



Genzyme and Osiris Partner to Develop and Commercialize First-in-Class Adult Stem Cell Products

CAMBRIDGE, Mass. & COLUMBIA, Md., Nov 04, 2008 (BUSINESS WIRE) -- Genzyme Corp. (Nasdaq: GENZ) and Osiris Therapeutics (Nasdaq: OSIR) announced today that they have entered a strategic alliance for the development and commercialization of Prochymal and Chondrogen, two novel, late-stage adult stem cell treatments that hold significant potential to treat a wide range of diseases. These stem-cell products are designed to provide therapeutic benefit by controlling inflammation, promoting tissue regeneration, and preventing scar formation.

Under the terms of the agreement, Osiris will commercialize Prochymal and Chondrogen in the United States and Canada, and Genzyme will commercialize the treatments in all other countries. Genzyme will make an up-front payment of \$130 million to Osiris, plus potential significant milestone and royalty payments.

Prochymal is currently being evaluated in two phase 3 trials for graft vs. host disease (GvHD) and one phase 3 trial for Crohn's disease; data from all three trials are expected in 2009. It is also being studied in phase 2 trials for type 1 diabetes and chronic obstructive pulmonary disease. A phase 2 trial of Prochymal for acute myocardial infarction and a phase 2/3 trial of Chondrogen for osteoarthritis of the knee are expected to begin soon.

Osiris is responsible for the clinical development costs for all ongoing trials, as well as future trials for additional indications through completion of phase 2 development. Osiris and Genzyme will share the cost of future Phase 3 and 4 clinical trials, with a 60 percent Osiris / 40 percent Genzyme split.

"This partnership further strengthens Genzyme's late-stage pipeline of products with the potential to support our growth beyond 2011," stated Henri A. Termeer, Genzyme's chairman and CEO. "Osiris is the clear leader in stem cell technology, which holds the promise to transform standards of care in a number of therapeutic areas in which Genzyme already has a strong presence."

"Today Genzyme and Osiris have forged a powerful partnership in the emerging field of stem cell therapy," said C. Randal Mills, Ph.D., President and Chief Executive Officer of Osiris. "This relationship greatly enhances our ability to effectively introduce this groundbreaking technology on a global basis."

Strong Strategic Fit

The collaboration will leverage Osiris' leadership position developing novel stem cell therapies, and Genzyme's regulatory and marketing infrastructure outside of the United States, as well as its expertise commercializing cell therapies. Genzyme developed and commercialized the first-ever cell therapy product approved by the FDA, Carticel(R) (autologous cultured chondrocytes), used in knee cartilage repair. The company also markets MACI(R) (matrix-induced autologous chondrocyte implantation), a second generation version of Carticel, in Australia and Europe, and manufactures Epicel(R) (cultured epidermal autografts), a cell therapy for treating patients with severe burns.

Prochymal for GvHD represents a strong strategic fit with Genzyme's existing global transplant franchise, which includes Thymoglobulin(R) (Anti-thymocyte Globulin [Rabbit]), used in the prevention and treatment of acute rejection in kidney transplant patients. Genzyme also expects to launch Mozobil(TM) (plerixafor) in the United States and Europe during the first half of next year, following regulatory approvals. Mozobil is intended to enable patients with certain types of cancers to successfully receive a stem-cell transplantation. The potential additional applications for Prochymal align with Genzyme's focus on immune diseases, cardiovascular disease, and endocrinology.

Chondrogen complements Genzyme's existing orthopaedics franchise, which includes Carticel, MACI and Synvisc(R) (hylan G-F 20), used to treat pain associated with osteoarthritis of the knee. The planned phase 2/3 trial for Chondrogen will explore the therapy's ability to not only treat osteoarthritic knee pain, but also its potential for disease modification.

Genzyme and Osiris last year entered into a collaboration to develop Prochymal for acute radiation syndrome. In January, the companies were awarded a \$224.7 million contract from the U.S. Department of Defense to develop Prochymal for this indication.

Deal Terms

Under the terms of the agreement, Genzyme will make a \$130 million up-front payment to Osiris, with \$75 million paid initially and \$55 million to be paid on July 1, 2009. In addition, Osiris also has the potential to receive a total of up to \$1.25 billion in milestone payments from Genzyme as follows:

Osiris is eligible to receive up to \$500 million in development and regulatory milestone payments for Prochymal related to GvHD, Crohn's disease, and other potential additional indications that the companies develop together.

Based on sales in Genzyme territories, Osiris is eligible to receive up to \$250 million in sales milestones for Prochymal as follows: \$100 million payable when annual sales reach \$500 million and \$150 million payable when annual sales reach \$1 billion.

Based on the results of the planned phase 2/3 trial of Chondrogen, Genzyme may elect to opt-out of further Chondrogen development, at which point all rights to Chondrogen will revert to Osiris with no further obligation by either company.

If Genzyme elects to continue with Chondrogen development, Osiris would be eligible to receive up to \$100 million in development and regulatory milestones based on the achievement of certain clinical trial results and regulatory approvals. Based on sales in Genzyme territories, Osiris would be eligible to receive up to \$400 million in sales milestones for Chondrogen.

Osiris is also eligible to receive significant escalating royalties on sales of Prochymal and Chondrogen within Genzyme territories.

About Prochymal and Chondrogen

Prochymal is a preparation of mesenchymal stem cells (MSCs) formulated for intravenous infusion. Chondrogen is a preparation of MSCs formulated for direct injection into the knee. The MSCs utilized in the products are isolated from the bone marrow of healthy young adult donors. They are grown in culture, permitting large-scale production. Because the cells can be expanded, thousands of doses can be produced from a single donation. Studies suggest MSCs are able to safely facilitate tissue repair through a number of mechanisms. Specifically, these studies have indicated that MSCs are able to down-regulate severe inflammation and work at the cellular level to rebuild damaged tissue through the coordinated release of tissue specific growth factors. In both GvHD and Crohn's disease, Prochymal is being tested in patients who have failed traditional therapies and have few, if any, treatment options remaining.

Prochymal has been granted Fast Track status by the FDA for GvHD and Crohn's disease, and is the first stem cell product to receive FDA expanded access approval, making the product available now to children with life-threatening GvHD. It has also been granted Orphan Drug designation by the FDA and EMEA for GvHD. U.S. regulatory approval in this indication is anticipated as early as the end of next year; E.U. approval is expected in 2010.

About Graft vs. Host Disease (GvHD) and Crohn's Disease

Both GvHD and Crohn's disease represent major unmet medical needs. GvHD is the most common complication of allogeneic stem cell transplantation, in which functional immune cells in the transplanted marrow recognize the recipient as foreign and mount an immunologic attack. Severe acute steroid-refractory GvHD is fatal in up to 90 percent of cases. Current treatments are marginally effective with significant side effects. Crohn's disease occurs when the immune system attacks the gastrointestinal tract. Autoimmune activity produces inflammation resulting in chronic inflammatory bowel disease. Patients with Crohn's disease have a mortality risk from the disease 50 percent greater than the general population. The disease significantly impacts patients' quality of life, and they require ongoing medical, surgical and dietary interventions.

About Genzyme

One of the world's leading biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. Since 1981, the company has grown from a small start-up to a diversified enterprise with more than 10,000 employees in locations spanning the globe and 2007 revenues of \$3.8 billion. In 2007, Genzyme was chosen to receive the National Medal of Technology, the highest honor awarded by the President of the United States for technological innovation.

With many established products and services helping patients in nearly 90 countries, Genzyme is a leader in the effort to develop and apply the most advanced technologies in the life sciences. The company's products and services are focused on rare inherited disorders, kidney disease, orthopaedics, cancer, transplant and immune disease, and diagnostic testing. Genzyme's commitment to innovation continues today with a substantial development program focused on these fields, as well as cardiovascular disease, neurodegenerative diseases, and other areas of unmet medical need.

Genzyme's press releases and other company information are available at www.genzyme.com and by calling Genzyme's investor information line at 1-800-905-4369 within the United States or 1-678-999-4572 outside the United States.

About Osiris Therapeutics

Osiris Therapeutics, Inc. is a leading stem cell therapeutic company focused on developing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. Prochymal is being evaluated in Phase III clinical trials for three indications, including acute and steroid refractory Graft versus Host Disease and also Crohn's disease, and is the only stem cell therapeutic currently designated by FDA as both an Orphan Drug and Fast Track product. Furthermore, Prochymal is being developed for the repair of heart tissue following a heart attack, the protection of pancreatic islet cells in patients with type 1 diabetes, and the repair of lung tissue in patients with chronic obstructive pulmonary disease. The Company's pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen for arthritis in the knee. Osiris is a fully integrated company, having developed capabilities in research, development, manufacturing, and distribution of stem cell products. Osiris has developed an extensive intellectual property portfolio to protect the company's technology including 47 U.S. patents each having one or more foreign counterparts. Osiris, Prochymal and Chondrogen are registered trademarks of Osiris Therapeutics, Inc. More information can be found on the company's website, www.Osiris.com. (OSIR-G)

Genzyme Safe Harbor Statement

This press release contains forward-looking statements regarding Genzyme's future business plans and strategies including, without limitation: its expectations regarding launching Mozobil in the U.S. and Europe and the timing thereof; its regulatory plans and expected timetables for collaboration product candidates, including the timing of receipt of data from three Prochymal phase 3 trials in GvHD and Crohn's disease, the anticipatory receipt of regulatory approvals for Prochymal for GvHD in the US in 2009 and in the EU in 2010, and the planned timing for the start of a phase 2 trial for Prochymal for acute myocardial infarction and a phase 2/3 trial for Chondrogen for osteoarthritis of the knee; its expectation that the collaboration with Osiris will support Genzyme's growth beyond 2011; and its assessment of the strategic fit of adult stem cell products with Genzyme's existing business. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those forecasted. These risks and uncertainties include, among others: the actual timing of the receipt of data from the Prochymal phase 3 trials; Genzyme's and Osiris's ability to accurately design, execute, understand and predict the outcome and impact of the clinical studies related to Prochymal and Chondrogen; the actual efficacy and safety of Prochymal and Chondrogen for treatment of the indications pursued by the collaboration; the actual outcome of submissions to regulatory authorities and the timing of regulatory responses; the ability of Genzyme and Osiris to successfully collaborate together to develop Prochymal and Chondrogen; and the risks and uncertainties described in Genzyme's SEC reports filed under the Securities Exchange Act of 1934, including the factors discussed under the caption "Risk Factors" in Genzyme's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008. Genzyme cautions investors not to place substantial reliance on the forward-looking statements contained in this press release. These statements speak only as of today's date and Genzyme undertakes no obligation to update or revise the statements.

Genzyme(R), Carticel(R), MACI(R), Epicel(R), Thymoglobulin(R), and Synvisc(R) are registered trademarks and Mozobil(TM) is a trademark of Genzyme Corporation. All rights reserved.

Osiris Safe Harbor Statement

This press release contains forward-looking statements. Forward-looking statements include statements about our expectations, beliefs, plans, objectives, intentions, assumptions and other statements that are not historical facts. Words or phrases such as "anticipate," "believe," "continue," "ongoing," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project" or similar words or phrases, or the negatives of those words or phrases, may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. Examples of forward-looking statements include, but are not limited to, statements regarding the following: our product development efforts; our clinical trials and anticipated regulatory requirements; the success of our product candidates in development; status of the regulatory process for our biologic drug candidates; implementation of our corporate strategy; our financial performance; our product research and development activities and projected expenditures, including our anticipated timeline and clinical strategy for MSCs and biologic drug candidates; our cash needs; patents and proprietary rights; ability of our potential products to treat disease; our plans for sales and marketing; our plans regarding our facilities; types of regulatory frameworks we expect will be applicable to our potential products; and results of our scientific research. Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions that could cause actual results to differ materially from those expected or implied by the forward-looking statements. Our actual results could differ materially from those anticipated in forward-looking statements for many reasons, including the factors described in the section entitled "Risk Factors" in our Annual Report on Form 10-K and Quarterly Reports filed on Form 10-Q, with the United States Securities and Exchange Commission. Accordingly, you should not unduly rely on these forward-looking statements. We undertake no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this press release or to reflect the occurrence of unanticipated events.

SOURCE: Genzyme Corp. and Osiris Therapeutics, Inc.

Media Contact, Genzyme
Erin Emlock, 617-768-6923

or

Investor Contact, Genzyme
Patrick Flanigan, 617-768-6563

or

Media Contact, Osiris
Schwartz Communications
Stacey Holifield, 781-684-0770

or

Investor Contact, Osiris
Erica Elchin, 443-545-1834

Copyright Business Wire 2008

News Provided by COMTEX