

Baudax Bio™ Launches as a New Pharmaceutical Company Aimed at Advancing Promising, Non-Opioid Analgesic Therapies

Company Launches with \$19 Million in Funding and Rights to IV Meloxicam, Along with Other Clinical-Stage Pipeline Assets

Trading of “BXRX” Begins Tomorrow on NASDAQ

MALVERN, Pa., Nov. 21, 2019 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX) today announced its launch as an independent, publicly traded pharmaceutical company focused on advancing non-opioid analgesics and other products for the hospital and other acute care settings. Beginning tomorrow, November 22, 2019, Baudax will trade on the NASDAQ Capital Market under the ticker symbol “BXRX.” When-issued trading under the symbol “BXR XV” continues until market close today.

“Baudax Bio will pursue the development of therapeutics, specifically focusing on innovative products for acute care settings where there is an urgent need and the potential for the greatest impact for patients,” said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. “We have rights to a pipeline of innovative product candidates, including intravenous (IV) meloxicam, our lead product candidate, and over time we may seek to expand our pipeline. In the near-term, our primary goal is to continue next steps following our successful U.S. Food and Drug Administration (FDA) appeal and to prepare a comprehensive response package. If approved, we believe IV meloxicam approval, ANJESO™, will be a novel non-opioid option for the management of moderate to severe pain.”

Baudax launches with \$19 million in funding from Recro Pharma, Inc., its former parent company, and holds the rights to a pipeline of pharmaceutical assets, including:

- **IV Meloxicam** – Baudax holds exclusive global rights to IV meloxicam, a post-Phase 3 non-opioid analgesic developed for the treatment of moderate to severe pain. If approved, IV meloxicam will be a novel IV non-opioid option for the management of moderate to severe pain. IV meloxicam successfully completed three Phase III clinical studies, including two Phase III efficacy studies and one Phase III safety study, four Phase II clinical studies, as well as other safety studies. Baudax recently received a written decision from the FDA granting an appeal for a Complete Response Letter the Company received relating to its IV meloxicam New Drug Application (NDA). Baudax is now in the process of preparing a comprehensive response to the FDA that includes proposed labeling and certain other information.
- **Two Neuromuscular Blocking Agents and A Reversal Agent** – Baudax holds

exclusive global rights to two novel neuromuscular blocking agents (NMBs) and a proprietary chemical reversal agent specific to these NMBs which were licensed from Cornell University in 2017. The reversal agent is a proprietary agent that rapidly reverses the NMB compounds. Used together, these agents allow for a very rapid induction of neuromuscular blockade for surgical settings, followed by a rapid reversal of the neuromuscular blockade. These novel agents have the potential to meaningfully reduce procedure recovery time in operating room or post-acute care settings, resulting in valuable cost savings to hospitals and ambulatory surgical centers. RP-1000 is an intermediate duration clinical-stage NMB drug candidate with one completed Phase I trial and with plans to initiate an additional dose escalation Phase I trial in the first half of 2020. RP-2000 is an ultra-short acting NMB drug candidate which is currently completing early pre-clinical and drug product work.

- **Intranasal Dexmedetomidine** – Baudax holds rights to intranasal dexmedetomidine (Dex-IN), a non-opioid alpha-2 adrenergic agonist being developed for possible uses in pain or sedation. IV dexmedetomidine (Precedex[®]) has a long history of use in the U.S. and Europe as a short-term sedative with both analgesic or anxiolytic properties and is widely used in intensive care unit settings and for procedural sedation. Baudax's Dex-IN demonstrated pain relief and a favorable tolerability profile in early-stage, placebo-controlled clinical studies. Baudax is pursuing potential product partnering for Dex-IN.

Experienced Leadership Team

Baudax Bio is led by a team of pharmaceutical industry veterans, including:

- **Gerri Henwood, President and Chief Executive Officer**, who brings over three decades of senior leadership experience in biopharmaceuticals, healthcare and life sciences, including as Founder, President and CEO of both Recro Pharma and Auxilium Pharmaceuticals.
- **Ryan D. Lake, Chief Financial Officer**, who brings almost 20 years of senior financial and life sciences leadership experience. He also currently serves as the Chief Financial Officer for Recro Pharma, Inc. Previously, he served in executive leadership positions at Aspire Bariatrics, Inc., DSM Biomedical, and Kensey Nash Corporation.
- **Stewart McCallum, MD, Chief Medical Officer**, who brings over 20 years of pharmaceutical and healthcare industry experience. Prior to Baudax, Dr. McCallum served as Chief Medical Officer of Recro Pharma. Before that, he served in roles of increasing responsibility at GlaxoSmithKline plc. Dr. McCallum joined industry from academia where he was a Surgeon and Professor of Urology at Stanford University Medical Center and the VA Palo Alto Health Care System.
- **John Harlow, Chief Commercial Officer**, who brings over 20 years of branded pharmaceutical experience, including commercial leadership roles in marketing, sales and operations. Prior to Baudax, Mr. Harlow served in roles of increasing responsibility at several world-class pharmaceutical companies including J&J, Novartis, King Pharmaceuticals (acquired by Pfizer), Shionogi, and Endo Pharmaceuticals.

In addition to Gerri Henwood, Baudax has appointed the following directors to the board:

- Alfred F. Altomari, Chairman of the Board – CEO of Agile Therapeutics
- Wayne B. Weisman – Partner, SCP Vitalife
- William Ashton – Principal, Harrison Consulting Group
- Winston J. Churchill – Partner, SCP Vitalife

About Baudax Bio

Baudax Bio is a pharmaceutical company focused on therapeutics for acute care settings.

The Company's lead product candidate is a proprietary intravenous (IV) form of meloxicam, a non-opioid, long-acting preferential COX-2 inhibitor. IV meloxicam has successfully completed two pivotal Phase III clinical efficacy trials, a large double-blind placebo-controlled Phase III safety trial, four Phase II clinical efficacy trials, as well as other safety studies. Upon IV meloxicam approval, ANJESO™, will be a novel non-opioid option 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," "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 this press release 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. Factors that could cause Baudax Bio's actual performance to materially differ from those expressed in the forward-looking statements set forth in this press release include, without limitation: the Company's ability to execute its strategy for further development and commercialization of IV meloxicam, the Company's ability to execute its strategic initiatives, the Company's ability to adequately resolve the outstanding labeling issues with the FDA for IV meloxicam, and the time frame associated with any such resolution; the Company's ability to raise future financing for continued product development and IV meloxicam commercialization; with regard to the Company's clinical trial results, whether there may be changes in the interpretation by the FDA of the data of the Company's clinical trials and the length, cost and uncertain results and timing of our ongoing clinical trials; with regard to the potential commercial opportunity of IV meloxicam, whether any FDA approval of IV meloxicam will include labeling restrictions and the potential that IV meloxicam does not receive regulatory approval or does not receive reimbursement by third party payors, that IV meloxicam is not accepted by the medical community, including physicians, patients, health care providers and hospital formularies or that a commercial market for IV meloxicam does not develop; the Company's ability to manage costs and

execute on its operational and budget plans; the Company's ability to achieve its financial goals; the Company's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection; the Company's lack of operating history as a standalone business; risks relating to the separation from Recro, including, among others, failure to achieve the anticipated benefits from the separation, reliance on Recro and other third parties to provide certain services post-separation, and the Company's ability to satisfy liabilities and potential indemnification obligations in connection with the separation. The forward-looking statements in this press release 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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