



Press Release

# VFMCRP and ChemoCentryx announce European Medicines Agency has accepted to review the Marketing Authorization Application for avacopan

- Companies have completed the EU regulatory application for marketing approval of avacopan
- Regulatory submission based on positive data from the pivotal phase-III ADVOCATE trial of avacopan

**St Gallen and Mountain View, CA, 3 November 2020** – Vifor Fresenius Medical Care Renal Pharma (VFMCRP) Ltd. and ChemoCentryx, Inc., today announced that the 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 polyangitis (GPA) and microscopic polyangitis (MPA)), a group of rare and severe autoimmune diseases with high need for targeted therapies.

If approved, avacopan would be the first orally administered selective complement 5a receptor inhibitor, for the treatment of patients with anti-neutrophil cytoplasmic antibody-associated vasculitis. Data from the global pivotal phase-III ADVOCATE trial demonstrated statistical superiority in sustaining remission at 52 weeks in the avacopan group compared to the prednisone group. In the trial, the avacopan group also showed significantly lower glucocorticoid toxicity, greater improvement in kidney function and greater improvement in health-related quality of life measures compared to the prednisone group.

The EMA will review the application under the centralized marketing authorization procedure. If approved avacopan would receive marketing authorization in all member states of the European Union (EU), as well as in Iceland, Liechtenstein and Norway. Approval is expected H2, 2021.

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**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 ChemoCentryx**

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. ChemoCentryx's lead drug candidate, avacopan (CCX168), successfully completed a pivotal Phase III trial in ANCA-associated vasculitis.

ChemoCentryx also has early stage drug candidates that target chemoattractant receptors in other inflammatory and autoimmune diseases and in cancer.

#### **About ADVOCATE and ANCA-Associated Vasculitis**

The ADVOCATE trial of avacopan was a global double-blind double-dummied Phase III trial of 331 patients with ANCA-associated vasculitis (ANCA vasculitis) in 20 countries.

ANCA 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 a major target. Treatment for ANCA vasculitis consists of courses of immuno-suppressants (cyclophosphamide or rituximab), combined with high-dose and often prolonged use of glucocorticoids which can be associated with significant adverse events. ANCA vasculitis is relapsing and remitting long term condition and patients are at risk of cumulative organ damage.

## **About 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 ANCA vasculitis. Avacopan therapy was designed to deliver effective control of the inflammatory vasculitic process and prevent relapse while also reducing the risk of treatment related damage. Moreover, avacopan's selective inhibition of only the C5aR1 leaves the beneficial C5a I 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.

## **Forward-Looking Statements**

ChemoCentryx cautions that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "potential," "continue" or "project" or the negative of these terms or other comparable terminology are intended to identify forward-looking statements. These statements include the Company's statements regarding whether avacopan will be approved for the treatment of ANCA vasculitis. The inclusion of forward-looking statements should not be regarded as a representation by ChemoCentryx that any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risks and uncertainties inherent in the ChemoCentryx business and other risks described in the Company's filings with the Securities and Exchange Commission ("SEC"). Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and ChemoCentryx undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. Further information regarding these and other risks is included under the heading "Risk Factors" in ChemoCentryx's periodic reports filed with the SEC, including ChemoCentryx's Annual Report on Form 10-K filed with the SEC on March 10, 2020 and its other reports which are available from the SEC's website (www.sec.gov) and on ChemoCentryx's website (www.chemocentryx.com) under the heading "Investors." All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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