Biora Therapeutics Announces Successful Completion of Second Device Performance Study in Human Subjects for its Targeted Therapeutics Platform

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Study demonstrated device functioned as designed when administered with food, potentially enabling non-fasted administration

SAN DIEGO, July 07, 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-611: Safety and Functionality Assessment of the Drug Delivery System (DDS) Capsule in humans. The study assessed whether the autonomous location functionality of the ingestible devices was impacted by a fed state as compared to a fasted state.

The study demonstrated that all capsules were safely ingested and exited the body naturally, with no serious adverse events reported. Of the 39 analyzed capsules, all devices indicated entry to the colon, activation, and deployment, regardless of fasted or fed schedule, with no failure modes observed in the analyzed devices.

"To our knowledge, there is no currently available ingestible medical device for delivering drug that is designed to be taken with food," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "These data suggest that the DDS capsule could be the first ingestible therapeutic delivery device that does not require fasting or other food restriction for use. This could be an important consideration for patients who need frequent administration of dosing in chronic diseases like ulcerative colitis."

"Having now completed two successful studies in humans, we are expecting to report on our third human study, the PM-602 clinical device performance study in active ulcerative colitis patients, during the third quarter of this year," continued Mr. Mohanty. "This is another step toward our previously stated goal of initiating a phase 1 trial by year end."

The PM-611 study included multiple dosage events. Participants were required to ingest a total of four capsules each, with administration occurring following excretion of the previous capsule, as per study protocol. A total of 46 capsules were ingested by 12 participants, with one participant ingesting only two capsules. Forty-three capsules were recovered for analysis and performance was measured by retrieving data from the recovered devices. Data was successfully retrieved from 39 capsules.

No drug was administered during the study. The primary safety endpoints were the number, severity, expectedness, and type of device-related adverse events throughout the ingestion period. Effectiveness endpoints included evaluation of localization and delivery functions, such as autonomous identification of entry to the colon and subsequent deployment in both fasted and fed states. More information on the PM-611 study will be released as analysis is completed and submitted for publication.

About the Drug Delivery System (DDS) and PGN-600 Program
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 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 previously shown to have no adverse events and was accurate in identifying entry into the colon in a fasted state.

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 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, 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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