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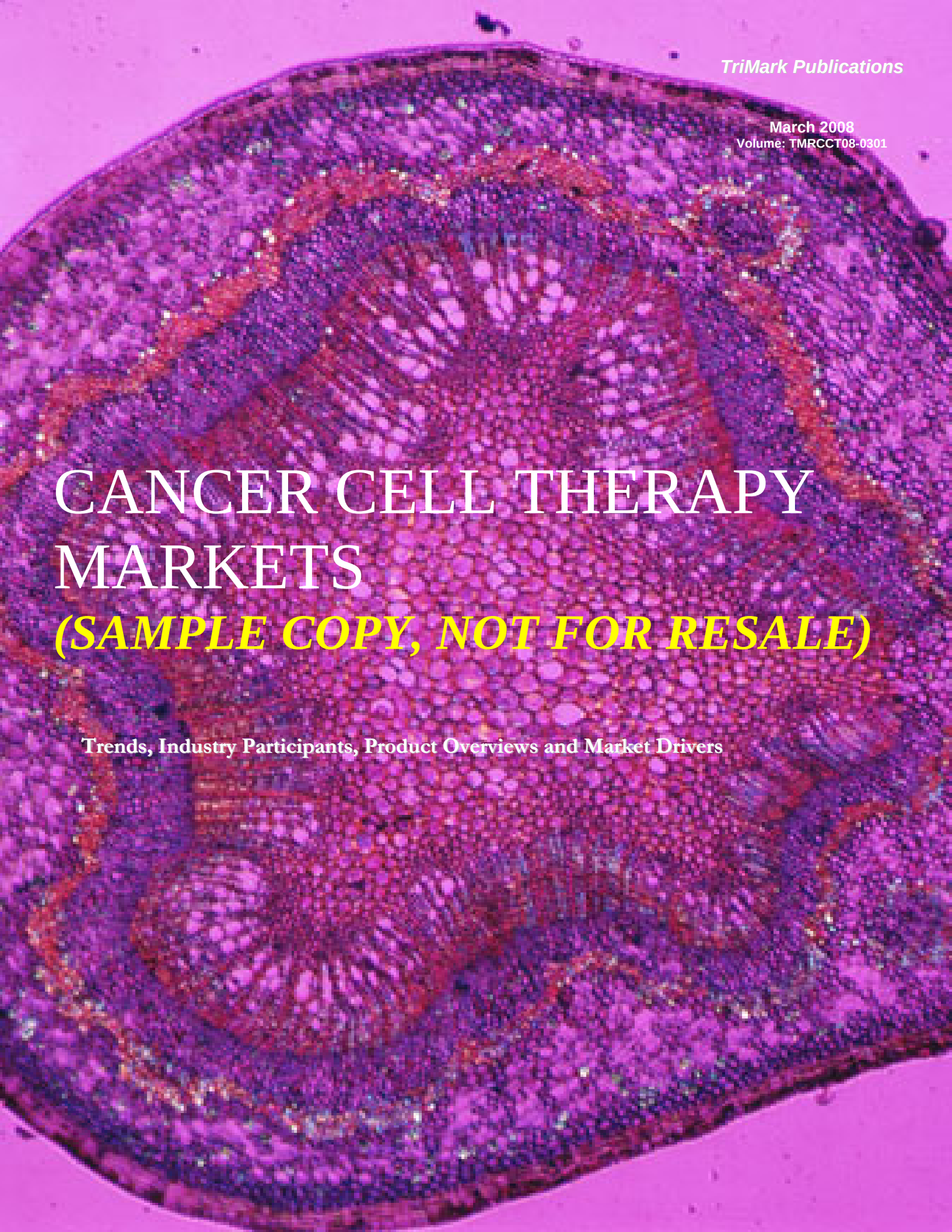

CANCER CELL THERAPY MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers

TABLE OF CONTENTS

INDEX OF FIGURES

INDEX OF TABLES

1. Overview

The purpose of this report is to describe the market segment of the cell therapy market aimed specifically at cancer therapy. This study includes all of the generally accepted clinical activities that are currently in use today for cell therapy for cancer patients. It examines these clinical preparations and their reagents and supplies as utilized in hospitals, clinics and doctor's offices for the treatment of cancer.

1.1 About this Report

A review of cellular agents that are related to the chemical and cellular constituents of blood or other tissues for cancer care of the patient is addressed in this report. The two most important areas where such agents are used are in the hospital and the clinic. The third place where these therapies are administered is in physician's office. Emphasis is on those companies and products that are actively developing and marketing cell therapeutic agents and supplies for treating cancer patients. The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for cell therapy.
- Understanding the different sectors of cell therapy for cancer, looking at the hospital market segment and, separately, at a description of the agents and supplies marketed by major companies in each segment.
- Obtaining a complete understanding of cell therapy for cancer from basic principles to their clinical applications.
- Discovering feasible market opportunities by identifying high-growth applications in different cancer cell therapeutic areas, focusing on the biggest and expanding markets.
- Focusing on global industry development through an in-depth analysis of the major world markets for cancer cell therapy technology, including growth forecasts.
- Presenting market figures regarding the current value of the cell therapy for cancer, market projections, market share, key players, sector and growth rates.

This study contains:

- Detailed analysis of recent trends in the cancer cell therapy marketplace.
- In-depth profiles of the leading companies with cancer cell therapy tools and technologies.
- A forecast for the cancer cell therapy market in the biotechnology industry.
- Views and principles on the cancer cell therapy industry from leading industry experts.
- Analysis of potential new cancer cell therapy applications in the clinical sector.
- Market predictions and trends analysis concerning U.S. expenditure on cancer cell therapy solutions.
- Projections for future applications of in cancer cell therapy of cancer treatments.
- Analysis of commercial cancer cell therapy business strategies.
- The latest news and M&A developments in the cancer cell therapy marketplace.
- A comprehensive overview and insight into cancer cell therapy business strategies.
- An in-depth examination of the subsections of each market segment of cancer cell therapy is conducted.

Analysis includes charts and graphs measuring product growth and trends within the cancer cell therapy marketplace. Company-specific information, including sales figures, product pipeline status and R&D trends, is provided. This review will also:

- Assess cancer cell therapy market drivers, from medical and scientific community perspectives.
- Discuss the potential benefits of cancer cell therapy for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the cancer cell therapy market and analyze the current size and growth of individual segments.
- Discuss profit and business opportunities by segment.
- Provide strategic recommendations for near-term business opportunities.
- Assess current commercial uses of the cancer cell therapy market.

The report contains:

- A comprehensive overview of the several categories of cancer cell therapy technology platforms that are—or will be—revolutionizing the use of diagnostic tests in hospitals.
- A chapter on each of the important cancer cell therapy categories and applications.
- Full descriptions of the technologies involved and how these differ from existing and emerging technologies.
- Analysis of the technological approaches undertaken by various competitors, as well as industry and end-user response to these products.
- Regulatory issues and legislation affecting use and marketing of cell therapy products.
- Market forecasts for each category of product, including profiles of selected competitors.

Also included is an analysis of current cancer cell therapy company acquisitions, licensing and product portfolios.

1.2 Scope of the Report

The cancer cell therapy products market is the particular focus of this study. Primary attention is paid to the clinical market segment, and, separately, to the instruments, reagents and technology platforms marketed by key companies in this segment. Other areas of cell therapy are described in the TriMark's market report titled *Cell Therapy Markets*.

An analysis of business trends, technology trends, and developing areas of cell therapy for cancer is provided, along with a review of the market for cell therapy equipment and supplies in the clinical and research market segments. This study defines U.S. and global market and analyzes factors that influence the size and growth of market segments. The reader should consult other TriMark Publications reports at http://www.trimarkpublications.com for detailed discussions of important individual market segments related to the cell therapy testing market.

1.3 Objectives

The goal of this study is to review the market for cell therapy as it is used to fight cancer. The report includes equipment and supplies using reagents and instruments for analysis of individual components in tissue samples, blood, serum or plasma. It defines the global market size and analyzes the factors that influence the size and the growth of the individual market segments. Additionally, the numbers of institutions using this type of cell therapy and the factors that influence the developing cell therapy for cancer market are discussed.

The report provides a detailed background on cell therapy strategies currently in place as well as an analysis of future prospects. It provides a breakdown of the steps involved in the stages of cell therapy with an extra emphasis on stem cells. A forecast and analysis of the market is provided as well as an overview of the current news in the cell therapy field. Interviews with industry experts provide a first hand look at what is current in the cell therapy area. Also included is an analysis of current cell therapy patents.

1.4 Methodology

This report is based upon interviews with sales and marketing professionals of companies in the cell therapy for cancer 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 also was obtained from interviews with founders, CEOs and vice presidents of some of the companies discussed in the report. Descriptions of the laboratories and patient facilities were derived from interviews with laboratory directors and medical technologists in these areas. Other sources of information included trade association publications and meetings, product brochures and catalogs, and company literature. Annual reports, 10k filings, and financial reports were used as the basis for data reported on publicly-held companies. Some of the 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.

The principal author of this report has over 35 years experience in the diagnostic testing and pharmaceutical market, holding senior science and executive positions. He has been a leader in the field of cancer diagnostics, and has served on a number of international committees and seminars on the subject.

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 study's 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 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 its 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 Executive Summary

This report by TriMark presents and discusses the sector of cellular therapy used for cancer. It considers the different types of cells primarily derived from the immune system that are deployed in a wide variety of technology platforms for the treatment of cancer. In cell therapy, cells are given to the patient as the therapeutic delivery system for a specific disease to achieve therapeutic benefit. Currently, the majority of cellular therapy for cancer is being utilized in the hematological cancers space.

Key trends that drive the oncology therapeutics space are:

- Extremely high development activity, several hundreds new products are in the pipeline.
- Fast-track U.S. Food and Drug Administration (FDA) programs which allow some therapies to be approved faster than before.
- Increasingly aged population.
- The incidence of some cancers is increasing (*i.e.*, colon and lung cancer).
- The time of treatment for cancers will be prolonged due to the ability to control the growth of tumors and metastases can be controlled.

Components of the hematopoietic system that can be leveraged for cancer cellular therapy are:

- Dendritic cells (DCs).
- Cytotoxic T lymphocytes (CTL).
- Natural killer cells.
- Tumor infiltrating lymphocytes (TIL).
- Hematopoietic stem cells (HSC).
- Adult stem cells.

The leading edge of cellular therapy for cancer is based upon the utilization of the various types of stem cells. For various blood disorders, primarily for hematological cancers, this field is experiencing resurgence. A practical and important difference between HSCs collected from adult human donors and from umbilical cord blood is simply quantitative. Doctors are rarely able to extract more than a few million HSCs from a placenta and umbilical cord—too few to use in a transplant for an adult, who would ideally get seven to ten million CD34+ cells per kilogram body weight, but often adequate for a transplant for a child. Cell therapy technologies overlap many other medical delivery platforms including:

- Gene therapy.
- Cancer vaccines.
- Drug delivery.
- Tissue engineering.
- Regenerative medicine.

Pharmaceutical applications of stem cells including those in drug discovery are also important. Various types of cells used, methods of preparation and culture, encapsulation and genetic engineering of cells are used in cell therapy techniques. A variety of sources of cells, both human and animal (xeno transplantation) are called upon. Methods of delivery of cell therapy vary widely from injections to surgical implantation using special devices.

Cell therapy has applications in a large number of disorders. The most important are diseases of the nervous system and cancer, the later which is the focus of this report. We forecast a burgeoning therapeutic industry based on each of these new sectors within five years. Many of these sectors using cell therapeutic methods will quickly move beyond current cancer therapy in effectiveness. The cell-based markets predicted for the largest expansion will be in diseases of the central nervous system, cancer and cardiovascular disorders. Cell therapy technologies and methods have already started to play an important role in the practice of medicine. HSC transplantation is replacing the old fashioned bone marrow transplants (BMT).

Stem cells are discussed throughout this report. They are becoming a central player in cell therapeutic methods as more information on their development and use is learned. Some light is thrown on the current controversy of embryonic sources of stem cells and comparison with adult sources. Other less controversial sources of stem cells are the placenta, cord blood and fat removed by liposuction. Stem cells can also be genetically modified prior to transplantation. The current political debate on the use of stem cells from embryonic sources (hESCs) is an essential consideration of any new therapy and regulations for cell therapy where stem cells are a part of the biological preparations.

Important areas of development for cell therapy for cancer in the future will include:

- Production of highly immunogenic proteins and peptides in order to induce strong anti-tumor responses in hosts.
- Development of specific anti-human monoclonal antibodies which will seek out and kill cancer cells with the necessity of a strong immune response.
- Development of cytokines and chemokines to manipulate the immune system.
- Development of more efficient vectors for gene therapy.

Specific recommendations for modifying cells for cancer therapy:

- Enrich cells by co-activation with CD3 monoclonal antibodies.
- Expand antigens in lymph nodes with anti-CD3 monoclonal antibodies.
- Expand specific CTL antigens using DCs loaded with tumor lysates or peptides.
- Arm T-cells with bidirectional antibodies to re-direct cytotoxicity to TTA.
- Use T-cells directed at TTA.
- Infuse T-cells transfused with cytokine genes.
- Transduce stem cells with chimeric receptors.

