VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA

Press Release

VFMCRP receives positive CHMP opinion for Tavneos® for the treatment of ANCA-associated vasculitis

- **Committee for Medicinal Products for Human Use (CHMP) recommends approval of first orally administered therapy for the treatment of ANCA-associated vasculitis (GPA and MPA) in Europe**
- **European Commission decision for EU Marketing Authorization expected in Q1 2022**

St. Gallen, Switzerland, 12 November 2021 – Vifor Fresenius Medical Care Renal Pharma (VFMCRP) today announced that the European Medicines Agency's (EMA) CHMP has recommended approval of Tavneos® (avacopan) in combination with a rituximab or cyclophosphamide regimen for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), the two main forms of ANCA-associated vasculitis. A positive opinion by the CHMP is a formal scientific recommendation supporting marketing authorization across the EU. CHMP Opinions are the basis for the European Commission's final Decision regarding marketing authorization for Tavneos®, which is expected in Q1 2022.

"We are very encouraged by the recommendation from the CHMP and we anticipate the final ratification by the European Commission in Q1 2022", commented Dr. Klaus Henning Jensen, Chief Medical Officer of Vifor Pharma. "There is an unmet need for additional therapeutic options for patients suffering from ANCA-associated vasculitis and the challenging side-effects of current standard of care. Tavneos® can become the new standard for the treatment of this systemic and debilitating disease, with the potential to significantly help an underserved patient population lead better, healthier lives."

The positive CHMP opinion is based on a full multi-trial development program, culminating in the results from the pivotal phase-III trial ADVOCATE in 331 patients with ANCA-associated vasculitis in 20 countries, comparing treatment regimens including Tavneos® to current standard of care treatment regimens with high dose glucocorticoid use. The study met its primary endpoints of disease remission at 26 weeks and sustained remission at 52 weeks, as assessed by the Birmingham Vasculitis Activity Score (BVAS). Avacopan regimen demonstrated superiority over standard of care at week 52 and showed renal improvement.

If approved by the European Commission, Tavneos® will receive marketing authorization in all member states of the European Union, as well as in Iceland, Liechtenstein and Norway.

Tavneos® has recently been approved by the U.S. Food and Drug Administration as an adjunctive treatment to standard therapy for adult patients with severe ANCA-associated vasculitis, as well as by Japan's Ministry of Health and Labor Welfare for the treatment of patients with GPA and MPA. VFMCRP holds the rights to commercialize Tavneos® outside the U.S.

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About Vifor Pharma Group

Vifor Pharma Group is a global pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is a partner of choice for pharmaceuticals and innovative patient-focused solutions. Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The company develops, manufactures and markets pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma and Vifor Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care). Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348).
For more information, please visit viforpharma.com.

About ANCA-associated vasculitis
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. Currently, treatment for ANCA-associated vasculitis consists of courses of non-specific immuno-suppressants (cyclophosphamide or rituximab), combined with the administration of daily glucocorticoids (steroids) for prolonged periods of time, which can be associated with significant clinical risk including death from infection.

About Tavneos® (avacopan)
Tavneos® (avacopan) is an orally administered small molecule that is a selective inhibitor of the complement C5a receptor C5aR1. By precisely blocking the receptor (the C5aR) for the pro-inflammatory complement system fragment, C5a on destructive inflammatory cells such as blood neutrophils, Tavneos® arrests the ability of those cells to do damage in response to C5a activation, which is known to be the driver of inflammation. Moreover, Tavneos® selective inhibition of only the C5aR1 leaves the beneficial C5a l pathway through the C5L2 receptor functioning normally.

Tavneos® was developed by ChemoCentryx Ltd. who is also developing Tavneos® for the treatment of patients with C3 Glomerulopathy (C3G) and hidradenitis suppurativa (HS). The U.S. Food and Drug Administration has granted Tavneos® orphan-drug designation for ANCA-associated vasculitis, C3G and atypical hemolytic uremic syndrome. The European Commission has granted orphan medicinal product designation for Tavneos® for the treatment of two forms of ANCA vasculitis: microscopic polyangiitis and granulomatosis with polyangiitis (formerly known as Wegener's granulomatosis), as well as for C3G.

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