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CITELINE COMMERCIAL

13 Aug 2024 | **News**

Galderma Gets First Biologic To Market With Nemluvio Approval

by Jessica Merrill

Nemluvio is a first-in-class IL-31 inhibitor that the US FDA approved for prurigo nodularis.

The Swiss dermatology company *Galderma S.A.* is poised to compete against bigger pharma rivals as it expands into the systemic dermatology treatment space. The company is launching its first biologic drug, the IL-31 inhibitor Nemluvio (nemolizumab) following US Food and Drug Administration approval for the treatment of prurigo nodularis (PN), a debilitating skin condition.

Galderma announced the FDA approval of the first-in-class drug on 13 August. Galderma has a long heritage in dermatology, but the Swiss specialty pharma has been best known for selling topical skin care products and injectable aesthetics, including the consumer product brand Cetaphil and wrinkle-reducer Dysport (abobotulinumtoxinA).

Under the direction of former pharmaceutical industry CEO Flemming Ornskov, who joined the company in 2019, Galderma has set its sights on systemic dermatology treatments. (Also see "*Ex Shire CEO Ornskov Resurfaces To Lead Skin Group Galderma*" - Scrip, 7 Oct, 2019.) It's all part of the evolution of the

Key Takeaways

- Galderma received US FDA approval for Nemluvio (nemolizumab) in the treatment of prurigo nodularis, becoming the dermatology specialist's first approved therapeutic biologic.
- Applications for a second indication in atopic dermatitis are under review in the US and EU, with an FDA decision expected later this year for the first-in-class IL-31 inhibitor.
- In both PN and AD, Nemluvio will

pureplay dermatology company, which went public on the Swiss stock exchange in March.

compete with a dominant market player, Sanofi and Regeneron's Dupixent (dupilimab), which targets IL-4 and IL-13.

While PN is the first approved indication for Nemluvio, the company is also expecting FDA approval in a larger indication, atopic dermatitis, later this year. Galderma announced positive Phase III data from two studies testing Nemluvio in atopic dermatitis last year and already has regulatory applications pending in the US and Europe, where action is expected during the first half of 2025. (Also see "*Galderma Readies Its First Therapeutic Biologic For Two US Launches In 2024*" - Scrip, 14 Mar, 2023.)

Nemluvio will be available immediately in the US, the company said. Galderma has also ramped up its commercial infrastructure to support the launch, including hiring field-based personnel as well as medical affairs and market access teams with biologics experience.

The drug will be entering a competitive market, going up against an entrenched dermatology drug, *Regeneron Pharmaceuticals, Inc.* and *Sanofi*'s blockbuster Dupixent (dupilumab), which gained a new indication for PN in 2022, marking the first drug approval for the indication. Physicians have a lot of experience with Dupixent, an IL-4/IL-13 inhibitor, however, which was first approved for atopic dermatitis in 2017 and has been approved for a wide array of indications since.

Nemluvio works differently by inhibiting IL-31, which is known to drive itch and is involved in inflammation and fibrosis, according to Galderma. PN is a rare skin condition that affects about 181,000 people in the US and causes chronic itch and skin nodules covering large areas of the body.

Galderma hopes to compete against Dupixent with long-term data that show efficacy out to 52 weeks and a fast onset of action. In a long-term extension trial, Galderma reported that 69.2% of continuous nemolizumab treatment and 64.5% of nemolizumab-naïve patients achieved Investigator's Global Assessment (IGA) score of 0 or 1, meaning clearance or almost clearance of skin lesions. Meanwhile, 56% of those receiving nemolizumab achieved at least a four-point reduction in itch, based on the peak-pruritus numerical rating scale (PP-NRS). (Also see "*Galderma Reveals Long-Term Nemolizumab Data As It Prepares To Take On Dupixent*" - Scrip, 11 Mar, 2024.)

The FDA approval was based on the results of the Phase III OLYMPIA 1 and OLYMPIA 2 clinical trials, which showed that 56% and 49% of Nemluvio-treated patients, respectively, achieved at least a four-point reduction in itch intensity at week 16 as measured by the PP-NRS.

In the two clinical trials supporting the approval of Dupixent for PN, the proportion of subjects with a four-point or more reduction in itch based on the worst itch numerical rating scale (WI-NRS) was 60% and 57.7% at 24 weeks.

Nemluvio could have a dosing advantage over Dupixent. Labeling recommends dosing every four weeks after two initial injections while Dupixent is dosed every two weeks. As for how the drugs will compete on price, that remains unclear for now. Galderma declined to disclose the wholesale acquisition cost of Nemluvio.

Galderma reported net sales across its entire product portfolio of $2.2bn during the first six months of 2024, growth of 10.8% on a constant currency basis.