DURECT Corporation Announces U.S. FDA Approval of POSIMIR® For Post-Surgical Pain Reduction for up to 72 Hours Following Arthroscopic Subacromial Decompression

POSIMIR is the only approved sustained-release bupivacaine product indicated for up to 72 hours of post-surgical analgesia from a single application

Conference Call Today, February 2, 2021 at 4:30pm ET

CUPERTINO, Calif., Feb. 2, 2021 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that the U.S. Food and Drug Administration (FDA) has approved POSIMIR® (bupivacaine solution) for infiltration use 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. The approval was based on positive data from a randomized, multicenter, assessor-blinded, placebo–controlled clinical trial in patients undergoing arthroscopic subacromial decompression surgery with an intact rotator cuff. The primary outcome measures were mean pain intensity and total opioid rescue analgesia administered, both evaluated over the first 72 hours after surgery versus placebo. POSIMIR demonstrated a statistically significant improvement in both primary outcome measures: a 1.3 point, or 20%, reduction in mean pain intensity on a 0-10 point pain scale (p=0.01), and a 67% reduction in I.V. morphine-equivalent rescue opioid use, from a median of 12 mg in the placebo group to 4 mg in the POSIMIR group (p=0.01). Please see important safety information including the Boxed Warning below and the POSIMIR full prescribing information.

“We are excited to announce the approval of POSIMIR, a novel, non-opioid, sustained-release local analgesic for the treatment of post-surgical pain following arthroscopic subacromial decompression surgery,” said James E. Brown, President and CEO of DURECT. “This FDA approval provides an important new option to help orthopedic surgeons in their efforts to minimize opioid use while managing acute pain for up to 72 hours after this painful surgery.”

“In my experience, POSIMIR was easy to administer into the subacromial space under arthroscopic guidance, where it can directly address the source of postsurgical pain,” said Sten Rasmussen, MD CBE PhD, Associate Professor, Department of Orthopaedic Surgery, Aalborg University Hospital, and Professor and Head of the Department of Clinical Medicine, Aalborg University, Denmark, a principal investigator in the POSIMIR registration trial. “A non-opioid product providing up to three days of local analgesia would be a significant benefit to patients.”

“The first 72 hours after surgery are typically when patients experience the most severe postsurgical pain,” said T J Gan, MD MHS FRCA MBA, Professor and Distinguished Endowed Chair, Department of Anesthesiology at Stony Brook University Renaissance School of Medicine. “So, a new sustained-release product providing continuous analgesia during this critical period is a welcome addition to the armamentarium for anesthesiologists and surgeons, especially as we aim to reduce the use of postsurgical opioids whenever possible.”

About POSIMIR

POSIMIR (bupivacaine solution) for infiltration use is a novel and proprietary product that combines the strength of 660 mg of bupivacaine base with the innovative SABER® 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. DURECT is in discussions with potential partners regarding the licensing of commercialization rights to POSIMIR, for which DURECT holds worldwide rights.

About Subacromial Decompression Shoulder Surgery

Subacromial decompression is a type of shoulder surgery used to treat impingement syndrome, a common repetitive-use injury that causes pain when the arm is raised over the head. The procedure is typically performed arthroscopically, meaning that several small incisions are made in the skin and muscle of the shoulder through which a camera lens (arthroscope) and surgical instruments are inserted during surgery. Arthroscopic subacromial decompression is generally considered outpatient surgery, and most patients go home within a few hours of surgery. The recovery period may extend from weeks to months, but the most intense pain typically occurs during the first 3 days after surgery and is often managed with oral opioids. There are over 600,000 surgeries involving arthroscopic subacromial decompression performed each year in the U.S.

Postmarketing Requirements

In connection with this approval, the Company or its licensee, will be required to conduct two postmarketing non-clinical studies.

Indications and Usage

POSIMIR (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, oropharyngeal pain, post-procedural contusion (bruising), procedural pain, pruritus, pyrexia, somnolence, surgical site bleeding, visible bruising and vomiting.

To report SUSPECTED ADVERSE REACTIONS, contact DURECT Corporation at 1-844-767-4647 or FDA at 1–800–FDA-1088 or www.fda.gov/medwatch.

Conference Call

The DURECT management team will host a conference call to discuss the contents of this press release today at 4:30pm ET / 1:30pm PT

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Toll Free: 877-407-0784
International: 201-689-8560
Conference ID: 13716187
Webcast: http://public.viavid.com/index.php?id=143426

The conference call will also be available by webcast on DURECT's homepage at www.www.durect.com under the "Investors" tab. If you are unable to participate during the webcast, the call will be archived on DURECT's website under "Event Calendar" in the "Investors" section.

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. DUR-928, the company's lead drug candidate is in clinical development for the potential treatment of alcohol-associated hepatitis (AH) for which FDA has granted a Fast Track Designation, COVID-19 patients, and non-alcoholic steatohepatitis (NASH). DURECT's proprietary drug delivery technologies are designed to enable new indications and enhanced attributes for small-molecule and biologic drugs. POSIMIR® (bupivacaine solution) for infiltration use, a non-opioid analgesic utilizing the innovative SABER® platform technology, is now FDA-approved. Full prescribing information about POSIMIR, including the Boxed Warning, can be found atwww.posimir.com. For more information about DURECT, please visit www.www.durect.com and follow us on Twitter https://twitter.com/DURECTCorp.

DURECT Forward-Looking Statement

The statements in this press release regarding the potential uses and benefits of POSIMIR, prospects of obtaining a commercialization partner for POSIMIR, as well as the potential for DUR-928 to treat patients with AH, NASH, COVID-19, or other acute organ injury and chronic liver diseases, and plans for clinical development of DUR-928 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 DURECT will not reach agreement with a commercialization partner for POSIMIR and that POSIMIR will not achieve a successful commercial launch, that the clinical trial of DUR-928 in AH is delayed due to COVID-19 or other factors or 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, protocol changes or lack of available patients, the risk that clinical trials of DUR-928 take longer to conduct than anticipated, do not confirm the results from earlier clinical or pre-clinical trials, or do not demonstrate the safety or efficacy or the life saving potential of DUR-928 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 Form 10-Q filed on November 3, 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 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. Full prescribing information for POSIMIR, including its boxed warning, can be found at www.POSIMIR.com.

View original content:http://www.prnewswire.com/news-releases/durect-corporation-announces-us-fda-approval-of-posimir-for-post-surgical-pain-reduction-for-up-to-72-hours-following-arthroscopic-subacromial-decompression-301220159.html

SOURCE DURECT Corporation

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