June 15, 2020

Baudax Bio Announces Full Commercial Launch of ANJESO™ and Receipt of Unique C-Code and Pass-Through Payment Status Effective July 1, 2020

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

MALVERN, Pa., June 15, 2020 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today announced the commercial launch of ANJESO™ (meloxicam) injection. ANJESO was approved by the U.S. Food and Drug Administration (FDA) on February 20, 2020. Baudax has hired, trained, and now deployed 50 acute care sales representatives across the country. Baudax also announced that the Centers for Medicare and Medicaid Services (CMS) has approved transitional pass-through status and established a new reimbursement code for ANJESO. The code, C9059, is scheduled to become effective July 1, 2020.

“We have assembled an acute care sales team with deep experience in the hospital market, and they completed their comprehensive virtual training by the end of May. As of June 1, the field has been meeting with key customers live and virtually across hospitals, ambulatory surgery centers and other strategic accounts to introduce ANJESO,” said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. “At Baudax, we believe ANJESO is a major advancement for physicians managing moderate to severe pain following a wide variety of surgical procedures. The receipt of pass-through status and the assignment of a unique C-code from CMS also marks another important milestone in our commercialization efforts for ANJESO. Hospitals and ambulatory surgical centers can use this new code in July to obtain reimbursement for the product.”

A C-code is a unique product code established by CMS to report claims for hospital outpatient department and ambulatory surgical center services and procedures. The formal receipt of the C-code facilitates the reimbursement of ANJESO until such later time as CMS may potentially approve a J-code and such approval becomes effective. Drugs that are administered in these settings can be reimbursed under a CMS administered transitional-pass-through payment. The pass-through payment was established by the U.S. government to help foster innovative drug development. Drug applications must meet certain qualifications for inclusion. The transitional pass-through status is temporary for three years and products are reimbursed under a C-code.

ANJESO is the first and only once-daily IV analgesic. It provides up to 24 hours of efficacy for the management of moderate to severe pain, has demonstrated safety and tolerability, is a COX-2 preferential IV NSAID and is available as a once-daily IV push.

For more information about ANJESO, visitwww.ANJESO.com or call 1-855-405-9983.

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 ≥ 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.ANJESO.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 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

Baudax Bio is a specialty pharmaceutical company focused on therapeutics for acute care settings. The Company's first commercial product, ANJESO™, had its New Drug Application approved by FDA on February 20, 2020 for the management of moderate to severe pain,

alone or in combination with other non-NSAID analgesics. ANJESO is a once daily IV NSAID with preferential Cox-2 activity, which has successfully completed three Phase III clinical trials, including two pivotal efficacy trials, a large double-blind Phase III safety trial and other studies for the management of moderate to severe pain. 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 publication on this internet site 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, the ongoing economic and social consequences of the COVID-19 pandemic, including any adverse impact on the commercial launch of ANJESO™ or disruption in supply chain, Baudax Bio’s ability to maintain regulatory approval for ANJESO, Baudax Bio’s ability to successfully commercialize ANJESO; the acceptance of ANJESO by the medical community, including physicians, patients, health care providers and hospital formularies; Baudax Bio’s ability and that of Baudax Bio’s third party manufacturers to successfully scale-up our commercial manufacturing process for ANJESO, Baudax Bio’s ability to produce commercial supply in quantities and quality sufficient to satisfy market demand for ANJESO, Baudax Bio’s ability to raise future financing for continued product development, payment of milestones and ANJESO commercialization, Baudax Bio’s ability to pay its debt and satisfy conditions necessary to access future tranches of debt, Baudax Bio’s ability to comply with the financial and other covenants under its credit facility, Baudax Bio’s ability to manage costs and execute on our operational and budget plans, the accuracy of Baudax Bio’s estimates of the potential market for ANJESO, Baudax Bio’s ability to achieve its financial goals; and Baudax Bio’s 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. These forward-looking statements 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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Source: Baudax Bio, Inc.