CANCER THERAPEUTICS MARKETS
(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers
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1. Overview

1.1 Introduction

Cancer is the second leading cause of death by disease in the United States, exceeded only by heart disease. Currently, 1 out of every 4 deaths in the U.S. is from cancer. In 2007, cancer claimed an estimated 559,650 American lives, or more than 1,500 people a day. Moreover, an estimated 1.44 million new cases of cancer were diagnosed. Approximately, 10.1 million Americans, now living, have a history of cancer. Although cancer occurs in all age groups, the incidence increases as people grow older. Nearly 77% of all cancers occur in people 55 years and older. However, pediatric cancer—though rare—is the nation’s leading cause of death by disease in children under the age of 15. An estimated 10,400 children in the U.S. were diagnosed with cancer in 2007 and 1,545 have died.

An estimated 12 million new cancer cases occurred worldwide in 2007, of which approximately 5.4 million cases occurred in economically developed countries and 6.7 million in economically developing countries. The corresponding total cancer deaths in 2007 were an estimated 7.6 million (about 20,000 cancer deaths a day), 2.9 million in economically developed countries and 4.7 million in economically developing countries.

However, cancer research has made remarkable progress, with several innovative therapies coming into the market in the past decade. There have been notable improvements over time in the relative five-year survival rates for many cancer sites and for all sites combined. In the U.S., death rates for 8 of the top 10 cancers remained level or declined during the 1990s, according to the Journal of National Cancer Institute report. The most notable decreases are in the death rates for breast cancer, prostate cancer, lung cancer, colon cancer and leukemia. This is, in no small measure, due to early detection and improved treatments, including more effective prescription drugs.

While the death rate from cancer is declining, the number of actual deaths is increasing because of an increasing population and longer life expectancy. Lifetime risk is the probability that an individual will develop cancer or die from it over the course of a lifetime. In the U.S., men have a one in two lifetime risk of developing cancer and women have a one in three risk.

Cancer is caused by both external (chemicals, radiation, viruses) and internal (hormones, immune conditions, inherited mutations) factors. These factors can act together or in sequence to initiate or promote abnormal cell growth and spread. Ten years or more may pass before exposures or mutations and detectable cancer.

Some cancers can be prevented. All cancers caused by cigarette smoking and the excessive use of alcohol can be completely prevented. In the U.S., in 2007, about 168,000 cancer deaths were due to tobacco use and nearly 19,000 were related to excessive use of alcohol, which frequently occurs in connection with cigarette smoking. Many other cancers that are related to diet can also be prevented. Scientific research suggests that as many as one-third of all cancer deaths may be related to obesity, physical inactivity, and nutrition, and can also be prevented. Certain cancers are related to infectious agents, such as hepatitis B virus (HBV), human papillomavirus (HPV), Helicobacter pylori, and others, and can be prevented through behavioral changes, vaccines, or antibiotics. In addition, many of the more than a million cases of skin cancers that were estimated to be diagnosed in 2007 could have been prevented by the use of proper protection from the sun.

Screening examinations administered by healthcare professionals can result in the early detection of some cancers—cancer of the breast, colon, rectum, cervix, prostate, oral cavity and skin. Treatment is more likely to be effective when the cancer is detected in its early stages. Self-examinations for cancer of the breast and skin also detect cancer early on. The cancers listed above, that can be prevented or detected earlier by screening, account for approximately half of all new cancer cases. The 5-year survival rate for those cancers is now about 90%. If everyone in the U.S. were regularly screened for cancer, the survival rate would be over 95%.

A simple cure for cancer does not seem likely. Cancer is not a single disease. Each type of cancer is complex. The causes and progress of each type of cancer is different. Tumors are composed of both normal cells and cancerous cells. Within a single tumor, the cells are in different stages of development.
Traditionally cancer has been treated with surgery, chemotherapy, hormones and radiation therapy, alone or in combination. Emerging technologies include photodynamic therapy, gene therapy, biological therapy (immunotherapy) and angiogenesis inhibitors. Pharmaceutical and biotechnology companies are investing billions of dollars to search out and develop weapons for the arsenal in the war against cancer. This report provides an overview of the global market for cancer therapeutics.

1.2 Goals and Objectives

The aim of this report is to provide in-depth information on the developing market for anti-cancer products and services. It includes detailed market analyses and discussions of industry trends in order to assess the impact on the current and emerging anti-cancer product markets. Forecasts and trends were developed from interviews with industry sources, as well as from assessment of available and emerging technologies. The study also focuses on the efforts of biotechnology companies and pharmaceutical firms to incorporate new technologies for developing anti-cancer drugs into their corporate strategies.

This review examines cancer therapeutic products now on the market, as well as those currently under development, that might be commercialized in the near future. It also profiles a number of firms that are actively involved in the marketing and development of products to be used in the treatment of cancer—both large multinational corporations, such as Bristol-Myers Squibb, GlaxoSmithKline, Roche/Genentech, and the smaller emerging biotechnology firms.

The report also provides an overview of the disease and data on cancers by site or type. It provides incidence and mortality data for different types of the disease. In addition, it provides a summary of each of the therapies that are being used to treat cancer. Industry influences on the cancer therapeutic market are also discussed.

1.3 Study, Scope and Format

The scope of the study is worldwide. The overview section provides extended definitions of the anti-cancer drugs to provide the reader with a clear understanding of the technology involved. It also provides an analysis of how drugs that combat cancer will transform the healthcare industry. The company profiles section includes a detailed discussion of the companies that have pioneered anti-cancer drug development and examines how their available products and services are transforming the practice of medicine.

1.4 Methodology

This study is based on interviews with sales and marketing professionals of companies in the cancer therapeutics market. They were queried, some several times, about their companies’ products and marketing strategies as well as their overall thoughts about their industry segment. Information was also obtained from interviews with founders, CEOs and vice presidents of some of the companies discussed in the report.

Sources of information for the study were trade association publications and meetings, product brochures and catalogs, and company literature. For all publicly held companies under discussion, an examination of the annual reports and financial reports were used as the basis of the data reported. Important data sources include reports by the Pharmaceutical Research and Manufacturers of America (PhRMA), the American Cancer Society, the Health for All Database of the World Health Organization (WHO), data published by the Canadian Cancer Society, as well as various health data from the Organization for Economic Cooperation and Development (OECD) and the U.S. Food and Drug Administration (FDA). Where possible and practicable, the most recent data available have been used.

The author of this report is a PhD in biochemistry with decades of experience in science writing and as a medical industry analyst. He has been a senior director of several large regional and national clinical testing laboratories. The senior editor is a doctoral level clinical scientist. He has over 30 years of experience in laboratory testing and instrument and reagent development technology, as well as extensive experience in senior level positions in biotech and medical service companies.
Some of the statistical information was taken from Biotechnology Associates’ databases and from TriMark’s private data stores. The information set forth 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, 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 with regard to commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this study.

**Primary Sources**

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects and Sector Snapshots that we publish annually. We extract relevant data and analytics from TriMark’s research of the past three years as part of this data collection. We also extract qualified data feeds from e-questionnaire responses and primary research responses for this compilation.

**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 our 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. The report conclusions are verified through intensive interviewing of top-ranking companies in the industry.

**TriMark Publications Report Research and Data Acquisition Structure**

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

- Completing an extensive secondary research effort on a an important market sector, including gathering all relevant information from corporate reporting, publicly-available databases, proprietary databases, direct meetings and personal interviews with key personnel.

- Formulating a study outline with the assigned writer, including important items:
  - 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.

- Launching a combination of primary research activities including two levels of questionnaires, executive-direct focused, company-specific, and region-specific communications to qualified and experienced senior executives worldwide.

- 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 Summary of Major Findings

The worldwide cancer-therapy market produced revenues of $34.6 billion in 2006. Treatment for cancer is estimated to become the largest sales value area at $55 billion by 2009, from the current $45 billion. New treatments are emerging all the time and could dramatically alter the cancer therapeutics market. Currently, there are more than 200 new medicines approved for the treatment of cancer. Researchers are constantly looking for safer and more efficacious therapies. Therapies are also being sought that will mitigate the side effects of other cancer therapies and/or improve the quality of life of the cancer survivor.

The biotechnology industry will play an ever-increasing role in cancer therapeutics. Basic research projects by these firms have already done much in characterizing the disease. Treatments are now focusing more on the molecular and cellular levels of the disease. With the advent of these new treatments, combination therapy is becoming increasingly important. One of the major challenges for oncologists is to provide the cancer patient with the proper combination of therapies. There is also a strong emphasis on the cost-effectiveness of each therapy, not only as regards to the price of the product, but also its side effects and toxicity, route of administration and treatment regimen.

The field of cancer drug research is one of the most active areas of research by the pharmaceutical industry. At the end of 2006, some 2,075 drugs were in development for all diseases and over 646 of these were targeted to treat cancer. Many of the 646 drugs in development in 2006 will be used to treat more than one type of cancer. For example, there were 79 drugs under development for breast cancer, the second leading cause of cancer deaths for women in the U.S.; 96 for lung cancer, the leading cause of cancer deaths for both American men and women; and 46 for skin cancer. Over 50 new oncology products will be launched in the next five years with new players entering the market. About 30% of all launches by 2010 will be in oncology.

The worth of the worldwide pharmaceutical market in 2006 was $643 billion. This represented a 7% increase over the previous year. The North American market, which accounts for 45% of global pharmaceutical sales, continued to drive the growth with a 8.3% increase to $290.1 billion, up from 5.4% the previous year. This strong growth was due to the impact in the U.S of the first year of the Medicare Part D benefit and the resulting increase in prescribing volume, as well as due to solid 7.6% growth in Canada. The five major European markets (France, Germany, Italy, Spain and the United Kingdom) grew at 4.4% to $123.2 billion, down from 4.8% growth in 2005, the third year of slowing performance. Sales in Latin America grew 12.7% to $33.6 billion, while Africa and Asia-Pacific (outside of Japan) grew 10.5% to $66 billion. The performances in individual countries varied widely. Japan, at $64 billion, experienced a decline of 0.4% in 2006, a result of the government’s biennial price cuts. Pharmaceutical sales in China grew 12.3% to $13.4 billion in 2006, compared with a 20.5% increase the previous year. India was one of the fastest growing markets in 2006, with pharmaceutical sales increasing 17.5% to $7.3 billion.

The 2008 worldwide pharmaceutical market is predicted to grow to nearly $735 to $745 billion. According to Murray Aitken, senior vice president, Healthcare Insight, IMS, “2008 marks an important inflection point for the global pharmaceutical market. For the first time, the seven largest markets will contribute just half of overall pharmaceutical growth, while the seven emerging markets will contribute nearly 25% of growth worldwide.” The seven “pharmemerging” markets (of China, Brazil, Mexico, South Korea, India, Turkey and Russia) are expected to grow 12% to 13% in 2008, to $85 to $90 billion. Driving this growth will be the flood of new drug targets identified through genomics technology.

The estimated worldwide market size for cancer therapeutics in 2006 was $34.6 billion, with an increase of 20.5% since 2005. This significant growth, the highest among the top ten therapeutic classes, was fueled by strong acceptance of innovative and effective therapies that are reshaping the approach to cancer treatments and outcomes. Today, 20% of the oncology products in late-stage development are targeted therapies, directed at specific molecules involved with carcinogenesis and tumor growth. IMS Health anticipates that up to 40% innovative new medicines will be launched in 2008, including four new oncology drugs for treating melanoma, prostate cancer and acute myeloid leukemia (AML). Products used in the treatment of cancer are expected to exceed $45 billion in value in 2008, contributing nearly 17% of audited market growth.
The rapidly emerging science of genomics is about to revolutionize various aspects of oncology practice, including how anti-cancer drugs are discovered and developed, how cancers are detected and classified and finally how patients are treated and monitored. Since the discovery of oncogenes and tumor suppressor genes, cancer has become one of the most important diseases in the design of therapeutic approaches based on genetics and genomics research and technologies.

Unlike the markets for monogenic diseases, most of which are caused by inherited mutations in a single gene, the market for cancer is enormous, and the commercial sector is expressing significant interest in clinical applications of genomics research. We estimate that the potential market for cancer therapeutics based on genomic solutions will be worth of $2 billion by 2008. Ranking with the computer industry, the biotechnology industry is positioned for substantial growth in this century. The amount of money invested in the U.S. biotechnology industry increased 156% in 5 years, soaring from $7.93 billion in 2001 to $20.31 billion in 2006. With $20.31 billion raised in 2006, this was the best year on record for biotech financing, excluding the bubble year of 2000. In fact, this industry has the promise to be the next high growth industry in the early years of the 21st century as it moves to become the foundation of a $300 billion medical care industry in the U.S. According to Beyond Borders, Global Biotechnology Report, the accounting firm Ernst & Young estimates that in 2006 there were 1,452 biotechnology companies in the U.S., out of which 336 were publicly held.

The main focus of the cancer drug market is to provide treatment for the four most common types of cancer—lung (small-cell and non-small-cell), breast, colorectal and prostate. These cancers have the greatest incidence of new cases and are responsible for the highest combined mortality—an approximate 60% of all cancer deaths worldwide. The treatment of these cancers provides a significant growth market potential for emerging therapeutics. These cancer segments have attracted the attention of pharmaceutical and biotechnology companies, which are developing a large and diverse array of investigational agents.

Competitor pipelines face significant changes in cancer treatment as it shifts toward molecular-based therapies. Ten of the top pharmaceutical and biotechnology companies have significant programs in oncology: Roche/Genentech, AstraZeneca, Bristol-Myers Squibb, Sanofi-Aventis, Merck, Eli Lilly, GlaxoSmithKline, Novartis, Johnson & Johnson and Genzyme. These ten companies sell 95% of current U.S. FDA-approved and marketed oncology drugs in the U.S., Europe and Asia. New additions to the drug development pipelines of these companies will represent large opportunities in the oncology market over the next few years.

Examples of how new therapeutic drugs can explode the top line are illustrated by a number of examples in this report. Among them, MabThera/Rituxan (rituximab) and Herceptin (trastuzumab) are the first such treatments to become available. They have generated encouraging sales in their first few years on the market, particularly U.S. Genentech’s Rituxan (developed by Biogen-Idec Pharmaceuticals), a treatment for non-Hodgkin’s lymphoma (NHL), launched in the U.S. at the end of 1997, that recorded sales of $162.6 million in 1998, an increase of 71.8% over $91.9 million in 1997. The product generated worldwide sales of $279.4 million in 1999, a growth of 17% since the previous year for Genentech (majority-owned by Roche, in 1997), and has become one of the leading cancer therapies in the world in terms of sales. Herceptin, a treatment for breast cancer launched in the fourth quarter of 1998, looks on course to be just as successful, with worldwide sales of $3.1 billion for Genentech/Roche in 2006, an 82% increase on sales since the previous year on the market, making it one of the most successful cancer products ever launched.

Currently, the important regional markets for cancer therapeutics are the U.S. and Canada, the European Union (E.U.) and Japan. Europe remains the largest importer of U.S. pharmaceuticals, accounting for 50% of all U.S. pharmaceutical exports. Mexico and Canada account for 19%. The North American Free Trade Agreement (NAFTA) is expected to increase U.S. exports of pharmaceuticals to these two nations.

Approximately, 9% of pharmaceutical R&D conducted worldwide is performed by U.S. firms. Japan follows with 8%. Of 152 major global drugs developed between 1975 and 1994, 45% originated in the U.S., 14% in the U.K. and 9% in Switzerland. U.S. firms dominate cancer R&D. Japan is currently investing heavily in R&D in an attempt to catch up with its foreign competitors.