News Release

# PiaSky Approved in Taiwan as First Subcutaneous Treatment for Paroxysmal Nocturnal Hemoglobinuria

- Approved as the first subcutaneous treatment for paroxysmal nocturnal hemoglobinuria (PNH) in Taiwan, applying Chugai's proprietary Recycling Antibody Technology
- Approval based on data including COMMODORE 2 study, which demonstrated non-inferiority in efficacy of every four weeks subcutaneous PiaSky compared to intravenous eculizumab every two weeks in the maintenance dosing period

TOKYO, May 19, 2025 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that Chugai Pharma Taiwan Ltd. (hereafter, CPT), a wholly-owned subsidiary of Chugai, obtained an orphan drug import drug license from the Taiwan Food and Drug Administration (TFDA) for Chugai's PiaSky® for "for the treatment of the patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg," on May 19, 2025. CPT is responsible for the development, regulatory submission, import, and sales of Chugai-originated products in Taiwan.

"We are very pleased that Chugai-originated PiaSky has been approved in Taiwan. Paroxysmal nocturnal hemoglobinuria (PNH) is a disease with limited treatment options in Taiwan and high unmet medical needs for patients and their families. PiaSky is designed to exert sustained effects at low doses by applying Chugai's proprietary Recycling Antibody® technology. We expect that this drug, which is the first PNH treatment in Taiwan to enable subcutaneous administration every 4 weeks during the maintenance period, will be widely useful for patients, their families, and healthcare professionals," said Yuji Habara, President of CPT.

This approval is based on the results of the Global Phase III COMMODORE 2 study in PNH patients who had not been previously treated with C5 inhibitors. In addition, the application included data from the Global Phase III COMMODORE 1 study in PNH patients switching from currently approved C5 inhibitors, and the Phase III COMMODORE 3 study conducted in China in PNH patients who had not been previously treated with C5 inhibitors.

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**[Reference Information]**
New Data Presented at EHA Show Chugai's Subcutaneously Administered Crovalimab Achieved Disease Control and was Well-Tolerated in People with Paroxysmal Nocturnal Hemoglobinuria (PNH) (Press release issued on June 12, 2023)
https://www.chugai-pharm.co.jp/english/news/detail/20230612170001_992.html

**About the COMMODORE 2 Study**
The COMMODORE 2 study is a phase III, randomized, open-label global study evaluating the efficacy and safety of PiaSky versus eculizumab in people with paroxysmal nocturnal hemoglobinuria (PNH) who have not been treated previously with C5 inhibitors. The study's co-primary efficacy endpoints measure transfusion avoidance and control of hemolysis (the ongoing destruction of red blood cells measured by lactate dehydrogenase levels). The adults* enrolled in the study were randomized in a 2:1 ratio to be treated with either subcutaneous (SC) PiaSky every four weeks or intravenous (IV) eculizumab every two weeks. The participants who were less than 18 years old were included in a descriptive arm and were treated with SC PiaSky every four weeks.[1,2]
*Including two patients aged less than 18 years old enrolled before the revision of the protocol

**About PiaSky**
PiaSky is a Chugai-originated anti-C5 recycling antibody created with our proprietary Recycling Antibody technology. Recycling antibodies are designed to achieve pH-dependent antigen binding so that a single antibody molecule can bind with the antigen multiple times, enabling a longer efficacy compared with a conventional antibody. Additionally, by introducing surface charge modification technology, it increases the clearance rate of the antigen from the blood, enabling more efficient neutralization of the antigen compared to conventional recycling antibodies, thereby reducing the required dosage. PiaSky is designed to target C5, a key component of the complement system, and is expected to control complement activity. It is also expected to reduce the treatment burden for people with PNH and their caregivers through subcutaneous administration every 4 weeks with a small volume of medicine. Since PiaSky binds to complement C5 at a different site from existing antibody drugs, it can be an effective treatment option for people with PNH with a specific C5 gene mutation reported in Asia (appears in approximately 3.2% of Japanese people with PNH), which causes existing antibody drugs not to bind to C5.[3,4]
PiaSky has been approved in China for the first time in February 2024, for the treatment of adults and adolescents (12 years of age and above) with PNH who have not been previously treated with complement inhibitors. In Japan, it was approved in March 2024 for the treatment of PNH and launched in May of the same year. It also obtained approval in the US in June 2024, in Europe in August 2024. In addition, clinical trials are ongoing for atypical hemolytic uremic syndrome (aHUS), and Roche is conducting trials for sickle cell disease (SCD) overseas.

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**Sources:**


1. Röth A, et al. Phase 3 randomized COMMODORE 2 trial: Crovalimab versus eculizumab in patients with paroxysmal nocturnal hemoglobinuria naive to complement inhibition. Am J Hematol. 2024 Sep;99(9):1768-1777.
2. COMMODORE 2 (NCT04434092). [Internet; cited April 2025] Available at: https://clinicaltrials.gov/study/NCT04434092.
3. Fukuzawa T, et al. Long lasting neutralization of C5 by SKY59, a novel recycling antibody, is a potential therapy for complement-mediated diseases. 2017; Sci Rep 7, 1080.
4. Nishimura J et al. Genetic variants in C5 and poor response to eculizumab. N Engl J Med. 2014 Feb 13;370(7):632-9.


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