Vfend® (voriconazole) – Expanded indication

- On January 29, 2019, the FDA approved Pfizer's Vfend (voriconazole), for use in pediatric and adult patients (2 years of age and older) in the treatment of the following fungal infections:
    - Invasive apergillosis. In clinical trials, the majority of isolates recovered were *Aspergillus fumigatus (A. fumigatus)*. There were a small number of cases of culture-proven disease due to species of *Aspergillus* other than *A. fumigatus.*
    - Candidemia in non-neutropenic patients and the following *Candida* infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and wounds.
    - Esophageal candidiasis
    - Serious fungal infections caused by *Scedosporium apiospermum* (asexual form of *Pseudallescheria boydii*) and *Fusarium spp.* including *Fusarium solani*, in patients intolerant of, or refractory to, other therapy.

- Previously, Vfend was approved for use in patients 12 years of age and older.

- The safety and effectiveness of Vfend have been established in pediatric patients 2 years of age and older based on evidence from adequate and well-controlled studies in adult and pediatric patients and additional pediatric pharmacokinetic and safety data.
    - A total of 105 pediatric patients aged 2 to less than 12 (n = 26) and aged 12 to less than 18 (n = 79) from two, non-comparative phase 3 pediatric studies and eight adult therapeutic trials provided safety information for Vfend use in the pediatric population.

- The recommended intravenous (IV) and oral dosing regimen for pediatric patients 2 to less than 12 years of age is provided below.

<table>
<tr><th rowspan="2"></th><th>Loading dose</th><th colspan="2">Maintenance dose</th></tr>
<tr><th>IV infusion</th><th>IV infusion</th><th>Oral</th></tr>
<tr><td>Invasive aspergillosis</td><td rowspan="3">9 mg/kg every 12 hours for the first 24 hours</td><td rowspan="3">8 mg/kg every 12 hours after the first 24 hours</td><td rowspan="3">9 mg/kg every 12 hours (maximum dose of 350 mg every 12 hours)</td></tr>
<tr><td>Candidemia in nonneutropenics and other deep tissue Candida infections</td></tr>
<tr><td>Scedosporiosis and Fusariosis</td></tr>
<tr><td>Esophageal Candidiasis</td><td>Not evaluated</td><td>4 mg/kg every 12 hours</td><td>9 mg/kg every 12 hours (maximum dose of 350 mg every 12 hours)</td></tr>
</table>

    - An IV infusion regimen should be used for therapy initiation. An oral regimen can be considered only after there is a significant clinical improvement.
    - The oral dose recommendation for children is based on studies in which Vfend was administered as the powder for oral suspension formulation. Bioequivalence between the Vfend powder for oral suspension and Vfend tablets has not been investigated in a pediatric population.