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Galderma Receives U.S. FDA Approval for Nemluvio® (Nemolizumab) for Patients with Moderate-to-Severe Atopic Dermatitis

December 13, 2024

Ad hoc announcement pursuant to Art. 53 LR

- Approximately 7% of people in the United States (U.S.) have atopic dermatitis – a common, chronic, and flaring inflammatory skin disease, characterized by persistent itch and recurrent skin lesions[1-4]
- 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[2,5-7]
- Nemluvio® (nemolizumab) is the first approved monoclonal antibody that specifically targets IL-31 receptor alpha, inhibiting the signaling of IL-31. IL-31 is a neuroimmune cytokine that drives itch and is involved in inflammation and epidermal dysregulation in atopic dermatitis[2,9-11]
- This approval follows Nemluvio's recent approval for the treatment of adults with prurigo nodularis from the U.S. Food and Drug Administration earlier in August 2024[12]

ZUG, Switzerland--(BUSINESS WIRE)--Dec. 13, 2024-- Galderma (SWX:GALD) today announced that the United States (U.S.) Food and Drug Administration (FDA) has approved Nemluvio® (nemolizumab) for the treatment of patients 12 years and older with moderate-to-severe atopic dermatitis, in combination with topical corticosteroids (TCS) and/or calcineurin inhibitors (TCI) when the disease is not adequately controlled with topical prescription therapies. This follows the recent U.S. FDA approval of Nemluvio for subcutaneous injection for the treatment of adults with prurigo nodularis in August 2024.[12]

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20241213562840/en/

Atopic dermatitis affects more than 230 million people worldwide, impacting approximately 7% of people in the U.S.[2-4] Often reported as one of patients' most problematic symptoms, 87% of people with atopic dermatitis say they are seeking freedom from itch, with speed of itch relief therefore also prioritized by both patients and physicians.[13-16] Atopic dermatitis is also a highly heterogenous disease and can be associated with several comorbid conditions, namely mental health disorders and other autoimmune- or immune-mediated diseases.[2,13,17-19] For this reason, there remains a need for more novel, effective treatment options, as while currently available treatments for atopic dermatitis may improve some signs and symptoms, many patients do not respond optimally to approved therapies and do not experience itch relief and clear skin to the same degree.[2,5-7]

Nemluvio is the first approved monoclonal antibody that specifically targets IL-31 receptor alpha, inhibiting the signaling of IL-31.[8] IL-31 is a neuroimmune cytokine that drives itch and is involved in inflammation and epidermal dysregulation in atopic dermatitis.[2,9-11]

"As just one example of our innovative, science-based pipeline, Nemluvio is an important and effective new treatment option for patients with atopic dermatitis, where unmet needs remain. Another key milestone on Galderma's journey, this FDA approval will accelerate the ongoing growth of our U.S. organization and our Therapeutic Dermatology Business, and underscores our commitment to delivering innovative first-in-class solutions to patients across the full spectrum of the fast-growing dermatology market."

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

This approval is based on positive results from the phase III ARCADIA clinical trial program which evaluated the efficacy and safety of Nemluvio in combination with background TCS, with or without TCI, versus placebo in combination with TCS, with or without TCI, in 1,728 patients aged 12 years or older with moderate-to-severe atopic dermatitis.[20]

Results demonstrated that patients treated with Nemluvio, administered subcutaneously every four weeks in combination with TCS, with or without TCI, showed statistically significant improvements on skin clearance in both co-primary endpoints. These were clearance (0) or almost-clearance (1) of skin lesions when assessed using the investigator's global assessment (IGA) score, and achieving a 75% reduction in the Eczema Area and Severity Index (EASI) - when compared to placebo in combination with TCS, with or without TCI, after 16 weeks of treatment.[20]

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 with Nemluvio in combination with TCS, with or without TCI, when compared to placebo in combination with TCS, with or without TCI.[20]

Overall, Nemluvio was well tolerated, and the safety profile was generally consistent between Nemluvio and placebo groups.[20]

"Despite currently available treatment options, atopic dermatitis continues to have a massive impact worldwide, with patients not only burdened by

intense itch and recurrent skin lesions, but also potentially several associated symptoms including sleep issues, pain, anxiety, and depression. I look forward to being able to offer this option to atopic dermatitis patients in my practice who are seeking relief from burdensome itch and lesions."

PROFESSOR JONATHAN SILVERBERG
LEAD INVESTIGATOR OF THE ARCADIA CLINICAL PROGRAM,
PROFESSOR OF DERMATOLOGY, GEORGE WASHINGTON UNIVERSITY
SCHOOL OF MEDICINE AND HEALTH SCIENCES, UNITED STATES

The FDA also approved Nemluvio as a pre-filled pen for subcutaneous injection for the treatment of adults with prurigo nodularis in August 2024.[12]

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion on December 12, 2024, recommending the approval of nemolizumab in the European Union (EU) for the treatment of both atopic dermatitis and prurigo nodularis.[21] The positive opinion will now be reviewed by the European Commission, which has the authority to approve medicines in all 27 EU member states as well as Iceland, Liechtenstein, and Norway.

Galderma also has marketing authorization applications for nemolizumab in both atopic dermatitis and prurigo nodularis under review by multiple additional regulatory authorities, including via the Access Consortium framework in countries such as Australia, Singapore, and Switzerland, as well as in Canada, Brazil, and South Korea.[22] Further submissions to other regulatory authorities will continue in 2025.

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

Media can find more information about atopic dermatitis in this media toolkit.

About Nemluvio® (nemolizumab-ilto)

Nemluvio® (nemolizumab-ilto) 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.[23,24]

Important Safety Information

Indications: NEMLUVIO® (nemolizumab-ilto) is a prescription medicine used:

- to treat adults and children 12 years of age and older with moderate-to-severe eczema (atopic dermatitis or AD) in combination with prescription therapies used on the skin (topical) when the eczema is not well controlled by topical therapies alone. It is not known if NEMLUVIO is safe and effective in children with atopic dermatitis under 12 years of age.
- to treat adults with prurigo nodularis. It is not known if NEMLUVIO is safe and effective in children with prurigo nodularis under 18 years of age.

Do not take NEMLUVIO if you are allergic to nemolizumab-ilto or to any ingredients in NEMLUVIO. **Before taking NEMLUVIO, tell your healthcare provider about all of your medical conditions, including if you:**

- are scheduled to receive any vaccination. You should not receive a live vaccine right before or during treatment with NEMLUVIO.
- are pregnant or plan to become pregnant. It is not known whether NEMLUVIO will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known whether NEMLUVIO passes into your breast milk and if it can harm your baby.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

NEMLUVIO may cause serious side effects, including: allergic reactions (hypersensitivity). Stop using NEMLUVIO and tell your healthcare provider or get emergency help right away if you get any of the following symptoms:

- Breathing problems or wheezing
- Swelling of the face, lips, mouth, tongue, or throat
- Fainting, dizziness, feeling lightheaded
- Fast pulse
- Swollen lymph nodes
- Joint pain
- Fever
- Skin rash (red or rough skin)
- Nausea or vomiting
- General ill feeling
- Cramps in your stomach area

The most common side effects of NEMLUVIO include:

- **Eczema**: headache, joint pain, hives (itchy red rash or wheals), and muscle aches
- **Prurigo Nodularis:** headache and skin rashes: atopic dermatitis (a type of eczema), eczema, and eczema nummular (scattered circular patches)

These are not all of the possible side effects of NEMLUVIO.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800- FDA-1088.

Please see full Prescribing Information including Patient Information.

About the ARCADIA clinical trial program[20,25,26]

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.[1-3] It affects more than 230 million people worldwide and is the most common inflammatory skin disease, impacting almost four times more people than psoriasis.[2,27] While currently available treatments for atopic dermatitis show some improvements of signs and symptoms, not all patients experience itch relief and clear skin to the same degree, and many do not respond optimally to approved therapies.[2,5-7]

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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Source: Galderma