



## PRESS RELEASE

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# CHEMOCENTRYX ANNOUNCES WITHDRAWAL OF PHASE II-BASED CONDITIONAL MARKETING AUTHORISATION (CMA) APPLICATION FOR ANCA-ASSOCIATED VASCULITIS IN EUROPE, PHASE III ADVOCATE TRIAL DATA RELEASE **PLANNED FOR Q4 2019**

Companies plan to file for full marketing approval to EMA and FDA in 2020

MOUNTAIN VIEW, Calif. and ZURICH, 24 January, 2019 - ChemoCentryx, Inc. and Vifor Fresenius Medical Care Renal Pharma Ltd., a company of Vifor Pharma Group, today announced that in light of the upcoming availability of data from the pivotal Phase III ADVOCATE trial - the largest controlled trial in active anti-neutrophil cytoplasmic antibody associated vasculitis (ANCA-associated vasculitis) - they have decided to withdraw the application for Conditional Marketing Authorisation (CMA) of avacopan for the treatment of ANCA-associated vasculitis based on Phase II data. Efforts will now be exclusively directed to file integrated regulatory submissions in 2020 with the European Medicines Agency (EMA) and United States Food and Drug Administration (FDA) for full (unconditional) marketing approval, after the planned release of topline data from the Phase III ADVOCATE clinical trial anticipated already in the fourth quarter of 2019.

"Since pivotal topline data will be available from our global Phase III ADVOCATE trial later this year, we have decided not to proceed with our limited Phase II-based CMA in Europe," said Thomas J. Schall, Ph.D., President and Chief Executive Officer of ChemoCentryx. "The pace of the worldwide ADVOCATE trial enrollment was considerably greater than originally anticipated when we applied for the European CMA; which was based on data from our Phase II CLEAR trial comprising 12 week dosing on some 67 patients. Since Phase III ADVOCATE assesses more than 300 ANCA vasculitis patients through 52 weeks of treatment, the imminent comprehensive data set will be much more powerful than those in the CMA application, therefore enabling a more consistent set of filings in Europe and the US. We would like to thank the Rapporteurs and the Committee for Medicinal Products for Human Use (CHMP) for the valuable support and guidance they provided to us as we look forward to topline ADVOCATE data in the fourth quarter this year."

Stefan Schulze, President of the Executive Committee and Chief Operating Officer of Vifor Pharma Group, commented, "We strongly support the decision to focus on a full Market Authorisation. We believe this will offer regulators and the companies a much clearer view of the performance of avacopan in the treatment of ANCA-associated vasculitis, a group of rare kidney autoimmune diseases that lead to significant morbidity and mortality, and where there is a clear unmet need for safer and more efficacious therapies."

### **FURTHER INFORMATION**

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### **About Avacopan**

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 (ANCA-associated vasculitis). In clinical studies to date, avacopan was shown to be well tolerated and provided effective control of the disease while allowing elimination of high-dose steroids, part of the current standard of care. 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 (aHUS). The European Commission has granted orphan medicinal product designation for avacopan for the treatment of two forms of ANCA-associated vasculitis: microscopic polyangiitis and granulomatosis with polyangiitis (formerly known as Wegener's granulomatosis),

as well as for C3G. 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. ChemoCentryx's Kidney Health Alliance with Vifor Pharma provides Vifor Pharma with exclusive rights to commercialise avacopan and CCX140 in markets outside of the U.S. ChemoCentryx also has early stage drug candidates that target chemoattractant receptors in other inflammatory and autoimmune diseases and in cancer.

## **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 the 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; Vifor Fresenius Medical Care Renal Pharma, a joint company with Fresenius Medical Care; Relypsa; and OM Pharma. Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348). For more details, please visit www.viforpharma.com.

#### About Vifor Fresenius Medical Care Renal Pharma Ltd. (VFMCRP)

Vifor Fresenius Medical Care Renal Pharma is 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 VFMCRP and its parent companies, please visit <a href="https://www.vfmcrp.com">www.vfmcrp.com</a>, <a href="https://www.vfmcrp.com">www.viforpharma.com</a> and <a href="https://www.vfmcrp.com">www.vfmcrp.com</a>, <a href="https://wfmcrp.com">www.vfmcrp.com</a>, <a href="https://wfmcrp.com">www.vfmcrp.com</a>, <a

### **About ChemoCentryx**

ChemoCentryx is a biopharmaceutical company developing new medications targeted at inflammatory and autoimmune diseases and cancer. ChemoCentryx targets the chemokine and chemoattractant systems to discover, develop and commercialise orally-administered therapies. ChemoCentryx is currently focusing on its late stage drug candidates for patients with rare diseases, avacopan (CCX168) and CCX140. CCX140 is an inhibitor of the chemokine receptor known as CCR2 and is currently being developed for patients with focal segmental glomerulosclerosis (FSGS), a debilitating kidney disease. The U.S. Food and Drug Administration has granted CCX140 orphan-drug designation for the treatment of FSGS.

#### **ChemoCentryx 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 the achievement of anticipated goals and milestones, whether avacopan will be shown to be effective in the treatment of ANCA Vasculitis, the timing of the Phase III ADVOCATE study top line data, whether the more comprehensive Phase III ADVOCATE data set will provide for a more powerful data set than the CLEAR Phase II dataset underlying the CMA application, whether submissions with the FDA and EMA for full marketing approval will be made next year and whether avacopan will be effective in ongoing or future clinical trials. 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 12, 2018 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.