

Biora Therapeutics Announces Improved Bioavailability Results for its Systemic Delivery Platform

February 16, 2023

Average bioavailability greater than 50% with high consistency observed in animal study

SAN DIEGO, Feb. 16, 2023 (GLOBE NEWSWIRE) -- Biora Therapeutics. Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today announced preliminary results from preclinical testing of its PGN-OB1 program, reporting an average bioavailability greater than 50% for a variant of adalimumab.

"In this preclinical study, we assessed the bioavailability of a variant of adalimumab when delivered via our liquid jet injection technology in a porcine model. Following administration of 56 mg of Biora's adalimumab variant (a dose similar to those of subcutaneously administered monoclonal antibodies), drug was detected in the blood in all animals with an average bioavailability of 51.3%, and variability similar to that seen with subcutaneous injection," said Sharat Singh, PhD, Head of Research at Biora Therapeutics. "These results are important, not only for the level of bioavailability, but also because of the relatively low variability, which demonstrate the potential of our liquid jet delivery technology to perform comparably to subcutaneous injection," continued Dr. Singh.

"To achieve this level of oral bioavailability with an over 50 mg dose of a monoclonal antibody similar to Humira[®] represents an important and significant development step forward in our program for oral delivery of biologics," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "As previously shared, we have been working on a next-generation device for our systemic delivery platform and we were looking to achieve at least the same level of performance as our previous generation device. We are thrilled with the results to date, which not only surpassed our previous average bioavailability of 25% in animal models, but also exceeded our expectations in regard to the consistency of the data," continued Mr. Mohanty. "Our work continues toward finalizing this next-generation autonomous device for preclinical use over the coming months, which we anticipate will enable us to progress our pharma collaboration opportunities and help us achieve our partnering goals this year."

The preclinical study included a single dose of 56 mg of a variant of adalimumab with a total of nine animals, using an improved version of Biora's liquid jet delivery device, which was administered and activated endoscopically, as is typical in a porcine model. The company expects to release detailed results in conjunction with planned presentation of the data.

Biora's proprietary systemic delivery platform uses liquid jets to deliver drug into the small intestine for systemic absorption, without the use of needles. The platform is designed to deliver almost any liquid drug, without requiring reformulation. Biora holds a comprehensive patent position with approximately 34 patents and applications that cover its delivery platform and methods for using the platform to treat a disease or condition in a patient using liquid jet delivery of a wide range of drugs. The company is planning additional preclinical studies during 2023 to evaluate the autonomous version of its next-generation device.

About Biora Therapeutics' Systemic Therapeutics Platform

Biora Therapeutics' systemic therapeutics platform uses an ingestible capsule for needle-free, oral delivery of biotherapeutics, using proprietary liquid jet delivery to achieve systemic bioavailability. Once swallowed, the device is <u>designed to transit through the digestive system and activate in the small intestine</u>, where liquid jets deliver drug directly into the intestinal tissue for uptake into systemic circulation. The capsule is approximately the size of a multivitamin and can deliver a wide range of large molecules, such as proteins, peptides, and nucleic acids, in liquid formulation up to 400µL.

Biora is developing multiple molecules under its systemic delivery platform, including PGN-OB1, a drug-device combination consisting of a variant of adalimumab delivered via the OBDS device, for the treatment of inflammatory conditions, and PGN-OB2, which consists of a GLP-1 receptor agonist delivered via the OBDS device, for the treatment of type 2 diabetes. The company is currently advancing development of the platform with <u>preclinical studies</u>.

About Biora Therapeutics

Biora Therapeutics is the biotech company that 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 envisions a world where patients have access to needle-free drug delivery and better therapeutic outcomes.

For more information, visit bioratherapeutics.com or follow the company on LinkedIn or Twitter.

Humira is a registered trademark of AbbVie, Inc.

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, 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 opportunities with current or future pharmaceutical collaborators, our ability to raise sufficient capital to achieve our business objectives, the ongoing COVID-19 pandemic, 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, 2021 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.

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

Media Contact media@bioratherapeutics.com