Tavneos™ (avacopan) – New orphan drug approval

- On October 8, 2021, ChemoCentryx announced the FDA approval of Tavneos (avacopan), as an adjunctive treatment of adult patients with severe active antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids.
    - Tavneos does not eliminate glucocorticoid use.
- ANCA-associated vasculitis is a systemic disease in which over-activation of the complement pathway further activates neutrophils, leading to inflammation and destruction of small blood vessels. This results in organ damage and failure, with the kidney as the major target, and is fatal if not treated.
- Tavneos is a first in-class a complement 5a receptor (C5aR) antagonist that inhibits the interaction between C5aR and the anaphylatoxin C5a. Tavneos blocks C5a-mediated neutrophil activation and migration. The precise mechanism by which Tavneos exerts a therapeutic effect in patients with ANCA-associated vasculitis has not been definitively established.
- The efficacy of Tavneos was established in a double-blind, active-controlled study in 330 patients with newly diagnosed or relapsed ANCA-associated vasculitis. Patients were randomized to one of the following treatment groups: Tavneos for 52 weeks plus prednisone-matching placebo for 20 weeks (Tavneos group) or Tavneos-matched placebo for 52 weeks plus prednisone (tapered from 60 mg/day to 0 over 20 weeks) (prednisone group). The primary endpoints were disease remission at week 26 and sustained disease remission at Week 52. Disease remission was defined as achieving a Birmingham Vasculitis Activity Score (BVAS) of 0 and no use of glucocorticoids for treatment of ANCA-associated vasculitis from week 22 to week 26. Sustained remission was defined as remission at week 26 and remission at Week 52, without relapse between week 26 and week 52.
    - Remission was achieved by 72.3% of patients in the Tavneos group and 70.1% of patients in the prednisone group at week 26 (difference: 3.4, 95% CI: -6.0, 12.8%).
    - At week 52, a significantly higher percentage of patients had sustained remission in the Tavneos group (65.7%) vs. the prednisone group (54.9%) (difference: 12.5, 95% CI: 2.6, 22.3; p = 0.013).
- Warnings and precautions for Tavneos include hepatotoxicity, hypersensitivity reactions, hepatitis B virus (HBV) reactivation, and serious infections.
- The most common adverse reactions (≥ 5%) with Tavneos use were nausea, headache, hypertension, diarrhea, vomiting, rash, fatigue, upper abdominal pain, dizziness, blood creatinine increased, and paresthesia.
- The recommended dosage of Tavneos is 30 mg (three 10 mg capsules) twice daily.
    - Before initiating Tavneos, liver function tests and HBV serology evaluations should be considered.
- ChemoCentryx expects to launch Tavneos in the next few weeks. Tavneos will be available as a 10 mg capsule.