DURECT Corporation Trading Halted Today; FDA Advisory Committee to Discuss POSIMIR® (bupivacaine extended-release solution) for Post-Surgical Analgesia

CUPERTINO, Calif., Jan. 16, 2020 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that NASDAQ has halted trading of the Company's common stock today.

The U.S. Food and Drug Administration's (FDA) Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) is holding a meeting today from 8 a.m. to 5 p.m. ET to discuss POSIMIR, an investigational medicine for the treatment of post-surgical pain. Although the FDA considers the recommendations of the AADPAC, recommendations by the panel are non-binding, and the final decision regarding pending regulatory actions for a product is made by the FDA.

The briefing materials and webcast information may be found on the FDA's website at https://www.fda.gov/advisory-committees/january-16-2020-meeting-anesthetic-and-analgesic-drug-products-advisory-committee-meeting#event-materials

About POSIMIR

POSIMIR is the Company's investigational post-operative pain relief depot product that utilizes DURECT's patented SABER® technology. POSIMIR is designed to be administered directly into the surgical site to deliver bupivacaine for up to three days after surgery. The FDA had previously assigned a user fee goal date of December 27, 2019; a new user fee goal date has not been assigned. POSIMIR has not been approved by the FDA for marketing in the U.S. for any indication.

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 AH and acute kidney injury (AKI) and chronic hepatic diseases such as NASH. 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, and a long-acting injectable SABER-based HIV investigational product being developed with Gilead. For more information about DURECT, please visit www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding the potential use of POSIMIR to treat post-operative pain, the potential benefits and uses of DUR-928 to treat acute organ injury such as AH and acute kidney injury (AKI) and chronic hepatic diseases such as NASH, and the potential development of a long-acting injectable SABER-based HIV product with Gilead 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 that the FDA Advisory Committee will not recommend approval of POSIMIR or that the FDA will not approve POSIMIR or if it does approve POSIMIR's use, that it will materially restrict its label, the risk of delays in clinical trials or adverse safety events from patients administered with DUR-928, the risk that the ongoing clinical trial of DUR-928 in NASH does not successfully achieve its endpoints, the risk that placebo controlled studies of DUR-928 required for regulatory approval will not replicate results from open label clinical trials or trials with small numbers of patients or historical controls, the risks that the long-acting injectable SABER-based HIV investigational product being developed with Gilead

will not succeed or that Gilead will abandon this program, and the risk of delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of any of our product candidates. Further information regarding these and other risks related to DURECT is included in DURECT's Form 10-Q filed on November 5, 2019 under the heading "Risk Factors" and in subsequent reports that we file with the Securities and Exchange Commission.

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

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SOURCE DURECT Corporation

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