DURECT Announces Positive Phase II Results on Chronogesic(TM) For Long-Term Pain Relief

CUPERTINO, Calif., Sept. 5 /PRNewswire/ —
DURECT Corporation (Nasdaq: DRRX) announced today the results of its Phase II clinical trial for its lead product Chronogesic(TM), a 3-month continuous infusion subcutaneous implant for the treatment of chronic pain. The clinical trial was conducted at 9 clinical sites in the United States and enrolled 66 adult patients with chronic pain resulting from a range of causes, including failed back surgery, trauma, arthritis, cancer pain and other chronic diseases. Prior to the study, these patients were using a variety of approved oral and transdermal opioid medications such as MS Contin, Oxycontin, Duragesic and Methadone. The objective of the first portion of the study was to determine the method by which patients can be transitioned from use of their pre-study opioid medication to Chronogesic(TM). In the second portion of the study, Chronogesic(TM) was implanted for up to 6 weeks to obtain information on safety and efficacy of Chronogesic(TM) in patients with chronic pain.

“Patients in the study reported a strong preference for Chronogesic(TM) as measured against their pain medication used prior to the study,” stated Dennis Fisher, MD, Vice President of Medical Affairs and Medical Director of DURECT. “From this study, we obtained the dose conversion information required to transition patients from commonly used opioid medications such as MS Contin, Oxycontin, Duragesic and Methadone to Chronogesic(TM). Additionally, we obtained very promising data that patients enrolled in the study had better pain control and a reduction in certain opioid side effects when compared to their pre-study medications.”

As part of the study, patients were asked to report on a variety of factors relating to their use of Chronogesic(TM).

Global Preference

At the end of the 6-week implant period, patients were asked to compare Chronogesic(TM) compared to their pre-study treatment. Sixty percent (60%) of patients preferred Chronogesic(TM) to their pre-study therapy (43% of patients “very much preferred” Chronogesic(TM) and 17% of patients “preferred” Chronogesic(TM) whereas 35% of patients preferred their pre-study treatment (9% of patients “very much preferred” the pre-study treatment and 26% of patients “preferred” the pre-study treatment). Five percent (5%) of patients indicated no preference between their pre-study treatment and Chronogesic(TM).

Pain Score Assessment

Patients were also asked about the adequacy of their pain treatment at various points in the trial. At the beginning of the trial, prior to receiving Chronogesic(TM), 29% of patients assessed their pre-study treatment as “good” or “very good.” In contrast, after 6 weeks of treatment with Chronogesic(TM), 57% of patients reported their treatment as “good” or “very good.”

Consistent with these findings, patients reported that their mean pain visual analog score, in which 0 is “no pain” and 10 is “worst pain imaginable,” improved during the trial from 5.5, prior to the start of Chronogesic(TM), to 4.8 after 6 weeks of treatment with Chronogesic(TM). Of note, those patients who reported that Chronogesic(TM) improved their pain status reported an improvement from a pre-study score of 5.8 to 3.8 after 6 weeks of Chronogesic(TM) treatment.

Side Effect Assessment

With respect to certain side effects commonly associated with opioids, patients in the study reported a decrease in both gastrointestinal “pain and discomfort” and “cramps” while using Chronogesic(TM) compared to their pre-study treatments. Patients were also assessed daily for sleep patterns. At the beginning of the trial, 17% of patients reported that they “never slept” compared to the end of the 6 weeks study on Chronogesic(TM), when only 7% of patients reported that they “never slept” during one or more nights of treatment.

“The results of the study exceeded our expectations,” stated James E. Brown, CEO of DURECT. “Given the advantages we anticipated Chronogesic(TM) would have over currently available therapies, such as increased patient convenience, better compliance and physician control of dosing, we would have been pleased with data showing that Chronogesic(TM) had equivalent pain control compared to other opioid medicines currently on the market. However, we saw better pain control and fewer side effects, resulting in a strong preference by patients for Chronogesic(TM) versus other medicines. The results of the study support our belief that Chronogesic(TM) offers patients a better quality-of-life alternative to currently available therapies for the long-term treatment of stable and opioid responsive chronic pain.”

Chronogesic(TM) is designed to deliver sufentanil on a continuous basis for 3 months for the treatment of chronic pain. Sufentanil is a FDA approved opioid that is currently used in hospitals as an anesthetic. Chronic pain is a significant problem associated with chronic diseases, including cancer and various neurological and skeletal disorders. Chronogesic(TM) is intended for patients whose chronic pain is stable, opioid responsive and results from a variety of malignant and non-malignant causes. Annual sales of opioids for the treatment of chronic pain are in excess of $2 billion.

“We believe the results validate our product development strategy,” stated Thomas A. Schreck, Chief Financial Officer of DURECT. “Given the strength of our results, we are accelerating our spending on product development, manufacturing, operations and commercialization efforts for Chronogesic(TM). As a result of these activities, we expect to incur additional expenditures in the third and fourth quarters of this year. We now anticipate that our third quarter estimated net loss attributable to common stockholders will range from $9.2 million to $9.6 million or 19 to 20 cents loss per share, and that our fourth quarter estimated net loss attributable to common stockholders will range from $10.0 million to $10.5 million or 21 to 22 cents loss per share.”

DURECT Corporation is pioneering the development and commercialization of pharmaceutical systems for the treatment of chronic debilitating diseases and enabling biotechnology-based pharmaceutical products. DURECT’s goal is to deliver the right drug to the right site in the right amount at the right time. DURECT’s pharmaceutical systems combine technology innovations from the

medical device and drug delivery industries with proprietary pharmaceutical and biotechnology drug formulations. These capabilities can enable new drug therapies or optimize existing therapies based on a broad range of compounds, including small molecule pharmaceuticals as well as biotechnology molecules such as proteins, peptides and genes. DURECT focuses on the treatment of chronic diseases including pain, CNS disorders, cardiovascular disease and cancer. In addition to holding an exclusive license from ALZA Corporation to develop and commercialize products in selected fields based on the DUROS(R) implant technology, DURECT also owns multiple proprietary drug delivery platforms including SABER(TM), a patented and versatile depot technology and the IntraEAR(R) catheters which have been used by physicians to treat inner ear disorders.

Founded in 1998, DURECT is headquartered in Cupertino, CA. The company's World Wide Web site can be accessed at http://www.www.durect.com. To join DURECT's email alert service, please register by selecting "Email Alerts" on the main Investor Relations web page at http://www.www.durect.com.

The statements in this press release regarding DURECT's clinical trials, products in development, product development plans, expected product benefits, potential product markets or anticipated spending and results of operations, are forward-looking statements involving risks and uncertainties that could cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, DURECT's ability to successfully complete clinical trials, develop, manufacture and commercialize its products, obtain product and manufacturing approvals from regulatory agencies, validate and qualify a manufacturing facility and manage its growth and expenses, as well as marketplace acceptance of DURECT's products. Further information regarding these and other risks is included in DURECT's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001 filed with the SEC on August 14, 2001, and Annual Report on Form 10-K for the fiscal year ended December 31, 2000 filed with the SEC on March 30, 2001, under the heading "Factors that May Effect Future Results."

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