VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA

# PRESS RELEASE

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# KISSEI TO MARKET AVACOPAN IN JAPAN FOR VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA

- **Kissei to have exclusive rights to develop and market avacopan in Japan**
- **Potential of avacopan further validated with expansion into Japanese market**
- **Deal further strengthens renal-alliance with Kissei**

VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA (VFMCRP) HAS GRANTED JAPANESE COMPANY KISSEI PHARMACEUTICAL CO LTD. EXCLUSIVE RIGHTS TO DEVELOP AND COMMERCIALISE AVACOPAN (CCX168) IN JAPAN.

Under the terms of the agreement, Kissei will have the exclusive right to develop avacopan (CCX168) in Japan and, once marketing authorisation has been granted, commercialise it in Japan. Vifor Fresenius Medical Care Renal Pharma will remain responsible for marketing avacopan everywhere else outside the United States and China, where it is commercialised by US biopharmaceutical company and Vifor Pharma licensor, ChemoCentryx.

The agreement with Kissei comes only two months after ChemoCentryx granted VFMCRP a territory expansion into Japan, which underscores the unmet medical need there and the potential of avacopan for treating it.

A focal point of the deal for Kissei is avacopan's potential for treating anti-neutrophil cytoplasmic auto-antibody (ANCA)-associated vasculitis (AAV). AAV is a rare, severe and often fatal autoimmune disease that is on the rise in Japan. AAV was officially designated an intractable disease by the Japanese Ministry of Health, Labor and Welfare. Intractable diseases are rare diseases for which no effective treatment exists but for which long-term treatment is required. Japan promotes research related to intractable diseases and financially supports patients with these diseases.

## FURTHER INFORMATION

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**Vifor Fresenius Medical Care Renal Pharma Ltd.**, a common company of Vifor Pharma Group and Fresenius Medical Care, develops and commercialises innovative and high quality therapies to improve the life of patients suffering from chronic kidney disease (CKD) worldwide. The company was founded at the end of 2010 and is owned 55% by Vifor Pharma Group and 45% by Fresenius Medical Care. For more information about Vifor Fresenius Medical Care Renal Pharma and its parent companies, please visit www.vfmcrp.com, www.viforpharma.com and www.freseniusmedicalcare.com.

**Vifor Pharma Group**, formerly Galenica Group, is a global specialty pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is the partner of choice for specialty 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; Vifor Fresenius Medical Care Renal Pharma, a joint company with Fresenius Medical Care; Relypsa; and OM Pharma. Vifor Pharma Group is listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348). For more information, visit www.viforpharma.com.

**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.

**Avacopan** is an orally-administered small molecule that is a selective inhibitor of the complement C5a receptor, or C5aR. Avacopan is in phase-III development for the treatment of anti-neutrophil cytoplasmic auto-antibody-associated vasculitis (AAV). In clinical studies to date, avacopan was shown to be safe, well tolerated and provided effective control of the disease while allowing elimination of high-dose steroids, part of the current standard of care. Avacopan is also being developed in patients with C3 glomerulopathy (C3G) and atypical hemolytic uremic syndrome (aHUS). The U.S. Food and Drug Administration has now granted avacopan orphan-drug designation for three indications, AAV, C3G and aHUS. The European Commission has granted orphan medicinal product designation for avacopan for the treatment of two forms of AAV microscopic polyangiitis and granulomatosis with polyangiitis (formerly known as Wegener's granulomatosis) and for CG3. Avacopan was also granted access to the European Medicines Agency's (EMA) PRIority MEdicines (PRIME) initiative, which supports accelerated assessment of investigational therapies addressing unmet medical need.

**ANCA-associated vasculitis (AAV)** is a rare, serious and often life-threatening disease. There are three sub-types of AAV: Wegener’s granulomatosis with polyangiitis (GPA), microscopic polyangiitis (MPA) and eosinophilic granulomatosis with polyangiitis (Churg–Strauss syndrome). AAV is triggered by anti-neutrophil cytoplasmic auto-antibodies and mediated by overactivated neutrophils through the terminal C5a complement damage pathway and C5a receptor. C5a and C5aR play a central role in the pathogenesis of AAV that results in the attack and destruction of the blood vessels, typically in the kidneys, lungs and other organs. AAV often occurs as a relapsing-remitting state characterized by recurring flares and accumulating irreversible organ damage that can lead to renal failure and death. The current standard of care for AAV is associated with significant safety issues. First year mortality is approximately 11 to 18 percent. The single major cause of premature mortality is not disease related adverse events, but rather infection that is thought largely to be a consequence of steroid administration. The multiple adverse effects of courses of steroid treatment (both initial courses and those that are repeated as a consequence of relapse) are major causes of both short-term and long-term disease and death. The current standard of care for AAV is associated with significant safety issues. First year mortality is approximately 11 to 18 percent. The single major cause of premature mortality is not disease related adverse events, but rather infection that is thought largely to be a consequence of steroid administration. The multiple adverse effects of courses of steroid treatment (both initial courses and those that are repeated as a consequence of relapse) are major causes of both short-term and long-term disease and death.