Biora Therapeutics Presents Data from Device Performance Study with Repeat Doses in Both Fasted and Fed States at Crohn's & Colitis Congress

January 19, 2023

Study demonstrates targeted delivery devices functioned as designed when administered with food, potentially enabling non-fasted administration

SAN DIEGO, Jan. 19, 2023 (GLOBE NEWSWIRE) -- Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today presented detailed results from its PM-611 study titled "Potential effects of food on a novel Drug Delivery System (DDS) to deliver therapeutic compound into the colon" during the Crohn's & Colitis Congress in Denver, CO, being held January 19-21, 2023.

"In this study, we assessed the safety and tolerability, localization, and delivery function of our DDS device with repeat device dosing in healthy volunteers, in a fasted state and with three different feeding schedules," said Sharat Singh, PhD, head of research at Biora Therapeutics. "Our results confirmed that the potential effect of food on the device function is minimal and suggest the possibility of administration without fasting or other food restriction, which could be an important consideration for patients, especially if under a daily dosing regimen," continued Dr. Singh.

"These final results indicate that our PGN-600 platform is potentially the first ingestible therapeutic delivery device to not require fasting or other food restriction for use," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "As we progress toward our IND filing during the first half of this year, we look forward to the significant impact this program could have on patient care for ulcerative colitis and other serious diseases."

The PM-611 study included multiple dosage events, with healthy volunteers ingesting four devices with four different fasting/fed scheduled over four weeks. A total of 46 devices were ingested by 12 participants. All devices were safely ingested and exited the body naturally, with no serious adverse events reported. No investigational drug was administered during the study. The poster can be viewed by visiting bioratherapeutics.com/publications.

With the completion of three successful device function studies in humans for its PGN-600 program focused on treatment of ulcerative colitis, Biora remains on track for an IND filing during the first half of 2023, followed by clinical trial initiation.

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, 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.

Biora's Drug Delivery System (DDS) is an ingestible device 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 device is designed to autonomously identify specific locations in the GI tract and release a therapeutic dose.

Biora is developing the PGN-600 program, which consists of a liquid formulation of tofacitinib delivered to the colon via the DDS device, for the treatment of ulcerative colitis. Studies in healthy volunteers have 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. 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 PGN-600 drug-device combination to evaluate drug concentration in tissue and plasma.

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 precision medicine, 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 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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