Biora Therapeutics to Host Virtual KOL Event on NaviCap™ Targeted Oral Delivery Platform and Results from Phase 1 Clinical Trial of BT-600 on July 17, 2024

July 8, 2024

SAN DIEGO, July 08, 2024 (GLOBE NEWSWIRE) -- Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company reimagining therapeutic delivery, today announced further details on its virtual event to be held on Wednesday, July 17, 2024. The event will feature Bruce Sands, MD, MS (Icahn School of Medicine at Mount Sinai) and Brian Feagan, MD, FRCPC (Schulich School of Medicine & Dentistry at the University of Western Ontario), who will discuss the unmet need and current treatment landscape for patients with ulcerative colitis (UC), as well as the value of colonic drug delivery for improving efficacy.

Biora leadership will highlight key results from the Phase 1 clinical trial of BT-600, an orally administered drug-device combination in development for the treatment of patients with ulcerative colitis (UC). BT-600 leverages Biora's ingestible NaviCap™ device to deliver a proprietary liquid formulation of tofacitinib directly to the colon.

"I look forward to sharing details of our Phase 1 results, which show the NaviCap platform reliably and precisely delivers drug throughout the colon, including the sites most commonly affected in patients with UC," said Ariella Kelman, MD, Chief Medical Officer of Biora Therapeutics. "Delivery of therapeutics directly to affected tissues in the colon could improve patient outcomes in UC. This clinical trial provides proof of concept for our anatomically targeted approach to therapeutic delivery and gives us confidence to study BT-600 next in patients with UC."

A live question and answer session will follow the formal presentations.

Virtual Event Details

Date:	Wednesday, July 17, 2024
Time:	2:00 PM Eastern / 11:00 AM Pacific time
Registration:	https://lifescievents.com/event/biora/

A replay will be available online following the event.

About Bruce Sands, MD, MS
Bruce Sands, MD, MS is the Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine at Mount Sinai, New York, NY. Dr. Sands was awarded his BA and MD from Boston University, and trained in internal medicine at the Hospital of the University of Pennsylvania. After completing GI fellowship at the Massachusetts General Hospital, he joined the faculty of Harvard Medical School and served as the Acting Chief of the Gastrointestinal Unit at MGH before moving to Mount Sinai in 2010 as Chief of the Dr. Henry D. Janowitz Division of Gastroenterology. Dr. Sands is widely recognized for his clinical investigations of new therapeutics for the inflammatory bowel diseases and has published over 250 original manuscripts. He was the lead investigator of the landmark studies ACCENT 2, UNIFI, and VARSITY, published in the New England Journal of Medicine.

About Brian Feagan, MD, FRCPC
Brian Feagan, MD, FRCPC is a Professor of Medicine at the Schulich School of Medicine & Dentistry at the University of Western Ontario, a gastroenterologist at London Health Sciences Centre in Ontario, Canada, and the Senior Scientific Director of Alimentiv, Inc. Dr. Feagan completed his MD at the University of Western Ontario, and his postdoctoral training included a residency in internal medicine and a clinical fellowship in gastroenterology in the Department of Medicine at UWO, and postgraduate training in the Department of Epidemiology and Biostatistics at McMaster University, Ontario. His research is focused on the development, validation and optimization of outcome measures to assess the efficacy of novel therapeutics in Crohn's disease (CD) and ulcerative colitis (UC), with a specific focus on the design and execution of large-scale randomized controlled trials. Dr. Feagan has been the principal investigator in over 140 multi-center randomized controlled trials in CD and UC.

About BT-600
BT-600 is a drug/device combination of Biora's NaviCap™ ingestible drug delivery device with a proprietary liquid formulation of tofacitinib, for the potential treatment of moderate to severe ulcerative colitis. The NaviCap device is orally administered and has been designed for anatomically targeted therapeutic delivery directly to the colon in this application.

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 activity 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 activity 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 ulcerative colitis. 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. Studies of the NaviCap device in healthy volunteers and patients with ulcerative colitis demonstrated successful delivery to the colon regardless of variable GI conditions, in both fasted and fed states.

About Ulcerative Colitis
Ulcerative colitis (UC) is a type of IBD that causes chronic inflammation and damage to the colon. Common symptoms include abdominal pain, increased bowel movements, stool urgency, and rectal bleeding. Despite the availability of advanced treatments for UC, including biologics, immunomodulators, and targeted synthetic small molecules, only about 40% of patients achieve clinical remission in induction trials. Surgical intervention is needed in approximately 20% of UC patients, with up to 10% of patients requiring surgical removal of the colon. About 1.5 million people are affected with UC in the United States alone, and ~40,000 new cases are diagnosed each year.

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 platform 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, 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 X.

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, our ability to maintain our listing on the Nasdaq Global Market, 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 Securities and Exchange Commission (SEC) and other subsequent documents, including Quarterly Reports on Form 10-Q, 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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