April 23, 2020

Baudax Bio Announces Presentation of New Phase IIIb ANJESO™ Data at the 45th Annual Regional Anesthesiology and Acute Pain Medicine Meeting

Two Virtual Posters Highlight New ANJESO Clinical Results, Along with Health Resource Utilization Data, When Administered Preoperatively Following Total Knee Arthroplasty

MALVERN, Pa., April 23, 2020 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today announced two virtual poster presentations highlighting new ANJESO™ (meloxicam) injection data at the 45th Annual Regional Anesthesiology and Acute Pain Medicine Meeting, hosted by the American Society of Regional Anesthesia (ASRA) and Pain Medicine.

“The data virtually published by ASRA this year demonstrate that ANJESO is not only efficacious and well tolerated when administered preoperatively to patients prior to total knee arthroplasty (TKA), but it is also associated with a decreased need for opioids following surgery,” said Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer of Baudax Bio. “From a health economic perspective, the study also demonstrated that use of ANJESO is associated with an average of approximately $2,300 in cost savings per patient, lower length of stay (LOS) and fewer hospital readmissions and emergency room (ER) visits during recovery. ANJESO is now available for ordering and delivery to U.S. customers, and we are actively preparing for the full commercial launch by June 2020.”

Both posters describe outcomes from a double-blind, placebo-controlled Phase IIIb study evaluating preoperative administration of ANJESO in 181 patients who had undergone a unilateral TKA. The first poster describes efficacy and safety data (ID# 759) and the second poster describes health resource utilization data (ID# 651). The study was designed to replicate conditions consistent with current clinical practice, including use of a standardized clinical care protocol based on common best practices for TKA procedures, including multimodal analgesia. Patients were randomized 1:1 to receive ANJESO (30mg) or placebo. The first study dose was administered after spinal anesthesia and prior to the start of surgery. Subsequent doses of ANJESO were administered every 24 hours. The primary objective of the study was to assess the effect of preoperative administration of ANJESO on opioid consumption in subjects undergoing open unilateral TKA compared to placebo. Secondary objectives included safety and tolerability, and effects on postoperative pain and healthcare utilization costs.

Efficacy and Safety Results Following Administration of Preoperative ANJESO Compared to Placebo

ANJESO-treated patients had significantly lower opioid consumption during the first postsurgical day, with a 31.7% reduction compared to placebo (mean 19mg vs. 28mg; $p<0.0001$). Significant reductions in opioid use were observed on subsequent days and throughout treatment. ANJESO-treated patients had a significantly lower Summed Pain Intensity (SPI) score on the first postsurgical day and throughout their inpatient course ($p\leq0.0001$). ANJESO-treated patients had a significantly longer time to first opioid rescue after surgery compared to placebo. ANJESO-treated subjects had lower incidences of all cause hospital readmissions, fewer subjects discharged to skilled nursing facilities, and fewer emergency room visits and doctor calls related to pain during the follow-up period.

With respect to safety, adverse events (AEs) were primarily mild or moderate in intensity and not related to study treatment, with a higher incidence of AEs reported in the placebo group. The incidence of serious AEs was higher in the placebo group. All serious AEs in the ANJESO group were assessed by the primary investigators to be not related to study treatment. No subject discontinued due to an AE. The overall rate of AEs of special interest (AESI; events related to concerns associated with NSAIDS) were lower in the ANJESO-treated group at 9.7% than the placebo group at 21.6%. Rates of individual events in the ANJESO group occurred at similar or lower rates compared to the placebo group. Laboratory and surgical wound healing assessments were similar between treatment groups. This study supports the efficacy and safety of ANJESO administered once daily, with administration beginning prior to start of surgery, as part of a standardized multimodal regimen in subjects undergoing primary unilateral TKA.

Healthcare Resource Utilization (HRU) Results Following Preoperative ANJESO Compared to Placebo

This study also evaluated HRU and costs, including total hospital costs, hospital LOS, hospital readmissions, ER visits, physician office visits, and phone calls due to pain, associated with preoperative administration of ANJESO compared to placebo, through postoperative day 30.

The total mean costs of hospital stay and total overall costs were lower in the ANJESO group compared to the placebo group, however, the differences were not statistically significant. Mean hospital LOS in days was lower in the ANJESO group compared to the placebo group (2.05 vs. 2.24 days). ANJESO was associated with 8.6% lower LOS in days compared to placebo, however, the difference was not statistically significant. There were fewer hospital readmissions (1 vs. 3), ER visits (0 vs. 4), and phone calls due to pain (4 vs. 9) for ANJESO versus placebo, respectively. There were no reports of unscheduled physician office visits due to pain in either group.

Mean total opioid use from hour 0-24, 0-48, and 0-72 hours was significantly lower among meloxicam IV compared to placebo ($p<0.0001$) and from hour 0 through hospital discharge (33.28mg vs. 44.87mg); ($p<0.001$). Time to the first oral opioid rescue medication was longer for the ANJESO group than placebo (7.31 vs. 5.22 hours; $p=0.0226$) and a similar trend was observed for mean time to first use of IV or oral opioid analgesia (4.75 vs. 3.09 hours; $p=0.0126$). While there was no significant association between opioid consumption and total hospital costs, every unit (1mg IV morphine equivalent) increase in opioid consumption was associated with a 0.5% increase in LOS in days ($p=0.0001$). The proportion of subjects with ≥1 opioid related adverse drug effects (ORADEs) were significantly higher for placebo than ANJESO (70.5% vs. 48.4%; $p=0.003$). Six ANJESO-treated patients (6.5%) had ≥1 AESI in

comparison to 12 placebo subjects (13.6%). Serious AEs were observed among 3 ANJESO-treated patients (3.2%) and 9 placebo subjects (10.2%).

The posters can be accessed online at
https://epostersonline.com/ASRASPRING20/search/meloxicam **or the following:**

Title: Efficacy and Safety of Preoperative Meloxicam IV in Primary Total Knee Arthroplasty
Lead Author: Alex Freyer
ID Number: 759
URL: https://epostersonline.com/ASRASPRING20/node/48

Title: Healthcare Resource Utilization Associated with Preoperative Meloxicam IV in Primary Total Knee Arthroplasty
Lead Author: Libby Black
ID Number: 651
URL: https://epostersonline.com/ASRASPRING20/node/19

For more information on this meeting, visit:https://www.asra.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 full commercial launch of ANJESO by late Q2 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

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 and ANJESO™ commercialization, 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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