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ARCADIA Clinical Trial Program Media Factsheet

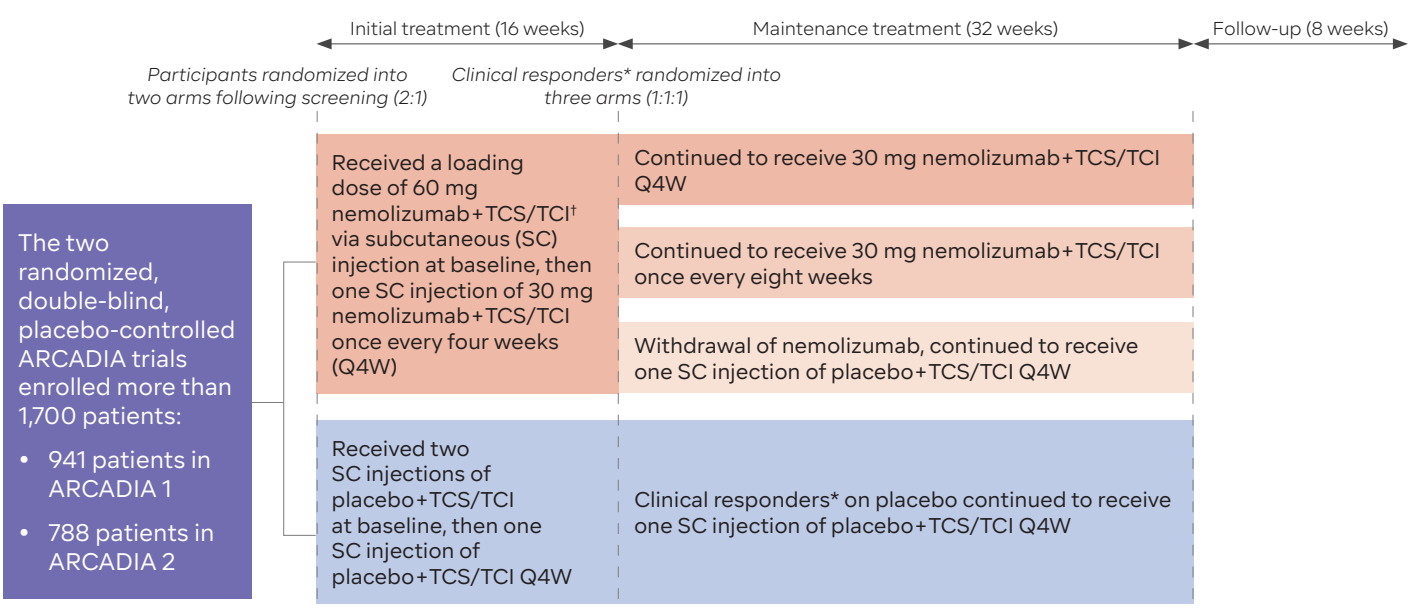
What are the ARCADIA trials?[1-3]

ARCADIA 1 and 2 were two identically designed, pivotal phase III trials that assessed the efficacy and safety of nemolizumab in **adolescent and adult patients with moderate-to-severe atopic dermatitis**.[1-3]

Nemolizumab is a first-in-class monoclonal antibody specifically designed to target the interleukin-31 (IL-31) receptor alpha and inhibit IL-31 signaling.[4]

The ARCADIA trials investigated nemolizumab† in over 1,700 patients with atopic dermatitis. The efficacy and safety of nemolizumab† was compared with placebo† after a 16-week treatment period.[1-3]

Trial design[1-3]

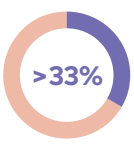


Clinical responders were defined as patients who achieved an Investigator's Global Assessment score of clear (0) or almost clear (1), or a 75% or greater improvement in the Eczema Area and Severity Index score.

Trial results[3,5]

The phase III ARCADIA 1 and 2 trials met **both co-primary endpoints** and all key secondary endpoints, demonstrating that **nemolizumab† significantly improved itch, skin lesions and sleep disturbance in adolescent and adult patients with moderate-to-severe atopic dermatitis.**[3,5]

Results across both trials at Week 16 showed that:[3,5]



More than a third of nemolizumab-treated† patients **reached clearance or almost-clearance of skin lesions** when assessed using the Investigator's Global Assessment score.

Over 40% of nemolizumab-treated† patients **achieved a 75% reduction in the Eczema Area and Severity Index**.

Over 40% of nemolizumab-treated† patients achieved an at least **four-point reduction in itch intensity** as measured by the peak-pruritus numerical rating scale.

Nemolizumab† also demonstrated **rapid onset of action on itch and sleep disturbance,** with statistically significant improvements in itch observed **as early as one week after treatment initiation**.[3,5]

The ARCADIA program also included a maintenance study of clinical responders at 48 weeks. Nemolizumab† maintained itch and skin responses when dosing once every four or eight weeks, **making it the first ever biologic in atopic dermatitis to maintain its efficacy with an eight-week dosing regimen**.[6]

Nemolizumab† was well tolerated, and its safety profile was consistent across treatment arms.[3,5,6]

The ARCADIA trials further demonstrate that **nemolizumab† has the potential to be a therapeutic solution** for patients suffering from moderate-to-severe atopic dermatitis.

†Nemolizumab and placebo were administered with background therapy (topical corticosteroids [TCS] with or without topical calcineurin inhibitors [TCI]).

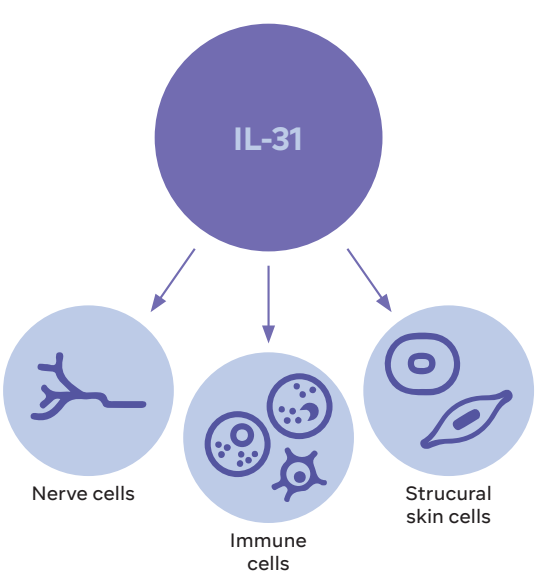
The burden of atopic dermatitis

Atopic dermatitis is a common, chronic, and flaring inflammatory skin disease, characterized by persistent itch and recurrent skin lesions.[7-9] It has a **significant negative impact on quality of life**.[10-13]

Atopic dermatitis affects **more than 230 million people worldwide** and is the most common inflammatory skin disease, impacting almost four times more people than psoriasis.[8,14]

- Approximately 7% of adults in the United States have atopic dermatitis.[15]
- Up to 17% of adults in Europe are diagnosed with atopic dermatitis each year.[16]

In atopic dermatitis, IL-31 acts as a bridge between the immune and nervous systems, and is a key mediator of itch, skin barrier disruption and is involved in inflammation.[8,17,18]



Regulatory status

Nemolizumab is currently under review by several regulatory authorities for the treatment of prurigo nodularis and moderate-to-severe atopic dermatitis, including the **U.S. Food and Drug Administration (FDA)**, the **European Medicines Agency** and **Health Canada**, as well as in **Australia, Singapore, Switzerland** and the **United Kingdom** via the Access Consortium.[19,20] Submissions to regulatory authorities in additional countries are ongoing.

Nemolizumab was initially granted Breakthrough Therapy Designation by the U.S. FDA in December 2019 for the treatment of pruritus associated with prurigo nodularis, a status reconfirmed in March 2023.[21]

Galderma has exclusive rights to the development and marketing of nemolizumab worldwide except in Japan and Taiwan. In Japan, nemolizumab (under the brand name Mitchga®) is approved for the treatment of prurigo nodularis and pruritus associated with atopic dermatitis.[22,23]

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