FDA Approves Asparlas

FDA Approves Asparlas (calaspargase pegol-mknl) for Acute Lymphoblastic Leukemia (ALL)

On December 20, 2018, the Food and Drug Administration approved calaspargase pegol-mknl (ASPARLAS, Servier Pharmaceuticals LLC), an asparagine specific enzyme, as a component of a multi-agent chemotherapeutic regimen for acute lymphoblastic leukemia (ALL) in pediatric and young adult patients age 1 month to 21 years. This new product provides for a longer interval between doses compared to other available pegaspargase products.

Approval was based on a demonstration of the achievement and maintenance of nadir serum asparaginase activity above the level of 0.1 U/mL when using calaspargase pegol-mknl, 2500 U/m2 intravenously, every 3 weeks. The pharmacokinetics of calaspargase pegol-mknl were studied when administered in combination with multiagent chemotherapy in 124 patients with B-cell lineage ALL.

The most common (incidence ≥ 10%) grade ≥ 3 adverse reactions were elevated transaminase, increased bilirubin, pancreatitis, and abnormal clotting studies. In a randomized trial, the safety profile of calaspargase pegol-mknl administered every 3 weeks was similar to that of pegaspargase administered every 2 weeks.

The recommended calaspargase pegol-mknl dose is 2,500 units/m^2 intravenously administered at a minimum dosing interval of every 21 days.

Calaspargase pegol-mknl received FDA orphan product designation.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

Source: FDA

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Asparlas (calaspargase pegol-mknl) FDA Approval History