Biora Therapeutics Announces Clinical Device Performance Study Results for its NaviCap™ Targeted Oral Delivery Platform

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Phase 1-ready device shows 100% success in human functional study of twelve subjects to date

SAN DIEGO, July 27, 2023 (GLOBE NEWSWIRE) -- Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today announced progress with its latest clinical device performance study, evaluating the device function and safety of its NaviCap™ targeted oral delivery platform.

“In this study evaluating twelve subjects to date, the NaviCap device accurately identified entry into the colon, triggered release of its non-drug payload, and achieved distribution throughout the colon in all subjects,” said Sharat Singh, PhD, Head of Research at Biora Therapeutics. “Importantly, we observed no early or late deployments,” continued Dr. Singh.

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.

“We are continuing to see excellent device performance in human studies with the NaviCap platform, following similar results in three previous functional studies in both healthy volunteers and patients with active ulcerative colitis,” said Ariella Kelman, MD, Chief Medical Officer of Biora Therapeutics. “With more than 40 study participants receiving over 70 NaviCap devices to date, the combined results build confidence as we proceed toward an IND application in the third quarter of this year for our BT-600 program for treatment of ulcerative colitis,” continued Dr. Kelman.

Biora’s BT-603 clinical device performance study was designed to evaluate the safety and tolerability of its phase 1-ready NaviCap device and the device’s localization and delivery function in healthy volunteers. During the study, NaviCap devices filled with a saline solution that included radioisotopes were ingested orally by healthy volunteers. Scintigraphic imaging was used to indicate device localization and payload delivery to the lower GI tract. No drug was administered as part of this study.

Sequential scintigraphic images of NaviCap delivery in a BT-603 study subject can be viewed on the company’s website .

About the NaviCap™ Targeted Oral Delivery Platform and BT-600
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 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 a therapeutic dose of up to 500µl.

Biora’s BT-600 program consists of a unique, liquid formulation of tofacitinib delivered to the colon via the NaviCap device, for the treatment of ulcerative colitis. Studies in healthy volunteers have demonstrated accurate localization and delivery in a fasted state and 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 BT-600 program during the second half of 2023.

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 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 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 therapeutics, 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 allowed patents or intended grants to result in issued or granted patents, our expectations regarding opportunities with current or future pharmaceutical collaborators, 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, 2022 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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