



Biora Therapeutics Announces Submission of IND Application to the U.S. FDA for BT-600 Program

September 25, 2023

BT-600 is a drug/device combination delivering a liquid formulation of tofacitinib via the NaviCap™ platform for the treatment of ulcerative colitis

IND application is supported by robust clinical device function data

SAN DIEGO, Sept. 25, 2023 (GLOBE NEWSWIRE) -- [Biora Therapeutics, Inc.](#) (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today announced submission of an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA). The IND application supports the next phase of development of BT-600, a drug/device combination designed to use Biora's NaviCap™ ingestible drug delivery device with a proprietary liquid formulation of tofacitinib, for the treatment of moderate to severe ulcerative colitis.

"Today's announcement is an important milestone for Biora Therapeutics. The IND application leverages clinical device function study data from four separate studies in both healthy volunteers and patients with active ulcerative colitis, with more than 40 study participants receiving over 80 NaviCap devices," said Ariella Kelman, MD, Chief Medical Officer of Biora Therapeutics. "We look forward to initiating our phase 1 study in the US this year and advancing this technology, which we believe could lead to better patient outcomes in ulcerative colitis," continued Dr. Kelman.

The IND application for BT-600 includes extensive manufacturing, preclinical, human device function, and toxicology data to support a first-in-human clinical trial for BT-600. The phase 1 trial of BT-600 is expected to be a randomized, double-blind, placebo-controlled study to evaluate safety, pharmacokinetics and pharmacodynamics, including effects on colon tissue, in healthy volunteers receiving the NaviCap device filled with a novel liquid formulation of tofacitinib at 5 mg and 10 mg doses. The NaviCap device has been designed for targeted delivery directly to the colon in this application.

The FDA will review the application and determine the acceptability of the data before Biora begins its first clinical trial for BT-600. It is possible that the FDA will require additional information.

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 Gltrac™ 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 submitted an Investigational New Drug (IND) application to begin a phase 1 study for its BT-600 program in September, 2023.

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](#) 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 [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 including phase 1 trial readiness, FDA acceptance, and trial commencement, 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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