FDA approves cresemba for serious fungal infections

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(HealthDay)—Cresemba (isavuconazonium sulfate) has been approved by the U.S. Food and Drug Administration to treat invasive aspergillosis and invasive mucormycosis, the agency said Friday in a news release.

These rare but serious fungal infections mostly affect people with weakened immune systems. The new drug, targeting the cell walls of the fungi, is available in oral and intravenous formulations.

Cresemba's safety and effectiveness were evaluated in clinical studies involving more than 500 people. The most common side effects included nausea, vomiting, diarrhea, headache, hypokalemia, constipation, dyspnea, coughing, and peripheral edema. More serious adverse effects could include liver problems and allergic reactions.

"Today's approval provides a new treatment option for patients with serious fungal infections and underscores the importance of having

available safe and effective antifungal drugs," Edward Cox, M.D., M.P.H, director of the Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research, said in a statement.

Cresemba is marketed by Astellas Pharma US, based in Northbrook, Ill.

More information: More Information