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Baudax Bio Initiates Phase II Clinical Trial Evaluating BX1000 in Patients Undergoing Surgery

MALVERN, Pa., Dec. 08, 2022 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX) a pharmaceutical company focused on innovative products for hospital and related settings, today announced the initiation of a clinical study evaluating the safety, tolerability profile, and intubation conditions of BX1000 for neuromuscular blockade (NMB) in patients undergoing elective surgery.

This randomized, double-blind clinical trial will study BX1000 in approximately 80 adult patients, 18-65 years of age, who undergo elective surgery utilizing total intravenous anesthesia (TIVA) in an outpatient setting. Patients will undergo elective surgery with an intravenous (IV) line for anesthesia and study drug administration. Once anesthetized, neuromuscular monitoring will be initiated via electromyography (EMG), and approximately 3-5 minutes after induction of anesthesia, the randomized NMB treatment will be administered as an IV bolus. Intubation conditions will be assessed at 60 seconds after administration of the NMB dose and will be reassessed at 90 and 120 seconds if needed, with tracheal intubation performed when clinically acceptable conditions are identified. These “intubating conditions” represent the endpoint for NDA approval for NMB agents. Following successful tracheal intubation, patients will proceed to undergo their elective surgical procedures according to the standard practice of the investigator or surgical unit. Patients will be monitored post-surgery in the anesthesia recovery area and will be transferred to the inpatient facility where they will remain for at least 8 hours following NMB administration, to be discharged at the discretion of the investigator. There will be an in-person follow-up visit and several telephonic safety follow ups as well.

“The initiation of this Phase II clinical study in patients undergoing elective surgery is an important step for the overall NMB program, and we look forward to data on BX1000’s safety, tolerability, and neuromuscular blocking profile,” said Gerri Henwood, Baudax Bio’s President and Chief Executive Officer. “We believe that BX1000, in combination with BX3000 (reversal agent), may permit precise control of the time patients are under neuromuscular paralysis. This could be significantly impactful for patients, surgeons, and anesthesiologists by enhancing safety, and possibly saving time and reducing costs related to delayed recovery from neuromuscular paralysis following surgical procedures. To date, no serious adverse events have been reported in the first group of patients enrolled and efficacy parameters have been recorded. We look forward to announcing the completion of the pre-planned first interim analysis of the BX1000 Phase 2 surgery trial early in 2023, with a target of completing full study enrollment by the end of March, 2023.”

About Baudax Bio’s Neuromuscular Blocking Agents (NMBs)

Baudax Bio holds exclusive global rights to two novel NMBs, BX1000, an intermediate duration, clinical stage agent, and BX2000, an ultra-short duration, clinical stage agent, as

well as a proprietary chemical reversal agent, BX3000, undergoing nonclinical studies intended to support an IND filing in 2023. BX3000 is a specific reversal agent that rapidly reverses BX1000 and BX2000. All three agents are licensed from Cornell University. Used together, we believe 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 rooms or post-acute care settings, resulting in valuable cost savings to hospitals and ambulatory surgical centers.

About Baudax Bio

Baudax Bio is a pharmaceutical company focused on innovative products for hospital and related settings. The Company has a pipeline of innovative pharmaceutical assets including two clinical-stage, novel neuromuscular blocking (NMBs) agents, one in a Phase II study and an additional unique NMB in a dose escalation Phase I study, as well as a proprietary chemical reversal agent specific to these NMBs. Baudax Bio has received approval for and marketed ANJESO®, the first and only 24-hour, intravenous (IV) COX-2 preferential non-opioid, non-steroidal anti-inflammatory (NSAID) for the management of moderate to severe pain. For more information, please visit 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. Forward-looking statements may include, without limitation, statements regarding the use of net proceeds from the offering. 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 market, economic and other conditions, 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 BX1000, BX2000 and BX3000, 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; Baudax Bio's ability to comply with all listing requirements of the Nasdaq Capital Market; 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. 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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