Biora Therapeutics Announces New Patents for Targeted Therapeutics Platform

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Marks 29 Patents Worldwide Directed to Biora's Device Localization Technology

SAN DIEGO, May 19, 2022 (GLOBE NEWSWIRE) -- Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutics, today announced a new patent related to its Drug Delivery System (DDS) platform under development.

The USPTO has issued U.S. Patent No. 10,835,152 entitled, "Electromechanical pill device with localization capabilities" and allowed U.S. Application No. 15/940,407 entitled, "Localization systems and methods for an ingestible device." Their European counterparts, European Patent numbers EP3197336 and EP3600009, have also granted. The three patents and one allowed application are directed to ingestible devices capable of auto locating in the gastrointestinal (GI) tract using reflected light emitted from the device. The technology is broadly applicable to any ingestible device, whether the device is for sampling, diagnostics, or drug delivery.

"We believe, as recent data has shown, that targeted delivery of therapeutics has the potential to improve patient outcomes in IBD. There is currently no way to deliver the appropriate therapeutic doses directly to the site of disease, and increasing the systemic dose is limited by toxicity issues," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "Therefore, it is critical to have a technology that enables delivery of targeted therapeutics directly to the GI tract, and we have created an accurate, standalone, localization technology for ingestible devices that is unique and proprietary."

Biora's intellectual property covers the use of reflected light for autolocation by an ingestible device. This technology, as used in Biora's DDS capsule for its lead program, is designed to deliver a therapeutic dose to predefined locations in the lower GI tract, while simultaneously limiting degradation or systemic absorption in the upper GI tract. The proprietary autolocation technology is based on anatomical features that are consistent between humans and functions independently of physiological conditions such as pH, motility, pressure, and bacterial enzymes, which can vary greatly between individuals and disease states. The device's autolocation is designed to function autonomously, without reliance on external devices or magnets, and is cost-effective to build, without cameras or other complex electronic systems.

The DDS platform can deliver liquid drug formulations, including peptides and proteins, which are difficult to formulate into orally available forms. The device has been used successfully in a human trial, and a clinical device performance study in active ulcerative colitis patients is currently recruiting.

Biora Therapeutics has developed a strong patent portfolio directed to its ingestible device localization technology, including 29 granted or allowed patents and applications and 10 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 corporate portfolio consisting of 82 patent families, including approximately 170 issued patents and 170 pending applications. The portfolio includes patents and applications directed to methods and devices for drug delivery, methods and devices for GI sampling and diagnostics, methods and compositions for treating disease, and molecular and protein tools, assays and diagnostics.

About the Drug Delivery System (DDS) and PGN-600
Biora Therapeutics' targeted therapeutics platform utilizes a novel approach that could improve IBD patient outcomes by maximizing the available dose at the site of disease while reducing systemic toxicity. 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.

Biora's Drug Delivery System is an ingestible capsule designed for targeted delivery of therapeutics to improve treatment of IBD. It is approximately the size of a fish oil capsule and delivers a payload of up to 500µl liquid or solid formulation. Once swallowed, the capsule is designed to autonomously identify specific locations in the GI tract and release a therapeutic dose. In normal healthy volunteers, the DDS was shown to be safe and accurate in identifying entry into the colon. Biora is a recipient of the Crohn's and Colitis Foundation IBD Ventures development grant to, in part, support development and further clinical evaluation of the DDS platform, which aims to improve quality of life for patients with inflammatory bowel disease.

Biora is developing the PGN-600 program, which consists of a liquid formulation of tofacitinib delivered to the colon via the DDS capsule, for the treatment of ulcerative colitis. The company has shown preclinically in canines that successful targeted delivery using PGN-600 can lead to reduced drug levels in blood and increased drug levels in tissue at least 25 times higher along the length of the colon as compared to the equivalent standard oral dose. Biora expects to initiate a phase 1 safety clinical trial of PGN-600 in late 2022.

About Biora Therapeutics
Biora Therapeutics is the biotech company that is reimagining therapeutics. 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 of our research and development 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" 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 precision medicine, 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 future revenue generating 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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