

US FDA approves Neurocrine Biosciences' genetic disorder drug

The drug, branded as Crenessity, is to be used together with glucocorticoid, a type of steroid, to control androgen levels in adults and pediatric patients aged 4 years and older with classic congenital adrenal hyperplasia (CAH).



Bengaluru: The U.S. Food and Drug Administration has approved Neurocrine Biosciences' drug to treat a type of genetic disorder, the health regulator's website showed on Friday.

The drug, branded as Crenessity, is to be used together with glucocorticoid, a type of steroid, to control androgen levels in adults and pediatric patients aged 4 years and older with classic congenital adrenal hyperplasia (CAH).

The drug is expected to be commercially available in about one week, a company spokesperson said.

CAH is a rare genetic disorder affecting the adrenal glands, which produce hormones such as cortisol and androgens.

Patients with the disease do not produce enough cortisol - an essential hormone that regulates stress levels - and produce too many androgens, a testosterone-like hormone.

Crenessity works by reducing excessive production of androgens, resulting in less amount of glucocorticoid treatment needed.

The approval is based on results from two trials in 182 adults and 103 children with the condition.

In the first trial, 122 adults received Crenessity twice daily, while 60 received a placebo, for 24 weeks.

Patients taking Crenessity reduced their daily glucocorticoid dose by 27% while keeping levels of an androgen hormone, called androstenedione, under control, compared to a 10% reduction in those receiving the placebo.

In the second trial, 69 pediatric patients received Crenessity twice daily and 34 received a placebo twice daily for 28 weeks. In it, those taking Crenessity reduced their daily glucocorticoid dose by 18% while keeping the hormone levels controlled, whereas patients on the placebo saw an almost 6% increase in their glucocorticoid dose.

Patients with the condition usually require high doses of glucocorticoids, beyond what is required to replace cortisol, because they also help lower excess androgen levels. (Reporting by Sriparna Roy in Bengaluru; Editing by Alan Barona)

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