



Osiris Therapeutics Announces Positive One Year Data from Chondrogen Trial for Knee Repair

Well controlled study shows clinically and statistically significant improvement in patients receiving first-in-class stem cell treatment for arthritis

COLUMBIA, Maryland – November 27, 2007 – Osiris Therapeutics, Inc. (NASDAQ: OSIR) announced positive one-year interim results in the evaluation of Chondrogen, a preparation of adult stem cells formulated for direct injection into the knee. The one year data showed improvement in joint condition that correlated with a clinically and statistically significant improvement in pain in patients with osteoarthritis (OA) who received Chondrogen as compared to those treated with the control, hyaluronic acid (HA).

Key Points from the Trial

- OA patients receiving Chondrogen experienced a statistically significant reduction in pain as compared to those receiving the control, HA.
- The magnitude of improvement in pain was clinically significant and superior to the improvement reported for other approved treatments.
- Patients receiving the control were 3.5 times more likely to experience degenerative bone changes associated with OA as compared to those receiving Chondrogen.
- The effects were dose dependent and pain scores improved from six months to one year following treatment, suggesting Chondrogen caused a biological modification of OA.
- Chondrogen was well tolerated at both dose levels and there were no serious events associated with administration

"These results are very promising given that a single injection of Chondrogen resulted in a clinically significant reduction in pain that was about double what we typically achieve with products currently available for OA" said C. Thomas Vangsness Jr., M.D., Professor of Orthopedic Surgery and Chief of Sports Medicine with the Keck School of Medicine at the University of Southern California. "These data have added significance given that superiority was observed over the control arm in this trial, HA, which is routinely used today for the treatment of osteoarthritis."

The Phase I/II double-blind, controlled study of 55 patients is evaluating the safety and exploratory effectiveness of Chondrogen in patients undergoing surgery to remove a torn meniscus. In patients with OA at the time of surgery, a statistically significant 20 mm reduction in pain, as measured by the visual analog scale (VAS), was observed in patients receiving a single injection of Chondrogen over patients receiving an injection of the control, HA, at one year (Chondrogen 48 mm vs. Control 28 mm, $p=0.05$). The reduction in pain increased even further to 37 mm with more severe osteoarthritic changes in the patient's joint ($p=0.004$, Chondrogen 56 mm vs. Control 19 mm). For comparison, currently available treatments for OA, such as HA which requires multiple injections, were approved by the Food and Drug Administration (FDA) based upon improvements of 9-23 mm over placebo.

There was also a positive dose-response effect. At one year, the improvement in pain relative to baseline, prior to surgery to remove damaged meniscus, was 56 mm for high dose Chondrogen, 26 mm for low dose Chondrogen, and 19 mm for the control.

"We are excited about the dramatic improvements seen in this trial, which offer hope to the 21 million Americans who suffer every day from the debilitating effects of osteoarthritis. Additionally, the durability of the effect may have a profound impact on cost of treating arthritis," said C. Randal Mills, Ph.D., President and CEO of Osiris Therapeutics. "These data allow us to advance our development efforts with confidence. With both clinically and statistically significant results in an approvable endpoint, we have started preparing for the appropriate registration trials. I would like to thank the investigators and patients for their continued support with this landmark study."



The beneficial effects of Chondrogen were also seen in physical measures of joint condition. Bony changes associated with osteoarthritis, such as subchondral sclerosis and osteophyte formation, were reported in 21% of patients receiving the control, but only 6% of Chondrogen-treated patients. Joint condition was determined from MRI analysis using centralized, independent, blinded orthopedic radiologists.

"A major problem with OA is that our current treatments only provide patients with short-term relief. Chondrogen is the first product evaluated in humans with the ability to modify the biological processes associated with arthritis and therefore hold the promise of a lasting effect," said Joel Boyd, M.D., an orthopedic surgeon at TRIA Orthopaedic Research Institute in Minneapolis, Minnesota, and a United States Olympic team physician. "The difference in improvement observed between patients receiving Chondrogen and HA continued to widen from six months to one year without the need for additional treatment. These results are consistent with the progressive nature of arthritis and support the preclinical data demonstrating Chondrogen can have a fundamental impact on the biological course of arthritis."

In addition to the benefits observed in OA, Chondrogen continued to demonstrate a strong safety profile. Through one year there were no serious adverse events attributed to Chondrogen, and there was no evidence of abnormal tissue formation. One of the goals of the study was to assess the ability of MRI to detect the volume of meniscus regeneration following meniscectomy. The MRI volume analysis method was deemed unsuitable for computational analysis because of the high level of variability seen between readings. As a result, no meaningful evaluation of meniscus regeneration can be made.

About the Phase I/II Chondrogen Trial

The Phase I/II trial is a randomized, prospective, double-blinded trial, conducted at seven leading sports medicine centers in the US to assess the safety of an injection of stem cells into the joint capsule and to gain preliminary efficacy data on the ability of Chondrogen to impact tissue regeneration and the development of osteoarthritis. Patients in the study underwent standard meniscectomy surgery to remove torn or damaged tissue in their meniscus. One week following surgery, the patients were given a single injection of either HA or a low dose (50 million cells) or high dose (150 million cells) of Chondrogen. Neither the patients nor the surgeons know what was given for the duration of the study. Patients will be followed for safety and additional preliminary efficacy such as pain, cartilage damage, and tissue repair for two years under the current study protocol. Non-invasive MRI is being used for examination of meniscus and cartilage condition.

About Chondrogen

Chondrogen is a preparation of mesenchymal stem cells specifically formulated for direct injection into the knee. The stem cells are obtained from the bone marrow of healthy adult donors. Chondrogen is currently being evaluated in a double-blind, controlled Phase I/II study for the treatment of arthritis of the knee in the setting of meniscectomy.

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 III clinical trials for both Graft versus Host Disease and Crohn's disease and is the only stem cell therapeutic currently designated by FDA as both an Orphan Drug and Fast Track product. Osiris has also partnered with Genzyme Corporation to develop Prochymal™ as a medical countermeasure to nuclear terrorism and other radiological emergencies. The Company's pipeline of internally developed biologic drug candidates under evaluation also includes Chondrogen™ for arthritis in the knee, and Provacel™, for repairing heart tissue following a heart attack. Osiris is a fully integrated company, having developed capabilities in research, development, manufacturing, marketing and distribution of stem cell products. 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 47 U.S. and 215 foreign patents owned or licensed. More information can be found on the company's website, www.Osiris.com. (OSIR-G)



Forward-Looking Statements

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 mesenchymal stem cells 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 filed 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.

**For additional information, please contact:
Erica Elchin, Osiris Therapeutics, Inc. at (443) 545-1834**

**Media Contacts:
Stacey Holifield/Andrew Law
Schwartz Communications
(781) 684-0770
Osiris@schwartz-pr.com**