DURECT Corporation Delays Enrolling Additional Patients in Its Phase III Clinical Trial for CHRONOGESIC Pending Clinical Trial Protocol Amendments

CUPERTINO, Calif., Aug 26, 2002 /PRNewswire-FirstCall via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) announced today that, following discussions between DURECT and the FDA on DURECT's on-going Phase III clinical trial for the CHRONOGESIC(TM) (sufentanil) Pain Therapy System, the FDA has requested that the clinical trial protocol be amended to provide for additional patient monitoring before enrolling additional patients in the clinical trial. This request was not in response to any observed patient safety or adverse event.

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

In a telephone conference on Friday, August 23, 2002, the FDA requested that DURECT put the on-going clinical trial on partial hold until the clinical trial protocol is amended and approved by the FDA to provide for additional patient monitoring. With respect to patients in the clinical trial who are already implanted with the CHRONOGESIC product, DURECT is implementing increased monitoring measures to allow such patients to continue participation in the clinical trial. DURECT intends to submit an amendment to the existing clinical trial protocol to provide additional monitoring measures for all patients. Upon agreement with the FDA on the amendment, new patient enrollment in this trial will resume.

"We believe we have had a successful start to our present Phase III clinical trial and feel confident that we will be able to address the FDA's requests expeditiously," said Dr. James E. Brown, DURECT's Chief Executive Officer.

"Our on-going discussions with the FDA have better defined the data we will need in order to gain approval of our CHRONOGESIC product," said Dr. Felix Theeuwes, Chairman and Chief Scientific Officer of DURECT. "We believe that these amendments to the protocol of our current Phase III study will allow us to collect the required safety and pharmacokinetic data in this early part of our Phase III program."

DURECT Corporation (www.www.durect.com) is pioneering the development and commercialization of pharmaceutical systems for the treatment of chronic debilitating diseases and enabling biotechnology-based pharmaceutical products. DURECT's goal is to deliver the right drug to the right site in the right amount at the right time. DURECT's lead product in development, the CHRONOGESIC(TM) (sufentanil) Pain Therapy System is a 3-month product for the treatment of chronic pain. DURECT owns three proprietary drug delivery platform technologies, including the SABER(TM) Delivery System (a patented and versatile depot injectable useful for protein delivery), the MICRODUR(TM) Biodegradable Microparticulates (microspheres injectable system) and the DURIN(TM) Biodegradable Implant (drug-loaded implant system).

NOTE: CHRONOGESIC(TM) is a trademark of DURECT Corporation. SABER(TM), MICRODUR(TM) and DURIN(TM) are trademarks of Southern BioSystems, Inc., a wholly owned subsidiary of DURECT Corporation. Other trademarks referred to belong to their respective owners.

The statements in this press release regarding DURECT's products in development, expected product benefits, product development and clinical trials plans and projected future financial results, 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 research, develop, manufacture and commercialize its products, obtain product and manufacturing approvals from regulatory agencies, timely enroll patients and clinical sites in connection with its clinical studies, effectively administer its clinical trials, manage its growth and expenses, finance its activities and operations, as well as marketplace acceptance of DURECT's products. Further information regarding these and other risks is included in DURECT's Annual Report on Form 10-K for the fiscal year ended December 31, 2001 filed with the SEC on March 28, 2002, under the heading "Factors that may affect future results," and other periodic reports filed with the SEC. CHRONOGESIC is under development by DURECT and has not been submitted or approved for commercialization by the US Food and Drug Administration or other health authorities.

SOURCE DURECT Corporation

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