# Biora Therapeutics Announces Supplemental Data from Phase 1 Clinical Trial of BT-600 as Presented at KOL Event

July 18, 2024

*Pharmacokinetic and tissue data confirm NaviCap platform delivers topically through the entire colon, with lower systemic concentrations, as desired*

*Data modeling suggests tofacitinib tissue concentrations greater than IC90 through at least 16 hours after dosing*

SAN DIEGO, July 18, 2024 (GLOBE NEWSWIRE) -- Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company reimagining therapeutic delivery, presented supplemental data from the Phase 1 trial of BT-600 during the company's virtual KOL event on Wednesday, July 17, 2024. BT-600, an orally administered drug-device combination, is 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.

"We are excited by the colon tissue drug exposure we are seeing in this trial," said Ariella Kelman, MD, Chief Medical Officer of Biora Therapeutics. "We observed levels above the IC50 at 24 hours and five half-lives after dosing, despite extensive pre-procedure colon prep. We know higher tissue levels are associated with better responses to tofacitinib in UC, and our model projects tissue levels well above IC90 through at least 16 hours post dose. This is especially notable since we studied daily doses of 5 mg and 10 mg in this trial, which are 50–75% lower than approved doses for conventional tofacitinib. We also observed lower systemic concentrations, which may be associated with reduced toxicity risks."

Tissue biopsies were performed to assess drug concentration in colonic tissues at 24 hours after dosing during the Phase 1 trial in healthy participants. Mean tissue concentrations for the splenic flexure, descending colon, and sigmoid colon were above the established IC50 for the JAK-STAT pathway, and a strong correlation was shown between tissue and corresponding plasma levels. The plasma/tissue correlation was used to model tissue levels at earlier time points, with the model projecting tissue levels above the IC90 through at least 16 hours after BT-600 5 mg or 10 mg doses.

"The results of this trial confirm that BT-600 can deliver drug topically throughout the length of the colon and could achieve both of our pharmacokinetic goals: higher tissue exposure and lower systemic concentrations. This certainly gives us confidence as we move into our planned clinical trial in UC patients," continued Dr. Kelman.

"There is an urgent need to break the therapeutic ceiling of 20–30% remission rates over placebo in UC," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "We plan to break through by changing the way gastrointestinal diseases are treated with our NaviCap platform, which can reliably deliver to specific locations within the GI tract. The clinical trial results for our current program, BT-600, demonstrate its potential and also provide proof of concept for the NaviCap platform's ability to deliver other molecules and drug classes in UC and beyond."

Biora's virtual KOL event on July 17 featured 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 discussed the unmet need and current treatment landscape for patients with UC, as well as the value of colonic drug delivery for improving efficacy. A replay of the live event can be accessed on the company's website.

**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.
- Biopsy results provided evidence of drug exposure extending to the distal colon, at common sites of disease.
- Modeling projects tissue levels at or above the estimated IC90 through at least 16 hours after dosing.
- Post-retrieval device analysis further confirmed that NaviCap devices accurately delivered drug in the colon, with no early release, and with >95% of devices detecting colon entry.

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

- All AEs were mild and consistent with those expected in a healthy population.
- No evidence of device or drug colon toxicity; colon tissue histology was within normal limits.
- There were no notable changes or differences in safety laboratory parameters between groups.

**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 model projections, 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," "projects," "projecting," "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.

**Investor Contact**
Chuck Padala
Managing Director, LifeSci Advisors
IR@bioratherapeutics.com
(646) 627-8390

**Media Contact**
Liz Robinson
CG Life
lrobinson@cglife.com