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Baudax Bio Provides Commercial and Corporate Update

ANJESO® Launch Underway; Over 50 Institutions have Added ANJESO to Their Formularies

ANJESO Users Giving Highly Positive Feedback; Average Order Size Has Increased 75% Since Launch, Despite Ongoing COVID-related Impact to Access

Company Executes Strategic Transaction to Simplify Capital Structure and Exchange Warrants

MALVERN, Pa., Oct. 20, 2020 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today provided an update regarding the initial commercial launch of ANJESO and provided an overview of other corporate initiatives and achievements.

“During the first half of 2020, we saw the approval and commercial launch of ANJESO, the first and only non-opioid, once daily, intravenous (IV) non-steroidal anti-inflammatory (NSAID) agent for the management of moderate to severe pain,” said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. “Overall, the ANJESO launch is progressing well and we are pleased with the early commercial uptake and feedback from physicians. Although we are seeing more customers placing orders and the order size is increasing, the commercial rollout continues to be impacted by the ongoing COVID-19 pandemic and we believe the revenue ramp will likely take more time than originally anticipated. Looking ahead to the remainder of 2020 and beyond, we are focused on securing hospital formulary adoption and incorporation into standard pain management protocols. We are also working with the surgical and anesthesia community to increase awareness of ANJESO and help ensure physicians and patients have access to this important product.”

ANJESO Launch and Commercial Rollout

The U.S. commercial rollout of ANJESO, Baudax’s lead asset indicated for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics, is progressing well. ANJESO became broadly available through wholesalers in the U.S in June 2020. As of today, over 50 institutions have added ANJESO to their formulary and the average order size has increased by nearly 75% since launch. The ANJESO re-order rate is a robust 50% with a deepening usage pattern. In just over 3 months on the market, ANJESO has been utilized across a wide variety of surgical and non-surgical procedures and is now beginning to be incorporated into surgical protocols and electronic health record (EHR) order sets, with demand increasing monthly. However, Baudax’s ongoing commercial efforts continue to be impacted by COVID-19 pandemic related obstacles, including an absence of hospital formulary meetings where new drugs can be adopted, as well as access within hospitals. Many hospital formularies just recently resumed meetings after a 6-month

absence. Despite there being a backlog of agents scheduled to be reviewed, the Company believes it will make steady progress getting ANJESO added to further hospital formularies in the months and quarters ahead.

“For the significant number of patients undergoing surgical procedures, there is an important need for new non-opioid options to manage their pain post-surgically,” said Harold K. Humphries, M.D., Anesthesiologist and Operations Officer at Greater Sacramento Surgery Center. “At our center, we have noticed that ANJESO alone works as well as peripheral nerve blocks for controlling postoperative pain in total knee replacement cases. We’ve also found that with ANJESO the utilization of our 23-hour stay program is reduced, resulting in significant savings with overhead costs, which markedly offsets the cost of the product itself. ANJESO is an excellent addition to our patient care protocols.”

Effective October 1, 2020, ANJESO is reimbursed by the Centers for Medicare and Medicaid Services (CMS), under a unique J code, facilitating reimbursement for use in the hospital outpatient, ambulatory surgery center and physician office settings of care.

Strategic Transaction to Simplify Capital Structure and Exchange Warrants

Effective October 19, 2020, the Company entered into exchange agreements with holders of its short dated (13 months) Series B Warrants and long dated (5 year) Series A Warrants providing for the immediate exchange of 0.2 shares of common stock per warrant, for either all Series A Warrants or Series B Warrants held by each holder, at the holders election. As a result of the warrant exchange, the exercise price of the remaining outstanding warrants (whether Series A Warrants or Series B Warrants, including warrants held by holders not participating in the exchange) was adjusted to $0.01 per share. Holders participating in the exchange also agreed to amend their Warrants not so exchanged to remove certain anti-dilution and variable pricing protective provisions. Additionally, following the completion of the warrant exchange, for holders participating in the exchange, to the extent such holder’s outstanding warrant is a Series A Warrant, the expiration date for such warrant was amended to April 26, 2021.

As a result of the warrant exchange, the exercise and exchange of all of the Series A Warrants and Series B Warrants (approximately 15 million warrants outstanding prior to the exchange) is expected to result in the issuance of approximately 9.8 million shares of the Company’s common stock in the aggregate. This Warrant restructuring transaction was done to improve the Company’s capital structure and remove certain financial overhang, which the Company believes negatively impacted its expected valuation and ability to attract additional capital investments.

“By executing this strategic warrant restructuring, we have cleaned up the balance sheet and significantly improved the capital structure of the Company through elimination of certain provisions that would have contributed to a financial overhang for the remaining 4-year plus life of the Series A warrants, all while minimizing the anticipated dilution for our shareholders by over 25%,” said Ryan D. Lake, Chief Financial Officer of Baudax Bio. “As of today, holders of approximately 90% of the Warrants are participating in the exchange. We sincerely appreciate the ongoing support of all of our shareholders and their willingness to work constructively with the Company and our bankers to execute this important transaction.”

Other material terms related to the Series A Warrant and Series B Warrant exchange and amendments can be found in the Company's current report on Form 8-K, which was filed with the Securities and Exchange Commission on October 20, 2020.

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 launched in the U.S. in June 2020 following its approval by the Food and Drug Administration in February 2020. ANJESO is indicated 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. ANJESO is 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).

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.baudaxbio.com.

About Baudax Bio

Baudax Bio is a pharmaceutical company focused on therapeutics for acute care settings. The launch of Baudax Bio's first commercial product ANJESO® began in June 2020 following its approval by the U.S. Food and Drug Administration in February 2020. 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. In addition to ANJESO, Baudax has a pipeline of other pharmaceutical assets including two novel neuromuscular blocking agents (NMBAs) and a proprietary chemical reversal agent specific to these NMBAs which is currently in preclinical studies, and intranasal dexmedetomidine which is being developed for possible uses in pain or sedation. 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. 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 its 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 its 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 Baudax Bio's business and future results included in its filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are based on information currently available to Baudax Bio, and Baudax Bio assume no obligation to update any forward-looking statements except as required by applicable law.

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