Innovation all for the patients

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Chugai Launches “PiaSky for Injection 340 mg” The First Subcutaneously Administered Anti-C5 Antibody in Japan for the Treatment of Paroxysmal Nocturnal Hemoglobinuria

- Launched as the first subcutaneously administered anti-complement C5 antibody treatment of a designated intractable disease, paroxysmal nocturnal hemoglobinuria in Japan. Expected to reduce the burden of treatment on patients by decreasing the administration time
- Second Chugai original medicine applied with our proprietary recycling antibody technology, enabling subcutaneous administration at low doses once every 4 weeks

TOKYO, May 22, 2024 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it launched PiaSky® for Injection 340 mg (generic name: crovalimab (genetical recombination)) (hereafter, PiaSky), a pH-dependent binding humanized anti-complement (C5) monoclonal antibody for the treatment of paroxysmal nocturnal hemoglobinuria (PNH). PiaSky had been approved by the Ministry of Health, Labour and Welfare (MHLW) on March 26, 2024 and was listed on the national health insurance (NHI) reimbursement price list today.

“We are very pleased to launch PiaSky as a new treatment for PNH. Anti-complement C5 antibodies are a standard of care for PNH, and PiaSky has become the first subcutaneously administered medicine in the class in Japan. By decreasing the administration time, we hope to reduce the burden on patients and caregivers and minimize interruptions to their day-to-day lives,” said Chugai’s President and CEO, Dr. Osamu Okuda. “This is the fifth launch in Japan of a Chugai originated antibody medicine. Japan is the first country in which PiaSky is launched, and the medicine is also under review for approval in PNH in the United States and Europe. Through our company’s technology-driven drug discovery strategy, Chugai will further advance research and development to continuously provide new value to patients affected by various diseases.”

PiaSky uses Chugai’s Recycling Antibody® technology. Unlike conventional antibodies that bind to an antigen only once, crovalimab has been engineered to bind to the antigen repeatedly, enabling low dose subcutaneous administration every four weeks. This is the second approval for a drug using the recycling antibody technology following Enspryng® for the treatment of neuromyelitis optica spectrum disorder (NMOSD).

This approval was based mainly on the results of the COMMODORE 2 study in patients with PNH who were naïve to C5 inhibitors and the COMMODORE 1 study in patients with PNH who switched to crovalimab from previously approved C5 inhibitors. Both are global phase III studies in collaboration with Roche, and Japan is also participating.

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

[Product Information]
Product name: PIASKY® for Injection 340 mg
Generic name: crovalimab (genetical recombination)
Indications: Paroxysmal nocturnal hemoglobinuria
Dosage and administration:
The usual Day 1 dose is 1000 or 1500 mg of crovalimab (genetical recombination) once by intravenous infusion, and subsequently, 340 mg is subcutaneously administered once on Days 2, 8, 15, and 22, and 680 or 1020 mg is subcutaneously administered once every 4 weeks from Day 29 onward, taking the patient's body weight into account.
Date of approval: March 26, 2024
Date of NHI reimbursement price listing: May 22, 2024
Date of launch: May 22, 2024
Drug price: PIASKY® for Injection 340 mg JPY 1,978,062 / bottle

[Reference Information]
Disease awareness website "Let's understand paroxysmal nocturnal hemoglobinuria (PNH) for a better tomorrow" (Japanese only)
https://www.chugai-pharm.co.jp/ptn/oshiete-pnh/ (Newly released on May 22)

Chugai Obtains Regulatory Approval for "Piasky 340mg" for Paroxysmal Nocturnal Hemoglobinuria in Japan (Press release March 26, 2024)
https://www.chugai-pharm.co.jp/english/news/detail/20240326160001_1056.html

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 June 12, 2023)
https://www.chugai-pharm.co.jp/english/news/detail/20230612170001_992.html

About PiaSky
PiaSky is an anti-C5 recycling antibody created with Chugai's 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. Crovalimab 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 patients and their caregivers through subcutaneous administration. Since crovalimab binds to complement C5 at a different site from existing antibody drugs, it can be an effective treatment option for patients with a specific C5 gene mutation reported in Asia (appears in approximately 3.2% of Japanese patients with PNH), which causes existing antibody drugs not to bind to C5.[1,2]
PiaSky has been approved in China 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, as Chugai's fifth global drug. Also, it is under review by other regulatory authorities, including in the US, EU, and Taiwan. In addition, clinical trials are ongoing for atypical hemolytic uremic syndrome (aHUS), and Roche is conducting trials for sickle cell disease (SCD) overseas.

About paroxysmal nocturnal hemoglobinuria

Paroxysmal nocturnal hemoglobinuria (PNH) is an acquired hematopoietic stem cell disorder characterized by intravascular hemolysis due to complement activation. It is caused by the clonal expansion of hematopoietic stem cells, driven by acquired mutations in the *PIG-A* gene.[3] While symptoms may vary in each individual, there are typically two types. One is symptoms attributed to the characteristic hemolysis in PNH, such as hemoglobinuria and thrombosis. The other is hematopoietic failures similar to those associated with aplastic anemia. PNH may cause complications, including chronic kidney disease and pulmonary hypertension. In Japan, PNH is a rare disease that is listed as one of the designated intractable diseases (designated intractable disease 62). 1,035 individuals have been granted the medical care recipient certificate for PNH as of the end of FY2022.[4]

Source:

1. Fukuzawa T, et al. Long lasting neutralisation of C5 by SKY59, a novel recycling antibody, is a potential therapy for complement-mediated diseases. 2017; Sci Rep 7, 1080.
2. Nishimura J et al. Genetic variants in C5 and poor response to eculizumab. N Engl J Med. 2014 Feb 13;370(7):632-9.
3. Working group for the development of the reference guide revision of diagnostic criteria and practice for paroxysmal nocturnal hemoglobinuria (PNH). Referenced Guide to Paroxysmal Nocturnal Hemoglobinuria Treatment Revised FY2022. (in Japanese only)
4. Portal Site of Official Statistics of Japan website (https://www.e-stat.go.jp/). Report on Public Health Administration and Services FY2022, Accessed May 2024. (in Japanese only)

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