Biora Therapeutics Announces Successful Completion of Device Performance Study in Ulcerative Colitis Patients for its Targeted Therapeutics Platform

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All Devices Successfully Detected Colon Entry in Patients with Active Ulcerative Colitis

SAN DIEGO, Aug. 10, 2022 (GLOBE NEWSWIRE) -- Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutics, today announced topline results from its recently completed study PM-602: A Scintigraphic Study to Evaluate the Localization and Delivery Function of a Drug Delivery System Capsule (DDS) in Subjects with Ulcerative Colitis in a Fasted State.

The study demonstrated that the device was well tolerated, and that the device performed as intended in active ulcerative colitis (UC) patients. In all seven patients, the device accurately identified entry into the colon, triggered release of a liquid payload, and achieved distribution across the entire colon.

“Given the different gastrointestinal physiology and disease activity in patients with active ulcerative colitis, it is critical that our device can accurately identify entry into the colon, activate, and release a payload in these patients,” said Sharat Singh, PhD, Head of Research at Biora Therapeutics. “The ability to detect colon entry and deliver drug across the entire colon is potentially transformative for the management of ulcerative colitis. We are not aware of any other oral drug delivery technology that can accurately detect colon entry, especially in the environment of inflammation, bleeding, and highly variable motility seen in active ulcerative colitis,” continued Dr. Singh.

“We have now completed three successful device function studies in humans that support the safety profile and performance of our targeted therapeutic device, in active UC patients and in healthy patients in both fed and fasted states,” said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. “These human studies are key steps in advancing toward our PGN-600 clinical program, and they also demonstrate the potential of the platform for localized delivery of other drugs.”

During the PM-602 study, Biora’s device was ingested orally by seven patients with active ulcerative colitis in a single dosage event. After identification of colon entry, the device released a saline solution payload that included radioisotopes. Serial gamma-scintigraphy images were used to independently determine device localization and payload delivery to the lower gastrointestinal tract. No investigational drug was administered during the study. More information on the PM-602 study will be released as analysis is completed and submitted for publication.

About Biora Therapeutics’ Targeted Therapeutics Platform
Biora Therapeutics’ targeted therapeutics platform utilizes a novel approach that could improve IBD patient outcomes by enabling delivery of therapeutics directly to the site of disease. The objective is to increase 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. Recent data have shown that targeted delivery of therapeutics has the potential to improve patient outcomes in IBD.

Biora’s Drug Delivery System (DDS) 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. Previous studies in healthy volunteers demonstrated accurate localization and delivery in a fasted state and also 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.

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.

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 and goals 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, risks related to the supply and manufacturing of and complexity of components in our devices, 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, competition from other companies, 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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