Primary Endpoint of Pivotal Phase III Clinical Trial Achieved for Remoxy(TM)

CUPERTINO, Calif., Dec. 6 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today that the pivotal Phase III trial for Remoxy had successfully met its primary endpoint ($p<0.01$) that was prospectively defined by the U.S. Food and Drug Administration (FDA) during the Special Protocol Assessment process. Remoxy, an investigational drug based on DURECT's patented ORADUR(TM) technology, is an abuse-deterrent version of long-acting oxycodone, a powerful painkiller available only by prescription. Remoxy is intended to meet the needs of physicians or pharmacists who appropriately prescribe or dispense long-acting oxycodone and who seek to minimize the risks of abuse, misuse or diversion. These successful results were reported today by Pain Therapeutics (Nasdaq: PTIE) and King Pharmaceuticals (NYSE: KG); Pain Therapeutics is DURECT's licensee of the rights to this investigational drug, and they in turn have sublicensed the commercialization rights to King Pharmaceuticals. According to Pain Therapeutics and King Pharmaceuticals, the FDA has agreed in writing that a single Phase III pivotal study is needed to support the regulatory approval of Remoxy. As a result, Pain Therapeutics has stated that they expect to file a New Drug Application for Remoxy in Q2 2008.

(Logo: http://www.newscom.com/cgi-bin/prnh/20020717/DRRXLOGO)

"These positive clinical trial results represent a major validating milestone for the ORADUR technology which has the potential to serve as a platform for multiple drugs that require controlled release in an abuse deterrent form, and it takes us one step closer to the first NDA filing based on our ORADUR technology," stated James E. Brown, DVM, President and CEO of DURECT. "The abuse of pain medications is a widespread problem in this country and addressing that issue is clearly in the public interest."

Pivotal Remoxy Phase III Study (as reported by Pain Therapeutics and King Pharmaceuticals)

Design

This pivotal Phase III randomized, double-blinded, placebo-controlled, multi-center study was designed to evaluate the analgesic efficacy of twice-daily Remoxy versus placebo over a 12-week treatment period. The study randomized 412 male and female patients. All patients were diagnosed with osteoarthritis of the knee or hip, as evidenced by x-ray and clinical criteria of the American College of Rheumatology. Additionally, all patients had pain intensity scores corresponding to moderate-to-severe pain.

Following informed consent, wash-out and dose titration, patients were randomized (1:1) into a double-blinded treatment period (12 weeks). During treatment, patients received twice-daily Remoxy or matching placebo. The total drug dose per patient per day ranged from 10-80mg. Pain intensity scores were assessed on a Likert pain scale. Concomitant pain medications or rescue medications were not allowed at any point during the 12-week treatment period.

This Remoxy study received a Special Protocol Assessment (SPA) from the FDA. With an SPA, the study design, endpoints and statistical analyses needed to support approval were agreed upon by the FDA prior to initiating the study and are considered binding.

Results

Pursuant to an SPA, the primary endpoint was defined as mean decrease in pain intensity scores between Remoxy and placebo during the 12-week treatment period. Top-line data indicates that the study achieved a statistically significant result in its primary endpoint ($p<0.01$). In addition, the study achieved statistically significant results in secondary endpoints such as Quality of Analgesia ($p<0.01$) and Global Assessment ($p<0.01$). No drug-related safety issues were noted in this study.

About ORADUR

ORADUR is a patented technology designed to transform drugs into sustained release oral products with the added benefit of being less prone to abuse.

About DURECT Corporation

DURECT Corporation is an emerging specialty pharmaceutical company developing pharmaceutical systems based on its proprietary drug delivery platform technologies. The Company currently has multiple late-stage pharmaceutical products in development addressing large markets in pain management, with a number of research programs underway targeting chronic disease and other therapeutic areas. For more information, please visit http://www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding Remoxy, its expected New Drug Application filing date, attributes and commercial potential, and other potential ORADUR-based products are forward looking statements involving risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, difficulties or delays in development, testing, regulatory approval, production and marketing of Remoxy and other potential ORADUR-based products, unexpected delays in the filing of a New Drug Application for Remoxy with the FDA, unexpected adverse side effects or inadequate therapeutic efficacy of Remoxy or other potential ORADUR-based products that could slow or prevent product approval or market acceptance (including the risk that current and past results of clinical trials are not necessarily indicative of future results of clinical trials), the uncertainty of patent protection for Remoxy and other potential ORADUR-based products and unanticipated research and development and other costs. Further information regarding these and other risks is included in DURECT's Form 10-Q dated November 8, 2007 under the heading "Risk Factors."

SOURCE DURECT Corporation
12/06/2007

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