

Omeros Reports Additional Phase 2 Data Showing Multiple Clinical Benefits In Patients Undergoing Meniscectomy Surgery

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SEATTLE, May 3, 2010 /PRNewswire via COMTEX News Network/ -- Omeros Corporation (Nasdaq: OMER) today announced additional data from a Phase 2 trial of OMS103HP, its PharmacoSurgery(TM) product candidate for arthroscopy, showing that patients treated with OMS103HP during arthroscopic meniscectomy surgery achieved statistically significant clinical benefits. OMS103HP is an investigational drug product that is added to arthroscopic irrigation solution and is designed to improve postoperative joint function and motion and reduce postoperative pain. Omeros plans to present these additional data tomorrow in its webcast presentation at the Deutsche Bank Health Care Conference at 2:50 p.m. EDT and, for those not attending, has provided the clinical trial results below.

About the Phase 2 Trial of OMS103HP

The Phase 2 clinical trial was a prospective, multicenter, double-blind, randomized, vehicle-controlled study. Of the 161 patients who were enrolled and treated, 143 patients met the predetermined surgical and data collection criteria and were included in the data analysis (71 OMS103HP and 72 vehicle). There were no significant differences in demographic characteristics between the two treatment groups.

Pain scores in the immediate 24-hour period and up to seven days postoperatively were measured using a validated, 100-point, visual analog scale (VAS). Range of motion assessments were made at baseline and day seven postoperatively. The protocol was amended to collect patient self reports using the Knee Injury and Osteoarthritis Outcome Score (KOOS), which consists of five subscale scores: symptoms, pain, activities of daily living, sport and recreation function, and knee-based quality of life. The KOOS subset consisted of 70 subjects (33 OMS103HP and 37 vehicle). OMS103HP was well tolerated, and adverse events were more frequent in the vehicle group.

Clinically relevant benefits included the following:

- The mean VAS pain scores within the first 24 hours following discharge from the recovery room demonstrated more pain in the vehicle group at the 2, 4, 6, 8 and 12-hour postoperative assessments. Averaged mean VAS scores over time for the first 24-hour postoperative period were 33.98 for OMS103HP and 38.35 for vehicle ($p=0.212$). The repeated measures model analysis yielded a statistically significant result that indicates the profile difference between the OMS103HP and vehicle groups for the VAS pain score varied over time ($p=0.004$, e.g., the peak difference was observed at eight hours with VAS scores of 37.5 for OMS103HP and 47.3 for vehicle).
- At the Day 7 assessment, OMS103HP and vehicle groups differed with respect to the assessment of passive flexion without pain ($p=0.022$; mean degree of flexion 121.6 versus 115.1, respectively). The proportion of subjects achieving flexion of greater than or equal to 95 (93.0% vs 85.0%), 110 (80.3% vs 68.1%) and 125 ($p=0.001$, 56.3% vs 29.1%) degrees at Day 7 was greater for the OMS103HP group.
- The KOOS subscale scores all achieved the 0.05 level of significance (symptoms, $p=0.046$; pain, $p=0.017$; sport and recreation function, $p<0.001$; and knee-based quality of life, $p=0.015$) with the exception of activities of daily living ($p=0.070$). All the scores showed a sustained and consistent treatment effect through Day 90.
- Subjects treated with OMS103HP were approximately two times more likely than vehicle-treated subjects to be in the highest quartile (i.e., greater than or equal to 75th percentile) of each of the sport and recreation subscale and overall KOOS scores (averaged across all five subscales). Conversely, vehicle-treated subjects were approximately two times more likely than OMS103HP-treated subjects to be in the lowest quartile (i.e., less than or equal to 25th percentile) of each of the sport and recreation subscale and overall KOOS scores.

"We are pleased with the outcome of this study, and believe that these data bode well for OMS103HP and our ongoing Phase 3 program evaluating the drug in arthroscopic ACL reconstruction. We look forward to reporting data from those trials later this year," stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros.

"Following knee arthroscopy for the treatment of a torn meniscus, patients have a highly variable return to normal function and especially work and sports performance," stated William E. Garrett, Jr., M.D., Ph.D., professor of orthopaedic surgery at Duke University Medical Center. "The efficacy observed in this study is clear from its series of objective measures and reliable

subjective measures of knee function and pain. Further, this study demonstrates that treatment on the day of surgery alone continued to provide functional improvements at one and three months postoperatively. This should benefit both patients and surgeons."

About OMS103HP

OMS103HP is being developed for use during arthroscopic surgery to improve postoperative joint motion and function and reduce postoperative pain. Designed to preemptively inhibit inflammation, OMS103HP is injected into standard arthroscopic irrigation solutions and perfused through the joint in low concentrations during surgery. It is currently being evaluated in a Phase 3 clinical program for anterior cruciate ligament (ACL) surgery and has also completed a Phase 2 clinical trial for meniscectomy surgery. If approved, OMS103HP would be the first commercially available drug delivered directly to the surgical site to improve function following arthroscopic surgery.

About Meniscectomy Surgery

Arthroscopic meniscectomy is a minimally invasive surgical procedure used to treat a torn meniscus cartilage in the knee. Only the torn segment of the meniscus is removed. Postoperative recovery to normal function may take months. Approximately four million arthroscopic operations were performed in the United States in 2006, including 2.6 million knee arthroscopy operations.

About Omeros Corporation

Omeros is a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products focused on inflammation and disorders of the central nervous system. The Company's most clinically advanced product candidates are derived from its proprietary PharmacoSurgery(TM) platform designed to improve clinical outcomes of patients undergoing a wide range of surgical and medical procedures. Omeros has five ongoing clinical development programs, including four from its PharmacoSurgery(TM) platform and one from its Addiction platform, the most advanced of which is in Phase 3 clinical trials. Omeros may also have the near-term capability, through its GPCR (G-protein coupled receptor) program, to add an unprecedented number of wholly new drug targets to the market. Behind its clinical candidates and GPCR platform, Omeros is building a diverse pipeline of antibody and small-molecule preclinical programs targeting inflammation and central nervous system disorders.

Forward-Looking Statements

This press release contains forward-looking statements as defined within the Private Securities Litigation Reform Act of 1995, which are subject to the "safe harbor" created by those sections. These statements include, but are not limited to, statements regarding the Company's ability to announce the results from its Phase 3 clinical trials of its lead product candidate later this year. Forward-looking statements are based on management's beliefs and assumptions and on information available to management only as of the date of this press release. Omeros' actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, without limitation, the risks, uncertainties and other factors described under the heading "Risk Factors" in the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 19, 2009. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and the Company assumes no obligation to update these forward-looking statements publicly, even if new information becomes available in the future.

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