VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA

Press Release

VFMCRP announces approval for TAVNEOS® (avacopan) for the treatment of ANCA-associated vasculitis in Japan

- **First orally administered therapy for the treatment of two types of ANCA-associated vasculitis approved in Japan**
- **Partner Kissei to market TAVNEOS® in Japan, with launch expected as soon as possible following National Health Insurance (NHI) price listing**

St. Gallen, Switzerland, 27 September 2021 – Vifor Fresenius Medical Care Renal Pharma (VFMCRP) today announced that Japan's Ministry of Health and Labor Welfare (MHLW) has granted its partner, Kissei Pharmaceutical Co., Ltd., 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.

"We are delighted that TAVNEOS® has been approved in Japan, the first market worldwide, and congratulate our partner Kissei for this significant milestone," said Abbas Hussain, CEO of Vifor Pharma Group. "ANCA-associated vasculitis is officially designated an intractable disease in Japan, indicating a rare disease without any effective treatment but for which long-term treatment is required. There is significant unmet medical need of over 10,000 patients in Japan, and we believe in the potential of TAVNEOS® for treating it. We are confident that Kissei will fully focus on bringing this breakthrough treatment to this patient population, helping them lead better, healthier lives."

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).

VFMCRP holds the rights to commercialize TAVNEOS® outside the U.S.. In June 2017, VFMCRP granted Kissei the exclusive right to develop and commercialize TAVNEOS® in Japan. Kissei expects to begin to market TAVNEOS® as soon as possible following NHI price listing. Outside Japan, TAVNEOS is currently in regulatory review with various agencies, including the U.S. Food and Drug Administration and the European Medicines Agency.

Contact and further information:

Media Relations
Nathalie Ponnier
Global Head Corporate Communications
+41 79 957 96 73
media@viforpharma.com

Investor Relations
Julien Vignot
Head of Investor Relations
+41 58 851 66 90
investors@viforpharma.com

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 Kissei Pharmaceutical Co., Ltd.
Kissei Pharmaceutical Co., Ltd. is a Japanese pharmaceutical company with approximately 70 years of history. Based on its management philosophy, “contributing to society through high-quality, innovative pharmaceutical products” and “serving society through our employees”, Kissei is concentrating on providing innovative pharmaceuticals to patients worldwide as a strongly R&D-oriented corporation. Kissei is engaged in R&D and licensing activities in the field of nephrology/dialysis, urology, and unmet medical needs in other disease areas. Kissei has an established collaboration with VFMCRP for sucroferric oxyhydroxide which Kissei fully developed in Japan as P-TOL® (known as Velphoro® in Europe/US) for the treatment of hyperphosphatemia. Since the launch in 2015, the market share of P-TOL® has been steadily expanding in Japan. For more information about Kissei Pharmaceutical, please visit www.kissei.co.jp.

About ChemoCentryx Inc.
ChemoCentryx is a biopharmaceutical company developing new medications for inflammatory and autoimmune diseases and cancer. ChemoCentryx targets the chemokine and chemoattractant systems to discover, develop and commercialize orally-administered therapies. Besides ChemoCentryx’s lead drug candidate, avacopan, ChemoCentryx also has early stage drug candidates that target chemoattractant receptors in other inflammatory and autoimmune diseases and in cancer**.**

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)
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, avacopan arrests the ability of those cells to do damage in response to C5a activation, which is known to be the driver of inflammation. Moreover, avacopan’s selective inhibition of only the C5aR1 leaves the beneficial C5a l pathway through the C5L2 receptor functioning normally.

ChemoCentryx is also developing avacopan for the treatment of patients with C3 Glomerulopathy (C3G) and hidradenitis suppurativa (HS). The U.S. Food and Drug Administration has granted avacopan orphan-drug designation for ANCA-associated vasculitis, C3G and atypical hemolytic uremic syndrome. The European Commission has granted orphan medicinal product designation for avacopan 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. In October 2020, European Medicines Agency (EMA) accepted to review the Marketing Authorization Application (MAA) for avacopan for the treatment of patients with ANCA-associated vasculitis (granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA)).

Vifor Pharma Group
Flughofstrasse 61
8152 Glattbrugg
Switzerland

Phone +41 58 851 8000
E-mail info@viforpharma.com
Web viforpharma.com