Innovation all for the patients

CHUGAI

Roche A member of the Roche group

Chugai's Nemolizumab Receives FDA Breakthrough Therapy Designation for the Treatment of Pruritus Associated with Prurigo Nodularis

- The U.S. Food and Drug Administration granted Breakthrough Therapy Designation for nemolizumab, an investigational drug under development by Galderma, for the treatment of pruritus associated with prurigo nodularis
- Prurigo nodularis is a rare disease associated with skin nodules and severe pruritus
- This is the eighth Breakthrough Therapy Designation received for five drug candidates created by Chugai

TOKYO, December 9, 2019 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) for nemolizumab, an anti-interleukin-31 (IL-31) receptor A humanized monoclonal antibody created by Chugai, for the treatment of pruritus associated with prurigo nodularis. The designation was received by Galderma, a global leader in skin health, with whom Chugai made a license agreement for the development and marketing of nemolizumab worldwide with the exception of Japan and Taiwan.

Prurigo nodularis 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. [1, 2, 3] Galderma presented results from its Phase 2 clinical study evaluating the safety and efficacy of nemolizumab in prurigo nodularis at the 28th Annual Congress of the European Academy of Dermatology and Venereology (EADV 2019).

"Nemolizumab is a first-in-class investigational drug targeting IL-31 receptor A, and created by utilizing Chugai's proprietary antibody engineering technology ACT-Ig. I am excited that this 8th BTD for five drug candidates from Chugai research was granted based on the Phase 2 clinical study that Galderma conducted," said Dr. Hisafumi Okabe, Chugai's Executive Vice President in charge of Research and Translational Research. "Patients' quality of life can be severely affected by symptoms of prurigo nodularis, however, there are limited treatment options available for this disease. We expect a great deal from Galderma's exceptional expertise in skin health to hopefully bring nemolizumab as a new treatment option to patients."

Galderma is now preparing for the initiation of a Phase 3 pivotal program with nemolizumab in adult patients with prurigo nodularis in 2020. Please refer below for the Galderma's press release regarding this BTD of nemolizumab:

- Galderma Investigational Therapy, Nemolizumab, Granted FDA Breakthrough Therapy Designation for the Treatment of Patients Suffering from Prurigo Nodularis (A press release issued on December 9, 2019) https://www.galderma.com/news/galderma-investigational-therapy-nemolizumab-granted-fda-

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324 Japan
Media Relations Group TEL:+81-(0)3-3273-0881 E-mail:pr@chugai-pharm.co.jp
Investor Relations Group TEL:+81-(0)3-3273-0554 E-mail:ir@chugai-pharm.co.jp

breakthrough-therapy-designation

[Note]
Press release issued on July 21, 2016:
Chugai and Galderma Announce Global License Agreement for Nemolizumab (CIM331), Novel Biologic for Skin Diseases
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: http://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

###