Drug Express

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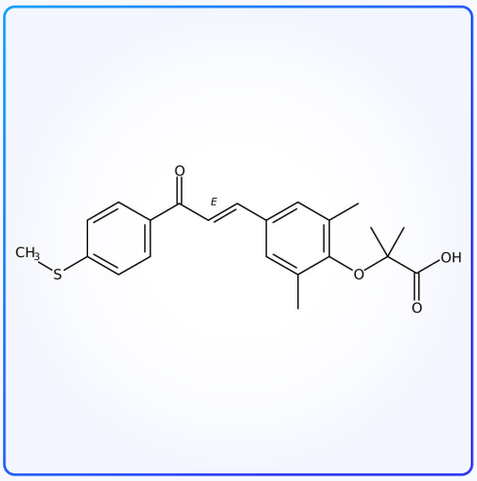
Weekly New Drug Approvals

Jun. 17th 2024

Elafibranor



FDA Approval Date: Jun 10th, 2024

Brand name: Iqirvo

Indication: Primary Biliary Cholangitis

Mechanism: PPARα agonists/PPARδ agonists

Dosage form: Tablet

Company: Ipsen

Elafibranor is a dual PPARα/δ agonist. Elafibranor and its main active metabolite GFT1007 are peroxisome proliferator-activated receptor (PPAR) agonists, both of which activate PPAR-α, PPAR-γ, and PPAR-δ in vitro.

- approval was supported by data from the Phase III ELATIVE trial. In November 2023, Ipsen and Genfit published data from the study in The New England Journal of Medicine, touting a 51% biochemical response rate as assessed through alkaline phosphatase levels, a biochemical marker often used as a surrogate endpoint in PBC studies. By comparison, only 4% of placebo counterparts hit the primary outcome.

- Elafibranor also met its key secondary endpoints, normalizing alkaline phosphatase levels in 15% of treated patients, compared to none in the placebo arm.

- The most common side effects associated with elafibranor included abdominal pain, diarrhea, weight gain, nausea and vomiting. Some patients developed myalgia, myopathy, rhabdomylosis, fractures and drug-induced liver injuries.