



Biora Therapeutics Announces Issuance of Key Patent for Oral Delivery of GLP-1 Receptor Agonists

September 13, 2022

Patent Covers Jet Delivery of GLP-1 Receptor Agonists to the Small Intestine for Treatment of Any Disease Including Type 2 Diabetes

SAN DIEGO, Sept. 13, 2022 (GLOBE NEWSWIRE) -- [Biora Therapeutics, Inc.](#) (Nasdaq: BIOR), the biotech company that is reimagining therapeutics, announced today that the United States Patent and Trademark Office (USPTO) has issued a patent related to the company's technologies for oral, systemic delivery of biologics, which uses an ingestible device designed to achieve systemic uptake through liquid jet delivery to the small intestine.

The USPTO has issued U.S. Patent No. 11,439,802 entitled, "Ingestible device for delivery of therapeutic agent to the gastrointestinal tract." The patent 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 to the small intestine to achieve systemic uptake.

GLP-1 receptor agonists are a class of drug approved for type 2 diabetes and weight loss but are also being evaluated by other parties in other diseases including fatty liver disease and atrial fibrillation. According to leading analytics firm GlobalData, the GLP-1 receptor agonist market is forecasted to be well over \$20 billion by 2025, with multiple billion-dollar drugs including Victoza[®], Trulicity[®], Ozempic[®], Rybelsus[®], and Mounjaro[®].

"This latest patent is important for us because it generally covers oral delivery of any GLP-1 RA using an ingestible device and jet delivery to the small intestine," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "It strengthens the intellectual property position for our PGN-OB2 candidate, which consists of a GLP-1 receptor agonist delivered via liquid jet into the small intestinal tissue for the treatment of type 2 diabetes," continued Mr. Mohanty. "The only oral GLP-1 receptor agonist available today is about 1% bioavailable. We believe we can do significantly better than that, having already shown preclinical bioavailability averaging over 20% with proteins."

While patent 11,439,802 is directed to methods of jet delivery of GLP-1 receptor agonist formulations to the small intestine, Biora Therapeutics also holds device patents and applications directed to its OBDS ingestible device, including U.S. Patent No. 11,007,356 entitled, "Ingestible device for delivery of therapeutic agent to the gastrointestinal tract." Biora Therapeutics' robust patent portfolio consists of 82 patent families, including approximately 170 issued patents and more than 170 pending applications worldwide, following the transfer of its liquid biopsy-related intellectual property to [Enumeram Molecular](#). The portfolio includes patents and applications directed to devices (including gastrointestinal "GI" localization, targeted delivery to the GI tract, jet delivery into GI tissue, and GI sampling), therapeutic treatment via ingestible devices (including PK/PD profiles, dosing regimens, drug combinations, and liquid drug formulations) and sampling and diagnostics (including sample preservation, testing, diagnostic markers, and protein and nucleic acid markers and assays).

About Biora Therapeutics' Systemic Therapeutics Platform

[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. 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-OB2** program, which consists of a GLP-1 receptor agonist delivered via liquid jet into the small intestinal tissue using the OBDS capsule, for the treatment of type 2 diabetes. Oral GLP-1 receptor agonists are preferred by patients, and research indicates that people who start treatment with an injectable GLP-1 receptor agonist have a 71% higher discontinuation rate than those starting oral therapy. The company is currently advancing development of PGN-OB2 with preclinical studies.

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](#).

Victoza[®], Trulicity[®], Ozempic[®], Rybelsus[®], and Mounjaro[®] are registered trademarks held by their respective owners.

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, risks related to the supply and manufacturing of and complexity of components in our devices, 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, competition from other companies, 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