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Gilead Terminates License Agreement for Long-Acting Injectable HIV Investigational Product

CUPERTINO, Calif., June 26, 2020 /PRNewswire/ — <u>DURECT Corporation</u> (Nasdaq: DRRX) today announced that Gilead Sciences, Inc., (Gilead) has provided notice that, effective as of December 22, 2020, it is terminating the License Agreement dated July 19, 2019 and a related R&D agreement between Gilead and DURECT related to the development and commercialization of a long-acting injectable HIV investigational product utilizing DURECT's SABER[®] technology.

As a result of this termination, DURECT anticipates recognizing remaining deferred revenue of approximately \$23.1 million in the second quarter of 2020, associated with the receipt of the upfront license and development milestone payment received in 2019 from Gilead. Therefore DURECT expects to recognize net income for the second quarter of 2020. Recognition of this deferred revenue is a non-cash financial item.

About DURECT Corporation

DURECT is a biopharmaceutical company committed to transforming the treatment of acute organ injury and chronic liver diseases by advancing novel and potentially lifesaving therapies based on its endogenous epigenetic regulator program.DURECT's lead candidate, DUR-928, has demonstrated the ability to regulate the expression of genes involved in lipid metabolism, inflammatory responses and cell survival. This drug candidate is under development for the treatment of alcoholic hepatitis (AH), COVID-19 patients with acute liver or kidney injury as well as nonalcoholic steatohepatitis (NASH).DURECT's proprietary drug delivery technologies are designed to enable new indications and enhanced attributes for small-molecule and biologic drugs. One late-stage product candidate in this category is POSIMIR[®] (bupivacaine extended-release solution), an investigational locally-acting, non-opioid analgesic intended to provide up to three days of continuous pain relief after surgery. For more information aboutDURECT, please visit <u>www.www.durect.com</u>.

DURECT Forward-Looking Statement

The statements in this press release regarding clinical development plans for DUR-928, including the potential use of DUR-928 to treat COVID-19 patients with liver or kidney injury, the potential use of DUR-928 to treat acute organ injuries, such as AH, and chronic liver diseases, such as NASH and the potential use of POSIMIR to provide pain relief after surgery 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 the clinical trial of DUR-928 in COVID-19 patients is delayed or stopped because of changes to the standard of care, the availability of alternative therapies, required protocol changes or lack of available patients, the risk that future clinical trials of DUR-928 are not started when anticipated, take longer to conduct than anticipated, do not replicate the results from earlier clinical or pre-clinical trials, or do not demonstrate the safety or efficacy of DUR-928 in a statistically significant manner, the risk that the FDA will not approve POSIMIR, the risk that additional time and resources may be required for development, testing and regulatory approval of DUR-928 or the Company's other product candidates, potential adverse effects arising from the testing or use of our drug candidates, our potential failure to maintain our collaborative agreements with third parties and risks related to our ability to obtain capital to fund operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q filed on May 11, 2020 under the heading "Risk Factors."

NOTE: POSIMIR[®] and SABER[®] are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. DUR-928 and POSIMIR are investigational drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities for any indication.



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