



Osiris Therapeutics Reports Positive Phase II Results Using PROCHYMAL™ in Treatment-Resistant Crohn's Disease

Outpatient stem cell treatment resulted in a statistically significant reduction in disease severity of patients who had failed to respond to standard of care

BALTIMORE, Maryland – October 19, 2006 – Osiris Therapeutics (NASDAQ: OSIR) announced positive results from a pilot phase II study using PROCHYMAL for the treatment of patients with moderate to severe Crohn's disease who had failed to respond to standard treatments such as steroids and infliximab (Remicade®). In the study, every patient evaluated reported a reduction in Crohn's Disease Activity Index or CDAI after receiving two infusions of PROCHYMAL. There was a statistically significant decrease in mean CDAI scores of 105 points by day 28 from 341 to 236 ($p=0.004$). The results will be presented by Dr. Jane Onken, Director of the Inflammatory Bowel Disease Clinic and Associate Professor of Medicine at the Duke University School of Medicine at the Annual Meeting of the American College of Gastroenterology on October 24. Dr. Onken was the lead investigator for the trial.

"To understand the significance of this trial, it is important to appreciate just how sick these patients were," said Dr. Onken. "On average, they had suffered with Crohn's disease for 14 years and were unable to find relief with currently available therapy. It was in this difficult-to-treat population that we observed clinical improvement upon administration of the stem cell therapy."

Crohn's disease is a life-long, chronic inflammatory disease of the intestines, often leading to abdominal pain, disability, and surgical removal of the affected portion of the bowel in more than half of patients with the disease. Crohn's disease affects over 500,000 patients in the US, with more than 20,000 new cases diagnosed each year. It most often begins between ages 15 and 35, although it can start at any age.

"Crohn's disease can be an extremely debilitating disease," said Michael Pandak, M.D. of the McGuire Veterans Affairs & Virginia Commonwealth University Medical Centers in Richmond, Virginia. Dr. Pandak was one of the investigators who treated several patients in the trial. "When Crohn's disease patients fail treatment with currently available medications, they often develop devastating complications that can result in the surgical removal of the affected portions of their intestines. What was exciting about this trial was the rapid clinical improvement seen in several difficult to manage patients from this population after just one to two weeks of stem cell therapy. The development of a novel treatment that might spare patients from many of the devastating complications of Crohn's could have a huge impact."

Trial Highlights

- With relatively low doses and a short treatment course, every patient evaluated had a reduction in disease severity by day 28.
- In patients who failed available drugs for Crohn's Disease, there was a statistically significant reduction in the mean CDAI score of 105 points by day 28.
- Improvement was rapid with an average CDAI reduction of 62 points by day 7.
- There appeared to be a positive correlation between dose and response, with patients receiving the high dose achieving a greater response (average CDAI reduction of 137 vs. 65).
- The treatment was well tolerated and there were no severe adverse events attributed to PROCHYMAL.

"It is important that these results be assessed within the proper perspective," said C. Randal Mills, Ph.D., President and CEO of Osiris Therapeutics. "We were looking to see if patients with Crohn's Disease that was resistant to other treatments would respond when given small amounts of PROCHYMAL. We were very pleased



to see a statistically significant effect. As we move into Phase III, we must work diligently to optimize the course of treatment to ensure patients receive the greatest benefit.”

About the Trial

The trial was a prospective, randomized, open label trial, conducted at 4 leading centers in the US. Patients with moderate to severe Crohn’s disease, defined as having a CDAI of at least 220, who had previously failed treatment with steroids and other immunosuppressive agents, were given two infusions of PROCHYMAL seven days apart. A total of 10 patients were treated, with 9 patients evaluated through the 28 day follow-up. One patient elected to exit the trial prior to completion. Patients were divided into two groups and received either low dose (2 million cells per kilogram) or high dose (8 million cells per kilogram) of PROCHYMAL on an outpatient basis. In addition to safety parameters, patients were evaluated for changes in CDAI and improvement in the Inflammatory Bowel Disease Questionnaire or IBDQ. Prior to entering the trial, patients who had been treated with infliximab or other biological agents were required to complete a washout period of 90 days to preclude the possibility that response was the result of a previous treatment.

Entering the trial, the average CDAI score at baseline was 341. Patients entering this study had suffered from Crohn’s Disease for an average of 14.2 years, and 80% of the patients required prior surgical intervention to treat their Crohn’s disease. In the study, one-third of the patients had a reduction of CDAI of greater than 100 points within 14 days of treatment. Each of these responders had failed previous treatment with infliximab (Remicade®). Mean IBDQ scores improved significantly from baseline to day 28 (113 to 146, p=0.008). One-third of the patients reported IBDQ scores of at least 170, indicating they had achieved clinical remission of their disease. Although not reaching statistical significance, there appeared to be correlation between dose and response. Patients receiving the high dose had a 72 point greater reduction in CDAI than those receiving low dose (CDAI reduction of 137 vs. 65). There were no infusional toxicities, nor were there any treatment related severe adverse events.

“We are very encouraged by these results,” said Lode Debrabandere, Ph.D., Vice President and General Manager of Inflammatory Diseases at Osiris. “Given the positive response that we observed with a relatively low dose and short treatment course, we are intensifying our development efforts. As a result, we have initiated communication with the FDA to move forward with the design and implementation of the Phase III program.”

PROCHYMAL is a preparation of mesenchymal stem cells specially formulated for intravenous infusion. The stem cells are obtained from the bone marrow of healthy adult donors. PROCHYMAL is also being evaluated in Phase III clinical trials for the treatment of Graft vs. Host Disease or GVHD. The Phase III study for GVHD is anticipated to be the final trial before the product is submitted to FDA, Canadian and European regulatory agencies for full approval. PROCHYMAL has been granted Fast Track and Orphan Drug status by FDA for GHVD. FDA established the Fast Track program to accelerate the development of drugs that show promise for treating life-threatening conditions. Orphan Drug designation provides incentives to companies that develop drugs for underserved patient populations.

About Osiris Therapeutics

Osiris Therapeutics, Inc. is a leading stem cell therapeutic company focused on developing and marketing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. Osiris currently markets and sells Osteocel® for regenerating bone in orthopedic indications. Prochymal™ is in Phase 3 clinical trials and is the only stem cell therapeutic currently designated by FDA as both an Orphan Drug and Fast Track product. The Company’s pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen™ for regenerating cartilage in the knee, and Provacel™, for repairing heart tissue following a heart attack. Osiris is a fully integrated company, having developed stem cell capabilities in research and development, manufacturing, marketing and distribution. Osiris has developed an extensive intellectual property portfolio to protect the company’s technology in the United States and a number of foreign countries including 46 U.S. and 164 foreign patents owned or licensed. (OSIR-G)

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Forward Looking Statements

This press release contains forward-looking statements. Forward-looking statements provide our current expectations or forecasts of future events. 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; 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 Registration Statement on Form S-1, File No: 333-134037, as filed with the United States Securities and Exchange Commission and declared effective on August 3, 2006. 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.

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