US FDA approves Novartis' kidney disease drug

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By Sriparna Roy

London: The U.S. Food and Drug Administration has approved the use of Novartis' drug to reduce excess protein in the urine of patients with a type of kidney disease, the health regulator's website showed on Wednesday.

The drug, Fabhalta, is already approved to treat adults with paroxysmal nocturnal hemoglobinuria, a rare blood disorder.

With the expanded approval, Novartis' drug entered the IgA nephropathy (IgAN) market and will compete with Swedish drugmaker Calliditas' Tarpeyo and Travere Therapeutics' Filspari.

IgAN - which mostly affects young adults - occurs when clumps of antibodies are deposited in kidneys, causing inflammation that damages their tiny filtering units.

Guggenheim analyst Vamil Divan sees the IgAN market valuing at $10 billion over time as more treatments come to market.

The FDA's latest approval was based on a late-stage trial where Fabhalta showed a 43.8% reduction in proteinuria when compared to placebo.

Proteinuria is excess protein in the urine and can be a sign of the kidney failing to filter properly.

The Swiss drugmaker is also developing two other experimental drugs - zigakibart and atrasentan - for the treatment of IgAN.

The IgAN opportunity is much more tied with the other two drugs than Fabhalta, Divan had told Reuters before the FDA decision.

Otsuka and Vera Therapeutics are also working on treatments for the disease. In April, Vertex Pharmaceuticals had struck a $4.9 billion deal with Alpine Immune Sciences, gaining access to its experimental IgAN drug.

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