US FDA approves Roche's drug for a chronic blood disorder

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London: The U.S. Food and Drug Administration on Thursday approved Roche's drug for a chronic blood disorder, the Swiss drugmaker said.

The drug crovalimab, branded as PiaSky, is a monthly under-the-skin or intravenous treatment for paroxysmal nocturnal hemoglobinuria (PNH).

PNH is a disorder in which red blood cells break apart prematurely. It can cause anemia, fatigue and blood clots, and can lead to kidney disease.

Roche said the disease affects around 20,000 people worldwide.

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"Crovalimab could provide an option to self-administer as infrequently as every four weeks, thereby reducing clinic visits for people with this lifelong condition," said Levi Garraway, chief medical officer of Roche.

Other treatments for PNH such as Astrazeneca's Ultomiris and eculizumab, sold as Soliris, and Amgen's Bkemv require infusion by healthcare professionals.

PiaSky was approved in China in February and Japan in March.

The drug is also being tested in two other blood disorders, atypical hemolytic uremic syndrome and sickle cell disease, and a kidney disease called lupus nephritis.

News Source:

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