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PRESS RELEASE

Galderma's Nemluvio® (nemolizumab) approved in the European Union for moderate-to-severe atopic dermatitis and prurigo nodularis

Ad hoc announcement pursuant to Art. 53 LR

- This approval from the European Commission is based on robust results from the phase III OLYMPIA and ARCADIA clinical trial programs, showing that Nemluvio has the potential to address the significant unmet needs of patients with atopic dermatitis and prurigo nodularis[1-3]
- There is a need for new treatment options for atopic dermatitis and prurigo nodularis to effectively relieve the signs and symptoms such as persistent itch, skin lesions and poor sleep quality[4-8]
- Nemluvio is the first approved monoclonal antibody that specifically targets IL-31 receptor alpha, inhibiting the signaling of IL-31, which drives itch and is involved in inflammation and skin barrier dysfunction in both atopic dermatitis and prurigo nodularis, and fibrosis in prurigo nodularis[5,8-10]
- Nemluvio is the first monoclonal antibody in Galderma's portfolio of innovative, science-based products, which span the full spectrum of the fast-growing dermatology market

Zug, Switzerland – February 14, 2025 – Galderma today announced that the European Commission has approved Nemluvio for both moderate-to-severe atopic dermatitis and prurigo nodularis in the European Union (EU). Nemluvio is now approved for subcutaneous use for the treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older who are candidates for systemic therapy, and for subcutaneous use for the treatment of adults with moderate-to-severe prurigo nodularis who are candidates for systemic therapy.[11]

"Throughout Galderma's four decades in dermatology we have consistently worked to meet the needs of patients and deliver first-in-class treatment options. This has been exemplified through the clinical and regulatory success achieved with our unique monoclonal antibody, Nemluvio. As the first biologic treatment in our Therapeutic Dermatology portfolio, Nemluvio shows our commitment to advancing dermatology by expanding into new areas of need."

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

Nemluvio is the first approved monoclonal antibody that specifically targets IL-31 receptor alpha, inhibiting the signaling of IL-31.[9] IL-31 is a neuroimmune cytokine that drives itch and is involved in inflammation and skin barrier dysfunction in both atopic dermatitis and prurigo nodularis, and fibrosis in prurigo nodularis.[5,8-10] It is also the first and only biologic approved for atopic dermatitis and prurigo nodularis with four-week dosing intervals from the start of treatment.[11]

This approval is based on results from the phase III ARCADIA and OLYMPIA clinical trial programs, in which Nemluvio significantly improved itch, skin lesions and sleep disturbance,

in patients with moderate-to-severe atopic dermatitis and adults with prurigo nodularis, respectively.[1-3]

Results from the ARCADIA 1 and ARCADIA 2 trials demonstrated that patients treated with Nemluvio, administered subcutaneously every four weeks in combination with background topical corticosteroids, with or without topical calcineurin inhibitors (+TCS/TCI), showed statistically significant improvements on skin clearance in both co-primary endpoints at Week 16, when compared to placebo +TCS/TCI.[1] The trials also met all key secondary endpoints, confirming significant responses on itch as early as Week 1 and statistically significant improvements in sleep disturbance.[1]

Both co-primary endpoints were also met in the OLYMPIA 1 and OLYMPIA 2 clinical trials, where Nemluvio monotherapy demonstrated significant and clinically meaningful improvements on itch and skin lesions at Week 16, when compared to placebo.[2,3] The trials met all key secondary endpoints, showing rapid reduction in itch due to prurigo nodularis and sleep disturbance within four weeks of treatment initiation.[2,3]

Nemluvio was well tolerated in all trials, and its safety profile was generally consistent with earlier data, and between trials.[1-3]

> "Atopic dermatitis and prurigo nodularis can severely impact quality of life due to the associated debilitating symptoms, including chronic itch, skin lesions, poor sleep quality and mental health conditions. With this approval, patients in the EU have a new treatment option, which extensive data has shown can help to safely, quickly, and effectively ease the key symptoms of these diseases and therefore the burden on patients' lives."
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> **PROFESSOR DIAMANT THAÇI**
> **LEAD INVESTIGATOR OF THE ARCADIA STUDIES IN EUROPE**
> **UNIVERSITY OF LUBECK, GERMANY**

> "Nemolizumab's benefits have been demonstrated in its comprehensive clinical trial programs in both atopic dermatitis and prurigo nodularis, including the OLYMPIA 1 and 2 studies, which make up the largest completed pivotal program in prurigo nodularis to date. These clinical data, plus its first-in-class mechanism of action and convenient dosing schedule, make it an important new therapeutic solution for dermatologists to support their patients."
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> **PROF. SONJA STÄNDER**
> **LEAD INVESTIGATOR OF THE OLYMPIA STUDIES IN EUROPE**
> **UNIVERSITY HOSPITAL MÜNSTER, GERMANY**

Nemluvio is also approved by the U.S. Food and Drug Administration for the treatment of atopic dermatitis and prurigo nodularis.[12] It is under review for the treatment of both diseases by several additional regulatory authorities around the world, including Canada, Brazil, and South Korea, and via the Access Consortium framework in countries such as Australia, Singapore and Switzerland. Further submissions to other regulatory authorities are ongoing.

As previously communicated, peak sales of Nemluvio are expected to reach more than 2 billion USD (expected beyond the 2023-2027 mid-term guidance period). Galderma anticipates Nemluvio to approach 'blockbuster' net sales run-rate by the end of 2027.

Media can find more information about atopic dermatitis and prurigo nodularis here.

About Nemluvio
Nemluvio was initially developed by Chugai Pharmaceutical Co., Ltd. In 2016, Galderma obtained exclusive rights to the development and marketing of nemolizumab worldwide, except in Japan and Taiwan. In Japan, nemolizumab is marketed as Mitchga® and is approved for the treatment of prurigo nodularis, as well as pruritus associated with atopic dermatitis in pediatric, adolescent, and adult patients.[13,14]

About the ARCADIA clinical trial program[1,15,16]
The ARCADIA program included two identically designed, pivotal phase III clinical trials, which enrolled more than 1,700 patients – ARCADIA 1 and ARCADIA 2.

These global, randomized, multicenter, double-blind, placebo-controlled phase III clinical trials evaluated the efficacy and safety of nemolizumab administered subcutaneously every four weeks compared to placebo (both administered with background topical corticosteroids with or without topical calcineurin inhibitors).

The trials were conducted in adolescent and adult patients (12 years and over) with moderate-to-severe atopic dermatitis for an initial treatment phase of 16 weeks. Patients who responded to treatment (defined as patients who achieved an investigator's global assessment score of clear (0) or almost clear (1), or a 75% or greater improvement in the eczema area and severity index score) were then re-randomized to a maintenance treatment phase for up to 48 weeks.

About atopic dermatitis
Atopic dermatitis is a common, chronic, and flaring inflammatory skin disease, characterized by persistent itch and recurrent skin lesions.[5,17,18] It is the most common inflammatory skin disease, impacting almost four times more people than psoriasis.[5,19] It affects approximately 10 to 40 million people in the European Union, with up to 66% of adults suffering with a moderate-to-severe form of the condition.[20,21] While currently available treatments may improve some signs and symptoms of the disease, many patients do not respond optimally to approved therapies and do not experience itch relief and clear skin to the same degree.[5-8]

About the OLYMPIA clinical trial program[2,3,22,23]
The OLYMPIA program included two identically designed, pivotal phase III clinical trials which enrolled 560 patients – OLYMPIA 1 and OLYMPIA 2. This is the largest clinical trial program conducted in prurigo nodularis to date, and the only program to include a long-term extension study.

These global, randomized, double-blind, placebo-controlled phase III clinical trials assessed the efficacy and safety of nemolizumab monotherapy compared with placebo in patients at least 18 years of age with moderate-to-severe prurigo nodularis over a 16- or 24-week treatment period for OLYMPIA 2 and OLYMPIA 1, respectively.

About prurigo nodularis
Prurigo nodularis is a chronic, debilitating, and distinct neuroimmune skin disease characterized by the presence of intense itch and thick skin nodules covering large body areas.[24-26] It is estimated to affect between 7-111 people per 100,000 in the European Union depending on the country.[27,28] The majority of patients report that the persistent itch negatively impacts their quality of life.[29] Furthermore, the intense itch associated with prurigo

nodularis results in significant sleep disturbance and further contributes to reduced quality of life.[30,31]

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.

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