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Stem Cell-Based Therapeutic Delivery Challenges & Opportunities

https://marketpublishers.com/r/SD3D8840907EN.html
Date: December 2008
Pages: 181
Price: US$ 1,134.00 (Single User License)
ID: SD3D8840907EN

Abstracts

This cutting edge & insightful report can be used to interpret & assess the potential of stem cell-based medicines. It provides opinions & market projections to:

assess the commercial potential of stem cell-based therapies in all of the key therapeutic areas: autoimmune diseases, cardiovascular, CNS & hematological malignancies;

identify key pharma & delivery specialists advancing the next generation of regenerative medicines;

gain an in-depth understanding of the technological manufacturing & delivery issues which face companies developing stem cell-based therapies;

evaluate the options available for delivering stem cell-based therapies now & in the future;

discover which companies are tackling the technological hurdles & are in a prime position to exploit new opportunities;

analyzes how the market will evolve over the next decade highlighting key trends, opportunities & challenges.

KEY FINDINGS:

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Stem cells have grabbed the attention of scientists across the globe and the pace of research has been astonishing. It is just 10 years since the first human embryonic stem cells (hESCs) were isolated and cultured; new therapies based on this research are now reaching the clinical phase of testing.

Many challenges have faced those aiming to develop therapies derived from stem cells including: ethical debates and funding, immune rejection, cancerous potential and issues surrounding the manufacture of stable, pure cell therapeutics.

It is evidence of the growing maturity of the field that many potential products have overcome these hurdles and have entered clinical testing.

Our research has revealed a total of 122 stem cell-derived therapeutic projects being undertaken in companies across the globe. The majority of these projects are in the earliest stages (28%) or in preclinical studies (43%). Of the projects that have reached clinical trials, only a handful have passed initial Phase 1/2 testing, with a total of eight (7%) being investigated in Phase 3 studies.

The market for stem cell therapeutics is forecast to grow from 2011, as the first products enter the marketplace, and is expected to generate global sales in excess of US$1.2 billion by 2015.

Autologous products, derived from a patient’s own tissue, will be the first to reach the market, bu ‘off-the-shelf’ allogeneic products may offer greater commercial potential. The first allogeneic product to achieve approval is likely to be Osiris Therapeutics’ Prochymal for graft versus host disease.

Delivery of stem cell-based therapeutics can be challenging. Osiris’ Prochymal is unique among those reviewed, as it is delivered intravenously, offering obvious commercial advantages. Other therapies are being delivered directly to the site of injury, involving state-of-the-art catheters and imaging systems. The delivery of stem cells for CNS disorders remains a challenging area.

Introduction

“Stem cell-derived therapeutics are on the brink of a new era, with a handful of therapies expected on the market within the next 2 or 3 years. Big pharma and biotech

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companies such as Pfizer and Genyzme have recently invested large sums in this exciting and fast-moving area, further demonstrating its growing maturity. The results of numerous Phase 1/2 clinical trials that are underway now will provide a clearer picture of the potential of stem cell-derived therapies for the future."

Dr Sara Sleigh

The pace of stem cell research is astonishing. It is less than 30 years since the discovery of the embryonic stem cell, and less than a decade since scientists determined the right conditions under which human embryonic stem cells (hESCs)could be directed to differentiate into a variety of cell types. Within the last few years, companies have built up sufficient data to support applications to start human clinical trials based on hESCs that have differentiated into oligodendrocytes for the treatment of spinal cord injury.

Embryonic stem cells are just part of the stem cell story. Adult stem cells, and those from other sources such as umbilical cord blood, have also been the subject of intense research over the past few years. While there has been a precedent for the use of bone marrow stem cells in the treatment of hematological malignancies, the development of new therapies based on cultured, expanded populations of specific cell types opens up a vista of new possibilities.

Regenerative medicine has a wide definition covering therapies that aim to repair, replace, restore and regenerate damaged or diseased cells, tissues and organs. Innovative therapies derived from stem cells fall within this definition and will, in the coming years, provide options for the treatment of a variety of diseases including: autoimmune diseases such as diabetes, Crohn's disease and osteoarthritis, CNS disorders and neurodegenerative diseases, heart diseases, as well as eye diseases.

Stem cell therapies are already offered at various locations across the globe, including China and Thailand, despite a lack of robust, randomized clinical trials demonstrating their safety and efficacy. The fact that stem cell therapies are available in these locations and that patients' travel across the globe to receive them illustrates the high unmet medical need associated with some of the targets being investigated. Clinical evidence from high quality clinical trials is now imperative in order to protect these vulnerable patient populations.

The challenges facing companies developing stem cell-derived therapies are high and range from ethical discussions surrounding the use of hESCs to difficulties associated

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with manufacture of cell-based products at scale and proving that products lack the potential to cause an immune response or cancer in a recipient. Nevertheless a growing pool of companies is investing heavily to bring this rapidly moving science to the clinic.

KEY QUESTIONS THIS REPORT ANSWERS:

Which companies & academic institutes are actively involved in stem cell therapy research?

What are the key areas of therapeutic focus for stem cell therapeutics in the near & long-term?

What are the key obstacles companies & delivery technologists need to overcome to commercialize stem cell-derived therapies?

How will the delivery technology drive the development of innovative stem cell-derived therapies in the future?

Which stem cell technologies & agents are likely to win in the near-term & long-term, & why?

Where are the market opportunities now & in the future?

When are stem cell-derived medicines likely to reach the market?

What do we predict will be the value of the stem-cell derived therapeutics by 2015 & 2020?

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Contents

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CHAPTER 4 STEM CELL-BASED THERAPIES FOR CNS DISEASES

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List Of Tables

LIST OF TABLES:

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