DURECT Announces License of ADHD Drug Candidate in Selected Asian and South Pacific Countries to Orient Pharma

CUPERTINO, Calif., Aug 18, 2009 /PRNewswire-FirstCall via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) today announced that it has signed a development and license agreement with Orient Pharma Co., Ltd., a diversified multinational pharmaceutical, healthcare and consumer products company with headquarters in Taiwan, under which DURECT has granted to Orient Pharma development and commercialization rights in selected Asian and South Pacific countries to a drug candidate based on DURECT's ORADUR(R) Technology and one specified active pharmaceutical ingredient for the treatment of attention deficit hyperactivity disorder (ADHD). This drug candidate (ORADUR-ADHD) is intended to provide once-a-day dosing with added tamper-resistant characteristics to address common methods of abuse and misuse of these types of drugs. North American, European, Japanese and select other countries' rights to this drug candidate are retained by DURECT.

Under this agreement, the parties will collaborate to perform a clinical development program through a Phase II study intended to produce a data package that will support later stage development of the drug candidate by DURECT as well as Orient Pharma in their respective territories. DURECT will be responsible for formulation and study design of the pre-defined clinical program which Orient Pharma will fund and execute. Orient Pharma would be responsible for all remaining development and commercialization activities for this ORADUR-ADHD product in the licensed territory. If commercialized, DURECT would receive a royalty on sales of ORADUR-ADHD by Orient Pharma. Orient Pharma will supply a portion of DURECT's commercial requirements for ORADUR-ADHD in all territories other than the United States.

"We're pleased to announce this collaboration with Orient Pharma which will put us in a position to generate Phase II data for our ORADUR-ADHD program, provide us with a commercial supply source as well commercially exploit this product opportunity in this region with an established company," stated James E. Brown, President and CEO of DURECT. "Abuse of stimulants remains a major healthcare problem and we look forward to working with Orient Pharma to applying our ORADUR technology to this product category."

"We believe that this ORADUR-ADHD product has the potential to be differentiated from existing products in its class by combining all day efficacy with tamper-resistance, and we are excited to collaborate with DURECT on this opportunity," stated Peter Tsai, Chairman of Orient Pharma. "This collaboration represents an important step in our company's establishment as a partner of choice in Southeast Asia for American biopharmaceutical companies."

Attention Deficit Hyperactivity Disorder (ADHD) is a neurobehavioral condition that is estimated to affect approximately 7.8% of US children ages 4-17, according to the US Centers for Disease Control and Prevention (CDC). The principal characteristics of ADHD are inattention, hyperactivity, and impulsivity. The condition presents itself in childhood and can be life long as 65% of children with ADHD continue to present symptoms as adults. According to the CDC, 2.5 million youth (56% of those with a diagnosis) were receiving medical treatment for this disorder. The National Survey on Drug Use & Health estimates that 1.4 million Americans over the age of 12 abuse stimulants for euphoric highs and increased performance or wakefulness. Sales of ADHD treatments were approximately $4.0 billion in 2008.

About ORADUR(R) Technology

The ORADUR Technology is a patented technology designed to transform short-acting oral capsule dosage forms into sustained release oral products, with the added benefit of being less prone to common methods of abuse and misuse than other controlled release dosage forms on the market today. REMOXY(R), a long acting oral formulation of oxycodone based on the ORADUR Technology intended to treat moderate to severe pain, has been submitted for and is awaiting approval with the U.S. Food and Drug Administration (FDA).

About DURECT Corporation

DURECT is an emerging specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with

late-stage development programs including REMOXY(R), POSIDUR(TM), ELADUR(TM), and TRANSDUR(TM)-Sufentanil. DURECT's proprietary oral, transdermal and injectable depot delivery technologies enable new indications and superior clinical/commercial attributes such as abuse deterrence, improved convenience, compliance, efficacy and safety for small molecule and biologic drugs. For more information, please visit www.www.durect.com.

NOTE: POSIDUR(TM), SABER(TM), ORADUR(R), TRANSDUR(TM), and ELADUR(TM) are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. REMOXY, POSIDUR, ELADUR and TRANSDUR-Sufentanil are drug candidates under development and have not been approved for commercialization by the FDA or other health authorities.

About Orient Pharma Co., Ltd.

Orient Pharma was established in 2008 and is located in the Central Taiwan Science Park in Yunlin. Orient Pharma is building a new pharmaceutical manufacturing facility that is designed to comply with the international standards of the U.S. FDA and the European PIC/S. The first phase of the project is expected to be finished by late 2009 and the entire construction is slated for completion in 2010.

Orient Pharma is applying its platform technologies for the development of specialty pharmaceutical products and is capable of manufacturing pharmaceutical products under cGMP. Current technologies include multi-stage liquid fill and transdermal. Products under development include a next-generation drug to lower cholesterol, new combinations, as well as others indicated for cardiovascular, Alzheimer's disease, and neurodegenerative disorders. Orient Pharma will use its new facility to manufacture its own products and also to conduct contract manufacturing business for international pharmaceutical companies.

DURECT Forward-Looking Statement

The statements in this press release regarding ORADUR-ADHD, its potential attributes including tamper-resistant and once-a-day dosing characteristics, intended clinical trials and potential data generated therefrom, future development plans, potential commercialization of ORADUR-ADHD and royalties to be received by DURECT 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, difficulties or delays in the development, testing, regulatory approval, production and commercialization of ORADUR-ADHD, and unexpected adverse side-effects or inadequate therapeutic efficacy of ORADUR-ADHD that could slow or prevent product approval or market acceptance (including the risk that current and past results of clinical trials and tests are not necessarily indicative of future results of clinical trials and tests). Further information regarding these and other risks is included in DURECT's Form 10-Q dated August 4, 2009 under the heading "Risk Factors."

SOURCE DURECT Corporation

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