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Shionogi and F2G report Phase 3 results for oral antifungal olorofim

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OASIS met its primary endpoint in patients with invasive aspergillosis unsuitable for or unresponsive to azole therapy

Shionogi and F2G have reported detailed results from the global Phase 3 OASIS study evaluating investigational oral antifungal olorofim against AmBisome, followed by standard of care, in adults with invasive aspergillosis.

The randomised study enrolled 225 patients whose infections could not be treated appropriately with mould-active azole therapies or had failed to respond to them. Patients were allocated two to one to receive olorofim or the comparator regimen.

OASIS met its primary endpoint of non-inferiority for all-cause mortality at Day 42, using a prespecified margin of 20 percentage points. Mortality was 23.8% with olorofim and 24.3% with the comparator, a difference of ?0.5 percentage points.

The companies first announced positive topline findings in June. The detailed results are being presented at IDWeek 2026.

Drug-related adverse events were reported in 35.8% of olorofim recipients and 63.9% of comparator recipients. Drug-related renal events occurred in 1.3% and 22.2%, respectively.

Drug-induced liver injury remains an important safety signal. Events assessed as at least possibly related to treatment occurred in 4.6% of olorofim recipients and 4.2% of comparator recipients.

Invasive aspergillosis primarily affects immunocompromised patients, with limited options available when azole therapy is unsuitable. Olorofim belongs to the orotomide antifungal class and has activity against Aspergillus species, including azole-resistant strains.

Olorofim remains investigational. F2G anticipates resubmitting its US New Drug Application by the end of 2026. Shionogi is responsible for development and commercialisation in Europe and Asia.