DURECT Announces Plans for a New POSIDURâ?¢ (SABERÂ®-Bupivacaine) Clinical Trial

CUPERTINO, Calif., June 23, 2015 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced that, based on feedback from the FDA, it plans to conduct a new POSIDURâ?¢ (SABERÂ®-Bupivacaine) Phase 3 clinical trial consisting of approximately 300 patients undergoing laparoscopic cholecystectomy (gallbladder removal) surgery. DURECT anticipates beginning the trial in the fall of 2015 and expects that it will take approximately one year to complete enrollment.

“With the FDA’s guidance in hand, we now have a clear path forward for POSIDUR,” stated James E. Brown, President and CEO of DURECT. “We believe that the data from this additional clinical trial will be supportive of the data we have seen in our other pivotal trials in hernia repair and shoulder surgery, and that these three pivotal trials will support a robust NDA resubmission, for which there would be a 6 month review per PDUFA guidelines. We have previous clinical trial experience with laparoscopic cholecystectomy, which is one of the most common general surgeries performed in the U.S. each year. We believe this is an excellent surgical model and that our overall clinical program for POSIDUR will support a broad label.”

About the new Phase 3 Clinical Trial

The study will be a randomized, parallel-group, double-blind, placebo-controlled, multicenter trial of POSIDUR in patients undergoing laparoscopic cholecystectomy. The objective of the study will be to evaluate the safety and efficacy of POSIDUR for the management of postoperative pain. Approximately 300 patients will be randomized on a one-to-one basis to receive either POSIDUR or placebo as a one-time intra-incisional instillation at the close of surgery. The primary efficacy endpoint will be pain intensity on movement over 0-72 hours after surgery.

Laparoscopic cholecystectomy

Cholecystectomy is a surgical procedure for removal of the gallbladder. Laparoscopic cholecystectomy, which is done using a camera and instruments inserted through a set of small incisions in the abdomen, has largely supplanted the traditional open approach, which requires an abdominal incision several inches in length. Approximately 800,000 such procedures are performed in the U.S. each year, most of them on an outpatient basis.

In a previous clinical trial consisting of 50 patients, when using the statistical analysis that will be employed in the upcoming trial, POSIDUR demonstrated an approximately 25% reduction in pain intensity on movement for the first 3 days after surgery (p=0.0235) when compared with the active control bupivacaine hydrochloride.

About POSIDUR

POSIDUR is an investigational post-operative pain relief depot that utilizes our patented SABER technology and is intended to deliver bupivacaine to the surgical site to provide up to three days of pain relief after surgery. We are in discussions with potential partners regarding licensing development and commercialization rights to POSIDUR, for which we hold worldwide rights, while at the same time we are evaluating whether to commercialize POSIDUR on our own in the U.S. in the event that we determine that is the preferred route of commercialization.

In April 2013, we submitted a New Drug Application (NDA) as a 505(b)(2) application, which relied in part on the FDA’s findings of safety and effectiveness of a reference drug (bupivacaine). In February 2014, we received a Complete Response Letter from the FDA. Based on its review, the FDA determined that they could not approve the NDA in its present form, stating the NDA did not contain sufficient information to demonstrate that POSIDUR is safe when used in the manner described in the proposed label, and the FDA indicated that additional clinical safety studies needed to be conducted. We had a face-to-face meeting with the FDA in September 2014 to discuss what needed to be done to address the issues cited in the Complete Response Letter. As a result of this meeting, and based on subsequent communications with the FDA, we plan to conduct the Phase 3 clinical trial described above to generate the data required for product approval.

About DURECT Corporation

DURECT is an innovative biopharmaceuticals company with expertise in drug discovery, drug delivery and drug development, applying those skills primarily to therapeutics in the fields of pain management, CNS disorders, acute organ injury and metabolic diseases. DURECT's proprietary oral, transdermal and injectable depot delivery technologies enable new indications and superior clinical/commercial attributes such as improved abuse deterrence, convenience, adherence, efficacy and safety for small molecule and biologic drugs. Late stage development programs of this nature include POSIDUR™ and REMOXY®. DURECT's Epigenomic Regulator Program includes the lead molecule DUR-928 in Phase 1 clinical testing. DUR-928 is an endogenous small molecule that is an epigenomic modulator of cellular activities involved in lipid homeostasis, metabolic disease, inflammation and cell survival. For more information, please visit www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding the anticipated POSIDUR Phase 3 clinical trial, including timing andpotential results, the potential resubmission of the NDA for POSIDUR to the FDA, the potential regulatory approval of POSIDUR by the FDA, potential product labeling, potential licensing transactions for POSIDUR, the potential benefits and uses of POSIDUR, and the potential uses and benefits of DURECT's other product candidates 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, the risk that trials and studies will not have satisfactory outcomes, the risk of adverse decisions by regulatory agencies, including product non-approval, delays and additional costs due to requirements imposed by regulatory agencies, potential adverse effects arising from the testing or use of POSIDUR, the potential that data submitted in response to the complete response letter will not be deemed sufficient by FDA or other regulatory agencies to support regulatory approval of POSIDUR, and the risk of obtaining marketplace acceptance of POSIDUR, avoiding infringing patents held by other parties and securing and defending patents of our own, and managing and obtaining capital to fund our growth, operations and expenses. Further information regarding these and other risks are included in DURECT's Form 10-Q for the quarter ending March 31, 2015, filed with the Securities and Exchange Commission on May 1, 2015, under the heading "Risk Factors."

NOTE: POSIDUR™ and SABER® are trademarks of DURECT Corporation. REMOXY, POSIDUR and DUR-928 are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/durect-announces-plans-for-a-new-posidur-saber-bupivacaine-clinical-trial-300103074.html

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