DURECT Announces Filing of Special 510(k) Application for its New Generation IntraEAR(R) Ear Catheter Product and Approval of Physician Sponsored Investigational New Drug Application for Treatment …

CUPERTINO, Calif., June 25 /PRNewswire/ —
DURECT Corporation (Nasdaq: DRRX) announced today that it has filed a Special 510(k) pre-market notification with the FDA for its next generation ear delivery catheter. Like its predecessor IntraEAR(R) catheters, the Microdose Cath(TM) is intended for the site-directed delivery of fluids to the round window area of the middle ear for the treatment of ear disorders.
Additionally, DURECT announced that the Naval Medical Center San Diego ("NMCSD") will be evaluating the IntraEAR(R) Microdose Cath(TM) as part of an FDA accepted physician-sponsored Investigational New Drug ("PIND") study. NMCSD will use the catheter as part of a blinded, non-active controlled study evaluating the use of gentamicin for the treatment of Meniere's disease. Due to the nature of the progression of Meniere's disease, the clinical evaluation period for this study may last up to two years.

Inner ear disorders, including tinnitus, hearing loss and Meniere's disease impact the lives of millions of people worldwide. Meniere's disease, which affects three to five million Americans, is a combination of vertigo, progressive fluctuating hearing loss, tinnitus and a sensation of pressure in the ear. Approximately 100,000 new cases are diagnosed each year in the US, 30,000 of whom continue to suffer after medical and dietary treatments fail.

"NMCSD has been a pioneer in the development of novel therapies for the many patients suffering from inner ear disorders such as Meniere's disease," said Tim Nelson, Vice President of Commercial and Business Development for DURECT. "In comparison to the patient outcomes of bolus injection of gentamicin, we believe the site directed treatment being studied by the NMCSD may help to minimize hearing loss while also better preserving balance function in Meniere's disease patients. DURECT is pleased that the NMCSD has taken the initiative to further evaluate this very promising therapy under a blinded, non-active controlled study."

DURECT Corporation is pioneering the development and commercialization of pharmaceutical systems to deliver the right drug to the right site in the right amount at the right time. DURECT's pharmaceutical systems combine technology innovations from the medical device and drug delivery industries with proprietary pharmaceutical and biotechnology drug formulations. These capabilities can enable new drug therapies or optimize existing therapies based on a broad range of compounds, including small molecule pharmaceuticals as well as biotechnology molecules such as proteins, peptides and genes.

DURECT's lead product in development is designed to deliver sufentanil on

a continuous basis for 3 months for the treatment of chronic pain. Sufentanil is a FDA approved opioid that is currently used in hospitals as an anesthetic. Chronic pain is a significant problem associated with chronic diseases, including cancer and various neurological and skeletal disorders. DUROS sufentanil is intended for patients whose chronic pain is stable, opioid responsive and results from a variety of malignant and non-malignant causes. Annual sales of opioids for the treatment of chronic pain exceed $1 billion. DURECT's second product in development continuously delivers hydromorphone to the spine. DURECT also sells FDA cleared catheters for the delivery of fluids to the inner ear and manufactures and sells and distributes the ALZET(R) osmotic pump product for use in laboratory research.

Southern BioSystems, Inc., a wholly owned subsidiary of DURECT Corporation, researches, develops and manufactures controlled-release drug delivery products to help clients commercialize human and veterinary pharmaceuticals. Southern BioSystems has three drug-delivery platforms: the proprietary SABER(TM) delivery system, microspheres and drug-loaded implants. SABER(TM) is a biodegradable highly viscous liquid that can be formulated for oral, parenteral dermal or other routes of administration. Southern BioSystems has the capabilities to formulate microspheres for oral, parenteral, dermal or other routes of administration. Southern BioSystems also develops drug-loaded implants and, through its subsidiary Birmingham Polymers, also manufactures biodegradable polymers.

Founded in 1998, DURECT is headquartered in Cupertino, CA. The company's World Wide Web site can be accessed at http://www.www.durect.com. The company's World Wide Web site for ALZET osmotic pumps, IntraEAR and Southern BioSystems, Inc. can be accessed at http://www.alzet.com, http://wsww.intraear.com and http://www.southernbiosystems.com, respectively. To join DURECT's email alert service, please register by selecting "Email Alerts" on the main Investor Relations web page at http://www.www.durect.com.

The statements in this press release regarding DURECT's products in development, product development plans, or expected product benefits, are forward-looking statements involving risks and uncertainties that could 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 develop, manufacture and commercialize its products, successfully complete clinical trials, obtain product and manufacturing approvals from regulatory agencies, and validate and qualify a manufacturing facility, as well as marketplace acceptance of DURECT's products. Further information regarding these and other risks is included in the company's S-1 registration statement, filed with the SEC on September 22, 2000, 424(b) prospectus filed with the SEC on September 28, 2000, Quarterly Report on Form 10Q for the quarter ended April 30, 2001 filed with the SEC on May 11, 2001 and Annual Report on Form 10K for the fiscal year ended December 31, 2000 filed with the SEC on March 30, 2001.

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