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BAUDAX BIO®

Baudax Bio Announces an additional Orange Book listed patent for ANJESO®

MALVERN, Pa., Nov. 19, 2020 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on therapeutics for acute care settings, recently announced the issuance of United States Patent No.10,709,713 (the '713 Patent) on July 14, 2020. The '713 Patent covers the use of ANJESO® to treat moderate to severe pain, and has been listed in the *United States Food and Drug Administration's (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* as it relates to ANJESO®.

The '713 Patent is an additional ANJESO® patent to be listed in the Orange Book with an expiry date of May of 2030. The '713 Patent joins four other patents listed in the Orange Book, amongst others owned or licensed by Baudax that currently provide exclusivity to the ANJESO® franchise.

"We are pleased by the progress we have made in the United States Patent and Trademark Office and the recognition of the inventive nature of our ANJESO® franchise," said Gerri Henwood, Baudax Bio's President and Chief Executive Officer. "The '713 Patent is expected to provide a significant barrier for generic entry and will likely be joined by other patents currently pending in the USPTO."

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).

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 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.

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