



Biora Therapeutics Achieves Positive Interim Results for Clinical Trial of BT-600, Advancing NaviCap™ Platform Development

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All pharmacokinetic endpoints were achieved, with a PK profile consistent with drug delivery and absorption in the colon

All NaviCap™ devices performed as intended and were well tolerated, with no safety signals observed

Multiple-ascending dose (MAD) portion of the trial is underway and progressing well

SAN DIEGO, April 04, 2024 (GLOBE NEWSWIRE) -- [Biora Therapeutics, Inc.](#) (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today shared additional positive interim results from the single-ascending dose (SAD) clinical trial of BT-600, which is a drug-device combination consisting of the orally administered NaviCap™ device that delivers a proprietary liquid formulation of tofacitinib to the colon. BT-600 is being developed for the potential treatment of patients with ulcerative colitis (UC). The SAD portion of the phase 1 randomized, double-blind, placebo-controlled clinical trial tested the tolerability and pharmacokinetics of BT-600 at 5 mg and 10 mg doses of tofacitinib, compared to placebo, in healthy adult participants.

"We are extremely pleased with the interim trial results, some of which we shared during our recent quarterly call, that demonstrate the NaviCap platform's unique ability to achieve localized delivery to the colon, with a corresponding reduction in systemic drug exposure," said Ariella Kelman, MD, Chief Medical Officer of Biora Therapeutics. "Direct delivery of JAK inhibitors to the colon has potential for improved efficacy driven by increased colonic tissue exposure, while reducing toxicity risks related to systemic exposure. We believe this could lead to better outcomes for patients suffering from UC."

According to the interim clinical data, all pharmacokinetic endpoints were met in all study participants. BT-600 was well tolerated with no serious adverse events. All devices performed as intended, with all participants receiving BT-600 showing systemic drug absorption. Tofacitinib was first detected in plasma at approximately six hours following administration, which is consistent with colonic delivery as opposed to absorption in the upper GI tract. The mean time to reach maximum concentration (T_{max}) was 8–10 hours following administration of BT-600, versus 0.5-1.0 hours for conventional oral tofacitinib. Tofacitinib was present in fecal samples of all subjects, further confirming delivery of the drug in the colon.

Colonic delivery of BT-600 was associated with 3–4x lower systemic absorption of tofacitinib, with a maximum plasma concentration (C_{max}) of 26 ng/mL for BT-600 at the 10 mg dose of tofacitinib, versus 88 ng/mL for conventionally administered oral tofacitinib at a 10 mg dose.

"Many IBD drugs could benefit from localized delivery—research shows that for JAK inhibitors, integrin inhibitors and TNF inhibitors, higher colon tissue concentrations correlate with better outcomes," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "Our NaviCap platform represents a new therapeutic approach to UC and beyond. We continue to demonstrate that our localized delivery technology can enable higher colon tissue concentrations, without subjecting patients to high systemic drug levels, and results from the SAD portion of our clinical trial further confirm the platform's capability."

Highlights from the interim results can be found [in the corporate presentation on Biora's website](#).

The multiple-ascending dose (MAD) portion of the trial, currently underway, will evaluate daily doses of BT-600 for 7 days at 5 mg and 10 mg tofacitinib or placebo. Final results are expected to be available in late Q2 2024.

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 are to evaluate the safety, pharmacokinetics and pharmacodynamics, including effects on colon tissue, of BT-600 when administered orally in healthy adult participants. The study, which is being conducted in the United States, consists of two parts. The first part is 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 is 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 \(NCT06275464\)](#).

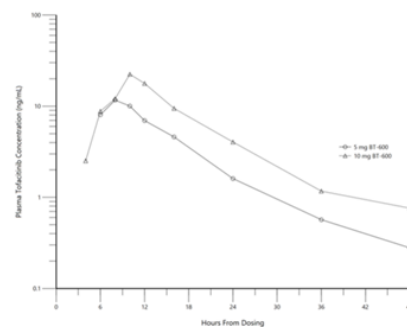
About the NaviCap™ Targeted Oral Delivery Platform

[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 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

Mean Plasma Tofacitinib Concentration

MEAN PLASMA TOFACITINIB CONCENTRATION FOLLOWING ADMINISTRATION OF A SINGLE ORAL DOSE OF 5 mg AND 10 mg BT-600



Following administration of a single oral dose of 5 mg and 10 mg BT-600

500µl. 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 UC also [demonstrated successful device performance in active UC patients](#).

About Ulcerative Colitis

Ulcerative colitis (UC) is a chronic disease that causes 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 clinical-stage [NaviCap™ targeted oral delivery platform](#) which is designed to improve outcomes for patients with inflammatory bowel disease through treatment at the site of disease in the gastrointestinal tract, and the preclinical-stage [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 efforts including our BT-600 clinical trial execution and data timelines, 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," "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 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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A photo accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/9067f7a9-c86c-419f-9741-1e7c5cca0a40>