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ASIA EDITION

# Chugai’s Paroxysmal nocturnal hemoglobinuria drug bags world’s first approval in China

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**Crovalimab is the second approved drug applying Chugai’s proprietary Recycling Antibody technology**

Japan's Chugai Pharmaceutical has announced that crovalimab, a humanised complement inhibitor C5 monoclonal antibody, has been approved by the National Medical Products Administration (NMPA) of People’s Republic of China for treatment of adults and adolescents (12 years of age and above) with Paroxysmal nocturnal hemoglobinuria (PNH) not been previously treated with complement inhibitors.

PNH is an acquired hematopoietic stem cell disorder characterizsd by intravascular haemolysis due to complement activation.

As F. Hoffmann-La Roche is responsible for the development of crovalimab outside Japan and Taiwan, the regulatory application was filed by a China affiliate of Roche. China is the first country in the world to approve crovalimab.

The approval is based on the results of several studies including COMMODORE 3 study, a multicenter, single-arm, phase III clinical trial conducted in China, and COMMODORE 2 study, a randomised, open-label global phase III study, for PNH without history of complement inhibitor treatment.

Crovalimab has been created using Chugai’s Recycling Antibody technology. While a typical antibody can bind to an antigen only once, crovalimab is engineered to bind to the antigen repeatedly, enabling sustained complement inhibition at a low dose and achieving subcutaneous administration every four weeks. Crovalimab is the second approved drug applying Chugai’s Recycling Antibody technology, following Enspryng for the treatment of neuromyelitis optica spectrum disorder (NMOSD).

The drug has been filed for approval as a new drug for PNH in Japan, the US, and EU. In addition, clinical trials are ongoing for atypical hemolytic uremic syndrome (aHUS), and Roche is conducting trials for sickle cell disease (SCD) and lupus nephritis overseas.