Revance Resubmits Biologics License Application for DaxibotulinumtoxinA for Injection for Glabellar Lines to the FDA

March 8, 2022

NASHVILLE, Tenn.--(BUSINESS WIRE)--Mar. 8, 2022-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company focused on innovative aesthetic and therapeutic offerings, today announced it has resubmitted its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for DaxibotulinumtoxinA for Injection for the treatment of moderate to severe glabellar lines in response to the Complete Response Letter (CRL) issued by the FDA in October 2021.

The resubmission follows the company's Type A meeting in December 2021 and the subsequent completion of the production of three consecutive drug substance lots and one drug product lot as part of the qualification of a new working cell bank (WCB), which was required by the FDA to address the outstanding observations related to the WCB and the drug substance manufacturing process.

About Revance

Revance is a commercial stage biotechnology company focused on innovative aesthetic and therapeutic offerings, including its next-generation, long-acting neuromodulator product, DaxibotulinumtoxinA for Injection. Revance has successfully completed Phase 3 clinical programs for DaxibotulinumtoxinA for Injection in glabellar (frown) lines, for which the company is currently pursuing U.S. regulatory approval, and in cervical dystonia. Revance is also evaluating DaxibotulinumtoxinA for Injection in adult upper limb spasticity. Revance owns a unique portfolio of premium products and services for U.S. aesthetics practices, including the exclusive U.S. distribution rights to the RHA® Collection of dermal fillers, the first and only range of FDA-approved fillers for correction of dynamic facial wrinkles and folds, and the OPUL™ Relational Commerce Platform. Revance has also partnered with Viatris (formerly Mylan N.V.) to develop a biosimilar to BOTOX®, which if approved, would be the first and only generic biosimilar to Botox® and Botox® Cosmetic. For more information or to join our team visit us at www.revance.com.

Forward Looking Statements

Any statements in this press release that are not statements of historical fact, including statements related to the requirements to address the FDA's observations and obtain regulatory approval of DaxibotulinumtoxinA for Injection in glabellar lines and our development of a biosimilar to BOTOX® with our partner, Viatris, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, events, circumstances or achievements reflected in the forward-looking statements will ever be achieved or occur.

Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from our expectations. These risks and uncertainties relate, but are not limited to: the results, timing, costs, and completion of our research and development activities and regulatory approvals; our ability to remediate deficiencies identified by the FDA and obtain FDA approval of the BLA for DaxibotulinumtoxinA for Injection for glabellar lines, including as a result of observations made by the FDA during the site inspection or other reasons; our ability to obtain funding for our operations; the timing of capital expenditures; the accuracy of our estimates regarding expenses, future revenues, capital requirements, our financial performance and the economics of DaxibotulinumtoxinA for Injection, the RHA® Collection of dermal fillers and OPUL™; the impact of the COVID-19 pandemic on our manufacturing operations, supply chain, end user demand for our products and services, the aesthetics market, commercialization efforts, business operations, regulatory meetings, inspections and approvals, clinical trials and other aspects of our business and on the market; our ability and the ability of our partners to manufacture supplies for our product candidates and to acquire supplies of the RHA® Collection of dermal fillers; the uncertain clinical development process, the risk that clinical trials may not have an effective design or generate positive results or that positive results would assure regulatory approval or commercial success; the applicability of clinical study results to actual outcomes; the rate and degree of economic benefit, safety, efficacy, commercial acceptance, market, competition and/or size and growth potential of the RHA® Collection of dermal fillers, OPUL™ and our drug product candidates, if approved; our ability to continue to successfully commercialize the RHA® Collection of dermal fillers and OPUL™ and our ability to successfully commercialize DaxibotulinumtoxinA for Injection, if approved, and the timing and cost of commercialization activities; the proper training and administration of our products by physicians and medical staff; our ability to expand sales and marketing capabilities; the status of commercial collaborations; changes in and failures to comply with privacy and data protection laws; our ability to effectively manage our expanded operations in connection with the acquisition of Hint, Inc; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; the cost and our ability to defend ourselves in product liability, intellectual property, class action or other lawsuits; the volatility of our stock price; and other risks. Detailed information regarding factors that may cause actual results to differ materially from the results expressed or implied by statements in this press release may be found in our periodic filings with the Securities and Exchange Commission (SEC), including factors described in the section entitled "Risks Factors" in our Form 10-K, filed with the SEC on February 28, 2022. The forward-looking statements in this press release speak only as of the date hereof. We disclaim any obligation to update these forward-looking statements.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220308005603/en/

Investors
Revance Therapeutics, Inc.:
Jessica Serra, 626-589-1007
Jessica.serra@revance.com
or
Gilmartin Group, LLC.:
Laurence Watts, 619-916-7620
laurence@gilmartinir.com

Media
Revance Therapeutics, Inc.:
Sara Fahy, 949-887-4476
sfahy@revance.com

Source: Revance Therapeutics, Inc.