DURECT Earns $10 Million Milestone Payment for Further Development of a Long-Acting Injectable HIV Investigational Product Utilizing DURECT's SABER® Technology

CUPERTINO, Calif., Sept. 9, 2019 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today that further development of a long-acting injectable HIV investigational product utilizing DURECT's SABER® technology has triggered a $10 million milestone payment from Gilead Sciences, Inc. to DURECT under the license agreement between the companies.

"We are pleased that Gilead has been rapidly advancing this program," stated James E. Brown, President and CEO of DURECT. "We believe that long-acting injectables using our SABER platform have the potential to improve the lives of people with HIV."

"Our license agreement with Gilead is part of DURECT's broader strategy to enter into selective collaborations and other arrangements for our technologies and product development programs," continued Dr. Brown. "By leveraging our resources with corporate collaborators, we believe we can retain commercial interest in multiple product candidates and maximize value for our shareholders."

DURECT's Collaboration with Gilead

In July 2019, DURECT and Gilead entered into an agreement granting Gilead the exclusive worldwide rights to develop and commercialize a long-acting injectable HIV product utilizing DURECT's SABER® technology. Under the terms of the agreement, Gilead made an upfront payment to DURECT of $25 million, and further development has triggered an additional $10 million milestone payment. Remaining milestones include the potential for up to an additional $65 million in development and regulatory milestones, up to an additional $70 million in sales-based milestones, as well as tiered royalties on product sales. Gilead also received exclusive access to the SABER platform for HIV and hepatitis B virus (HBV) and the exclusive option to license additional SABER-based products directed to HIV and HBV for an additional $150 million per product in upfront, development, regulatory and sales based milestones as well as tiered royalties on sales. The parties will collaborate on specified development activities with Gilead controlling and funding the development programs.

About SABER® Technology

DURECT's SABER Technology (Sucrose acetate isobutyrate extended release) is a patented technology designed to provide sustained release for long-acting injectable products. The SABER technology is also the basis of POSIMIR® (bupivacaine extended release solution under investigation for the management of postoperative pain).

About DURECT Corporation

DURECT is a biopharmaceutical company actively developing therapeutics based on its Epigenetic Regulator Program and proprietary drug delivery platforms. DUR?928, a new chemical entity in Phase 2 development, is the lead candidate in DURECT's Epigenetic Regulator Program. An endogenous, orally bioavailable small molecule, DUR-928 has been shown in preclinical studies to play an important regulatory role in lipid homeostasis, inflammation, and cell survival. Human applications may include acute organ injury such as alcoholic Hepatitis (AH) and acute kidney injury (AKI), chronic hepatic diseases such as nonalcoholic steatohepatitis (NASH), and inflammatory skin conditions such as psoriasis and atopic dermatitis. DURECT's advanced oral and injectable delivery technologies are designed to enable new indications and enhanced attributes for small-molecule and biologic drugs. Key product candidates in this category include POSIMIR® (bupivacaine extended-release solution), an investigational locally-acting, non-opioid analgesic intended to provide up to 3 days of continuous pain relief after surgery, a long-acting injectable SABER-based HIV investigational product being developed with Gilead, and ORADUR™-Methylphenidate ER Capsules, approved in Taiwan as Methydur Sustained Release Capsules, where it is indicated for the treatment of attention deficit hyperactivity disorder

(ADHD). In addition, for the assignment of certain patent rights, DURECT receives single digit sales-based earn-out payments from U.S. net sales of Indivior's PERSERIS™ (risperidone) drug for schizophrenia, which was commercially launched in February 2019. For more information about DURECT, please visit www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding the development of a long-acting HIV investigational product, potential milestone and royalty payments to DURECT, and the potential licensing by Gilead of additional products directed to HIV and HBV and, as well as statements about potential uses and benefits of DUR-928 and DURECT's oral and injectable delivery technologies, as well as potential revenues from commercial sales of Indivior's PERSERIS, 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 risks that additional milestones triggering payments to DURECT by Gilead will not be achieved and that the long-acting HIV product will not be developed, that Gilead may decide not to license additional products from DURECT, that potential adverse effects may arise from the testing or use of DUR-928, that POSIMIR may not be approved by the FDA, that ORADUR-Methylphenidate ER may not be commercially successful in territories where it is approved or approved in other territories, that Indivior will not generate significant sales of PERSERIS, that DURECT may not avoid infringing patents held by other parties or be unable to secure and defend its own patents, and DURECT'S ability to manage and obtain capital to fund operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q filed on August 2, 2019 under the heading "Risk Factors."

NOTE: POSIMIR®, SABER® and ORADUR™, are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. DUR-928, POSIMIR and ORADUR-Methylphenidate ER Capsules are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities. Full prescribing information for PERSERIS, including BOXED WARNING, and Medication Guide can be found at www.perseris.com.

View original content:http://www.prnewswire.com/news-releases/durect-earns-10-million-milestone-payment-for-further-development-of-a-long-acting-injectable-hiv-investigational-product-utilizing-durects-saber-technology-300914047.html

SOURCE DURECT Corporation

Corporate Contact, Mike Arenberg, DURECT, Chief Financial Officer, +1-408-346-1052, mike.arenberg@durect.com; Media Contact, Alison Chen, LifeSci Public Relations, +1-646-876-4932, achen@lifescipublicrelations.com