Biora Therapeutics Achieves ISO 13485 Certification

September 9, 2024

Underscoring the company's commitment to quality and excellence

SAN DIEGO, Sept. 09, 2024 (GLOBE NEWSWIRE) -- Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company reimagining therapeutic delivery, today announced it has been awarded ISO 13485:2016 certification by TÜV SÜD America, demonstrating the company's commitment to compliance with the most rigorous global regulatory and quality standards.

"We are proud of the robust systems our team has built, ensuring stringent control over development and manufacturing processes," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "This certification demonstrates our ongoing ability to meet exacting regulatory requirements as we continue to achieve clinical and developmental milestones for the NaviCap™ and BioJet™ platforms."

Biora successfully completed audits by TÜV SÜD America to verify that it has established and is maintaining a quality management system that meets all requirements of the ISO 13485:2016 standard for design, development, manufacturing, and distribution of Biora's products.

ISO 13485 is an internationally recognized quality standard for quality management systems, created by the International Organization for Standardization to ensure the safety and effectiveness of medical devices. It builds on the ISO 9001 standard with additional regulatory requirements specific to medical devices. In 2024, the U.S. Food and Drug Administration issued the Quality Management System Regulation (QMSR) Final Rule, which harmonizes U.S. requirements with global standards through the adoption of ISO 13485 standards for medical devices.

About Biora Therapeutics
Biora Therapeutics is a clinical-stage biotech developing two smart pill-based therapeutics platforms: the NaviCap™ platform for colon-targeted treatment of IBD, designed to improve patient outcomes through treatment at the site of disease in the gastrointestinal tract, and the BioJet™ platform for oral delivery of large molecules, designed to replace injection with needle-free, oral delivery with minimal changes to standard liquid formulations.

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-based data projections for the BT-600 program, 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.

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