

US FDA approves Asahi Kasei's drug for persistent herpes infections

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Bengaluru: The US FDA on Friday approved Japan's Asahi Kasei's drug for persistent herpes simplex virus sores in certain patients with weakened immune systems who have not responded to available antiviral treatments.

The oral drug, called pritelivir, was developed by German drugmaker Aicuris, which Asahi Kasei acquired in April

Pritelivir blocks proteins the herpes virus needs to copy its genetic material, stopping it from multiplying and allowing the drug to work against some infections resistant to older treatments

Older first-line drugs must be activated by a viral enzyme before blocking replication, and mutations that disrupt this activation can cause resistance

The US Food and Drug Administration's approval was based on a late-stage trial involving 101 participants, in which sores healed completely within 28 days in 62.7% of patients who were given pritelivir, compared to 34% receiving other treatments

The trial compared pritelivir with doctors' choice of intravenous foscarnet, the main approved alternative, or cidofovir and imiquimod - older medicines used off-label

The commonly reported side effects in the trial included headache, diarrhea, nausea, reduced appetite, vomiting and dizziness

Asahi Kasei had previously estimated pritelivir could serve about 15,000 US patients with weakened immune systems, and generate peak annual sales of more than \$400 million in the mid-to-late 2030s

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