DURECT Announces Update to CHRONOGESIC Program

CUPERTINO, Calif., Oct. 16 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today that it has received data from a preclinical animal test with its CHRONOGESIC(R) (sufentanil) Pain Therapy Product which indicate that a small number of units (less than 2% in total) utilizing the new system design under evaluation by the Company experienced a premature shutdown (stop in delivery of drug).

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

In parallel track with the CHRONOGESIC development program using the current system design, DURECT has been exploring additional mechanisms to prevent any premature shutdown, and has already generated feasibility data relating to these mechanisms.

The Company is currently investigating the impact of these new data on the timing of the development program, but the Company expects that this will delay the restart of the product's phase III clinical program previously anticipated to begin during the second half of 2003.

"We were disappointed to receive these unexpected data from the last of a series of confirmatory animal studies which just concluded on October 15," stated Jim Brown, CEO of DURECT. "We have not observed this phenomenon in any of our previous studies utilizing the revised system design. We continue to believe in the value of the CHRONOGESIC program, and we remain committed to bringing this therapy to the patients."

Conference Call and Webcast Information

DURECT Corporation will be hosting a conference call on Friday, October 17, 2003 at 8:30 a.m. Eastern Time/5:30 a.m. Pacific Time to discuss these recent developments. Participants can listen to the conference call via webcast on the Company's website, www.www.durect.com.

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. In addition to its rights to the CHRONOGESIC(R) product, 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(R), SABER(TM), MICRODUR(TM) and DURIN(TM) are trademarks of DURECT Corporation.

The statements in this press release regarding DURECT's products in development and product development 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 complete the design, development, and manufacturing process development of its products, manufacture and commercialize its products, obtain product and manufacturing approvals from regulatory agencies, manage its growth and expenses, manage relationships with third parties, 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, 2002 filed with the SEC on March 14, 2003, DURECT's Quarterly Report on Form 10Q and other periodic reports filed with the SEC under the heading "Factors that may affect future results."

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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