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Baudax Bio Announces Presentation of New Phase IIIb ANJESO™ Data at Digestive Disease Week 2020

Virtual Presentation Highlights New ANJESO Health Resource Utilization Data When Administered Preoperatively in Colorectal Surgery as Part of a Multimodal Analgesia Regimen

MALVERN, Pa., May 05, 2020 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today announced a virtual poster presentation highlighting ANJESO™ (meloxicam) injection data at Digestive Disease Week (DDW) 2020.

“The data virtually published by DDW demonstrate that ANJESO has positive impacts on many elements of healthcare resource utilization when administered preoperatively to patients prior to colorectal surgeries as part of a multimodal analgesic (MMA) regimen,” said Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer of Baudax Bio. “Key findings included statistically significant reductions in opioid use and in length of hospital stay by approximately 1 day, as well as lower incidence of opioid-related adverse events, all while achieving similar or slightly reduced average cost of the hospital stay. We are thrilled 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.”

The virtual presentation describes an economic sub-study of a double-blind, placebo-controlled Phase IIIb study evaluating preoperative administration of ANJESO as part of a MMA regimen compared to placebo in 55 patients who had undergone open or laparoscopic colorectal surgeries. The Phase IIIb study was designed to replicate conditions consistent with current clinical practice, including use of a standardized enhanced recovery after surgery protocol based on common best practices for colorectal surgeries. Patients were randomized 1:1 to receive ANJESO (30mg) or placebo. The first study dose was administered 30 minutes prior to the start of surgery. Subsequent doses of ANJESO were administered every 24 hours. The primary objective of the Phase IIIb study was to evaluate the safety and tolerability of preoperative dosing of ANJESO in subjects undergoing open or laparoscopic colorectal surgeries compared to placebo. The economic sub-study primary objective was to evaluate the impact of preoperative dosing of ANJESO on healthcare resource use (HRU) and healthcare costs.

HRU Results Following Preoperative ANJESO Compared to Placebo

This economic sub-study evaluated HRU and costs, including total hospital costs, hospital length of stay (LOS) and opioid use associated with preoperative administration of ANJESO compared to placebo. A subject-level database was developed to capture quantity of service, charges and date of service from UB-04 forms (from admission date to discharge),

captured in the IIIB clinical trial. A national cost:charge ratio was applied to convert 'charges' to 'costs'.

A total of 55 subjects (mean age: 60, female: 43%) were treated in the trial, with 54 subjects included in HRU analysis (n=27 per treatment; 1 excluded due to missing UB-04). The total mean costs of hospital stay were similar between the ANJESO group compared to the placebo group ($23,115 vs. $22,682; p=0.3370). After removing outliers (top 99th percentile), the total costs for the ANJESO group was numerically lower than the placebo group ($20,492 vs. $22,682; p=0.2196). Mean hospital LOS in days was numerically lower in the ANJESO group compared to the placebo group (86.2 vs. 111.7 hr; p=0.0162) and was statistically significant.

Mean total opioid use was significantly lower among the ANJESO group compared to placebo and from hour 0 through hospital discharge (29.22mg vs. 45.17mg; p<0.0339). The proportion of subjects with ≥1 opioid related adverse drug effects (ORADE) were higher for the placebo group than for the ANJESO group (63% vs. 41%). Presence of >1 ORADE was associated with a significant increase in LOS (exp (β)=1.303, p=0.0238) in hours (exp(β)=1.264, p =0.031) as compared to not having any ORADEs.

Title: Healthcare Resource Utilization (HRU) Associated with Preoperative Meloxicam IV in Colorectal Surgery
Lead Author: Libby Black
Presentation #: 503-2020
URL: https://ddw.apprisor.org/epsAbstractDDW.cfm?id=96

For more information on this meeting, visit:www.ddw.org.

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.

CONTACT:

Investor Relations Contact:
Argot Partners
Sam Martin / Claudia Styslinger
(212) 600-1902
sam@argotpartners.com
claudia@argotpartners.com

Baudax Bio, Inc.
Ryan D. Lake
(484) 395-2436
rlake@baudaxbio.com

Media Contact:
Argot Partners
David Rosen
(212) 600-1902
david.rosen@argotpartners.com

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