VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA

Press Release

VFMCRP receives EU approval for Tavneos® for the treatment of ANCA-associated vasculitis

- **First orally administered therapy for the treatment of the two main types of ANCA-associated vasculitis approved in Europe**
- **First launches expected in H1 2022**

St. Gallen, Switzerland, 19 January 2022 – Vifor Fresenius Medical Care Renal Pharma (VFMCRP) today announced that the European Commission has approved Tavneos® in combination with a rituximab or cyclophosphamide regimen for the treatment of adult patients with severe, active granulomatosis polyangiitis (GPA) or microscopic polyangiitis (MPA), the two main forms of ANCA-associated vasculitis. The approval is consistent with expectations and overall follows the U.S. Food and Drug Administration (FDA) approval of Tavneos® in October 2021 for the same indication. Tavneos® will receive marketing authorization in all member states of the European Union, as well as in Iceland, Liechtenstein and Norway.

“The European Commission’s approval of Tavneos® is a milestone for the treatment of ANCA-associated vasculitis in Europe and for patients living with this debilitating disease,” said Dr. Klaus Henning Jensen, Chief Medical Officer of Vifor Pharma. “We are confident that Tavneos® can become part of the new standard of care supporting better outcomes for patients, a better quality of life, and reduce the challenging side-effects of current treatment options. We look forward to working with EU member states to provide access to this important medicine, with first launches expected in the first half of 2022.”

“This is a significant step forward for patients in Europe living with this systemic condition,” said Prof. David Jayne, Professor of Clinical Autoimmunity, University of Cambridge. “They will now have available a new class of medication that meets major unmet medical needs in the treatment of ANCA-associated vasculitis.”

EU approval is based on a comprehensive 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 week 26 and sustained remission at week 52, as assessed by the Birmingham Vasculitis Activity Score (BVAS). Tavneos® demonstrated superiority over standard of care at week 52.

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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, in combination with 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 blocking the receptor (the C5aR) for the pro-inflammatory complement system fragment, C5a on 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-associated vasculitis: MPA and GPA (formerly known as Wegener's granulomatosis), as well as for C3G.

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