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PRESS RELEASE

GALDERMA'S RELFYDESS™ (RELABOTULINUMTOXINA) RECEIVES POSITIVE DECISION FOR USE IN EUROPE

Ad hoc announcement pursuant to Art. 53 LR

- Relfydess™ (RelabotulinumtoxinA) is the first and only ready-to-use liquid neuromodulator created with PEARL™ Technology, developed and manufactured by Galderma^{1,2}
- This positive decision is based on results from the phase III READY clinical trial program, which showed that Relfydess™ delivered sustained results for six months, combined with an onset of action as early as day one, for both frown lines and crow's feet³⁻⁸
- Galderma is committed to developing and delivering the broadest portfolio in Injectible Aesthetics
- Once national approvals have taken place, Relfydess™ will be the first neuromodulator in Europe to receive initial approval for two indications – frown lines and crow's feet – at the same time
- Relfydess™ also received marketing authorization from Australia's Therapeutic Goods Administration in June this year

Zug, Switzerland – July 30, 2024 – Galderma today announced that it has completed its European decentralized procedure (DCP), resulting in a positive decision for Relfydess™ (RelabotulinumtoxinA – previously referred to as QM1114). Relfydess™ is indicated for the temporary improvement in the appearance of moderate-to-severe glabellar lines (frown lines) at maximum frown and lateral canthal lines (crow's feet) seen at maximum smile, alone or in combination, in adult patients under 65 years, when the severity of these lines has an important psychological impact on the patient.⁹ Following the successful completion of the DCP, national approvals in the 16 concerned countries are now under finalization. Relfydess™ also received a marketing authorization in Australia earlier this year.

Relfydess™ is developed and manufactured by Galderma. It is the first and only ready-to-use liquid neuromodulator created with PEARL™ Technology that is designed to preserve molecule integrity to deliver a highly active, innovative, complex-free molecule, with up to 39% of patients seeing effects from day one and up to 75% of patients maintaining improvements for six months for frown lines and crow's feet.^{3,4,7,8} It is optimized for simple volumetric dosing, without reconstitution, to increase ease of use and help ensure consistent dose/volume.^{1,10}

“With Relfydess™, Galderma is introducing a highly differentiated and innovative neuromodulator, reinforcing our leadership and strong growth in this field, and our commitment to developing and delivering the broadest portfolio in Injectible Aesthetics. As per the decentralized European approach, our teams are now finalizing the approval procedures at the country level, so we're ready to launch in multiple markets early next year.”

**FLEMMING ØRNSKOV, M.D., MPH,
CHIEF EXECUTIVE OFFICER
GALDERMA**

This positive decision, and the previous Therapeutic Goods Administration approval in Australia, were based on results from the phase III READY (RElabotulinumtoxin Aesthetic Development Study) clinical trial program, which enrolled more than 1,900 participants. Results showed:^{3,4,7,8}

- Improvement in both frown lines and crow's feet versus placebo:
 - In READY-1 and READY-2, treatment with Relydness™ demonstrated a 96.3% none-or-mild responder rate for frown lines and 87.2% for crow's feet, after one month, vs 4.5% and 11.9% for placebo, respectively.
- Onset of action as soon as day one:
 - In READY-1 and READY-2, 39% of patients reported improvements for frown lines and 34% reported improvements for crow's feet from day one.
- Sustained results for six months:
 - In READY-1 and READY-2, up to 75% of patients maintained improvements for six months.
 - At month one, up to 96% achieved none-or-mild frown lines and crow's feet, which was sustained for six months in almost a quarter of patients.
- Patient satisfaction was maintained for six months following treatment.

“With the growing need for new innovations in the neuromodulator space, I'm excited that, with Relydness™, we have a new treatment that delivers both fast and sustained results in a simple and convenient formulation, so we can achieve the desired outcomes for our patients quickly, effectively, and without compromise.”

DR. SACHIN SHRIDHARANI
LEAD INVESTIGATOR OF READY-1 TRIAL
PLASTIC SURGEON AND FOUNDER OF LUXURGERY

Regulatory applications for Relydness™ for the treatment of frown lines and crow's feet will continue to be submitted and assessed by additional authorities globally.

About Relydness™ (RelabotulinumtoxinA)

Pioneered by Galderma, Relydness™ is the first and only ready-to-use liquid neuromodulator created with PEARL™ Technology that is designed to preserve molecule integrity.^{1,2} PEARL™ Technology is designed to deliver a highly active, innovative, complex-free molecule, with up to 39% of patients seeing effects from day one and up to 75% of patients maintaining improvements for six months.^{1-4,7,8} Relydness™ is optimized for simple volumetric dosing, without reconstitution, to increase ease-of-use and help ensure consistent dose/volume every time.^{1,10} It was entirely developed and manufactured by Galderma to expand its neuromodulator portfolio as part of the broadest Injectable Aesthetics portfolio on the market.

About the READY clinical trial program

The READY (RElabotulinumtoxin Aesthetic Development Study) phase III clinical program is composed of four phase III clinical trials which enrolled more than 1,900 participants.³⁻⁶ The READY trials investigated the safety, efficacy, rapidity of onset and/or durability of Relydness™ for six months on:

- Frown lines (READY-1).³
- Crow's feet (READY-2).⁴
- Frown lines and crow's feet when treated alone or simultaneously (READY-3).⁵

- Frown lines and crow's feet when treated alone or simultaneously with up to four repeated injections over 52 weeks (READY-4).⁶

About Galderma

Galderma (SIX: GALD) is the emerging pure-play dermatology category leader, present in approximately 90 countries. We deliver an innovative, science-based portfolio of premium flagship brands and services that span the full spectrum of the fast-growing dermatology market through Injectable Aesthetics, Dermatological Skincare and Therapeutic Dermatology. Since our foundation in 1981, we have dedicated our focus and passion to the human body's largest organ – the skin – meeting individual consumer and patient needs with superior outcomes in partnership with healthcare professionals. Because we understand that the skin we are in shapes our lives, we are advancing dermatology for every skin story. For more information: www.galderma.com.

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