Biora Therapeutics Shares Preclinical Data on Oral Delivery of Biologics at Controlled Release Society 2022

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Demonstrates OBDS Device Performance and Bioavailability in Animal Models

SAN DIEGO, July 14, 2022 (GLOBE NEWSWIRE) -- Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutics, today shared two posters that were presented at the Controlled Release Society (CRS) 2022 Annual Meeting, which is being held July 11-15, 2022, in Montreal, Canada. CRS is an international gathering of experts in the design, development, and implementation of novel drug delivery technologies.

"We are presenting results of early preclinical research on our systemic therapeutics platform at CRS, where we have developed preclinical models that enable further evaluation of device performance and pharmacokinetics," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "We also presented the results of a preclinical study, where we demonstrated monoclonal antibody bioavailability of up to 55% with an average of 25% in animals with drug detected in blood. This is an order of magnitude greater than current oral protein or peptide delivery methods."

The company presented a poster titled "Assessing the performance of an oral biotherapeutic delivery system (OBDS) using intra-duodenal endoscopy delivery in *Yucatan* minipigs," in which researchers for the company developed a method for endoscopic administration of OBDS capsules in a swine model, enabling preclinical evaluation of device performance and pharmacokinetics. Functionality of the endoscopic delivery method was demonstrated, showing that all OBDS capsules were successfully released in the small intestine to transit naturally and autonomously deploy in the intestine. Eight animals showed detectable drug levels of a variant of adalimumab with an oral bioavailability average of 25% (range from 7-55%), excluding one animal with a late deployment at 72 hours post-dose.

Biora also presented a poster titled "Development of *ex-vivo* and *in-vivo* models to assess the performance of an oral biotherapeutic delivery system (OBDS) capsule," which presented preclinical research used to determine the appropriate animal models to use for future assessment of device performance and pharmacokinetics for the OBDS capsule. The company demonstrated that due to similarity of human and swine intestine anatomy, a swine model is appropriate for assessment of bioavailability and human translational studies. However, the difficulties of oral delivery in swine support the use of a canine model for assessment of consistency and reproducibility. Researchers successfully demonstrated ≥83% deployment accuracy of OBDS capsules in the canine small intestine, and consistent deployment time post gastric emptying without early deployment in the stomach.

The posters can be viewed by visiting bioratherapeutics.com/publications.

About the Oral Biotherapeutics Delivery System (OBDS) and PGN-OB1
Biora Therapeutics' systemic therapeutics platform uses an ingestible smart capsule for needle-free, oral delivery of biotherapeutics, with the potential to deliver a broad range of large molecules including monoclonal antibodies, peptides, and nucleic acids. These substances cannot survive stomach acids and are too large to be absorbed in the intestine and, therefore, are currently delivered by injection. With more frequent administration, oral delivery has the potential to improve drug efficacy and safety profiles compared to current injection regimens.

Biora's Oral Biotherapeutics Delivery System (OBDS) is an ingestible capsule designed to use proprietary liquid jet delivery to increase systemic uptake and bioavailability of large molecules. Once swallowed, the capsule is designed to transit through the digestive system and trigger in the small intestine, where liquid jets deliver drug directly into the intestinal mucosa. The capsule is approximately the size of a multivitamin and can deliver up to 400µL of liquid formulation, such as proteins, peptides, and nucleic acids.

Biora is developing the PGN-OB1 program, which consists of a variant of adalimumab (PGN-001) delivered via liquid jet to the small intestinal mucosa using the OBDS capsule, for the treatment of inflammatory diseases. An oral variant of adalimumab presents a significant opportunity for the many patients who would like to avoid painful injections. The company has observed an average of 22% bioavailability in animals where drug was detected in blood across multiple early preclinical studies. These preclinical studies are intended to enable the first human studies to evaluate safety and device performance of the OBDS capsule in late 2022.

About Biora Therapeutics
Biora Therapeutics is the biotech company that is reimagining therapeutics. 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.

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 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" 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 precision medicine, 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 future revenue generating 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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