Biora Therapeutics Announces Positive Clinical Trial Results for BT-600

July 1, 2024

Drug-device combination leverages Biora's NaviCap ™platform to deliver tofacitinib directly to colonic tissue as a potential treatment for ulcerative colitis

BT-600 was well tolerated and met all trial objectives, demonstrating the NaviCap platform's ability to deliver therapeutics directly to the colon

Drug absorption in colonic tissue extended to distal colon, suggesting pan-colonic delivery

Company to host virtual event with key opinion leaders on July 17

SAN DIEGO, July 01, 2024 (GLOBE NEWSWIRE) -- Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company reimagining therapeutic delivery, today shared positive topline results from its clinical trial of BT-600, an orally administered drug-device combination in development for the potential 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. Results from this Phase 1 clinical trial involving 48 healthy volunteers met all trial objectives, with demonstrated drug absorption in colonic tissue that extended to the distal colon, suggesting pan-colonic delivery. Daily dosing with BT-600 was well tolerated by all participants.

"Successful completion of our Phase 1 clinical trial is an important milestone for Biora," said Ariella Kelman, MD, Chief Medical Officer of Biora Therapeutics. "All study objectives were met, and we confirmed that the NaviCap platform can deliver tofacitinib topically to the colon, with lower peak systemic exposure than with conventional oral delivery. These results support our plan to advance BT-600 into our Phase 1b clinical trial in patients with UC."

"We are extremely encouraged by the results from this trial, which demonstrate the NaviCap platform's ability to deliver drug to the location of disease, where it's needed," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "Our anatomically targeted approach has the potential to improve the efficacy of JAK inhibitors and other drug classes. We envision a portfolio of NaviCap-delivered therapeutics unlocking new treatment potential for patients with GI diseases."

"I would like to thank the study participants, clinicians, and our Biora team for conducting such a well-executed trial," continued Mr. Mohanty. "Our team continues to execute at a high level as we meet our NaviCap platform milestones, while the BioJet™ platform is also progressing well and is on track to meet our previously stated goals."

Summary of Key BT-600 Phase 1 Trial Results
Results from the Phase 1 clinical trial demonstrate a pharmacokinetic (PK) profile consistent with drug delivery and absorption in the colon for both single and multiple ascending dose (SAD/MAD) cohorts.

- First evidence of systemic absorption of tofacitinib was at six hours, consistent with colonic (vs. upper gastrointestinal) delivery. Maximal levels in the trial occurred at eight to ten hours vs. 30 minutes for conventional oral tofacitinib in other trials.
- Maximal systemic drug exposure was three to four times lower than that seen with conventional oral tofacitinib in other trials, demonstrating the NaviCap platform's ability to deliver locally to the colon and limit systemic drug exposure.

The distribution of colon tissue exposure suggests that pan-colonic delivery of tofacitinib was achieved.

- Sites in the distal colon were biopsied, following delivery of tofacitinib in the proximal colon, for evidence of tissue drug exposure
- Biopsy results provided evidence of drug exposure extending to the distal colon, at common sites of disease.
- Post-retrieval device analysis further confirmed that NaviCap devices accurately delivered drug in the colon, with 100% of devices (SAD) and 98% of devices (MAD) detecting colon entry.

NaviCap devices were well tolerated by participants in both the SAD and MAD cohorts.

Virtual Event Details
The company will host a KOL event with members of management and its Clinical Advisory Board to provide additional details regarding the Phase 1 trial and plans for the next phase of clinical development.

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

Attendees may register in advance using the webcast link above. A replay will be available online following the event.

Phase 1 Clinical Trial Design
The objectives of this Phase 1 randomized, double-blind, placebo-controlled, single and multiple ascending dose (SAD/MAD) clinical trial were to evaluate the safety and pharmacokinetics of BT-600 when administered orally in healthy adult participants. The trial, which was conducted in the United States, consisted of two parts: The first part was comprised of 24 participants receiving a single ascending dose of BT-600 with tofacitinib at 5 mg or 10 mg doses or placebo. The second part was comprised of 24 participants receiving multiple ascending-doses of BT-600 with tofacitinib at 5 mg or 10 mg doses or placebo daily for 7 days. The trial is listed at clinicaltrials.gov (NCT06275464). The "other trials" referred to in the summary of the Phase 1 clinical trial results above were conducted at different times, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made and no head-to-head clinical trials have been conducted.

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, including those involving BT-600 and our NaviCap platform, 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 "envision," "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "anticipate," "forward," "believe," "design," "estimate," "predict," "potential," "plan," "goal(s)" "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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