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BAUDAX BIO®

Baudax Bio Announces FDA Approval of ANJESO™ for the Management of Moderate to Severe Pain

ANJESO Is The Only Approved 24-Hour, Intravenous COX-2 Preferential NSAID that Offers Once-Daily Dosing

U.S. Commercial Launch Planned to Commence in Late April or Early May 2020

Management to Host Conference Call and Webcast Today at 4:30 p.m. ET

MALVERN, Pa., Feb. 20, 2020 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXR), a pharmaceutical company focused on therapeutics for acute care settings, today announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for ANJESO™ (meloxicam injection), which is indicated for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics.

“The approval of ANJESO marks a major advancement in the treatment landscape for managing moderate to severe pain,” said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. “With our nation currently in the midst of a national opioid epidemic, we are thrilled to be able to offer a novel, non-opioid therapeutic option with the potential to meaningfully impact the acute pain treatment paradigm. We expect to make ANJESO available to physicians and patients in late April or early May 2020.”

ANJESO is approved for the management of moderate to severe pain and will be administered as a once-a-day intravenous (IV) bolus push. ANJESO is the only available 24-hour, intravenous (IV) COX-2 preferential non-steroidal anti-inflammatory (NSAID) and offers once-daily dosing. The active ingredient meloxicam is a long-acting, preferential COX-2 inhibitor that possesses analgesic, anti-inflammatory and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase type 2 pathway (COX-2) and subsequent reduction in prostaglandin biosynthesis.

“The safety and efficacy of ANJESO have been well-established through several mid- and late-stage clinical studies,” said Stewart McCallum, M.D., Chief Medical Officer of Baudax Bio. “Moreover, data from our Phase III safety trial demonstrated that ANJESO is well tolerated and impacted opioid consumption compared to placebo, further highlighting its value to patients, providers and health systems.”

“The approval of ANJESO marks an important achievement for the medical community given the unmet need for non-opioid options in the pain treatment landscape,” said Dr. Keith Candiotti chair of the Department of Anesthesiology, Perioperative Medicine and Pain Management at the University of Miami. “While traditional opioid medications have proven effective at providing pain relief, the associated adverse side effects, including sedation and respiratory depression, have driven physicians to employ a multi-modal approach to treating

post-operative pain. With 24-hour, durable pain relief and a safety profile comparable to placebo, ANJESO has the potential to serve as a meaningfully differentiated analgesic alternative.”

The ANJESO approval is supported by two Phase III efficacy studies and one double-blind, placebo-controlled Phase III safety study. The results from these studies, as well as results from four Phase II clinical studies and other safety studies, comprised the NDA package.

The most common ADVERSE REACTIONS reported in $\geq 2\%$ of patients treated with ANJESO and at a greater frequency than placebo included: constipation, gamma-glutamyl transferase increased and anemia.

Please see “News & Investors” section of the Company’s website at www.baudaxbio.com for full Prescribing Information in addition to the full Important Safety Information provided below.

Baudax expects ANJESO will be available in the U.S. in late April or early May 2020. For more information, visit www.baudaxbio.com.

Conference Call and Webcast

Baudax Bio management will be hosting a conference call and webcast today beginning at 4:30 p.m. ET. To access the conference call, please dial (866) 220-5595 (local) or (615) 622-8062 (international) at least 10 minutes prior to the start time and refer to conference ID 4373423. A live audio webcast of the call will be available under “Events” in the Investor section of the Company’s website, <https://www.baudaxbio.com/news-and-investors/events>. An archived webcast will be available on the Company’s website approximately two hours after the event and will be available for 30 days.

ANJESO™ COMPREHENSIVE CLINICAL TRIALS

Phase 3 Efficacy Study Evaluating ANJESO Following Bunionectomy Surgery

In this multicenter, randomized, double-blind, placebo-controlled clinical trial, 201 patients were enrolled and randomly assigned to receive a postoperative regimen of ANJESO (30mg) or placebo in a 1:1 ratio, once every 24 hours for up to 3 doses following bunionectomy surgery, a representative hard tissue surgery. The ANJESO treatment arm demonstrated a statistically significant reduction in SPID48 ($p=0.0034$) compared to the placebo arm. The study also achieved 15 of the 19 secondary endpoints, including statistically significant differences in SPID6 ($p=0.0153$), SPID12 ($p=0.0053$), SPID24 ($p=0.0084$), SPID24-48 ($p=0.0050$), time to first use of rescue medication ($p=0.0076$), and several other rescue use and pain relief metrics during the first 48 hours, compared to placebo. The safety results demonstrated that ANJESO was well tolerated with no serious adverse events or bleeding events in the ANJESO-treated patients.

Phase 3 Efficacy Study Evaluating ANJESO Following Abdominoplasty Surgery

In this multicenter, randomized, double-blind, placebo-controlled clinical trial, 219 patients were enrolled and randomly assigned to receive a postoperative regimen of ANJESO (30mg bolus injection) or placebo in a 1:1 ratio, once every 24 hours. The ANJESO treatment arm demonstrated a statistically significant reduction in SPID24 ($p=0.0145$) compared to the

placebo arm. The study also achieved statistical significance for 10 of the secondary endpoints, including statistically significant differences in SPID12 ($p=0.0434$), time to perceptible pain relief ($p=0.0050$), subjects with $\geq 30\%$ improvement at 24 hours ($p=0.0178$), number of times patients required rescue in the first 24 hours after randomization ($p=0.0275$), as well as number of times rescued from 24 to 48 hours ($p=0.0009$), and several other pain relief metrics, compared to placebo. The safety results demonstrated that ANJESO was well tolerated with no difference in serious adverse events (SAEs) related to bleeding for ANJESO treated patients versus placebo (1 each).

Phase 3 Safety Study Evaluating ANJESO Following Major Surgery

This multicenter, randomized, double-blind, placebo-controlled Phase III clinical trial, included patients who had undergone major elective surgical procedures which were expected to result in hospitalization for at least 24-48 hours. Major surgical procedures included total hip and knee replacements, spinal, GI, hernia repair, and gynecologic surgeries, as well as a range of other surgeries. Patient demographics were balanced across treatment groups and included 40% male patients and about 23% of patients who were over age 65. Unlike the pivotal efficacy trials, minimum pain scores were not required for treatment. Sites were permitted to use opioids and other pain management modes according to their “standard of care” and meloxicam or placebo was added to this regimen. Patients were randomized in a 3:1 ratio to receive either ANJESO or IV placebo daily for up to 7 doses. A total of 721 patients received at least one dose of study medication. In patients age 65 and over, the percentage of patients reporting at least one AE was approximately 7% less in the ANJESO treatment arm compared to the placebo arm. The total occurrence of patients with at least one serious adverse event (SAE) was observed to be lower in the ANJESO group, 2.6%, (14/538 meloxicam patients) than in the placebo group, 5.5%, (10/183 placebo patients). In this safety study only two SAE events were listed as possibly related to study treatment. Both of these SAEs occurred in one placebo treated patient. No deaths were reported in either treatment group. Approximately 3% of patients in each study group discontinued.

INDICATION AND USAGE

ANJESO is indicated for use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics.

Limitation of Use: Because of delayed onset of analgesia, ANJESO alone is not recommended for use when rapid onset of analgesia is required.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Risk

- Non-steroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.
- ANJESO is contraindicated in the setting of coronary artery bypass graft (CABG)

surgery.

Gastrointestinal Risk

- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

CONTRAINDICATIONS

ANJESO is contraindicated in patients with:

- Known hypersensitivity (eg, anaphylactic reactions and serious skin reactions) to meloxicam or any components of the drug product.
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.
- In the setting of coronary artery bypass graft (CABG) surgery.
- Moderate to severe renal insufficiency patients who are at risk for renal failure due to volume depletion

WARNINGS AND PRECAUTIONS

Hepatotoxicity: Elevations of ALT or AST have been reported in patients with NSAIDs. In addition, rare, sometimes fatal, cases of severe hepatic injury including fulminant hepatitis, liver necrosis, and hepatic failure have been reported. Inform patients of warning signs and symptoms of hepatotoxicity. Discontinue ANJESO immediately if abnormal liver tests persist or worsen or if clinical signs and symptoms of liver disease develop.

Hypertension: NSAIDs including ANJESO can lead to new onset of hypertension or worsening of preexisting hypertension, which may contribute to the increased incidence of cardiovascular (CV) events. Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure.

Heart Failure and Edema: NSAID use increased the risk of myocardial infarction (MI), hospitalization for heart failure, and death. Avoid use of ANJESO in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure. If ANJESO is used in patients with severe heart failure, monitor patients for signs of worsening heart failure.

Post MI Patients: Avoid the use of ANJESO in patients with recent MI unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events. If ANJESO is used in these patients, monitor for signs of cardiac ischemia.

Renal Toxicity: Long-term administration of NSAIDs has resulted in renal papillary necrosis, renal insufficiency, acute renal failure, and other renal injury. ANJESO is not recommended in patients with moderate to severe renal insufficiency and is contraindicated in patients with moderate to severe renal insufficiency who are at risk for renal failure due to volume depletion. Correct volume status in dehydrated or hypovolemic patients prior to initiating ANJESO. Monitor renal function in patients with renal or hepatic impairment, heart failure,

dehydration, or hypovolemia. Avoid use of ANJESO in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function. If ANJESO is used in patients with advanced renal disease, monitor patients for signs of worsening renal function.

Anaphylactic Reactions: Meloxicam has been associated with anaphylactic reactions in patients with and without known hypersensitivity to meloxicam and in patients with aspirin-sensitive asthma. Seek emergency help if an anaphylactic reaction occurs.

Exacerbation of Asthma Related to Aspirin Sensitivity: ANJESO is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity).

Serious Skin Reactions: NSAIDs, including ANJESO, can cause serious skin reactions, including exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal and can occur without warning. Discontinue ANJESO at first appearance of skin rash or other signs of hypersensitivity.

Hematologic Toxicity: Anemia has occurred in NSAID-treated patients. Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia. NSAIDs, including ANJESO, may increase the risk of bleeding events. Monitor patients for signs of bleeding.

DRUG INTERACTIONS

Drugs That Interfere With Hemostasis (e.g., warfarin, aspirin, SSRIs/SNRIs): Monitor patients for bleeding who are concomitantly taking ANJESO with drugs that interfere with hemostasis. Concomitant use of ANJESO and analgesic doses of aspirin is not generally recommended.

Angiotensin Converting Enzymes (ACE) Inhibitors, Angiotensin Receptor Blockers (ARB), or Beta-Blockers: Concomitant use with ANJESO may diminish the antihypertensive effect of these drugs. Monitor blood pressure.

ACE Inhibitors and ARBs: Concomitant use with ANJESO in elderly, volume depleted, or those with renal impairment may result in deterioration of renal function. In such high risk patients, monitor for signs of worsening renal function.

Diuretics: NSAIDs can reduce natriuretic effect of furosemide and thiazide diuretics. Monitor patients to ensure diuretic efficacy including antihypertensive effects.

ADVERSE REACTIONS

The most common adverse reactions in controlled clinical trials occurring in $\geq 2\%$ of patients treated with ANJESO and at a greater frequency than placebo include: constipation, gamma-glutamyl transferase increased, and anemia.

USE IN SPECIFIC POPULATIONS

Pregnancy: Use of NSAIDs during the third trimester of pregnancy increases the risk of premature closure of the fetal ductus arteriosus. Avoid use of NSAIDs in pregnant women starting at 30 weeks gestation.

Infertility: NSAIDs are associated with reversible infertility. Consider withdrawal of ANJESO in women who have trouble conceiving.

Please see full Prescribing Information, including Boxed Warning at www.baudaxbio.com.

About ANJESO™

ANJESO (meloxicam) injection is a proprietary, long-acting, preferential COX-2 inhibitor that possesses analgesic, anti-inflammatory and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase type 2 pathway (COX-2) and subsequent reduction in prostaglandin biosynthesis. ANJESO was approved by the U.S. Food and Drug Administration in February 2020 for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics. Because of the delayed onset of analgesia, ANJESO alone is not recommended for use when rapid onset of analgesia is required. The Company expects to launch ANJESO in late April or early May 2020. The ANJESO product approval was supported by two pivotal Phase III clinical efficacy trials, a large double-blind, placebo-controlled Phase III safety trial and four Phase II clinical efficacy trials, as well as other safety studies. As a non-opioid, Baudax Bio believes ANJESO has the potential to overcome many of the issues associated with commonly prescribed opioid therapeutics, including respiratory depression, constipation, excessive nausea and vomiting, as well as having no addictive potential, while maintaining meaningful analgesic effects for relief of pain. ANJESO was designed using the NanoCrystal® platform, a technology that enables enhanced bioavailability of poorly water-soluble drug compounds. NanoCrystal® is a registered trademark of Alkermes Pharma Ireland Limited (APIL).

About Baudax Bio, Inc.

Baudax Bio is a specialty pharmaceutical company focused on therapeutics for acute care settings. The Company's lead product candidate is a proprietary intravenous (IV) form of meloxicam, a non-opioid, once a day preferential COX-2 inhibitor. IV meloxicam has successfully completed two pivotal Phase III clinical efficacy trials, a large double-blind placebo-controlled Phase III safety trial, four Phase II clinical efficacy trials, as well as other safety studies. As a non-opioid, IV meloxicam has the potential to overcome many of the issues associated with commonly prescribed opioid therapeutics, including respiratory depression, constipation, excessive nausea and vomiting, as well as having no addictive potential while maintaining meaningful analgesic effects for relief of pain. For more information please visit www.baudaxbio.com.

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties. Such forward-looking statements reflect Baudax Bio's expectations about its future performance and opportunities that involve substantial risks and uncertainties. When used herein, the words "anticipate," "believe," "estimate," "may," "upcoming," "plan," "target," "goal", "intend" and "expect" and similar expressions, as they relate to Baudax Bio or its management, are intended to identify such forward-looking statements. These forward-looking statements are based on information available to Baudax Bio as of the date of this press release and are subject to a number of risks, uncertainties, and other factors that could cause Baudax Bio's performance to differ materially from those expressed in, or

implied by, these forward-looking statements. Baudax Bio assumes no obligation to update any such forward-looking statements. These forward-looking statements are subject to risks and uncertainties including, among other things, our ability to maintain regulatory approval for ANJESO™, our ability to successfully commercialize ANJESO™; the acceptance of ANJESO™ by the medical community, including physicians, patients, health care providers and hospital formularies; our ability and that of our third party manufacturers to successfully scale-up our commercial manufacturing process for ANJESO™, our ability to produce commercial supply in quantities and quality sufficient to satisfy market demand for ANJESO™, our ability to raise future financing for continued product development and ANJESO™ commercialization, our ability to manage costs and execute on our operational and budget plans, the accuracy of our estimates of the potential market for ANJESO™, our ability to achieve our financial goals; and our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection. These forward-looking statements should be considered together with the risks and uncertainties that may affect our business and future results included in our filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are based on information currently available to us, and we assume no obligation to update any forward-looking statements except as required by applicable law. The forward-looking statements in this press release should be considered together with the risks and uncertainties that may affect Baudax Bio's business and future results included in Baudax Bio's filings with the Securities and Exchange Commission at www.sec.gov.

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