DURECT Announces Positive Results from Relday™ Phase 1 Clinical Trial

CUPERTINO, Calif., Jan. 3, 2013 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced that its licensee, Zogenix Inc. (Nasdaq: ZGNX), today reported positive single-dose pharmacokinetic (PK) results from the Phase 1 clinical trial of Relday™, an investigational candidate of a proprietary, once-monthly subcutaneous formulation of risperidone for the treatment of schizophrenia. According to Zogenix, adverse events in the Phase 1 trial in patients diagnosed with schizophrenia were generally mild to moderate and consistent with other risperidone products.

(Logo: http://photos.prnewswire.com/prnh/20020717/DRRXLOGO)

The Phase 1 clinical trial for Relday was conducted as a single-center, open-label, safety and PK trial of 30 patients with chronic, stable schizophrenia or schizoaffective disorder. Per Zogenix, based on the favorable safety and PK profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, Zogenix has extended the study to include a 100 mg dose of the same formulation. The addition of this dose arm to the study will enable evaluation of dose proportionality across the full dose range that would be anticipated to be used in clinical practice. Zogenix expects to complete the extension of the Phase 1 clinical trial during the second quarter of 2013.

James E. Brown, D.V.M., President and CEO of DURECT, stated, “We’re pleased with these results from the first Relday study and with Zogenix‘s extension of the study to a higher dose. We believe this formulation of risperidone, designed to be dosed once a month through a subcutaneous rather than intramuscular injection, would provide patient and clinician benefits relative to existing risperidone products. Relday joins POSIDUR™ (SABER®-bupivacaine), for which we anticipate filing an NDA in the first quarter of 2013, as our second depot injectable therapeutic in clinical development.”

About Relday™

On July 11, 2011, DURECT and Zogenix entered into a development and license agreement for the purpose of developing and commercializing Relday, a proprietary, long-acting injectable formulation of risperidone using our SABER® depot technology. Risperidone is one of the most widely prescribed medications used to treat the symptoms of schizophrenia and bipolar I disorder in adults and teenagers 13 years of age and older. The global long-acting injectable antipsychotic market was approximately$2 billion in 2011. The leading product in the category requires twice-a-month dosing via intramuscular injections and drug reconstitution prior to use. We believe that Relday may offer an improved pharmacokinetic profile, reduction in injection volume and a simplified dosing regimen relative to existing risperidone products. Under the agreement, we granted Zogenix worldwide development and commercialization rights to Relday.

About DURECT‘s Depot Programs

In addition to two products in development using our depot technology (POSIDUR and Relday), we have multiple feasibility projects underway and one animal health drug (SucroMate™ Equine) which is approved and being commercialized through our licensee (CreoSalus, Inc.). DURECT has developed significant capabilities in the area of depot injectable technology which allows for proprietary product development with delivery periods of days to months. Programs utilizing our depot technology also benefit from the custom polymer expertise residing within our Birmingham, Alabama group where we manufacture polymeric components under the LACTEL® brand name for 13 FDA approved products.

About DURECT Corporation

DURECT is a specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with late-stage development programs including REMOXY®, POSIDUR™, ELADUR®, and TRANSDUR®-Sufentanil. DURECT‘s proprietary oral, transdermal and injectable depot delivery technologies enable new indications and superior clinical/commercial attributes such as abuse deterrence, improved convenience, compliance, efficacy and safety for small molecule and biologic drugs. For more information, please visit www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding the potential uses, benefits, commercial opportunity and possible market of Relday, extension of the Relday Phase 1 study to include a 100 mg dose of the same formulation in order to enable evaluation of dose proportionality across the full dose range that would be anticipated to be used in clinical practice, the expectation of completing the extension of this Phase 1 clinical trial during the second quarter of 2013, and the anticipation that an NDA will be filed for POSIDUR in the first quarter of 2013 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 or Zogenix's difficulty or failure to obtain approvals from regulatory agencies with respect to clinical trials and other development activities, or their respective abilities to design, enroll, conduct and complete clinical trials, failure of such clinical trials to produce intended results, delays of Zogenix's Phase 1 clinical trial extension, unfavorable safety or PK results, possible adverse events associated with the use of Relday, delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development of POSIDUR or development, approval or sale of Relday, interruptions of supplies of key components of Relday or POSIDUR, our ability to complete the design, development and manufacturing process development of Relday, and to manufacture, commercialize and obtain marketplace acceptance of Relday, and avoid infringing patents held by other parties and secure and defend patents of our own, and manage and obtain capital to fund our growth, operations and expenses. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. Additional risks and uncertainties relating to DURECT and its business can be found under the heading "Risk Factors" in DURECT quarterly report on Form 10-Q for the quarter ended September 30, 2012 and other filings with the SEC. DURECT does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any statements are based.

SOURCE DURECT Corporation

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