



## Results of Phase II Study with Chugai's Nemolizumab for Prurigo Nodularis Published in the *New England Journal of Medicine* Online

- Phase II study results for the treatment of prurigo nodularis were published in the *New England Journal of Medicine* Online
- Galderma is now preparing for the initiation of a Phase III pivotal study with nemolizumab in adult patients with prurigo nodularis in 2020

TOKYO, February 20, 2020 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced that results from a phase II study (NCT03181503) conducted by [Galderma](#), a global leader in skin health, investigating nemolizumab in adult with moderate-to-severe prurigo nodularis (PN) were published the *New England Journal of Medicine* Online. Nemolizumab is an anti-interleukin-31 (IL-31) receptor A humanized monoclonal antibody created by Chugai.

In this study, 70 patients with moderate to severe PN and severe pruritus were randomized to receive subcutaneous nemolizumab 0.5 mg/kg every 4 Weeks from baseline to Week 8 or matching placebo injections (at weeks 0,4 and 8). Nemolizumab met the primary endpoint of a greater improvement in Peak Pruritus Numerical rating scale (PP-NRS) from baseline to Week 4 compared to placebo. The baseline PP-NRS was 8.4 in both groups. At week 4, in nemolizumab arm PP-NRS was reduced from baseline by 4.5 (53.0%) compared to 1.7 (20.2%) in placebo;  $P < 0.001$ . At week 18 (10 weeks after the last dose), 38 percent of the patients who received nemolizumab were clear or almost clear of PN compared to 6 percent of the patients who received placebo;  $P = 0.001$ . Nemolizumab was well tolerated and safety profile appeared consistent with the known safety profile of the medicine. The full publication is available at <https://www.nejm.org/doi/full/10.1056/NEJMoa1908316>.

“Nemolizumab is a first-in-class investigational antibody targeting IL-31 receptor A created by Chugai. IL-31 is known to have a key role in pathogenesis of pruritus in PN. We hope the study results will help scientists to better understand the pathology of the disease,” said Dr. Yasushi Ito, Chugai’s Executive Vice President, Co-head of Project & Lifecycle Management Unit. “Galderma will start a phase III study for PN to investigate the efficacy and safety of nemolizumab. We expect a great deal from Galderma’s exceptional expertise in skin health to hopefully have a positive results from the study.”

PN is a chronic skin disease with thick skin nodules covering large body areas and associated severe pruritus. It is a rare disease and may affect daily life.<sup>1, 2, 3)</sup> The US Food and Drug Administration granted the Breakthrough Therapy designation for nemolizumab for the treatment of pruritus associated with PN. Galderma and Chugai made a license agreement for the development and marketing of nemolizumab worldwide with the exception of Japan and Taiwan. Galderma is now preparing for the initiation of a phase III pivotal study with nemolizumab in adult patients with PN in 2020.

Galderma's press release regarding the journal publication of phase II study results for nemolizumab is:

- Galderma Announces New England Journal of Medicine Publication from Phase 2 Study of Investigational Therapy Nemolizumab in Patients with Moderate to Severe Prurigo Nodularis (A press release issued on February 20, 2020)

<https://www.galderma.com/news/galderma-announces-new-england-journal-medicine-publication-phase-2-study-investigational>

[Note]

• Chugai's Nemolizumab Receives FDA Breakthrough Therapy Designation for the Treatment of Pruritus Associated with Prurigo Nodularis (A press release issued on December 9, 2019)

[https://www.chugai-pharm.co.jp/english/news/detail/20191209180000\\_676.html](https://www.chugai-pharm.co.jp/english/news/detail/20191209180000_676.html)

• Chugai and Galderma Announce Global License Agreement for Nemolizumab (CIM331), Novel Biologic for Skin Diseases (A press release issued on July 21, 2016)

<https://www.chugai-pharm.co.jp/english/news/detail/20160721083000.html>

## References

1: Prurigo Nodularis. American Osteopathic College of Dermatology. [Internet; cited December, 2019]

Available from: <https://www.aocd.org/page/PrurigoNodularis>

2: Prak AH and De la Rosa KM. Prurigo Nodularis. Medscape Reference. [Internet; cited December, 2019]

Available from: <https://emedicine.medscape.com/article/1088032-overview>

3: Watsky K. Prurigo nodularis. UpToDate. [Internet; cited December, 2019] Available

from: <https://www.uptodate.com/contents/prurigo-nodularis>

###