

## Galderma Provides Progress Update Regarding RelabotulinumtoxinA Regulatory Submission in the United States

July 1, 2026

- Galderma received a Complete Response Letter from the FDA with comments related to observations during manufacturing site inspection and analytical method optimization
- Relfydess is approved in 33 markets and already launched in more than 20, including across Europe, the Middle East and Australia, with an encouraging early launch trajectory supported by positive healthcare professional feedback
- Regulatory filings in other territories are ongoing and remain on track

*Ad hoc announcement pursuant to Art. 53 LR*

ZUG, Switzerland--(BUSINESS WIRE)--Jul. 1, 2026-- Galderma (SIX: GALD) today provided progress updates regarding the regulatory review of its pending Biologics License Application ("BLA") for RelabotulinumtoxinA with the U.S. Food and Drug Administration ("FDA"). The Company has received a Complete Response Letter (CRL) from the FDA with comments related to observations during manufacturing site inspection and analytical method optimization. As part of its review, the FDA conducted a Pre-License Inspection (PLI) of Galderma's manufacturing site. All other aspects of the BLA, including safety- and efficacy-related parts, did not solicit deficiencies to be addressed.

The FDA made observations during the PLI for which Galderma is putting in place corrective and preventive actions. Galderma will also be seeking further guidance through continued open dialogue with the FDA toward resolution of the relevant observations. Galderma plans to rapidly respond to the CRL and advancing RelabotulinumtoxinA in the U.S. remains a top priority.

The observations do not impact approvals, launches, or regulatory reviews in other International markets.

### **Global launches progressing on track**

As of today, Relfydess is approved in 33 markets and already launched in more than 20, including in Europe, the United Kingdom, the Middle East, Asia, and Australia, with an encouraging early launch trajectory supported by positive healthcare professional feedback. Since 2022, this Galderma manufacturing site has completed 10 inspections from key regulatory authorities from around the world serving as the basis for International Relfydess launches. Regulatory filings in other territories are ongoing and remain on track.

### **Building a dermatology powerhouse**

Galderma remains on a clear path to become the world's undisputed dermatology powerhouse spanning the full spectrum of fast-growing markets across Injectable Aesthetics, Dermatological Skincare and Therapeutic Dermatology.

In Injectable Aesthetics, Galderma is firmly positioned on a trajectory to global leadership – not only in sales and market share, but also in innovation – supported by fully integrated in-house capabilities across discovery, research, development, manufacturing and commercialization of best-in-class products.

We will continue to build on this momentum through our robust pipeline, expanding the number of early-stage assets under development. Galderma leads the industry in the number of active aesthetic development programs, further reinforcing its leadership position in the U.S. and globally.

Galderma has the largest and most innovative Injectable Aesthetic portfolio on the market. Given our strong market position, we believe we are exceptionally well placed to capitalize on opportunities in this fast-growing market.

### **About Relfydess (relabotulinumtoxinA)**

Pioneered by Galderma, Relfydess is the first and only ready-to-use liquid neuromodulator created with PEARL Technology that is designed to preserve molecule integrity. PEARL Technology is designed to deliver a highly active, innovative, complex-free molecule, creating a product that enables up to 39% of patients seeing effects from day one and up to 75% of patients maintaining improvements for six months. Relfydess is optimized for simple volumetric dosing, without reconstitution, to increase ease-of-use and help ensure consistent dose/volume every time.

### **About Galderma**

Galderma (SIX: GALD) is the 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](http://www.galderma.com).

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