MedicalXpress

Gov't panel backs drug for delusions in Parkinson's patients

March 29 2016, by Matthew Perrone

Federal health experts have endorsed an experimental drug intended to treat psychotic delusions and behaviors that often afflict patients with Parkinson's disease, the debilitating movement disorder.

The panel of Food and Drug Administration advisers voted 12-2 Tuesday that the benefits of the drug from Acadia Pharmaceuticals outweigh the risks. That vote—considered a recommendation for approval—is non-binding, though the FDA often follows the advice of its panelists.

San Diego-based Acadia Pharmaceuticals Inc. has asked the FDA to approve pimavanserin to treat hallucinations, delusions and irrational behavior associated with Parkinson's disease, a neurodegenerative disease that primarily causes tremors and other movement problems.

Approximately half of all Parkinson's patients suffer from the psychotic problems, according to the FDA. There are no FDA-approved drugs currently available for the condition. Parkinson's is the second-most common neurodegenerative disease in the U.S., after Alzheimer's.

While Acadia's drug had only modest benefits in most patients and was linked to serious safety issues, most panelists ultimately said it would fill an important need.

"We all want the effect size to be larger but it's certainly convincing in the sense that it is here and meaningful," said Dr. Tobias Gerhard of the

Rutgers University, who voted in favor of the drug.

During a public hearing session at Tuesday's meeting, patients and doctors detailed harrowing stories of Parkinson's patients lashing out at family members due to paranoia and delusions. Medical experts still disagree on whether such problems are caused by the underlying Parkinson's disease itself or the drugs used to manage it.

FDA scientists presented a complex, mixed review of pimavanserin's performance and whether its benefits outweighed significant, hard-to-define risks.

On a questionnaire measuring hallucinations and other symptoms, patients taking the drug showed a 23 percent improvement over patients taking a fake pill. According to FDA reviewers, that change represented a "minimal improvement" based on commonly-used clinical measures.

At the same time, negative health events, including death, were more than twice as likely in the drug group, affecting nearly 8 percent of patients. There was no clear explanation for the increased health problems seen with the drug compared to patients taking the sham treatment.

Ultimately, the FDA concluded that for every two patients who experienced a major reduction in their psychotic symptoms, one patient would suffer a serious adverse event.

Still, with virtually no alternatives, most panelists backed the drug.

"Even if the effects are modest you have to compare it with what's available right now, which based on what we've been presented with, is nothing," said Dr. David Brent of the University of Pittsburgh School of Medicine, who chaired the panel.

The FDA will make its own decision on whether to approve the drug by May 1.

Pimavanserin is part of the antipsychotic family of medications, including Abilify, Zyprexa and Seroquel, which are used to treat schizophrenia and bipolar disorder. Acadia believes that its drug's unique interaction with dopamine receptors makes it an effective treatment for psychosis in Parkinson's patients.

Shares of Acadia Pharmaceuticals Inc. were halted ahead of the meeting. On Monday, shares rose more than 17 percent to close at $23.81 in anticipation of the FDA panel meeting.