

# **Baudax Bio Announces Publication of ANJESO® Network Meta-Analysis in the Peer-Reviewed Journal BMC Anesthesiology**

## **ANJESO Found to Provide Superior Pain Relief with Similar or Better Safety Compared to Other Approved IV Non-Opioid Analgesics**

MALVERN, Pa., Nov. 20, 2020 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today announced the [online publication](#) of a Network Meta-Analysis (NMA) for ANJESO (meloxicam) injection in the peer-reviewed medical journal BMC Anesthesiology. ANJESO was recently launched in the U.S. and is indicated for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics.

“The management of post-operative pain remains a significant issue, including providing adequate pain control beyond immediate postsurgical recovery,” said Jonathan Jahr, M.D., Professor Emeritus, Anesthesiology, University of California, Los Angeles School of Medicine. “Based on the results of multiple clinical trials, ANJESO (meloxicam) injection has been found to provide relief of moderate to severe acute pain, alone or in combination with other analgesics within the first 15 minutes after dosing and up to 24 hours after dosing compared to placebo. Specifically, ANJESO (meloxicam) injection provided superior pain relief for abdominoplasty, bunionectomy and hysterectomy when compared with acetaminophen, ibuprofen, and ketorolac, while also demonstrating a compelling profile with respect to reducing morphine consumption. Notably, ANJESO (meloxicam) injection was significantly more effective at reducing pain intensity than all comparators for those procedures in which pain intensity scores were recorded.”

“We believe that ANJESO offers an effective, non-opioid therapeutic option for the management of postsurgical pain for eligible patients,” said Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer of Baudax Bio. “As the only intravenous IV NSAID that lasts up to 24 hours, ANJESO has an equal or better safety profile than that of other IV non-opioids, and benefits patients by reducing their opioid consumption post-surgery. The results of this meta-analysis add to the growing body of data supporting our ongoing ANJESO commercial launch efforts.”

### **ANJESO Network Meta-Analysis Results**

The published NMA results are based on the screening of over 2,300 studies, whereby 27 studies were identified and included in the analysis. Randomized clinical trials from 2000 to 2019 which involved at least one of the following procedures: open abdominal surgery, bunionectomy, open hysterectomy, orthopedic joint replacement surgery (including knee, ankle, hip, shoulder) were evaluated for inclusion. The literature search included publications

that reported clinical effectiveness, safety and tolerability in adult patients receiving post-operative pain treatments. For this NMA, ANJESO was indirectly compared with only those IV treatments that were available at the time in the U.S., including acetaminophen, ibuprofen, and ketorolac. Studies for other non-opioid analgesics such as parecoxib and diclofenac were used for indirect comparison with the placebo arms in those studies.

The NMA found that among patients reporting moderate to severe postoperative pain, ANJESO was superior in pain reduction for abdominoplasty, bunionectomy and hysterectomy when compared with acetaminophen, ibuprofen, and ketorolac. In reducing morphine consumption, ANJESO was associated with significantly less morphine milligram equivalents (MME) utilization versus all comparators for abdominal procedures, hysterectomy, and versus acetaminophen in orthopedic procedures. Elsewhere MME utilization outcomes for ANJESO were largely equivalent or nominally better than other comparators.

The odds of opioid-related adverse events (ORADEs) were significantly higher for all comparators compared to ANJESO for orthopedic (gastrointestinal) and hysterectomy (respiratory). These results suggest ANJESO may provide better pain relief with a similar or better reduction in ORADEs compared to other approved IV NSAIDs.

### **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 NMBA's 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](http://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](http://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.

### **CONTACT:**

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

Baudax Bio, Inc.  
Ryan D. Lake

(484) 395-2436  
[rlake@baudaxbio.com](mailto:rlake@baudaxbio.com)

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

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