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Japan approves first orally administered therapy for rare autoimmune renal disease

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For the treatment of antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis



Swiss firm Vifor Fresenius Medical Care Renal Pharma (VFMCRP) has announced that Japan's Ministry of Health and Labor Welfare (MHLW) has granted its partner, Kissei Pharmaceutical, marketing authorization approval for TAVNEOS® for the treatment of patients with granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA), the two main types of ANCA-associated vasculitis, a rare and severe autoimmune renal disease with high unmet medical need.

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.

The approval is based on the marketing authorization application filing by Kissei which was supported by positive clinical data from the pivotal phase-III trial ADVOCATE in a total of 331 patients with MPA and GPA in 18 countries and regions, including Japan. TAVNEOS® demonstrated superiority over standard of care at week 52 based on Birmingham Vasculitis Activity Score (BVAS).