Innocoll and DURECT Announce U.S. launch of POSIMIRÂ®

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- ***POSIMIRÂ® is now commercially available in the U.S. for the treatment of post-surgical pain in adults following arthroscopic subacromial decompression surgery***
- ***DURECT recently received an $8 million milestone payment for a new patent issuance and has now earned a $2 million milestone payment for first commercial sale of POSIMIR***

ATHLONE, Ireland and CUPERTINO, Calif., Sept. 26, 2022 /PRNewswire/ — Innocoll Pharmaceuticals Limited, a commercial-stage biotechnology company and portfolio business of Gurnet Point Capital, and DURECT Corporation (Nasdaq:DRRX) today announced the recent commercial launch of POSIMIRÂ® (bupivacaine solution) in the United States. POSIMIR is an FDA-approved non-opioid, sustained-release local analgesic for the treatment of post-surgical pain in adults following arthroscopic subacromial decompression surgery.

“We are excited to bring a potential cornerstone of multi-modal post-operative pain management to surgeons with the launch of POSIMIR,” said Louis Pascarella, Chief Executive Officer of Innocoll. “The launch of POSIMIR establishes Innocoll as a leader in non-opioid pain management with two commercialized bupivacaine-based, sustained-release, non-opioid products and we look forward to bringing this new option to patients.”

“We are pleased that Innocoll, with its dedicated hospital sales and marketing organization, has launched POSIMIR inthe United States and recorded its first sales,” added James E. Brown, President and Chief Executive Officer of DURECT Corporation. “Bringing a new non-opioid analgesic option with POSIMIR is a welcome next step in the evolution of pain management for patients.”

Per the terms of the collaboration between Innocoll and DURECT, Innocoll will make a $2 million payment to DURECT triggered by the first commercial sale of POSIMIR. Previously, in August 2022, DURECT was issued a new patent by the US Patent Office, extending US patent coverage of POSIMIR to at least 2041, resulting in an $8 million milestone payment by Innocoll to DURECT. These payments are in addition to the $4 million upfront license fee received in January 2022. As the launch progresses, DURECT will receive tiered, low double-digit to mid-teen royalties on net product sales inthe United States, as well as additional milestone payments up to $122 million in the aggregate, depending on the achievement of certain commercial, regulatory and intellectual property milestone payments with respect to POSIMIR.

In addition to the exclusive right to develop and commercialize POSIMIR inthe United States, Innocoll also has been granted the right to conduct additional development activities to expand the approved indications for POSIMIR, and DURECT’s contract manufacturing supply agreement for POSIMIR has been assigned to Innocoll. DURECT retains all commercial rights to POSIMIR throughout the rest of the world.

About POSIMIR

POSIMIRÂ® (bupivacaine solution) for infiltration use is a novel and proprietary product that combines the strength of 660 mg of bupivacaine base with the innovative SABERÂ® platform technology, enabling continuous sustained delivery of a non-opioid local analgesic over 3 days in adults. POSIMIR contains more bupivacaine than any other approved single-dose sustained-release bupivacaine product. At the end of surgery, POSIMIR is administered into the subacromial space under direct arthroscopic visualization, where it continuously releases bupivacaine for 72 hours or more.

Indications and Usage

POSIMIRÂ® (bupivacaine solution) for infiltration use is indicated in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression.

Limitations of Use

Safety and effectiveness have not been established in other surgical procedures, including soft tissue surgical procedures, other orthopedic procedures, including for intra-articular administration, and boney procedures, or when used for neuraxial or peripheral nerve blockade.

Full Prescribing Information, including the Boxed Warning, is available at www.POSIMIR.com

Important Safety Information

BOXED WARNING: Risk of Potential Adverse Embolic Effects Resulting From Inadvertent Intravascaular Injection. Inadvertent intravascular injection could cause POSIMIR droplets to be deposited in the pulmonary and other capillary beds. Administer POSIMIR into the subacromial space at the end of arthroscopic shoulder surgery. Direct arthroscopic visualization must be used to confirm proper placement of the needle tip before injecting POSIMIR.

In POSIMIR clinical studies, no inadvertent intravascular injections were observed. Do not inject POSIMIR intravascularly.

POSIMIR is contraindicated in patients with a known hypersensitivity to any amide local anesthetic, or other components of POSIMIR, as well as in patients undergoing obstetrical paracervical block anesthesia. There is a risk of joint cartilage necrosis with unapproved intra-articular use of POSIMIR. Unintended intravascular injection of POSIMIR may be associated with systemic toxicities, including CNS or cardiorespiratory depression and coma, progressing ultimately to respiratory arrest. As with other local anesthetics, patients should be monitored for central nervous system, cardiovascular, and allergic reactions. Avoid additional use of local anesthetics within 168 hours following administration of POSIMIR. Cases of methemoglobinemia have been reported in association with use of local anesthetics. There have been reports of chondrolysis (mostly in the shoulder joint) following intra-articular infusion of local anesthetics, which is an unapproved use. POSIMIR should be used cautiously in patients with impaired hepatic and cardiovascular function. Adverse events reported with an incidence greater than or equal to 10% and greater than control following POSIMIR administration in shoulder surgery were dizziness, dysgeusia, dysuria, headache, hypoesthesia, paresthesia, tinnitus, and vomiting. Adverse events reported with an incidence greater than or equal to 10% and greater than control following POSIMIR administration in soft tissue surgical procedures were anemia, bradycardia, constipation, C-reactive protein increased, diarrhea, dizziness, dysgeusia, headache, nausea, post-procedural contusion (bruising), procedural pain, pruritus, pyrexia, somnolence, surgical site bleeding, visible bruising and vomiting.

To report SUSPECTED ADVERSE REACTIONS, contact Innocoll at 1-833-606-1421 or FDA at 1â??800â??FDA-1088 or www.fda.gov/medwatch.

About Innocoll

Innocoll Pharmaceuticals Limited is a global biotech pharmaceutical company headquartered in Athlone, Ireland and is a subsidiary of Innocoll Biotherapeutics Holding Limited. The Innocoll group of companies is focused on the development and commercialization of pharmaceutical technologies to meet some of today's most important healthcare challenges.
Innocoll is a portfolio business of Gurnet Point Capital. www.innocoll.com

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. Larsucosterol (also known as DUR-928), DURECT's lead drug candidate, binds to and inhibits the activity of DNA methyltransferases (DNMTs), epigenetic enzymes which are elevated and associated with hypermethylation found in alcohol-associated hepatitis (AH) patients. Larsucosterol is in clinical development for the potential treatment of AH, for which FDA has granted a Fast Track Designation; non-alcoholic steatohepatitis (NASH) is also being explored. In addition, POSIMIRÂ® (bupivacaine solution) for infiltration use, a non-opioid analgesic utilizing the innovative SABERÂ® platform technology, is FDA-approved and has been exclusively licensed to Innocoll Pharmaceuticals for development and commercialization in the United States. For more information about DURECT, please

visit www.www.durect.com and follow us on Twitter https://twitter.com/DURECTCorp.

DURECT Forward-Looking Statement

This press release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to: the commercial launch of POSIMIR by Innocoll and potential future payments we may receive from Innocoll, the potential to develop larsucosterol for AH, NASH or other indications, and the potential benefits, if any, of our product candidates. Actual results may differ materially from those contained in the forward-looking statements contained in this press release, and reported results should not be considered as an indication of future performance. The potential risks and uncertainties that could cause actual results to differ from those projected include, among other things, the risk that Innocoll may not commercialize POSIMIR successfully, the risk that the AHFIRM trial takes longer to conduct than anticipated due to COVID-19 or other factors, the risk that ongoing and future clinical trials of larsucosterol do not confirm the results from earlier clinical or pre-clinical trials, or do not demonstrate the safety or efficacy of larsucosterol in a statistically significant manner, 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 most recent Securities and Exchange Commission (SEC) filings, including its annual report on Form 10-K for the year ended December 31, 2021 and quarterly report on Form 10-Q for the quarter ended June 30, 2022 under the heading "Risk Factors." These reports are available on our website www.durect.com under the "Investors" tab and on the SEC's website at www.sec.gov. All information provided in this press release and in the attachments is based on information available to DURECT as of the date hereof, and DURECT assumes no obligation to update this information as a result of future events or developments, except as required by law.

NOTE: POSIMIRÂ® is a trademark of Innocoll Pharmaceuticals Limited in the U.S. and a trademark of DURECT Corporation outside of the U.S. SABERÂ® is a trademark of DURECT Corporation. Other referenced trademarks belong to their respective owners. Larsucosterol (DUR-928) is an investigational drug candidate under development and has not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities for any indication.

SOURCE: Innocoll Pharmaceuticals Limited and DURECT Corporation

SOURCE DURECT Corporation