



Biora Therapeutics Announces New Patent for its NaviCap™ Targeted Oral Delivery Platform

December 19, 2023

Patent addresses targeted delivery of JAK inhibitors to the gastrointestinal tract

SAN DIEGO, Dec. 19, 2023 (GLOBE NEWSWIRE) -- [Biora Therapeutics, Inc.](#) (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today announced that it received an Issue Notification from the U.S. Patent and Trademark Office for a patent related to the treatment of gastrointestinal (GI) disorders through targeted delivery of JAK inhibitors for its NaviCap™ targeted oral delivery platform under development.

US Patent Application No. 17/313,339, entitled "Treatment of a Disease of the Gastrointestinal Tract with a JAK Inhibitor and Devices," will issue as US Patent No. 11,857,669 on January 2, 2024. The patent is directed to methods of treating a GI disease by delivering a therapeutically effective amount of a JAK inhibitor at a desired location in the GI tract, where the therapeutically effective amount of the JAK inhibitor is less than an amount that is effective when the JAK inhibitor is administered systemically. The patent covers many JAK inhibitors, including those that are approved or in development for a range of indications.

"This is another big IP win for us, as it encompasses the novel treatment paradigm of our BT-600 program, which is designed to use targeted delivery of a JAK inhibitor to potentially achieve better therapeutic effect in ulcerative colitis, at lower doses than those required with systemic delivery," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "We are eager to prove this out as we initiate our phase 1 trial for BT-600 shortly."

The NaviCap ingestible device platform is protected by a patent portfolio consisting of 30 patent families, including 86 granted patents and 81 pending applications. Included in the NaviCap portfolio are 34 granted patents and 6 pending applications directed to the device's proprietary autonomous localization technology and to various therapeutic targets for the treatment of inflammatory bowel disease, including, but not limited to, Janus kinases (JAK), TNF-alpha, integrins, chemokines, IL-12/23, S1P, and IL-10 inhibitors, and the delivery of antibodies, peptides, small molecules, nucleic acids, stem cells, bacterial yeast, or phages to the gastrointestinal tract. Biora's total corporate portfolio consists of 73 patent families, including approximately 190 issued patents and 135 pending applications filed in major jurisdictions around the world, including the US, Europe, China, Japan, South Korea, Israel, Australia, Canada, and Mexico.

About the NaviCap™ Targeted Oral Delivery Platform and BT-600

[Biora's NaviCap targeted oral therapeutics platform](#) utilizes a novel approach that could improve patient outcomes by enabling delivery of therapeutics directly to the site of disease, increasing therapeutic levels in tissue while reducing systemic uptake. For the 1.8 million patients in the United States who suffer from inflammatory bowel disease (IBD), existing therapeutics offer less than ideal efficacy, likely because of the challenges with safely achieving sufficient drug levels in the affected tissues. [Research has shown](#) that targeted delivery of therapeutics has the potential to improve patient outcomes in IBD.

The NaviCap platform uses an ingestible device [designed for targeted delivery of therapeutics](#) to improve treatment of IBD. Once swallowed, Biora's Gltrac™ autolocation technology enables the device to autonomously identify targeted locations in the GI tract and release a therapeutic dose of up to 500µl.

Biora's BT-600 program consists of a unique, liquid formulation of tofacitinib delivered to the colon via the NaviCap device, for the treatment of ulcerative colitis. Studies in healthy volunteers have demonstrated [accurate localization and delivery in a fasted state](#) and demonstrated the device's [ability to function in both fasted and fed states](#), making it potentially the first ingestible therapeutic delivery device that does not require fasting or other food restriction for use. A device function study in participants with active ulcerative colitis (UC) also [demonstrated successful device performance in active UC patients](#). The company recently received FDA clearance for its Investigational New Drug (IND) application to begin a phase 1 study for BT-600.

About Biora Therapeutics

Biora Therapeutics is reimagining therapeutic delivery. By creating innovative smart pills designed for targeted drug delivery to the GI tract, and systemic, needle-free delivery of biotherapeutics, the company is developing therapies to improve patients' lives.

Biora is focused on development of two therapeutics platforms: the [NaviCap™ targeted oral delivery platform](#) which is designed to improve outcomes for patients with inflammatory bowel disease through treatment at the site of disease in the gastrointestinal tract, and the [BioJet™ systemic oral delivery platform](#), which is designed to replace injection for better management of chronic diseases through needle-free, oral delivery of large molecules.

For more information, visit [bioratherapeutics.com](#) or follow the company on [LinkedIn](#) or [Twitter](#).

Safe Harbor Statement or Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this press release, including statements concerning the progress and future expectations and goals of our research and development and clinical efforts and research collaboration plans and expectations are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan," "target," or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our plans, estimates, and expectations, as of the date of this press release. These statements

involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this press release. Such risks, uncertainties, and other factors include, among others, our ability to innovate in the field of therapeutics, our ability to make future filings and initiate clinical trials on expected timelines or at all, our ability to obtain and maintain regulatory approval, clearance, or acceptance of our clinical trials or products on expected timelines or at all, our plans to research, develop, and commercialize new products, the unpredictable relationship between preclinical study results and clinical study results, our expectations regarding allowed patents or intended grants to result in issued or granted patents, our expectations regarding opportunities with current or future pharmaceutical collaborators, our ability to raise sufficient capital to achieve our business objectives, and those risks described in “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC and other subsequent documents, including Quarterly Reports, that we file with the SEC.

Biora Therapeutics expressly disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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