Generic Name:
Fostamatinib disodium hexahydrate
Trade Name:
Tavalisse
Company:
Rigel Pharmaceuticals
Notes:

Rigel Pharmaceuticals announced FDA approval of fostamatinib disodium hexahydrate to treat thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

The agent is an oral spleen tyrosine kinase (SYK) inhibitor that targets the underlying autoimmune cause of the disease by impeding platelet destruction, providing an important new treatment option for adult patients with chronic ITP.

FDA approval was supported by data from the FIT clinical program, which included two randomized, placebo-controlled Phase III trials and an open-label extension, as well as an initial proof of concept study. The studies included 163 patients with ITP and was supported by a safety database of more than 4,600 participants across other indications in which fostamatinib has been evaluated.

Rigel plans to launch the new drug in the United States in late May 2018.

Medication Monitor Categories:
New Drug Approvals