DURECT and Voyager Pharmaceutical Announce the Acceptance of DURIN(TM) Investigational New Drug Application and Clinical Protocol by the FDA for the Treatment of Alzheimer's Disease

CUPERTINO, Calif., Dec. 20 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX), an emerging specialty pharmaceutical systems company, and Voyager Pharmaceutical Corporation, a privately held specialty pharmaceutical company focused on diseases of aging, announced today the acceptance of the Investigational New Drug Application ("IND") and clinical protocol by the FDA for a DURIN(TM)-based leuprolide acetate treatment of Alzheimer's disease under development. This trial will consist of a pharmacokinetic study in normal, healthy volunteers. The objectives of the clinical study are to determine the safety and tolerability of the DURIN leuprolide implant, as well as evaluate the pharmacokinetic profile of the product following administration. Voyager Pharmaceutical is currently engaged in patient enrollment for this study, which will be conducted in parallel with two ongoing Phase II Alzheimer's studies being conducted by Voyager.

"We are pleased to meet this milestone with the first IND accepted for our DURIN platform technology," said James E. Brown, DVM, president and chief executive officer of DURECT. "This product fits with DURECT's mission of utilizing our proprietary drug delivery platforms to develop products that treat chronic debilitating diseases. It has been a pleasure to work with Voyager to bring this product to this point in clinical development."

"The launch of this study using our unique dose of DURIN-leuprolide acetate optimized for the treatment of Alzheimer's Disease is an exciting event for Voyager," added Patrick S. Smith, President and CEO of Voyager Pharmaceutical. "In 2005, we expect to complete this study, our ongoing Phase II study in women and an interim analysis of our ongoing Phase II study in men. Based on the results of these three studies, we plan to move into Phase III pivotal studies for our DURIN-leuprolide Alzheimer's product during the second half of 2005. It is our belief that the dosage form that we are developing in our partnership with DURECT is ideally suited for producing a convenient and effective therapy for long-term care for Alzheimer's patients. We are very excited to advance this program into clinical trials with DURECT."

According to the Alzheimer's Association and National Institute of Aging, Alzheimer's disease is an incurable, neurodegenerative disorder that affects more than 4.5 million Americans. The disease typically leads to progressive memory loss, impairments in behavior and language and physical deterioration. Current direct and indirect costs for caring of Alzheimer's patients are estimated at $100 billion annually.

DURECT's DURIN biodegradable implant technology is a platform for short- and long-term parenteral drug delivery lasting in duration from weeks to six months. The technology is based on the use of biodegradable polymer excipients, which have a proven record of safety and effectiveness in approved

drug delivery and medical device products. Voyager Pharmaceutical owns a broad-based patent covering the use of leuprolide acetate and other compounds for the treatment of Alzheimer's Disease.

About DURECT Corporation

DURECT Corporation is an emerging specialty pharmaceutical systems company focused on the development of pharmaceutical systems based on its proprietary drug delivery platform technologies that treat chronic debilitating diseases and enable biotechnology products. These platform technologies include the SABER(TM) Delivery System (a patented and versatile depot injectable useful for protein and small molecule delivery), the ORADUR(TM) sustained release oral gel-cap technology (an oral sustained release technology with several potential abuse deterrent properties), the DURIN(TM) Biodegradable Implant (drug-loaded implant system) and the MICRODUR(TM) Biodegradable Microparticulates (microspheres injectable system). DURECT also partners with pharmaceutical companies to develop and commercialize proprietary and enhanced pharmaceutical products based on its technologies. DURECT has five disclosed on-going development programs of which three are in collaboration with pharmaceutical partners. Additional information about DURECT is available at www.www.durect.com.

About Voyager Pharmaceutical Corporation

Voyager Pharmaceutical is a privately held specialty pharmaceutical company based in Raleigh, NC focused on disease of aging. The company's proprietary approach applies a new understanding of the role of gonadotropins and other hormones in Alzheimer's disease and many other diseases. In addition to its Alzheimer's Disease program, Voyager is pursuing active research programs in other areas, including cancer, Parkinson's Disease and ALS (Amyotrophic Lateral Sclerosis). Further information about Voyager Pharmaceutical can be found at www.voyagerpharma.com.

The statements in this press release regarding DURECT's and Voyager Pharmaceutical'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 and Voyager Pharmaceutical's abilities 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 these 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, 2003 filed with the SEC on March 11, 2004, DURECT's Quarterly Report on Form 10Q and other periodic reports filed with the SEC under the heading "Factors that may affect future results."

The DURIN leuprolide and other products mentioned above are under development and have 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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