A new era of wellness in human health

Regenerative medicine can help to tackle an array of health issues, here Aiswariya Chidambaram, Senior Research Analyst at Frost & Sullivan hails it as having the potential to transform healthcare...

Regenerative medicine aims to augment, repair, replace, or regenerate tissue and organs damaged by disease, injury, or the natural aging process. It encompasses a wide array of novel technologies and therapeutic approaches, which include cell therapies, using stem cells; genetic manipulation; small molecules and biomolecules; and synthetic and bio-based materials that act as a scaffold for cell or tissue growth. While a vast majority of currently available treatments for chronic and fatal diseases are palliative or delay disease progression, regenerative medicine is uniquely capable of altering the underlying disease mechanism. Although regenerative medicine is in a relatively early stage of development, a significant number of products, particularly cell therapy (CT)-based products and tissue engineered (TE) products, are already commercially available on the market.

Cell therapy to fuel regenerative medicine market growth

Cell therapy is the largest and the highest revenue-generating segment in the regenerative medicine market with nearly 50 cell therapy-based regenerative products approved and marketed in at least one country. Cell Therapy is primarily of 2 types, namely cell-based immunotherapies that involve different approaches to manipulate (e.g. induce, enhance, or suppress) cells of the immune system to combat diseases, and stem cell therapy that facilitates the self-replication of embryonic or adult stem cells even after periods of extended dormancy, unspecialised in function, and able to differentiate into various specialised cell types under appropriate conditions.

Organogenesis' Apligraf – comprised of living cells, proteins, and collagen, and used for wound healing in venous leg ulcers and diabetic foot – was the first cell therapy-based product to be approved by the US Food and Drug Administration (FDA) and launched in 1998. The recent FDA approval of Dendreon's Provenge, a cell-based immunotherapy for the treatment of late-stage prostate cancer in 2010, has initiated significant resurgence in the field of immunotherapy and personalised medicine. Currently, there are no licensed stem cell products approved by the US FDA although a handful of products are commercialised in other regulated markets such as Europe and South Korea. Collectively, the top 20 cell therapy products treated over 500,000 patients in 2011 and nearly 140,000 patients in 2012, generating revenues of $730m and $900m respectively.

Nearly 80% of commercially available cell therapy products target skin/non-healing wounds and musculoskeletal conditions. Different cell types are being evaluated in over 1,900 clinical trials globally for a wide range of indications and include primary cells, progenitor cells, adult stem cells, embryonic stem cells, and recently, induced pluripotent stem cells (iPSCs). According to the Alliance for Regenerative Medicine (ARM), in 2012 nearly 60,000 stem-cell transplants were performed worldwide and over 160,000 patients were treated with cell therapy products, generating revenue of over $900m. 2012 witnessed the approval of the highest number (7) of cell-therapy products by regulatory agencies globally, while 5 such approvals were granted between 2009 and 2011, and none from 2002 to 2008.

Clinical activity buzz to increasingly attract investors

Given the increasing approval rates and clinical activity, regenerative medicine proves to be an

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extremely attractive sector for investors and managed to raise a combined public and private investment of over $1bn in 2012. Currently, more than 2,500 regenerative medicine clinical trials are on-going, investigating a host of new product candidates for a myriad of clinical indications such as cardiovascular disease, peripheral vascular disease, diabetes, stroke, central nervous system (CNS) disorders, spinal cord injuries (SCIs), ocular disease, musculoskeletal disorders, wounds and soft tissue damage, cancer, and several other debilitating autoimmune and inflammatory diseases. 2012 garnered an investment of over $900m from private investors and public markets besides earning grants of over $300m, totaling approximately $1.2bn. Furthermore, industry consolidation in the form of acquisitions of profitable cell therapy companies by big pharma and strategic investments in up-coming cell-based therapy organisations are increasing in an attempt to embrace future technologies and stay competitive in the industry.

Critical unmet need and potential game-changing strategies

Given the rapid rise of the aging baby boomer population and increasing prevalence of chronic diseases, it is certain that regenerative medicine will play an important role in patient care, particularly in therapies that avoid traditional drugs, devices, and surgery. However, the lack of consensus and strategic interaction at various levels of the regenerative medicine community (government, industry, academia, insurance payers, patients and physicians) warrants the establishment of a common point of contact at the national level acting as a liaison between FDA, CMS, NIH, NCHS, other federal agencies, and the private sector. Moreover, insurance payers are not convinced of the overall cost benefits, particularly for indications such as wound healing and skin substitutes. Hence, it is extremely important to create an exclusively defined list of critical therapeutic indications with unmet needs that represent national priorities in healthcare and establish a more efficient reimbursement coverage framework that will work in coordination with an accelerated clinical approval process.

Furthermore, the time, cost and complexity of clinical trials pose a challenge with regard to attracting investment from big pharma and gaining approval from regulatory authorities. Enabling better clinical trial design by expanding geographic access as well as enabling more effective utilisation of historical data from the NCHS, CMS, CDC, and other relevant agencies could be a potential solution. Thus, governments all over the world are working to support the development of regenerative medicine by framing and implementing legislative policies favoring the establishment of centers of excellence, manufacturing infrastructure, research networks, and economic diversification. ■

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