Filspari® (sparsentan) – Updated indication, accelerated approval converted to full approval

- On September 5, 2024, Travere Therapeutics announced the full FDA approval of Filspari (sparsentan), to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.
- This FDA action converts the accelerated approval of Filspari to a full approval and updates the indication.
    - The original accelerated approval was to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio ≥ 1.5 g/g.
- The full approval of Filspari for the updated indication was based on PROTECT, a randomized, double-blind, active-controlled study in 404 adults with primary IgAN on a stable dose of maximally-tolerated renin-angiotensin system (RAS) inhibitor treatment. Patients were randomized to either Filspari or irbesartan. The key endpoint for the full approval was the rate of change in estimated glomerular filtration rate (eGFR) over a 110-week period following initiation of randomized therapy.
    - The mean eGFR slope from baseline to week 110 was -3.0 mL/min/1.73 m^2 per year for Filspari and 4.2 mL/min/1.73 m^2 per year for irbesartan, corresponding to a treatment effect of 1.2 mL/min/1.73 m^2 per year (95% CI: 0.2, 2.1; p = 0.0168).
- Filspari carries a boxed warning for hepatotoxicity and embryo-fetal toxicity.
    - Filspari is only available through a restricted distribution program called the Filspari Risk Evaluation and Mitigation Strategies (REMS).
- The recommended initial dose of Filspari 200 mg orally once daily. After 14 days, the dose should be increased to the recommended dose of 400 mg once daily, as tolerated.