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

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SAN DIEGO, June 28, 2023 (GLOBE NEWSWIRE) -- Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today announced that it has been awarded a group of US and European patents related to several additional therapeutic targets for its NaviCap™ targeted oral delivery platform under development.

The patents are directed to methods of treating ulcerative colitis using an ingestible device that delivers one or more therapeutic agents to the proximal part of the large intestine. The patents cover a range of therapeutic targets, including Janus kinases, integrins, chemokines, IL-12/23 and IL-10, and, in some cases, cover the delivery of antibodies, peptides, small molecules, nucleic acids, stem cells, bacteria, yeast, or phages to the gastrointestinal tract.

The European Patent Office has issued European Patent No. EP3554539B1 entitled “Treatment of a disease of the gastrointestinal tract with an integrin inhibitor,” European Patent No. EP3554485B1 entitled “Treatment of a disease of the gastrointestinal tract with a JAK inhibitor and devices,” European Patent No. EP3601531B1 entitled “Treatment of a disease of the gastrointestinal tract with live biotherapeutics,” European Patent No. EP3600416B1 entitled “Treatment of a disease of the gastrointestinal tract with an immune modulatory agent released using an ingestible device,” and European Patent No. EP3554541B1 entitled “Treatment of a disease of the gastrointestinal tract with a chemokine/chemokine receptor inhibitor.” In addition, the European Patent Office intends to grant European Publication No. EP3554540A1 entitled “Treatment of a disease of the gastrointestinal tract with an IL-12/IL-23 inhibitor released using an ingestible device.”

The U.S. Patent and Trademark Office has issued US Patent No. 11,597,762 entitled “Treatment of a disease of the gastrointestinal tract with an IL-12/IL-23 inhibitor released using an ingestible device,” US Patent No. 11,426,566 entitled “Treatment of a disease of the gastrointestinal tract with a TLR modulator,” US Patent No. 11,523,772 entitled “Treatment of a disease of the gastrointestinal tract with an immunosuppressant,” and US Patent No. 11,596,670 entitled “Treatment of a disease of the gastrointestinal tract with IL-10 or an IL-10 agonist.”

“The NaviCap platform has the potential to transform treatment options for many diseases of the gastrointestinal tract by enabling more effective delivery of therapeutics directly to the site of disease in the intestine,” said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. “These patents expand our coverage for additional therapeutic targets as we continue to strengthen our intellectual property portfolio.”

The NaviCap ingestible device platform utilizes a unique and proprietary device localization technology protected under 34 granted or allowed patents and applications and 6 pending applications in major jurisdictions around the world, including the US, Europe, China, Japan, South Korea, Israel, Australia and Mexico. These patents are part of Biora’s larger corporate portfolio consisting of 73 patent families, including approximately 180 issued patents and 145 pending applications.

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 GItrac™ 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 plans to submit an Investigational New Drug (IND) application to begin a Phase 1 study with its BT-600 program during the second half of 2023.

About Biora Therapeutics
Biora Therapeutics is the biotech company that 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 envisions a world where patients have access to needle-free drug delivery and better therapeutic outcomes.

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, 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 or clearance of our 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, the ongoing COVID-19 pandemic, 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, 2021 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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