Generic Name:
Inotersen
Trade Name:
Tegsedi
Company:
Akcea Therapeutics and Ionis Pharma
Notes:

Akcea Therapeutics and Ionis Pharma announced FDA approval of inotersen for treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adults. It reduces the production of transthyretin (TTR) protein through a once-weekly S.C. injection. In hATTR amyloidosis, TTR protein misfolds and accumulates as amyloid deposits throughout the body.

FDA?s approval of inotersen was based on results from the Phase III NEURO-TTR study in patients with hATTR amyloidosis with symptoms of polyneuropathy.

Results demonstrated that patients treated with inotersen experienced significant benefit compared with patients treated with placebo across both coprimary endpoints: the Norfolk Quality of Life Questionnaire?Diabetic Neuropathy and modified Neuropathy Impairment Score +7, a measure of neuropathic disease progression.

Inotersen is associated with risk of thrombocytopenia and glomerulonephritis. Enhanced monitoring is required to support early detection and management of these identified risks. For full prescribing information, including a boxed warning, please visit www.TEGSEDI.com. Inotersen is being marketed with a Risk Evaluation and Mitigation Strategy (REMS).

The most common adverse effects include injection-site reactions (such as redness or pain at the injection site), nausea, headache, tiredness, low platelet counts, and fever.

Medication Monitor Categories:
New Drug Approvals