BIOPHARMADIVE

DIVE BRIEF

FDA expands use of Neurocrine drug to Huntington's patients

Analysts expect the approval to intensify the market competition between Neurocrine's Ingrezza and a similar drug from Teva.

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Dive Brief:

- The Food and Drug Administration has approved a new treatment for patients with Huntington's disease, expanding the use of a medicine developed by the San Diego-based biotechnology company Neurocrine Biosciences.
- Neurocrine's drug, Ingrezza, is now cleared for use in adults who have a disorder often associated with Huntington's. Known as chorea, this disorder is characterized by sudden, involuntary muscle movements, and it can be caused by a variety of diseases or, sometimes, medications like levodopa.
- The FDA based its decision on results from two clinical trials, one of which remains ongoing. The studies have shown the severity of chorea significantly improves in patients who receive Ingrezza for a few months. Neurocrine's drug will now compete more directly with Austedo, a Teva Pharmaceutical medicine that, like Ingrezza, is approved to treat chorea as well as another neurological condition called tardive dyskinesia.

Dive Insight:

Ingrezza should help address an unmet need in the treatment of Huntington's-associated chorea, according to Charles Duncan, an analyst who covers Neurocrine for the investment firm Cantor Fitzgerald. In a note to clients, Duncan wrote that in the U.S. there are about 30,000 Huntington's patients, of which roughly 90% experience chorea. And among that group, approximately 70% have moderate-to-severe forms of the disorder.

Huntington's patients have had access to a couple other chorea treatments. Xenazine, approved in 2008, and Austedo, cleared for use in 2017, are believed to work in a way similar to Ingrezza. However, some analysts argue that Neurocrine's product may hold certain advantages.

For one, Ingrezza may have a "dosing convenience," according to Phil Nadeau of TD Cowen. The drug's label for chorea instructs healthcare providers to start with a 40 mg dose and titrate up to 60 mg or 80 mg depending on a patient's response and tolerance. Meanwhile, the extended-release version of Austedo starts with 12 mg — which Nadeau called a "small fraction" of the maximal 48 mg dose — and increases 6 mg a week as it titrates up.

Nadeau also notes how the main study that supported Ingrezza's approval appears to show a larger effect on chorea severity than the one that backed Austedo. "While physicians and investors are aware of the caveats of cross-trial comparisons, these results suggest that Ingrezza may produce a greater clinical benefit," the analyst wrote.

Nadeau and his team estimate that annual sales of Ingrezza will reach $1.8 billion this year and grow to $3 billion by 2027. Neurocrine last year recorded $1.4 billion in net sales from the drug.

Like Austedo, Ingrezza's label will be updated with a black box warning for depression and suicidal thoughts and behavior in patients with Huntington's. According to Cantor's Duncan, around 4.7% and 7.2% of participants in that key Ingrezza study reported depression or suicidal ideation, respectively.