

**DIVE BRIEF**

Karuna submits schizophrenia drug for US approval

If cleared by the FDA, the drug would offer the first new mechanism of action for treating schizophrenia in decades.

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Permission granted by Karuna Therapeutics

Dive Brief:

- Karuna Therapeutics has submitted an application seeking Food and Drug Administration approval of KarXT, a drug that works in a new way to treat schizophrenia.
- While current treatments act on mood-regulating chemicals such as dopamine, KarXT focuses on a neurotransmitter called acetylcholine that affects brain function. Studies supporting the application found that the new drug could reduce symptoms of schizophrenia without some of the common side effects that plague existing medications, Karuna said Thursday.
- Critically, Karuna's submission came before Oct. 1, when hard-line Republicans may force a government shutdown that prevents the FDA from accepting new applications. By acting now, Karuna should get an answer from regulators around this time next year, RBC Capital Markets analyst Brian Abrahams wrote in a note to clients.

Dive Insight:

The filing is a major milestone for Karuna, as it seeks to transform from a company best known for one promising experimental drug into a commercial operation with a deeper bench of medicines. Karuna tapped Allergan veteran Bill Meury as CEO in December and in February bought up the pipeline of the faltering Goldfinch Bio.

If approved, KarXT would be entering a market with a huge need for new options. About 2.8 million people in the U.S. suffer from schizophrenia, and almost a third don't respond to currently available therapies, per Karuna. Even more patients only get a partial benefit from existing medicines or can't handle them because of side effects.

Doctors are eager for alternative treatments and appear to view the KarXT data favorably, according to RBC's Abrahams. He expects the medicine to win approval and bring in peak sales of \$1.2 billion.

The drug also received a vote of confidence in March, when Royalty Pharma bought a portion of royalty rights held by PureTech Health, which had originally advanced KarXT.