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PeDRA 2026: Nemolizumab Phase II Data Show Long-Term Symptom Relief for Children Aged 2 to 11 Years With Moderate-to-Severe Atopic Dermatitis

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- Patient-reported outcomes from a phase II study of nemolizumab in children aged 2 to 11 with moderate-to-severe atopic dermatitis show meaningful reductions in itch severity, better sleep and improved quality of life, maintained for a year[1]
- Currently, there are limited approved treatment options for children living with moderate-to-severe atopic dermatitis, despite the high unmet need – the disease can significantly reduce quality of life for children and create burden on their families[2-8]
- These findings expand on the clinical evidence base for nemolizumab, which has multiple global approvals for adult and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis, and adults with prurigo nodularis[9,10]

ZUG, Switzerland--(BUSINESS WIRE)--Oct. 15, 2026-- Galderma (SIX: GALD), the pure-play dermatology category leader, today announced new phase II data showing that nemolizumab provided meaningful improvements in itch, sleep disturbance, and quality of life in children aged 2 to 11 years with moderate-to-severe atopic dermatitis, sustained through Week 52.[1] The results will be presented at The Pediatric Dermatology Research Alliance (PeDRA) Annual Conference.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20261014705800/en/

Up to 25% of children are affected by atopic dermatitis - the most common inflammatory skin disorder in this population - and around one-third of these children have moderate-to-severe disease.[11,12] Atopic dermatitis creates a high burden for both the patients and their loved ones, with persistent itch and recurrent skin lesions often disrupting sleep, school, and social confidence.[2-8] Despite the high prevalence and significant burden, treatment options are limited in the pediatric setting for those with moderate-to-severe disease.[3]

"The burden of atopic dermatitis on children and their families remains considerable, with symptoms affecting quality of life, emotional wellbeing and day-to-day functioning. There is a continued need for treatment options that can deliver meaningful benefits for patients with moderate-to-severe disease. The results seen in this phase II study of nemolizumab are promising, with sustained improvements in itch severity, sleep disturbance and quality of life observed for up to one year."

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Delivering sustained improvements in itch, sleep and quality of life in children with atopic dermatitis

This phase II multicenter, open-label study assessed the pharmacokinetics, safety and efficacy of nemolizumab in pediatric patients aged 2 to 11 years with moderate-to-severe atopic dermatitis, as well as patient-reported outcomes and quality of life.[1] Children were enrolled into three cohorts based on age and weight, and received weight-tiered nemolizumab dosing plus topical therapy. Patient-reported outcomes and quality of life results demonstrated meaningful improvements in itch, sleep disturbance, and quality of life, sustained through Week 52:[1]

- Improvements in itch were achieved early in treatment and sustained over one year of follow-up, with Peak Pruritus Numerical Rating Scale four point-response rates between 56%-72% across cohorts at Week 16, and similar and/or higher responses seen at Week 52.
- Reductions in sleep disturbance as measured by the Sleep Disturbance Numerical Rating Scale were similarly achieved early in treatment and maintained through Week 52, with scores improving by -70 to -78% across cohorts at Week 16, and further improvements at Week 52.
- Mean Children's Dermatology Life Quality Index (for children ≥4 years) scores improved by -10.7, -12.0, and -12.0 from baseline at Week 52 across cohorts.
- Improvements were also observed in both age-appropriate quality of life measures, including the Infants' Dermatitis Quality of Life index (for children <4 years) and Patient-Oriented Eczema Measure (for children ≥4 years).

Nemolizumab was well tolerated, with no new safety signals. These phase II findings are consistent with the previously established safety and efficacy of nemolizumab in adults and adolescents with moderate-to-severe atopic dermatitis.[9,10]

"At Galderma, we are committed to advancing science-based solutions for atopic dermatitis, supporting patients and their families through continued research and innovation, with the goal of delivering treatment options that can meaningfully improve quality of life. These new data further support the robust clinical evidence we have collected on nemolizumab and underscore its potential to address the needs of a broader patient population,

including young children living with moderate-to-severe atopic dermatitis."

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For more information about the impact of atopic dermatitis on children and families, read this article and watch this video.

About nemolizumab

Nemolizumab is the first approved monoclonal antibody that specifically targets and inhibits the signaling of IL-31 – a neuroimmune cytokine that drives itch and is involved in inflammation, epidermal dysregulation and fibrosis in both atopic dermatitis and prurigo nodularis.[9,10,13,14]

Nemolizumab 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. In Japan, nemolizumab is marketed as Mitchga® and is approved for the treatment of prurigo nodularis in adults and children aged 13 years and older, as well as pruritus associated with atopic dermatitis in adults and children between the ages of 6 and 12.[15,16]

Nemolizumab (under the name Nemluvio®) was approved by the United States Food and Drug Administration for the treatment of adults with prurigo nodularis, and patients 12 years and older with moderate-to-severe atopic dermatitis, in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.[9] To date, nemolizumab is approved for both adolescents and adults with moderate-to-severe atopic dermatitis and adults with prurigo nodularis in more than 40 countries around the world. Additional regulatory submissions and reviews are ongoing.

Nemluvio Important Safety Information

INDICATIONS: NEMLUVIO® (nemolizumab-ilto) is an interleukin-31 receptor alpha antagonist indicated for:

- the treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.
- the treatment of adults with prurigo nodularis.

CONTRAINDICATION: NEMLUVIO is contraindicated in patients with known hypersensitivity to nemolizumab-ilto or to any of the excipients in NEMLUVIO.

WARNINGS AND PRECAUTIONS: Hypersensitivity reactions have been reported with NEMLUVIO use. If clinically significant hypersensitivity reaction occurs, immediately institute appropriate therapy, and discontinue NEMLUVIO. Avoid use of live vaccines during treatment with NEMLUVIO.

ADVERSE REACTIONS: Most common adverse reactions (incidence ≥1%) are:

- Atopic Dermatitis: headache (including migraine), arthralgia, urticaria, and myalgia.
- Prurigo Nodularis: headache, dermatitis atopic, eczema, and eczema nummular.

USE IN SPECIFIC POPULATIONS:

Pregnancy: There are no adequate and well-controlled studies on NEMLUVIO in pregnant women. The limited available information on NEMLUVIO use during pregnancy is not sufficient to inform a drug-associated risk of major birth defects or miscarriage in humans. Human IgG antibodies are known to cross the placental barrier; therefore, NEMLUVIO may be transmitted from the mother to the developing fetus.

Lactation: There are no data on the presence or transfer of NEMLUVIO in human milk, the effects on the breastfed infant, or the effects on milk production. Human IgG is known to be present in human milk. The effects of local gastrointestinal and limited systemic exposure to NEMLUVIO on the breastfed infant are unknown. NEMLUVIO has not been administered to nursing/lactating women. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NEMLUVIO and any potential adverse effects on the breastfed child from NEMLUVIO or from the underlying maternal condition.

Pediatric Use: The safety and effectiveness of NEMLUVIO have not been established in pediatric patients younger than 12 years of age for the treatment of moderate-to-severe atopic dermatitis or pediatric patients younger than 18 years of age for the treatment of prurigo nodularis.

Please see full Prescribing Information including Patient Information.

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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