Avacopan: Adis Evaluation

Key Points

- A complement 5a receptor antagonist developed by ChemoCentryx for the treatment of autoimmune diseases including ANCA-associated vasculitis
- Received its first approval on 27 September 2021 in Japan and was subsequently approved in the USA on 7 October 2021
- Approved for use in Japan in the treatment of MPA and GPA and in the USA as an adjunctive treatment in adults for severe active ANCA-associated vasculitis (specifically MPA and GPA) in combination with standard therapy including glucocorticoids (avacopan does not eliminate glucocorticoid use)

Summary

Avacopan (TAVNEOS™) is a complement 5a receptor (C5aR) antagonist developed by ChemoCentryx for the treatment of autoimmune diseases including anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis. The therapeutic effects of avacopan are attributed to the inhibition of C5aR activity on neutrophils, however, the exact mechanism of therapeutic efficacy in patients with ANCA-associated vasculitis has not been established.

In September 2021, avacopan received its first approval in Japan for the treatment of microscopic polyangiitis (MPA) and granulomatosis with polyangiitis (GPA), the two most common forms of ANCA-associated vasculitis, where it is being commercialized by Kissei Pharmaceutial through a partnership with Vifor Pharma. In October 2021, avacopan was approved in the USA as an adjunctive treatment in adults for severe active ANCA-associated vasculitis (specifically MPA and GPA) in combination with standard therapy including glucocorticoids (avacopan does not eliminate glucocorticoid use). Avacopan has received a positive opinion in the EU, and is also undergoing regulatory review in Switzerland and Canada. Avacopan is being investigated for the treatment of complement component 3 glomerulopathy, hidradenitis suppurativa, lupus nephritis and IgA nephropathy.

This article summarizes the milestones in the development of avacopan leading to these first approvals in Japan and the USA