DURECT Announces Selection with Orient PHARMA of Lead Formulation for ORADUR®-Methylphenidate

CUPERTINO, Calif., Aug. 1, 2013 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that it and its collaborator Orient PHARMA Co., Ltd., a diversified multinational pharmaceutical, healthcare and consumer products company with headquarters in Taiwan, have selected a lead formulation for the lead program in DURECT's ORADUR-ADHD program, ORADUR-Methylphenidate. This lead formulation was chosen based on its potential for rapid onset of action, long duration with once-a-day dosing and target pharmacokinetic profile as demonstrated in a recent Phase 1 trial. In addition, this product candidate will utilize a small capsule size relative to the leading existing long acting products on the market and incorporates DURECT's ORADUR anti-tampering technology. Orient PHARMA is planning to meet with the Taiwan Food and Drug Administration (TFDA) later this year to discuss the Phase 3 program in that market and is developing its plans for further development in the defined Asian and South Pacific countries to which it has rights from DURECT. DURECT retains rights to all other markets in the world, notably including the U.S., Europe and Japan, and is initiating licensing discussions with other companies now that the lead formulation has been selected.

(Logo: http://photos.prnewswire.com/prnh/20020717/DRRXLOGO)

"We're pleased with the PK profile that has been achieved with ORADUR-Methylphenidate, which suggests that this product candidate would be an attractive alternative for patients with ADHD and their physicians," stated James E. Brown, D.V.M., President and CEO of DURECT.

Attention Deficit Hyperactivity Disorder (ADHD) is a neurobehavioral condition that is estimated to affect over 5 million (approximately 9%) of U.S. children ages 3-17, according to the U.S. Department of Health and Human Services. The principal characteristics of ADHD are inattention, hyperactivity, and impulsivity. The condition presents itself in childhood and can be life long as a significant number of children with ADHD continue to present symptoms as adults. Over 50% of children with ADHD are estimated to be treated by medication, with stimulants such as amphetamine or methylphenidate as first-line treatments. U.S. sales of ADHD treatments were approximately $8.4 billion in 2012, a 15% increase over 2011. The 2010 National Survey on Drug Use & Health estimates that 1.1 million Americans over the age of 12 abuse stimulants for euphoric highs and increased performance or wakefulness. In addition, according to the Drug Enforcement Administration (DEA), serious methylphenidate abusers often snort or inject methylphenidate for its intense euphoric effects or to alleviate the severe depression and craving associated with a stimulant withdrawal syndrome.

About the DURECT – Orient PHARMA Relationship
In August 2009, we entered into a development and license agreement with Orient PHARMA Co., Ltd., under which we granted to Orient PHARMA development and commercialization rights in certain defined Asian and South Pacific countries to ORADUR-Methylphenidate. DURECT retains rights to North America, Europe, Japan and all other countries not specifically licensed to Orient PHARMA. If commercialized, we will be entitled to receive a royalty on sales of ORADUR-Methylphenidate by Orient PHARMA. Orient PHARMA has committed to supply a portion of DURECT's commercial requirements in all territories other than the U.S. for ORADUR-Methylphenidate.

About DURECT Corporation
DURECT is a specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with late-stage development programs including POSIDUR™, Remoxy®, ELADUR®, and TRANSDUR®-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.

About Orient PHARMA
Orient PHARMA Co., Ltd. (Orient PHARMA) was established in 2008 and includes a new pharmaceutical plant located at Central Taiwan Science Park

in Yunlin County meeting extensive governmental regulations including PIC/S GMP, EU GMP, and FDA 21CFR. In addition, Orient PHARMA has obtained Taiwan FDA PIC/S GMP Certificate in 2011 and U.S. FDA CGMP Certificate in 2013.

Orient PHARMA's R&D strategy is focused on researching and developing drugs for the CNS (central nervous system) including anti-psychotic, Alzheimer's disease, psychostimulants, and anti-Parkinson medicines. Orient PHARMA not only focuses on the development of new drug targets, but also collaborates with global partners in Europe, U.S., and Japan to develop new injections, new formulations, new indications and new products. For more information, please visit www.oppharma.com.

Forward-Looking Statements

The statements in this press release regarding the ORADUR-Methylphenidate product candidate, a possible meeting with the Taiwan FDA and a Phase 3 program in Taiwan, the potential benefits and uses of the ORADUR-Methylphenidate product candidate, discussions with potential partners regarding licensing and potential commercialization, and royalties on sales, of ORADUR-ADHD by Orient PHARMA 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, the risk of adverse decisions by regulatory agencies, including product non-approval, delays and additional costs due to requirements imposed by regulatory agencies, potential adverse effects arising from additional testing or use of the ORADUR-Methylphenidate product candidate, the potential that the data that we have generated may not be deemed sufficient by the Taiwan FDA or the U.S. FDA or other regulatory agencies to support regulatory approval of the ORADUR-Methylphenidate product candidate, our potential inability to license rights to the ORADUR-Methylphenidate product candidate on commercially acceptable terms, or at all, and the risk of obtaining marketplace acceptance of the ORADUR-Methylphenidate product candidate, avoiding infringing patents held by other parties and securing and defending patents of our own, and managing and obtaining capital to fund our growth, operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q for the period ending March 31, 2013 under the heading "Risk Factors."

NOTE: POSIDUR™, SABER®, ORADUR®, TRANSDUR®, and ELADUR™ are trademarks of DURECT Corporation. POSIDUR, Remoxy, ORADUR-Methylphenidate, ELADUR and TRANSDUR-Sufentanil are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities.

SOURCE DURECT Corporation

Matthew J. Hogan, Chief Financial Officer, DURECT, 408-777-4936