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CDSCO gives positive recommendation to Servier to use Vorasidenib for brain cancer patients

06 August 2025 | News

Committee grants a waiver for local Phase-III clinical trials, acknowledging the drug's orphan drug status in other countries



Servier India, a research-driven pharmaceutical organisation focused on oncology and specialty therapeutic areas, has received a positive recommendation from the Subject Expert Committee (SEC) under the Central Drugs Standard Control Organization (CDSCO) to import and market Vorasidenib Tablets 10 mg and 40 mg in India.

The committee granted a waiver for local Phase-III clinical trials, acknowledging the drug's orphan drug status in other countries and the unmet medical needs in India. The committee further recommended that Servier should conduct Phase IV clinical trial on Indian patients for which the protocol should be submitted to CDSCO within 3 months of approval of the drug for review by the committee.

Vorasidenib is a therapy for treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma (brain tumours) with a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation following surgery including biopsy, sub-total resection, or gross total resection.

Headquartered in France, Servier relies on a strong geographical footprint; its medicines are available in close to 140 countries. The group achieved a revenue of €5.9 billion in 2024.