

# Dermata and Revance Enter Clinical Trial Collaboration Agreement for the Topical Application of Xyngari(TM) with Daxxify(R)

- *The Companies intend to first initiate a Phase 2a clinical trial evaluating Xyngari™ with Daxxify® to treat primary axillary hyperhidrosis -*
- *If successful, the Companies may explore clinical development in additional indications -*
- *Xyngari™ with Daxxify® has the potential to be the first approved needle-free intradermal delivery of a botulinum toxin product -*

**SAN DIEGO, CA and SOUTH SAN FRANCISCO, CA** / [ACCESS Newswire](#) / January 21, 2025 / Dermata Therapeutics, Inc. (NASDAQ:DRMA)(NASDAQ:DRMAW) ("Dermata") and Revance Therapeutics, Inc. (Nasdaq: RVNC) ("Revance" together with Dermata "Companies") today announced the Companies have entered into a clinical trial collaboration agreement to evaluate the topical application of Xyngari™ (formerly known as DMT310), Dermata's topical *Spongilla* powder, with Daxxify® (daxibotulinumtoxinA-lanm), Revance's botulinum toxin type A. The Companies intend to first evaluate Xyngari™ with Daxxify® for the topical treatment of primary axillary hyperhidrosis and may explore additional indications through a broader partnership in the future.

"We are excited to partner with Revance to further clinical development of our unique program, using our Xyngari™ product for a needle-free, intradermal delivery of a botulinum toxin, like Daxxify®, to the dermis," said Gerald Proehl, Chairman, President, and Chief Executive Officer of Dermata. "This clinical development collaboration will provide the cooperative framework to fully evaluate the treatment effect of Xyngari™ with Daxxify® for treating hyperhidrosis and potentially additional medical and aesthetic indications. We believe that the unique broad coverage ability of Xyngari™, with a long-lasting botulinum toxin like Daxxify®, could provide patients with a potentially superior treatment option than current injections of a botulinum toxin with a needle."

"Revance is excited to partner with Dermata to jointly explore the potential for Daxxify® and Xyngari™ for the needle-free treatment of axillary hyperhidrosis and to expand the opportunities for Daxxify® beyond injections," commented Mark Foley, Chief Executive Officer of Revance.

## Phase 2a Clinical Trial Design

The Phase 2a clinical trial will evaluate the efficacy, safety, and tolerability of Xyngari™ and Daxxify® versus Xyngari™ and placebo in patients with moderate-to-severe axillary hyperhidrosis for 16 weeks. The trial will be randomized (1:1:1:1), double-blind, placebo-controlled, enrolling approximately 48 patients across sites in the United States. The

endpoints will be the percent of patients with greater than 50% reduction in gravimetrically measured sweat production from baseline, the percent of patients with gravimetric sweat production less than 50mg, and the mean absolute change from baseline in gravimetrically measured sweat production. Patients will be evaluated at 4 regular intervals.

Daxxify® has received approval in the United States for specific uses in treating moderate to severe glabellar lines and cervical dystonia, while Xyngari™ is currently in a Phase 3 clinical program in moderate-to-severe acne. Daxxify's proprietary formulation is manufactured without the use of animal or human proteins and contains highly purified 150 kDa core neurotoxin and the patented peptide excipient RTP004.

### **Xyngari™ with Botulinum Toxin Program**

Xyngari™ with botulinum toxin is the Dermata's treatment regimen that uses the unique mechanical features of Xyngari™ to facilitate the intradermal delivery of a botulinum toxin by topical application rather than through multiple injections with a needle. Xyngari's™ microscopic spicules penetrate the stratum corneum to create microchannels into the dermis allowing for the topical application and penetration of botulinum toxin. Dermata has successfully completed proof-of-concept Phase 1 clinical trials using Xyngari™ with a botulinum toxin for the treatment of primary axillary hyperhidrosis and for the treatment of multiple aesthetic skin conditions. Both studies showed promising efficacy results and appeared to be safe and well tolerated by patients.

### **About Dermata Therapeutics**

Dermata Therapeutics is a late-stage biotechnology company focusing on the treatment of medical and aesthetic skin diseases and conditions. Dermata's lead product candidate, Xyngari™ (formerly DMT310), is its first product candidate being developed from its *Spongilla* technology platform. Xyngari™ is a once-weekly, topical product candidate derived from a naturally sourced freshwater sponge with multiple unique mechanisms of action. In addition to acne, Xyngari™ has been studied for the treatment of psoriasis and rosacea. Dermata's second program, uses Xyngari™ as a new method for needle-free intradermal delivery of botulinum toxin for the treatment of multiple aesthetic and medical skin diseases and conditions. Dermata is headquartered in San Diego, California. For more information, please visit <http://www.dermatarx.com/>.

### **About Revance**

Revance is a biotechnology company setting the new standard in healthcare with innovative aesthetic and therapeutic offerings that enhance patient outcomes and physician experiences. Revance's portfolio includes Daxxify® (DaxibotulinumtoxinA-lanm) for injection and the RHA® Collection of dermal fillers in the U.S. Revance has also partnered with Viartis Inc. to develop a biosimilar to onabotulinumtoxinA for injection and Shanghai Fosun Pharmaceutical to commercialize Daxxify® in China.

Revance's global headquarters and experience center is located in Nashville, Tennessee. Learn more at [Revance.com](http://Revance.com), [RevanceAesthetics.com](http://RevanceAesthetics.com), [Daxxify.com](http://Daxxify.com), [HCP.DAXXIFYCervicalDystonia.com](http://HCP.DAXXIFYCervicalDystonia.com), or connect with on [LinkedIn](https://www.linkedin.com/company/revance).

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Therapeutics, Inc. Resilient Hyaluronic Acid® and RHA are trademarks of TEOXANE SA.

## **Daxxify® (daxibotulinumtoxinA-lanm) injection IMPORTANT SAFETY INFORMATION INDICATIONS**

Daxxify® (daxibotulinumtoxinA-lanm) injection is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients and for the treatment of cervical dystonia in adults.

### **WARNING: DISTANT SPREAD OF TOXIN EFFECT**

**The effects of Daxxify® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. Daxxify® is not approved for the treatment of spasticity or any conditions other than cervical dystonia and glabellar lines.**

## **IMPORTANT SAFETY INFORMATION**

### **Contraindications**

Daxxify® contraindications include hypersensitivity to any botulinum toxin preparation or any of the components in the formulation and infection at the injection site(s).

### **Warnings and Precautions**

Please refer to Boxed Warning for Distant Spread of Toxin Effect.

The potency units of Daxxify® are not interchangeable with preparations of other botulinum toxin products. Recommended dose and frequency of administration should not be exceeded. Patients should seek immediate medical attention if respiratory, speech or swallowing difficulties occur. Use caution when administering to patients with pre-existing cardiovascular disease. Concomitant neuromuscular disorders may exacerbate clinical effects of treatment.

### **Adverse Reactions**

The most commonly observed adverse reactions are:

Glabellar lines ( $\geq 1\%$ ): headache (6%), eyelid ptosis (2%) and facial paresis (1%).

Cervical dystonia ( $\geq 5\%$ ): headache (9%), injection site pain (8%), injection site erythema (5%), muscular weakness (5%), and upper respiratory tract infection (5%).

### **Drug Interactions**

Co-administration of Daxxify® and aminoglycoside antibiotics, anticholinergic agents or any other agents interfering with neuromuscular transmission or muscle relaxants should only be performed with caution as the effect of Daxxify® may be potentiated. The effect of

administering different botulinum neurotoxins during course of treatment with Daxxify® is unknown.

### **Use in Specific Populations**

Daxxify® is not recommended for use in children or pregnant women.

Please see Daxxify® full Prescribing Information, including Boxed Warning and Medication Guide.

To report side effects associated with Daxxify®, please visit [safety.revance.com](http://safety.revance.com), or call 1-877-373-8669. You may also report side effects to the FDA at 1-800-FDA-1088 or visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### **About DAXXIFY**

Daxxify® (DaxibotulinumtoxinA-lanm) for injection is the first and only FDA approved long-lasting, peptide formulated neuromodulator product with approved indications in the U.S. for the temporary improvement of glabellar lines (frown lines) and for the treatment of cervical dystonia in adults. Daxxify® is powered by Peptide Exchange Technology™, Revance's proprietary, synthetic, 35-amino-acid stabilizing excipient, and is developed free of human serum albumin or animal-based components.<sup>1-5</sup> Manufactured in the U.S., Daxxify® is the first true innovation in neuromodulator product formulation in over 30 years.

### **Dermata Forward-Looking Statements**

Statements in this press release that are not strictly historical in nature are forward-looking statements. These statements are based on the Company's current beliefs and expectations and new risks may emerge from time to time. Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors including, but are not limited to, statements related to: expectations with regard to the potential market acceptance of any of the Company's product candidates; timing of trials and data events; expectations with regard to the timing and/or results or responses from meetings with regulatory bodies, including the FDA; the success, cost, and timing of its product candidate, Xyngari™, development activities and ongoing and planned clinical trials alone or with another compound; and whether the results of Xyngari™ with another compound will lead to future product development, partnerships, or approvals. These forward-looking statements are generally identified by the use of such words as "may," "could," "should," "would," "believe," "anticipate," "forecast," "estimate," "expect," "intend," "plan," "continue," "outlook," "will," "potential" and similar statements of a future or forward-looking nature. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks and uncertainties inherent in drug development, approval and commercialization, and the fact that past results of clinical trials may not be indicative of future trial results. For a discussion of these and other factors, please refer to Dermata's filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and Dermata

undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

### **Dermata Investors:**

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### **Relevance 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 (including treatment intervals) of Daxxify® for the treatment of cervical dystonia; our opportunity in aesthetics and therapeutics; the potential to set a new standard in healthcare; patient outcomes and physician experiences; development of an onabotulinumtoxinA biosimilar with our partner, Viatrix; and commercialization of Daxxify® in China with our partner, Shanghai Fosun Pharmaceutical; 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 and the timing of events to differ materially from our expectations. These risks and uncertainties relate to, but are not limited to: our ability to obtain funding for our operations; the timing of capital expenditures; the accuracy of our estimates regarding expenses, revenues, capital requirements, supply chain and operational efficiencies; our financial performance and the economics of Daxxify and the RHA Collection of dermal fillers; our ability to comply with our debt obligations; the impact of macroeconomic factors on our manufacturing operations, supply chain, end user demand for our products, commercialization efforts, business operations, regulatory meetings, inspections and approvals, clinical trials and other aspects of our business and on the market; our ability to maintain approval of our products; our ability and the ability of our partners to manufacture supplies for Daxxify and our drug product candidates; our ability to acquire supplies of the RHA Collection of dermal fillers; the uncertain clinical development process; our ability to obtain, and the timing relating to, regulatory submissions and approvals with respect to our drug product candidates and third-party manufacturers; 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, duration, commercial acceptance, market, competition and/or size and growth potential of Daxxify, the RHA Collection of dermal fillers, and our drug product candidates, if approved; our ability to successfully commercialize Daxxify and to continue to successfully commercialize the RHA Collection of dermal fillers; the timing and cost of commercialization activities; securing or maintaining adequate coverage or reimbursement by third-party payers for Daxxify; the proper training and administration of our products by physicians and medical staff; our ability

to maintain and gain acceptance from injectors and physicians in the use of Daxxify for aesthetic and therapeutic indications; our ability to strengthen professional partnerships; our ability to expand sales and marketing capabilities; the status of commercial collaborations; changes in and failures to comply with laws and regulations; our ability to continue obtaining and maintaining intellectual property protection for our products; the cost and our ability to defend ourselves in product liability, intellectual property, class action or other lawsuits; our ability to limit or mitigate cybersecurity incidents; 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 "Risk Factors" in our Form 10-K for the year ended December 31, 2023, filed with the SEC on February 28, 2024. 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.

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