# Revance Submits Supplemental Biologics License Application (sBLA) for DAXXIFY™ (DaxibotulinumtoxinA-lanm) for Injection for the Treatment of Cervical Dystonia

October 20, 2022

*- sBLA filing based on the pivotal ASPEN Phase 3 program demonstrating DAXXIFY's median duration of response of 24 weeks in the treatment of cervical dystonia*

*- Anticipated PDUFA target action date in 2023*

NASHVILLE, Tenn.--(BUSINESS WIRE)--Oct. 20, 2022-- Revance Therapeutics, Inc. (Nasdaq: RVNC) a biotechnology company focused on innovative aesthetic and therapeutic offerings, today announced that it has submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) for DAXXIFY™ for the treatment of cervical dystonia. Cervical dystonia is a painful and disabling chronic condition in which the neck muscles contract involuntarily, causing abnormal movements and awkward posture of the head and neck.[1]

The sBLA submission is supported by data from the ASPEN Phase 3 clinical development program, which included the ASPEN-1 and ASPEN-OLS studies, completed in 2020 and 2021, respectively. The submission follows the recent FDA approval of DAXXIFY™ for the temporary improvement of moderate to severe frown lines (glabellar lines) in adults.[2]

"We are very pleased to submit our sBLA for cervical dystonia, potentially expanding our label indication for DAXXIFY™, and positioning us to enter the nearly $1 billion U.S. muscle movement disorder market," said Mark J. Foley, Chief Executive Officer. "DAXXIFY™ has demonstrated significant potential in the muscle movement disorders category with our ASPEN Phase 3 study in cervical dystonia and JUNIPER Phase 2 study in upper limb spasticity. Today's sBLA filing advances our opportunity in treating cervical dystonia, underscored by DAXXIFY's median duration of up to 24 weeks. We are very much looking forward to potentially helping patients achieve long lasting symptom relief from this debilitating condition."

Results from the pivotal Phase 3 trial (ASPEN-1) suggest that DAXXIFY™ has the potential to reduce frequency of cervical dystonia treatments by up to 50% annually and provide a long duration of efficacy before symptoms wear off. The ASPEN-1 trial demonstrated two efficacious and generally well-tolerated dose levels, 125U and 250U, of DAXXIFY™ compared to placebo. Both patient and clinician reports of improvement and treatment satisfaction were consistent. Median duration of effect was 24.0 and 20.3 weeks, for the 125 Unit and 250 Unit dose groups, respectively. Results from the Phase 3 ASPEN-OLS study reinforced the long-term safety and efficacy of DAXXIFY™ from ASPEN-1 with up to four consecutive treatments. The incidence of dysphagia (difficulty swallowing) and muscle weakness, two adverse events of particular interest with botulinum toxin treatments for cervical dystonia, was low in the ASPEN-1 pivotal study: dysphagia (1.6%, 3.8%) and muscular weakness (4.8%, 2.3%), for the 125U and 250U, respectively.

**About Cervical Dystonia**

According to the Dystonia Medical Research Foundation, cervical dystonia is a painful condition in which the neck muscles contract involuntarily, causing abnormal movements and awkward posture of the head and neck. The movements may be sustained (tonic), jerky (clonic), or a combination. Cervical dystonia (also referred to as spasmodic torticollis) may be primary (meaning that it is the only apparent neurological disorder, with or without a family history) or may be the result of secondary causes (such as physical trauma).

First-line treatment for cervical dystonia is usually neuromodulator (botulinum toxin) injections, but additional treatments can include oral medications, surgery, and complementary therapies. Neuromodulators block the communication between the nerve and the muscle, relaxing the muscle, which alleviates abnormal involuntary movements and postures. Current neuromodulator treatments for cervical dystonia have a duration of effect of approximately three months. Cervical dystonia can occur at any age, although most individuals first experience symptoms in middle age. The condition affects a few hundred thousand adults and children in the United States. The U.S. and global market opportunities for treating cervical dystonia were $325 million and $438 million, respectively as of 2021.[3] Further, the U.S. and global market opportunities for treating muscle movement disorders with botulinum toxins, which include cervical dystonia and spasticity (upper and lower limb), were $930 million and $1.2 billion, respectively as of 2021.

**About Revance**

Revance is a commercial stage biotechnology company setting the new standard in healthcare with innovative aesthetic and therapeutic offerings that elevate patient and physician experiences. Revance's aesthetics portfolio of expertly created products and services, including DAXXIFY™, the RHA® Collection of dermal fillers, and OPUL®, the first-of-its-kind Relational Commerce platform for aesthetic practices, deliver a differentiated and exclusive offering for the company's elite practice partners and their consumers. Revance has also partnered with Viatris Inc. to develop a biosimilar to BOTOX®, which will compete in the existing short-acting neuromodulator marketplace. Revance's therapeutics pipeline is currently focused on muscle movement disorders including evaluating DaxibotulinumtoxinA for Injection in two debilitating conditions, cervical dystonia and upper limb spasticity.

Revance is headquartered in Nashville, Tennessee, with additional office locations in Newark, Pleasanton and Irvine, California. Learn more at www.Revance.com or connect with us on LinkedIn.



**Forward-Looking Statements**

Any statements in this press release that are not statements of historical fact, including statements related to our PDUFA date; our market opportunity; the potential label expansion of DAXXIFY™, the potential benefits, safety, efficacy and duration of DAXXIFY™; development of a biosimilar to

BOTOX® with our partner, Viatris; statements about our business strategy, timeline and other goals, plans and prospects; and the outcomes for and experiences of patients; 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: our ability to successfully commercialize DAXXIFY™ and to continue to successfully commercialize the RHA® Collection of dermal fillers and OPUL®; the results, timing, costs, and completion of our research and development activities and regulatory approvals; 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 DAXXIFY™, 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 DAXXIFY™ and 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 DAXXIFY™, the RHA® Collection of dermal fillers, OPUL® and our drug product candidates, if approved; reports of adverse events or safety concerns involving DAXXIFY™ or the RHA® Collection of dermal fillers; 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 DAXXIFY™ and 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" on our Form 10-K filed with the SEC on February 28, 2022 and including, without limitation, our Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 9, 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.

SOURCES


1. Dystonia Medical Research Foundation. Retrieved from: https://dystonia-foundation.org/what-is-dystonia/types-dystonia/cervical-dystonia/. Accessed 8/11/20
2. Data on File. Draft DAXXIFY™ Package Insert.Newark, CA: Revance Therapeutics, Inc, 2022.
3. Decision Resources Group Therapeutic Botulinum Toxin Market Analysis Global 2022.


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