



#### Press Release

# VFMCRP and ChemoCentryx announce topline data from phase-II LUMINA-1 trial of CCX140 in Focal Segmental Glomerulosclerosis (FSGS)

**ST GALLEN, CH and MOUNTAIN VIEW, Calif., 18 May, 2020** – Vifor Fresenius Medical Care Renal Pharma (VFMCRP) and ChemoCentryx, Inc., (NASDAQ: CCXI) today announced topline data from a forty-six (46) patient phase-II dose-ranging trial in the orphan kidney disorder, primary Focal Segmental Glomerulosclerosis (FSGS). The LUMINA-1 trial tested CCX140, an orally-administered selective inhibitor of the chemokine receptor known as CCR2, in primary FSGS subjects. In the study, CCX140 did not demonstrate a meaningful reduction in proteinuria relative to the control group after 12 weeks of blinded treatment.

Stefan Schulze, Chief Executive Officer Vifor Pharma Group comments, "Unfortunately, the results of the phase-II LUMINA-1 trial are not what we have hoped for in the interests of patients suffering from this debilitating disease. These kind of setbacks are part of clinical development activities and do not affect our confidence in our strategy and ability to deliver strong growth from new and existing products in the future. Our overall partnership and collaboration with ChemoCentryx has been highly successful and is unaffected by this development."

"With the CCR2 inhibitor CCX140 we desired to help people with FSGS," said Thomas J. Schall, Ph.D., President and Chief Executive Officer of ChemoCentryx. "Regrettably the data observed in the dose-ranging phase-II LUMINA-1 trial of CCX140 do not provide a productive way forward in this patient population. While CCX140 won't move forward in FSGS, an entirely different situation exists with our lead program, the C5aR inhibitor avacopan. With the avacopan program, we remain intensely focused on our NDA submission for patients with ANCA-associated vasculitis mid-year, along with data readouts for the renal disease C3 glomerulopathy (C3G) by the end of the year, the dermal indication HS in Q3, and we are actively exploring the expansion of avacopan's unique potential in kidney disease."

LUMINA-1 was a dose-ranging phase-II study enrolling 46 patients with primary FSGS. The primary efficacy measure was a change in proteinuria (measured by urine protein to creatinine ratio, UPCR) in four blinded treatment groups (three active CCX140 doses vs placebo) from baseline to week 12. At week 12, all subjects including those in the placebo group were then treated with the highest dose of CCX140, 15 mg twice daily (BID) for an additional 12 weeks of treatment, after which UPCR changes from week 12 to week 24 were also assessed. In the intent to treat (ITT) analysis of UPCR changes at week 12 relative to baseline, the 15 mg BID CCX140 group exhibited the greatest reduction of UPCR (median reduction from baseline 0.9 g/g or approximately 30%, and approximately 25% reduction from baseline 0.45

Vifor Pharma Group Flughofstrasse 61 8152 Glattbrugg Switzerland Phone +41 58 851 8000 E-mail info@viforpharma.com Web viforpharma.com g/g; or approximately 22%, and approximately 23% reduction from baseline for the geometric mean). Also, after crossover of the blinded portion of the trial to 15 mg BID active dosing, the previous placebo group did not appear to exhibit an additional reduction of UPCR. CCX140 at all doses was well-tolerated, with no serious adverse events (SAE's) during the blinded trial and a numerically lower rate of treatment-emergent adverse events in the CCX140 treatment groups than in the placebo group. A full analysis of the LUMINA-1 data is underway and expanded results are expected to be announced at a medical meeting later this year.

About LUMINA-1 LUMINA-1 was a multi-center, randomized, double-blind, placebo-controlled dose-ranging study designed to evaluate the safety and efficacy of CCX140 in patients primary FSGS with  $\geq$ 1 gram/day baseline proteinuria (protein in the urine). The study enrolled a total of 46 patients worldwide, randomizing them to one of four arms (1:1:1:1). Patients received a placebo or CCX140 dosed at 5 mg once-daily, 10 mg twice daily, or 15mg twice daily over 12 weeks. All patients enrolled in the study remained on background therapy of either Angiotensin converting enzyme inhibitors (ACEi) or Angiotensin II receptor blockers (ARBs). After the 12-week randomization period, all patients were eligible for an additional 12 weeks of CCX140 treatment in an open-label extension (OLE) with the highest safe dose of CCX140, which was 15mg twice daily. There was a four week follow up period from week 24-28 where no CCX140 was administered.

# About CCX140

CCX140 is an orally-administered inhibitor of the chemokine receptor known as CCR2. CCX140 was previously evaluated in a phase-II placebo-controlled, clinical trial in patients with diabetic nephropathy. CCX140 treatment in these patients resulted in a statistically significant reduction in proteinuria.

#### About Vifor Pharma and Vifor Fresenius Medical Care Renal Pharma

Vifor Pharma Group is a global specialty pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. Vifor Pharma Group 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. 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.

# 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 commercialize orally-administered therapies. ChemoCentryx is currently focusing on two late stage drug candidates with distinctly-different mechanisms of action for patients with rare and orphan diseases, avacopan (CCX168) and CCX140.

Avacopan is an orally-administered small molecule that is a selective inhibitor of the complement C5a receptor, or C5aR. In the pivotal phase-III ADVOCATE trial, avacopan demonstrated the ability to induce vasculitis remission at 26 weeks and statistical superiority in sustaining vasculitis remission at 52 weeks. The topline safety results revealed an acceptable safety profile in this serious and life-threatening disease with fewer subjects having serious after events in

Vifor Pharma Group Flughofstrasse 61 8152 Glattbrugg Switzerland Phone +41 58 851 8000 E-mail info@viforpharma.com Web viforpharma.com the avacopan group than in the glucocorticoid-containing 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 and C3G. ChemoCentryx expects to release avacopan topline data from its ACCOLADE phase-II trial in C3G by the end of 2020 and from its phase-II AURORA trial in HS in the third quarter 2020. 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.

The Company's other late stage drug candidate is CCX140, an inhibitor of the chemokine receptor known as CCR2, which is being evaluated in the phase-II LUMINA-2 trial in patients with focal segmental glomerulosclerosis (FSGS) with the more severe nephrotic levels of proteinuria.

The U.S. Food and Drug Administration has granted CCX140 orphan-drug designation for the treatment of FSGS.

ChemoCentryx's Kidney Health Alliance with Vifor Pharma provides Vifor Pharma with exclusive rights to commercialize 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.

Vifor Pharma Group is a global specialty pharmaceuticals company. For more information, visit www.viforpharma.com.

A common company of Vifor Pharma Group and Fresenius Medical Care, develops and commercializes innovative and high quality therapies to improve the life of patients suffering from chronic kidney disease (CKD) worldwide. For more information about Vifor Fresenius Medical Care Renal Pharma and its parent companies, please visit <u>www.vfmcrp.com</u>, <u>www.viforpharma.com</u> and <u>www.freseniusmedicalcare.com</u>.

# **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, when full data analysis of LUMINA-1 and topline LUMINA-2 clinical data might become available or announced, whether the avacopan NDA for ANCA vasculitis will be filed mid-year, the timing of topline data from the avacopan Phase II studies in the treatment of HS and C3G and whether the Company's drug candidates will be shown to 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 10, 2020 and its other reports which are available from the SEC's website (www.sec.gov) and on ChemoCentryx's website

Vifor Pharma Group Flughofstrasse 61 8152 Glattbrugg Switzerland Phone +41 58 851 8000 E-mail info@viforpharma.com Web viforpharma.com (<u>www.chemocentryx.com</u>) 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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