Nemluvio® (nemolizumab-ilto) – New indication

- On December 13, 2024, Galderma announced the FDA approval of Nemluvio (nemolizumab-ilto), 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.

- Nemluvio is also approved for the treatment of adults with prurigo nodularis.

- The approval of Nemluvio for the new indication was based on two randomized, double-blind, placebo-controlled trials (ARCADIA 1 and ARCADIA 2) in a total of 1,728 patients 12 years of age and older with moderate-to-severe atopic dermatitis not adequately controlled by topical treatments. In both studies, the co-primary endpoints were the: (1) proportion of patients with an Investigator's Global Assessment (IGA) success (defined as an IGA of 0 [clear] or 1 [almost clear] and a ≥ 2-point reduction from baseline) at week 16; and (2) proportion of patients with Eczema Area and Severity Index (EASI)-75 (≥ 75% improvement in EASI from baseline) at week 16.

    - In ARCADIA 1, **IGA success was achieved in 36% and 25% of patients receiving Nemluvio and placebo,** respectively (difference of 12, 95% CI: 6, 17). EASI-75 was achieved in 44% and 29% of patients, respectively (difference 15, 95% CI: 9, 21).
    - In ARCADIA 2, **IGA success was achieved in 38% and 26% of patients receiving Nemluvio and placebo**, respectively (difference of 12, 95% CI: 6, 19). EASI-75 was achieved in 42% and 30% of patients, respectively (difference 12, 95% CI: 6, 19).

- The most common adverse reactions (≥ 1%) with Nemluvio use for atopic dermatitis were **headache (including migraine), arthralgia, urticaria, and myalgia**.

- The recommended dose of Nemluvio for the treatment of atopic dermatitis is an initial dose of 60 mg (two 30 mg subcutaneous injections), followed by 30 mg **subcutaneous injection given every 4 weeks**.

    - After 16 weeks of treatment, for patients who achieve clear or almost clear skin, a subcutaneous dosage of 30 mg every 8 weeks is recommended.