Biora Therapeutics Announces Bioavailability Results for Oral Delivery of GLP-1 Receptor Agonist

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Preclinical data demonstrate potential to orally deliver peptides and monoclonal antibodies at bioavailability levels more than double the company's current target

SAN DIEGO, Feb. 23, 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-OB2 program, reporting an average bioavailability of 37% for semaglutide, a GLP-1 receptor agonist. Semaglutide is currently marketed as two subcutaneously administered formulations under the brand names Ozempic® for the treatment of diabetes and Wegovy® for weight management. An oral formulation of a GLP-1 molecule that uses a different delivery technology, brand name Rybelsus®, is also currently marketed for the treatment of diabetes, with studies demonstrating bioavailability of less than 1%.[1]

"In this preclinical study, we assessed the bioavailability of semaglutide when delivered via our liquid jet technology in a porcine model. Following administration of semaglutide, drug was detected in blood with an average bioavailability of 37%, and with variability similar to that observed by others with subcutaneous injection," said Sharat Singh, PhD, Head of Research at Biora Therapeutics. "The only oral GLP-1 receptor agonist available today is about 1% bioavailable. Despite its low bioavailability, there is remarkable patient demand for the oral formulation. Based on our recent preclinical study results, we believe we can achieve significantly higher oral bioavailability with our ingestible pill," continued Dr. Singh.

"These results demonstrate the potential of our oral liquid jet delivery technology to deliver multiple large molecules, with first a monoclonal antibody, as we announced recently, and now a peptide both exceeding a bioavailability target of 15% set by us and our pharma collaborators for progression of the platform," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "With strong patent protection for our liquid jet delivery platform and methods to deliver a range of drugs, including a patent that covers jet delivery of any GLP-1 receptor agonist to the small intestine, our work continues toward finalizing this next-generation device over the coming months and subsequently progressing our pharma collaborations."

Biora's PGN-OB2 preclinical study included a single dose of a liquid formulation of 0.96 mg of semaglutide, a GLP-1 receptor agonist. Eight animals were dosed using the liquid jet delivery device, which was administered and activated endoscopically, as is typical in a porcine model, with comparison to a control animal with drug administered intravenously. 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's patent portfolio includes U.S. Patent No. 11,439,802 entitled, "Ingestible device for delivery of therapeutic agent to the gastrointestinal tract", which is directed to methods for using an ingestible device to treat a disease or condition in a patient using jet delivery of a glucagon receptor agonist (RA) or a glucagon-like peptide-1 (GLP-1) receptor agonist formulation, such as semaglutide, to the small intestine to achieve systemic uptake. Biora previously announced that it achieved average bioavailability of >50% with adalimumab, a monoclonal antibody, using the same platform. The company is planning additional preclinical studies during 2023 to evaluate the autonomous version of its next-generation systemic delivery 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 designed to transit through the digestive system and activate in the small intestine, 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 preclinical studies.

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.

Ozempic®, Wegovy®, and Rybelsus® are registered trademarks of Novo Nordisk A/S.

1. Overgaard RV, Navarria A, Ingwersen SH, Bækdal TA, Kildemoes RJ. Clinical Pharmacokinetics of Oral Semaglutide: Analyses of Data from Clinical Pharmacology Trials. *Clin Pharmacokinet*. 2021;60(10):1335-1348.

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.

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