumors

Development Status: Phase I

Headquarters: Louisville, CO

Number of Employees: 36

About Us:

“We are a biopharmaceutical company focused on developing therapeutic products for cancer and infectious diseases based on our proprietary Tarmogen® platform. The Tarmogen platform activates the immune system by stimulating cellular immunity, known as T cell immunity, in contrast to traditional vaccines, which predominately stimulate antibody production. We have four Tarmogen product candidates in six ongoing clinical trials. Our lead cancer product candidate, GI-4000, is being evaluated in combination with gemcitabine in a fully enrolled, placebo-controlled Phase 2b trial in resected pancreas cancer. Our lead infectious disease product candidate, GI-5005, has completed a Phase 2b trial in patients with chronic hepatitis C virus, or HCV, infection.”

Officers and Directors:

Timothy C. Rodell, M.D. – CEO and President

David Apelian, M.D., Ph.D., MBA – Senior VP Research & Development and CMO

C Jeffrey Dekker – VP, Finance

John Frenz – Ph.D. – VP, Operations

Company Website: www.globeimmune.com

More Information: <http://www.fiercebiotech.com/special-reports/biotechs-5-key-attacks-pancreatic-cancer/gi-4000-biotechs-5-key-attacks-pancreatic-c>



Product Name: GI-4000 (therapeutic vaccine)

Indication (a): colorectal cancer, pancreatic cancer

Indication (b): colorectal cancer (first-line therapy), colorectal cancer (second-line therapy), NSCLC

Development Status (a): Phase II

Development Status (b): Phase I

Headquarters: Woodland Hills, CA

Number of Employees: 4

About Us:

“ImmunoCellular Therapeutics, Ltd. is a clinical-stage biotechnology company that is focused on developing new immune-based products to treat and diagnose cancer. Our products and technologies are designed to harness the power of the immune system to improve the treatment and diagnosis of cancer. We are developing active immunotherapies that target not only regular tumor cells, but also the cancer stem cells believed to cause cancer growth and recurrence. Using our proprietary discovery technology, we also identify and develop monoclonal antibodies that may be used to treat and diagnose a wide range of cancers. Our most advanced clinical programs are in glioblastoma multiforme, but our product candidates also have potential applications in many other cancers with high unmet medical need.”

Officers and Directors:

John S. Yu, M.D. – Interim CEO and President

David Fractor – CFO

James G. Bender, Ph.D., M.P.H. – VP, Product Development and Manufacturing

Company Website: www.imuc.com

More Information: <http://www.fiercevaccines.com/special-reports/10-promising-therapeutic-vaccines/ict-107-10-promising-therapeutic-vaccines>

LOOKING TOWARDS THE FUTURE

In spite of the various challenges, the future of the cancer vaccine industry looks optimistic, with several promising cancer vaccines in the pipeline. However, the biotech and pharmaceutical companies cannot do it alone; the much anticipated cancer vaccines will only be able to emerge on the market with the help of contract manufacturing organizations, contract research organizations, clinical trial organizations, consultants and banks, and others. We look forward to seeing all that can be accomplished through these future partnerships.



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We'd love to meet you too...

The World Vaccine Congress & Expo is now in its 13th year. It is the world's biggest and most comprehensive event for the vaccine industry.

Over 60% of our attendees come from the world's leading pharma and biotechs.

Our expo market place is the only one of its kind for the vaccine industry.

Combining a high level conference with a focused exhibition and adding in guaranteed meetings with targeted buyers in a 1-2-1 Partnering format makes this event the one must-attend event for the whole vaccine market.

To learn more about the World Vaccine Congress, visit the website.

Be sure to check out our blog for more information about strategy and innovation in vaccines.



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Strategy and innovation in vaccines