

# REVANCE<sup>®</sup>

## Revance to Present Data from Phase 2 JUNIPER Clinical Trial Evaluating DAXXIFY™ (DaxibotulinumtoxinA-lanm) Injection for the Treatment of Upper Limb Spasticity at the International Congress of Parkinson and Movement Disorder Society (MDS)

September 15, 2022

- Oral poster showcasing positive results from Revance's Phase 2 JUNIPER clinical trial, which demonstrated long-term efficacy and safety with DAXXIFY™ for the treatment of upper limb spasticity (ULS) in adults after stroke or traumatic brain injury
- Study results indicate that DAXXIFY™ at the 500U dose is effective and well tolerated for treating adult ULS
- Study results demonstrated DAXXIFY™ had a median duration of response of 24 weeks

NASHVILLE, Tenn.--(BUSINESS WIRE)--Sep. 15, 2022-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a commercial stage biotechnology company focused on innovative aesthetic and therapeutic offerings, today announced an oral presentation by Dr. Atul Patel, JUNIPER clinical investigator, will take place on Friday, September 16 at 2:30 pm GMT+ 2 at the International Congress of Parkinson's Disease and Movement Disorders ( MDS Congress) in Madrid, Spain. The presentation will include results from Revance's JUNIPER Phase 2 clinical trial evaluating the efficacy and safety of three doses of DAXXIFY™ compared to placebo for adults with upper limb spasticity (ULS) after stroke or traumatic brain injury.

DAXXIFY™ was found to be effective and well tolerated for treating adult ULS in the Phase 2 JUNIPER study. The duration of response observed in JUNIPER suggests that DAXXIFY™ has the potential to reduce the frequency of adult ULS treatments by up to 50% annually.

"As an investigator in the JUNIPER trial, I am delighted to present data from JUNIPER for the first time at this year's MDS Congress," said Atul Patel, MD, and Medical Director, Kansas Institute of Research. "The data indicates that duration for DaxibotulinumtoxinA for Injection is strong and has the potential to reduce the frequency of adult upper limb spasticity treatments, delivering improvement in patients' quality of life and the opportunity to expand treatment care. With current treatments, 60% of patients report spasticity symptoms return less than 3 months after treatment. <sup>1</sup> The need for a new treatment option is considerable as patients have overwhelmingly indicated the desire for a longer lasting option."

The JUNIPER Phase 2 study showed that of the three doses studied (250U, 375U, and 500U), the 500U dose of DAXXIFY™ met one of the co-primary endpoints at the pre-specified timepoint (Week 6) and found statistical significance for both co-primary endpoints when analyzed post hoc (Week 4). The study also demonstrated a median duration of response of 24 weeks, while being generally well tolerated. The results from this Phase 2 trial further demonstrate the efficacy, safety and durability of Revance's unique neuromodulator formulation in a second therapeutic application following the previously reported results in cervical dystonia and informs dosing strategy for the adult upper limb spasticity Phase 3 program.

### Oral Presentation & Poster:

- **Title:** DaxibotulinumtoxinA for Injection in Adults with Upper Limb Spasticity After Stroke or Traumatic Brain Injury: A Randomized Placebo-Controlled Study (JUNIPER)
- **Presented by:** Dr. Atul T. Patel
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The above abstracts are available online via the MDS Congress website at <https://www.mdscongress.org/>

### About JUNIPER Clinical Trial

The company's JUNIPER study was a randomized, double-blind, placebo-controlled, parallel group, dose-ranging, multi-center trial to evaluate the efficacy and safety of DAXXIFY™ (DaxibotulinumtoxinA-lanm) injection for the treatment of adult upper limb spasticity in adults following stroke or traumatic brain injury. The study was conducted at 21 sites in the United States and enrolled 83 male and female patients between the age of 18 to 75 years old. Patients were randomized into one of four treatment groups: 250U, 375U, 500U and placebo. The study was designed to run up to 36 weeks, with two co-primary outcome measures: mean change from baseline in muscle tone measured with the MAS in primary target muscle group of the elbow, wrist, or finger flexors at Week 6; and mean score of the PGIC at Week 6. The first 73 subjects, who were dosed before enrollment was paused in March 2020 due to the COVID-19 pandemic, were followed up for 36 weeks, and the succeeding 10 subjects were followed up to Week 12.

Additional information about the JUNIPER study can be found at [here](#).

### About Upper Limb Spasticity

Upper limb spasticity is a neurological condition that affects the ability to move the arms and can affect hands, fingers, wrist, forearm, elbow and shoulder. It occurs most commonly after a stroke or brain injury.<sup>2</sup> Although not life-threatening, it can significantly impact a patient's ability to perform daily tasks, such as getting dressed and hygiene care and may also be painful. The prevalence of spasticity (upper limb and lower limb spasticity) is estimated to be 12 million people worldwide yet less than 20% of patients seek treatment.<sup>3</sup> Botulinum toxin treatment is the standard of care for

management of upper limb spasticity.<sup>4</sup> Other treatments include oral and intrathecal muscle relaxants, physical therapy, splints, casts & braces, electrical stimulation, and surgery.<sup>2</sup> Long-acting symptom relief is a current unmet need for upper limb spasticity patients as the benefits of currently approved botulinum toxin treatments lasts for a median duration of approximately 3 months.<sup>4</sup> Spasticity, one of the largest of the muscle movement disorder indications, is a \$756 million global opportunity that is expected to grow to over \$1 billion by 2025.<sup>5</sup>

## 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™ (DaxibotulinumtoxinA-ianm) for injection, 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](http://www.Revance.com) or connect with us on LinkedIn.

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## Forward-Looking Statements

Any statements in this press release that are not statements of historical fact, including statements related to the potential benefits, safety, efficacy and duration of DaxibotulinumtoxinA for Injection; 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 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 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 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 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

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