Biora Therapeutics Presents Clinical Data on Device Function of the NaviCap™ Platform at Digestive Disease Week 2024

May 20, 2024

Four clinical device performance studies successfully demonstrate the NaviCap platform's ability to deliver therapeutics directly to the colon under variable GI conditions and eating schedules

SAN DIEGO, May 20, 2024 (GLOBE NEWSWIRE) -- Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, presented a poster titled "Results of human device function studies for the NaviCap™ Targeted Oral Delivery Platform in healthy volunteers and patients with UC" at the Digestive Disease Week® conference in Washington DC, on Sunday, May 19, 2024.

"In four separate clinical studies, we evaluated the functionality and safety of the NaviCap device in healthy participants and in patients with active ulcerative colitis (UC)," said Ariella Kelman, MD, Chief Medical Officer of Biora Therapeutics. "The NaviCap device was well-tolerated in 81 administrations to 47 participants, releasing its payload in the colon, regardless of variable GI transit time, the level of inflammation, or the presence of blood in stool. The NaviCap platform's ability to function across variable GI conditions and eating schedules illustrates its potential to deliver therapeutics locally to the colon of patients with UC."

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 its payload.

Four clinical device performance studies evaluated the functionality and safety of the NaviCap device. Three studies (PM-601, PM-602, and BT-603) used gamma scintigraphy to assess delivery of radiolabeled payload into the colon in either healthy participants or patients with active UC, and one study (PM-611) assessed device function in healthy participants in both fasted and fed states. All devices were safely ingested and exited the body naturally, with no serious adverse events reported. No investigational drug was administered during the studies. The poster can be viewed by visiting bioratherapeutics.com/publications.

About Digestive Disease Week
Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and online meeting from May 18-21, 2024. The meeting showcases more than 5,600 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

About the NaviCap™ Targeted Oral Delivery Platform
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 anatomically targeted, direct delivery of therapeutics to the GI tract 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 recently announced completion of its Phase 1 SAD/MAD clinical trial to evaluate the safety and PK/PD of BT-600 in healthy volunteers. BT-600 is a drug-device combination consisting of the orally administered NaviCap™ device that delivers a unique, liquid formulation of tofacitinib directly to the colon for the potential treatment of moderate to severe ulcerative colitis. Highlights from the SAD interim results can be found in the corporate presentation on the company's website . Final SAD/MAD results are expected to be available in late Q2 2024.

About Biora Therapeutics
Biora Therapeutics 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 is focused on development of two therapeutics platforms: the NaviCap™ targeted oral delivery platformwhich is designed to improve outcomes for patients with inflammatory bowel disease through treatment at the site of disease in the gastrointestinal tract, and the BioJet™ systemic oral delivery platform, which is designed to replace injection for better management of chronic diseases through needle-free, oral delivery of large molecules.

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, preclinical and clinical trial activities, and partnering and collaboration efforts with third parties, 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,” “anticipate,” “forward,” “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 FDA filings and initiate and execute 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 or partners, our ability to raise sufficient capital to achieve our business objectives, 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, 2023 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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