US FDA approves Takeda, Protagonist's drug for rare blood cancer

The approval of rusfertide brings a highly anticipated, less-invasive treatment option for thousands of patients who have historically relied on frequent bloodletting procedures to manage their condition.

Bengaluru: The U.S. Food and Drug Administration has approved a first-of-its-kind drug from Takeda Pharmaceutical and Protagonist Therapeutics to treat a rare blood cancer, the health regulator said on Friday.

The approval of rusfertide brings a highly anticipated, less-invasive treatment option for thousands of patients who have historically relied on frequent bloodletting procedures to manage their condition.

The drug treats polycythemia vera, a rare, slow-growing blood cancer affecting roughly 90,000 Americans. The condition causes the bone marrow to overproduce red blood cells, thickening the blood and sharply raising the risk of life-threatening clots, strokes and heart attacks.

Rusfertide, branded as Mimrylo, will be made available to patients within 48 hours of FDA approval, Teresa Bitetti, president of Takeda's global oncology business unit, told Reuters in an interview.

While the company did not disclose the exact list price of the drug at launch, Bitetti said the company would "price this in a way that is fair to the value, but then also ensures that there's access for patients."

Takeda is projecting peak global sales for the drug in the range of $1 billion to $2 billion.

For decades, treatment has largely relied on therapeutic phlebotomy, a procedure that involves regularly removing blood to keep red blood cell levels under control.

Mimrylo works by mimicking hepcidin, the body's master iron-regulating hormone, to restrict iron availability and prevent the bone marrow from overproducing red blood cells.

The FDA's decision was based on late-stage trials, in which the drug, alongside standard of care, helped patients control their red blood cell levels, reducing the need for painful blood draws, and improving symptoms like fatigue.

Takeda secured the global rights to co-develop and commercialize the drug from its developer Protagonist through a 2024 licensing agreement.

News Source:

https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/us-fda-approves-takeda-protagonists-drug-for-rare-blood-cancer/133639600?utm_source=latest_news&utm_medium=homepage