



# DURECT Corporation Announces Completion of Clinical Trial Enrollment for DURIN(TM)-Based Leuprolide Product Candidate

CUPERTINO, Calif., and RALEIGH, N.C., Jan 28, 2005 /PRNewswire-FirstCall via COMTEX/ — 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 completion of enrollment for the recently approved study for the DURIN(TM)-based leuprolide acetate product candidate for Alzheimer's disease under development by the parties (the DURIN(TM)-leuprolide implant). The U.S. Food and Drug Administration (FDA) accepted Voyager's Investigational New Drug Application (IND) and clinical protocol in late December, 2004, and this unique formulation is being used in the present study in healthy volunteers to evaluate the product candidate's bioavailability, as well as determine its safety and tolerability following administration. Voyager has completed the enrollment and initial dosing of all screened subjects necessary to complete the trial.

"We are pleased with the progress of this development program. In the last two weeks, the program has achieved two important milestones. First, Voyager has completed enrollment in the 50-patient Phase I pharmacokinetic study for the DURIN-based product candidate. Second, Voyager has completed dosing in its Phase II dose ranging study in women utilizing the active agent," said James E. Brown, DVM, president and chief executive officer of DURECT. "This product candidate 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 through clinical development."

"The full enrollment of this study brings Voyager closer to introducing an innovative long-term care therapy for Alzheimer's patients," said Patrick S. Smith, President and CEO, Voyager Pharmaceutical Corp. "We are pleased with the recruiting and enrollment efficiency of our clinical site, and fully expect our upcoming meeting with the FDA will result in an approval of our plans to proceed with our pivotal studies during the second half of 2005."

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 pharmaceuticals 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.durect.com](http://www.durect.com).

NOTE: SABER(TM), ORADUR(TM), DURIN(TM) and MICRODUR(TM) are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners.

#### 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](http://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 these products, manufacture and commercialize these products, obtain product and manufacturing approvals from regulatory agencies, manage their growth and expenses, manage relationships with third parties, finance their activities and operations, as well as marketplace acceptance of these products. Further information regarding these and other risks is included in DURECT's Quarterly Report on Form 10Q for the quarter ended September 30, 2004 filed with the SEC on November 5, 2004 under the heading "Factors that may affect future results."

#### SOURCE DURECT Corporation

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