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# **Baudax Bio Initiates Phase IV Clinical Trial Evaluating ANJESO® in Pediatric Patients Following Surgery**

MALVERN, Pa., March 08, 2022 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX) a pharmaceutical company focused on commercializing and developing innovative products for acute care settings, today announced initiation of a clinical study evaluating the safety and pharmacokinetics (PK) of ANJESO (meloxicam) injection in pediatric patients (ages 2 to <17 years old) following surgery.

This multicenter, open-label clinical trial will study ANJESO in multiple age groups of children who undergo elective surgery in either an inpatient or outpatient setting. Approximately 90 patients will be enrolled across three age groups (12 to <17, 7 to <12 and 2 to <7 years old) to establish safety for all three age groups. All enrolled patients will be included in the safety assessment and analyses, while PK will be assessed using a subset of each age group (12 patients per age group). Patients will undergo elective surgery on Day 1 with appropriate anesthesia according to the investigator's clinical standard of care practice and in accordance with institutional standards. At the end of the surgical procedure, each patient will receive their first dose of ANJESO as an IV bolus injection, according to the weight of the patient. Additional doses may be administered every 24 hours and patients may receive a maximum of three doses of ANJESO in the study. PK endpoints for determination of ANJESO concentrations in plasma will be based on population PK analysis.

"We are extremely pleased to initiate this important new clinical study in pediatric patients following elective surgery, and look forward to elucidating ANJESO's safety and PK profile in these younger patients who undergo an estimated 3.9 million elective surgeries in the U.S. each year, from the simple, such as appendectomies and herniorrhaphies to complex thoracic, gastrointestinal, orthopedic, and genitourinary, surgeries," said Gerri Henwood, Baudax Bio's President and Chief Executive Officer. "ANJESO continues its upward growth in the marketplace in adult patients and as an important non-opioid pain management option, we believe it has significant potential for pediatric patients as well."

## **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 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).

## **About Baudax Bio**

Baudax Bio is a pharmaceutical company focused on commercializing and developing innovative products for acute care settings. ANJESO is the first and only 24-hour, intravenous (IV) COX-2 preferential non-steroidal anti-inflammatory (NSAID) for the management of moderate to severe pain. In addition to ANJESO, Baudax Bio has a pipeline of other innovative pharmaceutical assets including two novel neuromuscular blocking agents (NMBAs) and a proprietary chemical reversal agent specific to these NMBAs. For more information, please visit [www.baudaxbio.com](http://www.baudaxbio.com).

## **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, including Baudax Bio's ability to realize any anticipated benefits from the reverse stock split, including maintaining its listing on the Nasdaq Capital Market and attracting new investors. These risks and uncertainties include, among other things, risks related to the ongoing economic and social consequences of the COVID-19 pandemic, Baudax Bio's ability to advance its current product candidate pipeline through pre-clinical studies and clinical trials, Baudax Bio's ability to raise future financing for continued development of its product candidates such as BX-1000, BX-2000 and BX-3000, 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, 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 Baudax Bio's filings with the Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov). These forward-looking statements are based on information currently available to Baudax Bio, and Baudax Bio assumes no obligation to update any forward-looking statements except as required by applicable law.

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