DURECT Provides an Update on Its Post-Operative Pain Depot (SABER(TM)-Bupivacaine) Program

CUPERTINO, Calif., April 27 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX), an emerging specialty pharmaceuticals company, provided an update on its post-operative pain relief depot, SABER(TM)-Bupivacaine program. DURECT announced results from its Phase II Australian clinical study in hernia patients and the initiation of dosing in the first U.S. clinical trial, a Phase II, placebo-controlled trial in hernia patients.

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

Commenting on the program, Dr. Felix Theeuwes, Chairman and Chief Scientific Officer of DURECT, said, “We are pleased with how this dosage form performs in the clinic, in particular its ease of use in the clinical setting and the controlled local delivery of bupivacaine at the surgical site, where SABER-Bupivacaine is applied. This performance is reflected in the good pharmacokinetics and safety data obtained in this first Phase II study. Based on the well known efficacy of immediate release bupivacaine, the clinical experience generated from local infusions of bupivacaine via catheter around surgical sites, and the good safety and pharmacokinetics data from this trial, we feel confident that the remainder of our Phase II program will define the optimum dosing of SABER-Bupivacaine for local post-surgical pain management.”

Phase II Australian Hernia Study

Trial Design

The Phase II trial was a dose escalation trial conducted in three cohorts, where three doses, low (Cohort 1), intermediate (Cohort 2) and high (Cohort 3), of SABER-Bupivacaine was evaluated following repair of inguinal hernia. In Cohorts 1, 2 and 3, a total of 6, 15 and 60 patients were enrolled, respectively. Cohorts 2 and 3 included control groups of 5 and 15 patients, respectively, who received commercial bupivacaine as a comparator. Prior to dose escalation, safety and an acceptable pharmacokinetic profile were established. The primary end points of the study were safety and pharmacokinetics. The study also assessed a variety of other secondary endpoints including, among others, pain intensity, pain relief and supplemental analgesic medication usage. Although the study was not designed as an efficacy study to provide statistical conclusions on such secondary endpoints, results from these evaluations are intended to guide the design of future Phase II and Phase III clinical studies.

Study Results
The results to date from the study are as follows:

All primary end-points of the study were achieved:

-- Safety -- Good safety was observed across all Cohorts, with no

clinically significant drug related adverse events observed with 61 patients exposed to SABER-Bupivacaine. SABER-Bupivacaine injections also appeared to be well tolerated by patients.

- Pharmacokinetics -- Evaluation of plasma bupivacaine concentrations showed that, across all Cohorts, SABER-Bupivacaine achieved:
  - sustained plasma concentrations of bupivacaine as measured up to 72 hours
  - no evidence of burst or spike in plasma concentrations of bupivacaine upon injection
  - dose linear pharmacokinetics of bupivacaine

Secondary End-points (in Cohort 2 and Cohort 3 with comparator controls groups):

- In Cohort 2 (n=15), the patients who were administered SABER-Bupivacaine showed better pain relief, lower pain intensity and reduced supplemental analgesic usage compared with the patients using commercial bupivacaine as measured during the first 4 days after treatment.
- In Cohort 3 (n=60), no significant difference was observed in pain relief, pain intensity and supplemental analgesic usage between the patients who were administered SABER-Bupivacaine compared with the patients using commercial bupivacaine as measured during the first 4 days after treatment.

Update on Phase II Program

Dosing has been initiated in the first clinical trial in the U.S., a Phase II, placebo-controlled trial intended to enroll up to 90 patients following hernia surgery. In addition, a Phase II trial in hernia patients is on-going in the United Kingdom. During the remainder of this year, we intend to initiate several Phase II trials in the U.S. and in other countries in a variety of soft-tissue and orthopedic surgery models for the purpose of selecting the optimal dose and the pain models to be used for our pivotal trials. Pending the successful completion of these Phase II trials and approval of regulatory authorities, we will continue into Phase III trials.

About SABER-Bupivacaine

Our SABER-Bupivacaine depot under development is a sustained-release formulation of bupivacaine, an off-patent local anesthetic, using our patented SABER delivery system for the treatment of post-surgical pain. SABER-Bupivacaine is intended to be administered by the surgeon around the incision at the time of surgery. Placed in the tissues near or adjacent to the surgical site, this formulation is designed to provide sustained regional analgesia from a single dose. We believe that by delivering effective amounts of a potent anesthetic to the location from which the pain originates, adequate pain control can be achieved with minimal exposure to the remainder of the body, and hence minimal side effects. SABER-Bupivacaine is intended to provide local analgesia of 3 days or more, which we believe coincides with the time period of greatest need for post-surgical pain control in most patients.

We retain the full commercialization rights to SABER-Bupivacaine.

About DURECT Corporation

DURECT Corporation is an emerging specialty pharmaceutical company focused on the development of pharmaceutical systems based on its proprietary drug delivery platform technologies that treat chronic debilitating diseases and enable biotechnology products. Additional information about DURECT is available at www.www.durect.com.

NOTE: SABER(TM) is a trademark of DURECT Corporation. Other referenced trademarks belong to their respective owners.

DURECT Forward-Looking Statement

The statements in this press release regarding DURECT's products in development, anticipated product benefits and clinical trial results and future clinical trial plans 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, DURECT's ability to successfully design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of the product candidate, obtain product and manufacturing approvals from regulatory agencies and manufacture and commercialize the product candidate, as well as marketplace acceptance of the product candidate. Further information regarding these and other risks is included in DURECT's Annual Report on Form 10-K filed with the SEC on March 16, 2006 under the heading "Risk Factors."

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