Global Regenerative Medicine Market Is Poised for Strong Growth

BOSTON – July 14, 2016 – A strong development pipeline for regenerative medicine (RM) therapies aimed at treating a broad range of unmet medical needs signals rapid growth in global RM product sales that could have significant and positive impacts on public health, according to a newly completed analysis by the Tufts Center for the Study of Drug Development.

Today, there are 640 privately held and publicly traded companies in Europe, Japan, and the U.S. that are actively engaged in developing RM therapies, said Christopher-Paul Milne, research associate professor and director of research at Tufts CSDD at Tufts University School of Medicine, who conducted the analysis.

RM therapies boost the body’s natural ability to heal itself, use healthy cells, tissues, or organs from a living or deceased donor to replace damaged ones, or deliver specific types of cells or cell products to diseased tissues or organs to restore tissue and organ function.

Milne noted that RM-enabling technologies—traditionally based on research in transplantation science, biomechanics, stem cell biology, molecular biology, vector engineering, advanced materials, immunology and recombinant DNA technology—have taken a quantum leap forward with the introduction of cell- and gene-based therapies, and tissue engineering.

Despite strong prospects for RM therapies, developers face "substantial challenges," not least of which are uncertain reimbursement prospects, according to Milne.

"Payers in the U.S. and elsewhere increasingly are applying strict cost-benefit analyses to a growing number of medicines to guide reimbursement policy, which means developers will have to show that the benefits of RM products justify their cost," Milne said.

Key findings from the analysis, reported in the July/August Tufts CSDD Impact Report, released today, include the following:

- Cell therapy products account for 76% of the 915 RM products currently in development in Europe, Japan, and the U.S., with gene therapy products accounting for the balance.
- The Japan and Asia-Pacific region is the fastest growing market for RM therapies through 2020.
- While regulators in Europe and Japan have put in place specific pathways for RM product development, the U.S. Food and Drug Administration does not plan to do so, but Congress is considering such a bill.

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About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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