CANCER VACCINES MARKETS
(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers
# TABLE OF CONTENTS

1. Overview 5
   1.1 About this Report 5
   1.2 Scope of the Report 6
   1.3 Objectives 6
   1.4 Methodology 6
   1.5 Executive Summary 7

2. Overview of Cancer 9
   2.1 Cancer Statistics 9
   2.2 The Cost of Cancer 13
   2.3 Cancers Being Targeted by Vaccine Therapies: Overview of Disease and Market 16

3. Introduction to Cancer Vaccines 24
   3.1 Overview of the Types of Cancer Vaccines 24
   3.2 Antigen/Adjuvant Vaccines 27
   3.3 DNA Vaccines 33
   3.4 Vector-based Vaccines 35
   3.5 Tumor Cell Vaccines 35
   3.6 Dendritic Cell (DC) Vaccines 37
   3.7 Anti-Idiotype Vaccines 38

4. Prophylactic Vaccines on the Market and in Development 40
   4.1 Cervical Cancer (HPV) 40
   4.2 Prophylactic Breast Cancer Vaccine in Development 42

5. Therapeutic Vaccines on the Market and in Development 43
   5.1 Breakthroughs in the Cancer Vaccine Market: Vaccines on the Market 43
   5.2 Vaccines in Development (by Type of Vaccine) 45

6. Challenges and Issues in Cancer Vaccine Development 74
   6.1 Eliciting Appropriate Immune Response Against Cancer 74
   6.2 Clinical Trial Design 78
   6.3 Combination Therapies 82

7. Regulatory Issues 84
   7.1 Pharmaceutical Product Regulation 84
   7.2 New Drug Application (NDA) or Biologics License Application (BLA) 86
   7.3 Post-Approval Phase 86
   7.4 Fast-Track Review 87
   7.5 Orphan Drug Designation and Exclusivity 88
   7.6 What Regulatory Guidance Is Needed for Companion Biomarkers? 88
   7.7 Oncology Biomarker Qualification Initiative 89
   7.8 IRB Approval in Clinical Trials 89
   7.9 U.S. Patent and Trademark Office (USPTO) 89

8. Trends Affecting the Cancer Vaccine Market 90
   8.1 Screening and Cancer Detection 90
   8.2 Public Perception of Vaccines 90
   8.3 Insurance Issues 91
   8.4 New Technological and Scientific Developments 91
   8.5 Personalized Medicine 91

9. Business Landscape 93
   9.1 Technology and Market Trends 93
INDEX OF FIGURES

Figure 2.1: Estimates of National Expenditures for Cancer Care in 2006 by Cancer Site 14
Figure 2.2: Person-Years of Life Lost (PYLL) in the U.S. Due to Cancer, Male, 2006 15
Figure 2.3: Person-Years of Life Lost (PYLL) in the U.S. Due to Cancer, Female, 2006 16
Figure 3.1: Antigen Presentation 25
Figure 3.2: Antigen/Adjuvant Cancer Vaccine Immunotherapy Process 27
Figure 3.3: DNA Cancer Vaccine Immunotherapy Process 34
INDEX OF TABLES

Table 2.1: Estimated New Cancer Cases and Deaths in the U.S. by Sex for all Cancer Sites, 2010
Table 2.2: Estimated New Cancer Cases and Deaths for Ten Leading Cancer Sites in the U.S. in 2010
Table 2.3: Worldwide Number of New Cancer Cases and Deaths by Leading Cancer Sites and by Level of Economic Development, 2008
Table 2.4: Number of New Cancer Cases and Deaths by World Area, 2008
Table 2.5: Estimated Annual Costs of Cancer in the U.S. in Billions, 2008
Table 2.6: Cancer Vaccines in the Pipeline, by Cancer Type
Table 2.7: Infectious Agents Involved in Cancer
Table 2.8: Cancer Vaccine Technologies
Table 2.9: Antigens Commonly Found in Cancer Vaccines
Table 2.10: Adjuvants Commonly Found in Cancer Vaccines
Table 2.11: Cervical Cancer Vaccines on the Market
Table 2.12: Therapeutic Vaccines on the Market
Table 2.13: Pipeline of Therapeutic Cancer Vaccines, by Type of Vaccine
Table 2.14: Antigen/Adjuvant Vaccines in Development
Table 2.15: DNA and RNA Vaccines in Development
Table 2.16: Vector-based Vaccines in Development
Table 2.17: Autologous Tumor Cell Vaccines in Development
Table 2.18: Allogeneic Tumor Cell Vaccines in Development
Table 2.19: Dendritic Cell Vaccines in Development
Table 2.20: Anti-Idiotype Vaccines in Development
Table 2.21: Competitors with Phase III Cancer Vaccine Candidates in Their Pipelines
Table 2.22: Mechanisms of Immune Evasion by Cancers
Table 2.23: Key Recommendations for Cancer Vaccine Clinical Trial Design
Table 2.24: Challenges and Strategic Recommendations for Clinical Trial Design
Table 2.25: Combination Strategies to Enhance a Vaccine’s Anti-Tumor T-Cell Response
Table 2.26: Focus Areas for the FDA Critical Path Initiative
Table 2.27: Industry Challenges and Strategic Recommendations for Commercialization
Table 2.28: Required Elements of a Manufacturing Facility
Table 2.29: CMO Qualification Audit—Points to Investigate
Table 2.30: Strategies for Marketing Cancer Vaccines

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1. Overview

1.1 About this Report

Cancer vaccines have the potential to become a significant force in future cancer treatments. In 2010, Dendreon’s Provenge became the first cancer vaccine approved by the FDA, generating renewed interest and support for this type of cancer immune therapy. This relatively new commercial market for cancer vaccines is poised to dramatically increase to over $7 billion by 2015. The purpose of this TriMark Publications report is to supply comprehensive information on the developing market for cancer vaccines. This study surveys almost all of the companies known to be marketing, manufacturing, or developing cancer vaccines in the world, providing in-depth analysis of the current and emerging technologies in the cancer vaccines market. Each company is extensively examined, with a section on its history, product line, business and marketing analysis, and a subjective commentary of the company’s market position. Moreover, this report provides detailed discussions of cancer vaccines funding trends, intellectual property, market opportunities, research collaborations, partnership activities, regulatory issues and guidelines for establishing new ventures. Detailed tables and charts with sales forecasts and market share data are also included.

This study contains:

- Detailed analysis of recent trends in the cancer vaccines marketplace.
- Profiles of the leading companies with cancer vaccines tools and technologies.
- A comprehensive overview of cancer vaccines business strategies.
- The latest news and M&A developments in the cancer vaccines marketplace.

Also included in this report are:

- An overview of the disease and market potential of specific types of cancers being targeted by cancer vaccines developers.
- A full analysis, including the pros and cons, of the existing and emerging technologies used in creating cancer vaccines.
- A detailed discussion of the technical challenges in developing cancer vaccines.
- A synopsis of the issues involved in designing clinical testing for cancer vaccines.
- A review of regulatory issues and legislation affecting use and marketing of cancer vaccines.

The following key questions are answered by this report:

- How can therapeutic cancer vaccine clinical trials be optimized to aid regulatory approval and commercial success?
- What lessons can stakeholders learn from Provenge’s developmental and commercial pathway?
- What is the optimal design of a therapeutic cancer vaccine?
- What candidates are in the current therapeutic cancer vaccines pipeline?
- What are the key pipeline therapeutic cancer vaccines candidates in late-stage development?
- What are the clinical and commercial attributes of key late-stage therapeutic cancer vaccines candidates?
- Which biopharmaceutical companies are involved in the arena?
- What revenues will therapeutic cancer vaccines products generate over the next coming decade?
- Which cancer types will realize the greatest benefits from vaccines?
- What major challenges face the arena over the coming years and how can these be overcome?
- What advice do leading expert immunology/oncology vaccines developers give to stakeholders in the arena?
- What are the greatest commercial opportunities within the future therapeutic cancer vaccines market?
1.2 **Scope of the Report**

This study provides a comprehensive examination of the prophylactic and therapeutic cancer vaccines market. Cancer vaccines are defined as agents that stimulate or restore the immune system’s role of fighting off disease. Other areas of anti-cancer therapeutics are described in TriMark’s other market reports titled *Cancer Cell Therapy Markets* and *Cancer Therapeutics Markets*. A completed list of cancer-related market research reports can be found at [http://www.trimarkpublications.com](http://www.trimarkpublications.com).

The report includes the following items:

- Therapeutic vaccines (autologous/patient-specific and allogeneic/off-the-shelf).
- Prophylactic vaccines.
- Current and emerging vaccine technologies.
- Factors that influence the size and growth of the U.S. and global markets.
- Challenges in clinical testing and regulatory issues in cancer vaccines development.

1.3 **Objectives**

The main objectives of this analysis are to:

- Provide a complete understanding of cancer vaccines, from basic principles to their clinical applications.
- Identify viable technology drivers through a comprehensive look at platform technologies for cancer vaccines.
- Identify the challenges and risks in cancer vaccines development and commercialization.
- Present market figures regarding market projections, market share, key players and growth rates of the cancer vaccines.
- Describe specific product candidates that show the most promise for regulatory approval.
- Identify and analyze the major challenges within therapeutic cancer vaccines R&D including clinical trial standardization recommendations, designing optimal vaccines and the lessons learned from Provenge’s development pathway.
- Clinical and commercial analysis of key Phase III oncology vaccine candidates.
- Sales growth rates to 2020 for key products in development.

1.4 **Methodology**

The author of this report holds a master’s degree in immunology and has many years of laboratory experience investigating cancer immunotherapies as well as experience in science and medical writing. The editor is a Ph.D. in biochemistry from the University of Minnesota with many decades of experience in science writing and as a medical industry analyst. He has been a senior director of several large regional and national healthcare laboratories. Company-specific information is obtained mainly from industry trade publications, academic journals, news and research articles, press releases and corporate websites, as well as annual reports for publicly-held firms. Additional sources of information include non-governmental organizations (NGOs) such as the World Health Organization (WHO) and governmental entities, such as the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Where possible and practicable, the most recent data available have been used.

Some of the statistical information was taken from Biotechnology Associates’ databases and from TriMark’s private data stores. The information in this study was obtained from sources that we believe to be reliable, but we do not guarantee the accuracy, adequacy or completeness of any information or omission or for the results obtained by the use of such information. Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals regarding commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this report.
Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects, as well as Sector Snapshots that it publishes annually. TriMark extracts relevant data and analytics from its research as part of this data collection.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government-affiliated trade releases and other published information as part of its secondary research materials. The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations.

TriMark Publications Report, Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report in TriMark Publications includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly-available data and proprietary databases.
- Formulating a study outline with the assigned writer, including important items, as follows:
  - Market and product segment grouping, and evaluating their relative significance.
  - Key competitors’ evaluations, including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
  - End-user research to evaluate analytical significance in market estimation.
  - Supply chain research and analysis to identify any factors affecting the market.
  - New technology platforms and cutting-edge applications.
- Identifying the key technology and market trends that drive or affect these markets.
- Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.
- Completing a confirmatory primary research assessment of the report’s findings with the assistance of expert panel partners from the industry being analyzed.

1.5 Executive Summary

The field of cancer vaccines is entering an exciting phase, with years of research culminating in the practical clinical application of the technology. The first FDA approval of a therapeutic cancer vaccine has demonstrated the potential for these novel types of treatments to successfully enter a major market. Several other cancer vaccines candidates currently undergoing late-stage clinical development are expected to enter the market within the next five to ten years. These cancer vaccines will likely generate sizeable sales due to:

- Their development as a niche product to fulfill unmet therapeutic needs.
- Their potential to be used with existing cancer therapeutics, either in conjunction or in sequence.
- The possibility that they may be used as long-term treatments (immunizations & booster shots).
Cancer vaccines are a diverse group of therapies that may be divided into the following categories:

- Antigen/adjuvant vaccines.
- DNA vaccines.
- Vector-based vaccines.
- Tumor cell vaccines.
- Dendritic cell vaccines.
- Anti-idiotype vaccines.

The main goal of each of these types of vaccines is to stimulate the immune system to recognize and attack cancerous cells. However, each kind of vaccine has its pros and cons, and there has been no consensus as to which method best achieves the goal of eliminating cancers.

Following are key trends and challenges that drive the cancer vaccine space:

- A rise in the incidence of many cancers, including those associated with an increasingly-aging patient population.
- Increased interest from big pharmaceutical companies that will generate more opportunities for funding and product development.
- Continued pressures concerning product reimbursements.
- Growth of personalized medicines that, in some cases, may require companion biomarkers to assess a patient’s eligibility for the treatment. As such, there will be an increase in companion diagnostic tests developed in parallel with cancer vaccines.
- Well-designed, scientifically sound and FDA-accepted clinical trials that will demonstrate the vaccine’s maximum clinical efficacy and potential as an anti-cancer treatment.
- Investigation of the vast array of potential combinations of cancer vaccines with other types of cancer therapies.
- Cancer vaccine design that will stimulate a sufficient anti-cancer immune response without generating an autoimmune reaction.
- Improvements in vaccine manufacturing methods that will result in quicker vaccine production in greater quantities and more standardized vaccine products.
- Identification of more reliable biomarkers and/or immune responses to a particular vaccination protocol and their use in assessing the efficacy of the therapies prior to endpoint evaluations.
- Novel vaccine delivery methods such as nanoemulsion-based delivery, microdelivery systems for intradermal administration of vaccines and polymer-encased vaccines that may further improve the efficacy of existing vaccine protocols.