ELADUR(TM) Development Update: DURECT Receives Orphan Drug Designation for Bupivacaine for Post-Herpetic Neuralgia

CUPERTINO, CA, June 30, 2008 / PRNewswire-First Call via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) announced today that the US Food and Drug Administration (FDA) has granted to DURECT orphan drug designation for bupivacaine for relief of persistent pain associated with post-herpetic neuralgia (PHN). Bupivacaine is the active pharmaceutical ingredient in ELADUR™, DURECT's investigational transdermal drug patch. If ELADUR is the first bupivacaine product approved for PHN, under the 1983 Orphan Drug Act ELADUR will receive seven years of market exclusivity following the approval of the product by the FDA.

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

"The receipt of orphan drug status enhances the product opportunity for ELADUR, including providing a more favorable development pathway," stated James E. Brown, DVM, President and CEO of DURECT. We are continuing to develop ELADUR as a potentially best in class transdermal product for those suffering from PHN.

ELADUR is an investigational transdermal drug patch intended to deliver bupivacaine for up to 3 days from a single application, as compared to a wearing time limited to 12 hours with currently available anesthetic patches (e.g., Lidoderm®, an FDA-approved lidocaine patch for post-herpetic neuralgia pain management). Bupivacaine, the active agent in ELADUR, is a potent, FDA-approved long-acting local anesthetic used in regional anesthesia for local tissue infiltration, nerve block, and epidural and intrathecal anesthesia. DURECT currently retains full commercial rights to this product candidate.

DURECT has previously announced positive results for ELADUR from a 60 patient Phase IIa clinical trial of patients suffering from post-herpetic neuralgia. In this study, ELADUR showed improved pain control versus placebo during the 3-day continuous treatment period. In addition, ELADUR appeared to be well tolerated overall, and patients treated with ELADUR and placebo exhibited similar safety profiles. A poster describing this study was presented at the 27th Annual Scientific Meeting of the American Pain Society on May 8, 2008 and is accessible on our website (http://www.www.durect.com/wt/durect/page_name/Publications).

About DURECT Corporation

DURECT is an emerging 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.

NOTE: ORADUR™, POSIDUR™, ELADUR™ and TRANSDUR™ are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. Remoxy, POSIDUR, ELADUR and TRANSDUR-Sufentanil are drug candidates under development and have not been approved for commercialization by the US Food and Drug Administration or other health authorities.

DURECT Forward-Looking Statement

The statements in this press release regarding ELADUR, its anticipated attributes and commercial potential, its potential to be a best in class transdermal product for those suffering from PHN and its potential to receive seven years of market exclusivity as an orphan drug 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 ELADUR may not be the first bupivacaine product approved for PHN, DURECT's ability to design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of ELADUR, obtain product and manufacturing approvals from regulatory agencies and manufacture and commercialize ELADUR, as well as marketplace acceptance of the product candidate. Further information regarding these and other risks is included in DURECT's Form 10-Q dated May 8, 2008

under the heading Risk Factors.

SOURCE DURECT Corporation
06/30/2008
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