Generic Name:
Omacetaxine mepesuccinate
Trade Name:
Synribo
Company:
Teva
Notes:

FDA announced the accelerated approval of omacetaxine mepesuccinate to treat adults with chronic myelogenous leukemia (CML). This novel agent is indicated for the treatment of adult patients with chronic or accelerated phase CML with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKIs). Omacetaxine mepesuccinate's mechanism of action has not been fully elucidated but includes inhibition of protein synthesis.

The drug is given as a 1.25 mg/m^2 induction dose administered by subcutaneous injection twice daily for 14 consecutive days of a 28-day cycle, with cycles repeated every 28 days until patients achieve a hematologic response. Patients are then treated with a maintenance dose of 1.25 mg/m^2 given twice daily for 7 consecutive days of a 28-day cycle.

Approval was based on data from a combined cohort of patients whose cancer progressed after previous treatment with two or more TKIs. All patients were treated with omacetaxine mepesuccinate. For patients with chronic phase CML, 14 out of 76 patients (18.4%) achieved a major cytogenetic response after a mean of 3.5 months. The median duration of the major cytogenetic response was 12.5 months. For those in the accelerated phase, 5 out of 35 patients (14.3%) achieved a major hematologic response after a mean of 2.3 months, with a median duration of 4.7 months.

The most common adverse events with omacetaxine mepesuccinate, occurring at a frequency of 20% or more, included thrombocytopenia, anemia, neutropenia/febrile neutropenia, diarrhea, nausea, weakness and fatigue, injection site reaction, and lymphopenia.

Medication Monitor Categories:
New Drug Approvals
Use:

Management of CML