

New antifungal as effective as existing drugs with fewer adverse events

September 7 2014

A newly developed antifungal, isavuconazole, is as effective as an existing drug, voriconazole, against invasive mold disease in cancer patients with less adverse effects, according to phase 3 clinical data presented at the 54th Interscience Conference on Antimicrobial Agents and Chemotherapy, an infectious disease meeting of the American Society for Microbiology.

"There is a growing need for new antifungal therapies like isavuconazole because serious <u>fungal infections</u> caused by *Aspergillus* and other molds are on the rise due to the increasing numbers of immunosuppressed patients, including those with active cancer. These infections are associated with high morbidity and mortality. If approved, isavuconazole has the potential to be an important new option for the treatment of these life-threatening fungal infections," says Andrew Ullman of Julius Maximilians University in Wuerzburg, Germany, one of the researchers presenting data.

Invasive fungal infections are important causes of morbidity and death for patients with hematological malignancies. Many leukemia and lymphoma patients receive high-dose chemotherapy, sometimes followed by stem cell transplantation, compromising their immune systems. The genus *Aspergillus* comprises several hundred species of mold that are ubiquitous in the environment but pose little threat to people with healthy immune systems. Immunocompromised patients, however, are more vulnerable to infection.



Ullman presented results from a large randomized Phase 3 study comparing the efficacy and safety of isavuconazole, a newly developed antifungal, with <u>voriconazole</u> in a subset of <u>patients</u> with uncontrolled cancer. The results showed that isavuconazole was as effective as voriconazole for treatment of invasive mold disease. In addition, isavuconazole had significantly fewer drug-related adverse events than voriconazole.

"In this study, isavuconazole had significantly fewer adverse events than voriconazole, particularly in the eye, skin, and hepatobiliary (liver, gall blabber, and bile duct) organ classes. These results show the potential of isavuconazole as a potent antifungal in the fight against invasive mold disease," says Kieren Marr of Johns Hopkins University who also presented data from the clinical trial.

Isavuconazole is an investigational once-daily intravenous and oral broadspectrum antifungal being developed by Astellas and Basilea Pharmaceutica International Ltd. for the treatment of life-threatening invasive fungal infections. Recently Astellas submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for isavuconazole for the treatment of invasive aspergillosis and invasive mucormycosis (also known as zygomycosis).

More information: This research was presented as part of the ASM's 54th ICAAC held September 5-9, 2014 in Washington, DC.

Provided by American Society for Microbiology

Citation: New antifungal as effective as existing drugs with fewer adverse events (2014, September 7) retrieved 27 April 2024 from <u>https://medicalxpress.com/news/2014-09-antifungal-effective-drugs-adverse-events.html</u>



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