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ChemoCentryx Provides Corporate Update Including Development Strategy for Lead Programs in Rare Renal Diseases

-- Company Initiates Phase III "ADVOCATE" Clinical Trial for Complement Receptor Inhibitor Avacopan in ANCA Vasculitis; Development Path Outlined in Rare Kidney Disease for Chemokine Receptor Inhibitor 'CCX140' --

MOUNTAIN VIEW, Calif., Jan. 09, 2017 (GLOBE NEWSWIRE) -- ChemoCentryx, Inc., (Nasdaq:CCXI), today provided a corporate update on its pipeline progress and development strategy for its expanding rare renal disease portfolio, which includes the Company's late stage compounds avacopan (CCX168) as well as CCX140. Avacopan and CCX140 are potent, orally-administered small molecules that selectively inhibit the complement C5a receptor (C5aR), and the chemokine receptor known as CCR2, respectively. Both compounds are in clinical development for the treatment of serious renal diseases.

CCX140: Overview of Recent Agreement with Vifor Pharma and Expanding the Multi-Product Kidney Health Alliance

In December 2016, ChemoCentryx announced the expansion of its kidney health alliance with Vifor Pharma to include the development and commercialization of CCX140 for renal diseases.

This second alliance expands upon a May 2016 agreement between the two companies through which Vifor Pharma licensed rights to commercialize avacopan (formerly called CCX168) for orphan and rare renal diseases in Europe and certain other territories. Combined, the two alliances included $135 million in upfront cash commitments, $1.2 billion in potential development, regulatory and sales milestone payments and royalties in the teens to mid-twenties on net sales in the Vifor Pharma territories.

The December 2016 alliance will focus initially on the development of CCX140 in rare kidney diseases. Specifically, in 2017 ChemoCentryx plans to initiate controlled trials of CCX140 in patients with the rare renal disease known as focal segmental glomerulosclerosis (FSGS). Currently there are no FDA approved treatments for FSGS, a rare form of chronic disease kidney which affects approximately 80,000 patients in the U.S. and Europe, with 5,500-9,500 new cases each year. Progressive FSGS can lead to end-stage renal disease, ultimately requiring kidney transplant or renal dialysis and total health expenditures of hundreds of thousands of dollars each year per patient. CCX140 successfully completed a Phase II clinical trial in patients with diabetic nephropathy (DN), a form of chronic kidney disease (CKD). CCX140 treatment in DN resulted in a statistically significant reduction in proteinuria. Reduction in proteinuria is widely considered as a beneficial outcome in the treatment of CKD including FSGS, and experts regard the reduction of proteinuria as the likely registration endpoint for a new therapeutic in FSGS.

ChemoCentryx is responsible for the clinical development of CCX140. Development costs in FSGS are equally shared between the parties, with ChemoCentryx's expenditures being capped. ChemoCentryx retains marketing rights for CCX140 for rare renal disease including FSGS in the U.S. and China, while Vifor Pharma has commercialization rights in the rest of the world. Separately, Vifor Pharma will retain an option, exercisable at a defined future time, to solely fund, develop, and commercialize (with pre-defined economics to ChemoCentryx under such option) CCX140 in more prevalent forms of CKD. In the event Vifor Pharma exercises its CKD option, ChemoCentryx would retain co-promotion rights in the U.S.

Developing and ultimately marketing CCX140 in FSGS adds a second drug candidate to ChemoCentryx's rare renal disease portfolio (in addition to avacopan), representing a strategic complement to the Company's forward integration plan.

Avacopan: Initiation of Worldwide Phase III "ADVOCATE" Clinical Trial in AAV

In December 2016, the Company initiated the ADVOCATE (Avacopan Development in Vasculitis to Obtain Corticosteroid elimination and Therapeutic Efficacy) Phase III clinical trial. Anti-neutrophil cytoplasmic auto-antibody (ANCA) -associated vasculitis (AAV). AAV is a type of rare autoimmune inflammation caused by auto-antibodies that activate inflammatory cells

to attack and destroy the blood vessels. More than 70 percent of AAV patents exhibit renal disease manifestations, including progression to end-stage renal disease. Patients also suffer marked health detriments as a result of current high dose chronic steroid administration in the established treatment regimen for AAV. Avacopan successfully completed two randomized, controlled Phase II clinical trials. Data from those trials showed that avacopan induced a rapid reduction in vasculitis severity, led to improved patient reported outcomes, and allowed elimination of chronic high dose steroids and their associated deleterious effects.

ADVOCATE is a worldwide study to include up to 200 clinical sites (of which approximately 180 are presently identified) in 300 patients with newly diagnosed or relapsing AAV. The study comprises two arms: the therapeutic arm contains 30mg twice-daily oral doses of avacopan and eliminates corticosteroids, and the control arm contains a placebo and maintains a standard regimen of high dose chronic steroids. All patients will also receive a standard background immunosuppressant, (either cyclophosphamide or rituximab). Primary endpoints will be measured by Birmingham Vasculitis Activity Score (BVAS), assessing disease remission at weeks 26 and 52. Other key endpoints include reduced time to remission, enhanced quality of life, and decreased corticosteroid-related toxicities. The ADVOCATE Phase III trial design was discussed in detail with both the U.S. FDA and European Medicines Agency (EMA), and agreement was reached on the design and goals of the trial. ChemoCentryx believes that ADVOCATE, if successful, should initiate avacopan's commercial opportunity by achieving a label in Europe and in the US.

Avacopan: Expansion to Additional Rare Renal Indications in 2017

The Company's development plan for avacopan also includes expanding the drug's clinical footprint into additional rare renal diseases. Beyond the ADVOCATE trial in AAV, two additional development programs are slated for 2017. In the first, the Company intends to conduct a clinical trial with avacopan in Complement 3 Glomerulopathy (C3G), a rare renal disease (estimated at a thousand new cases per year in the US) for which there is no approved therapy. Encouraging, though limited, data for avacopan in C3G have already been obtained. Specifically, a C3G patient has been successfully treated with avacopan administered under a special protocol in the UK (comparable to compassionate use in the US), for well over a year. In addition, a clinical trial of avacopan will be conducted in atypical hemolytic uremic syndrome (aHUS). The rationale for further studying avacopan in this indication comes from an ongoing pilot study in aHUS patients, showing avacopan dosing leads to a marked diminution in the thrombogenic activity of serum of these patients. In consultation with regulatory agencies, the Company intends to employ endpoints of both trials which if successfully met could support registration of the drug.

"Our aim is to build value for patients and shareholders alike by bringing forward unique medicines for diseases where treatments are limited or non-existent," said Thomas J. Schall, Ph.D., President and Chief Executive Officer of ChemoCentryx. "Rare kidney diseases are not just life-altering, they are life-threatening. We intend to be a major force in helping people with rare renal disease, and have built a portfolio of unique drugs in service of that goal. By incorporating these novel compounds into a strong kidney health alliance with a highly experienced renal care partner abroad, we markedly enhance the potential for clinical adoption and ultimate commercial success of our programs. We are achieving major steps in our forward integration plan and value building strategy: moving forward avacopan into Phase III for AAV, expanding its clinical scope in C3G and aHUS, and by initiating development with CCX140 in FSGS."

Other Programs to be Updated at Medical Conferences This Year

In addition to anticipated avacopan and CCX140 related medical conference presentations in 2017, data from the ongoing Phase Ib study with CCX872, the Company's second inhibitor of the chemokine receptor known as CCR2, in patients with advanced pancreatic cancer will be presented at the 2017 Gastrointestinal Cancers Symposium in San Francisco, CA on Friday, January 20, 2017.

Financial Update

With the successful closing of two alliances in 2016, the Company reported proforma September 30, 2016 cash and investments of approximately $186 million.

Presentation at the 35th Annual J.P. Morgan Healthcare Conference

Thomas J. Schall, Ph.D., President and Chief Executive Officer, will present at the 35th Annual J.P. Morgan Healthcare Conference on Wednesday, January 11, 2017 at 12:00 p.m. PT. A live audio webcast of the presentation can be accessed through the Investors section of the Company's website at www.ChemoCentryx.com. A replay of the webcast will be available on the Company's website for two weeks following the live presentation.

About Avacopan

Avacopan (CCX168) is an orally-administered small molecule that is a selective inhibitor of the complement C5a receptor, or

C5aR, and is the lead drug candidate in the Company's orphan and rare disease program. Avacopan is in Phase III development for anti-neutrophil cytoplasmic auto-antibody (ANCA)-associated vasculitis (AAV). Avacopan has successfully completed Phase II development for the treatment of AAV and appears to be safe, well tolerated and successful in allowing reduction and elimination of high-dose steroids, part of standard of care for AAV patients, while providing effective control of the disease in clinical studies to date. Avacopan is also in development for the treatment of atypical hemolytic uremic syndrome (aHUS) and complement 3 glomerulopathy (C3G). The U.S. Food and Drug Administration granted orphan-drug designation for avacopan for the treatment of patients with AAV, (which includes Wegener's granulomatosis, microscopic polyangiitis, and Churg-Strauss syndrome) and also for the treatment of patients with atypical hemolytic uremic syndrome (aHUS). The European Commission has granted orphan medicinal product designation for avacopan for the treatment of microscopic polyangiitis and granulomatosis with polyangiitis (formerly known as Wegener's granulomatosis). Both conditions are forms of AAV. 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.

About CCX140

CCX140 targets the chemokine receptor known as CCR2 and has successfully completed a Phase II clinical trial in patients with diabetic nephropathy where it was shown to be safe and well tolerated while demonstrating statistically significant improvements in kidney function. CCR2 is found on subsets of monocytes and macrophages, which are cells of the immune system believed to play an important role in inflammatory processes. Blocking CCR2 is intended to reduce the abnormal monocyte- and macrophage-driven inflammatory response implicated in renal diseases such as diabetic nephropathy. CCR2 may also have a direct role in the function of other specialized cells in the kidney, where its inhibition would correlate with a positive therapeutic effect.

About ChemoCentryx

ChemoCentryx, Inc. is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing orally-administered therapeutics that target the chemokine and chemoattractant systems in order to treat autoimmune diseases, inflammatory disorders and cancer. The chemokine system is a biological network that regulates inflammation via a collection of secreted chemokine molecules, or ligands, and their specific cell surface receptors. Based on its proprietary drug discovery and drug development platform, ChemoCentryx has generated multiple clinical and preclinical-stage programs, each targeting distinct chemokine and chemoattractant receptors with different small molecule compounds. Avacopan (CCX168), a C5aR inhibitor, is in Phase III development for the treatment of anti-neutrophil cytoplasmic auto-antibody-associated vasculitis (AAV). Avacopan has successfully completed Phase II development for the treatment of AAV and appears to be safe, well tolerated and successful in allowing reduction and elimination of high-dose steroids, part of standard of care for AAV patients, while providing effective control of the disease in clinical studies to date. Avacopan is also in Phase II studies for the treatment of atypical hemolytic uremic syndrome (aHUS). ChemoCentryx has licensed exclusive rights to Vifor Pharma to commercialize avacopan in Europe and certain other markets outside of the U.S. and most of Asia. CCX872, a CCR2 inhibitor, successfully completed Phase I development and is in development for the treatment of non-resectable pancreatic cancer. CCX140, a distinct CCR2 inhibitor, successfully completed a Phase II clinical trial where it was shown to be safe and well tolerated while demonstrating statistically significant improvement in albuminuria in patients with diabetic nephropathy. ChemoCentryx has licensed exclusive rights to Vifor Pharma to commercialize CCX140 in markets outside of the U.S. and China. Other clinical programs include CCX507, a next generation CCR9 inhibitor, which has successfully completed Phase I development, vercirnon (also known as Traficet-EN or CCX282) a specific CCR9 inhibitor for the treatment of inflammatory bowel disease, and CCX354, a CCR1 inhibitor which successfully completed a Phase II clinical trial for the treatment of rheumatoid arthritis. ChemoCentryx also has several programs in advanced preclinical development.

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 timing of initiating clinical endpoint trials of avacopan and CCX140, the enrollment period of the ADVOCATE Phase III trial, whether the Company's drug candidates will be shown to be effective in ongoing or future clinical trials, what measure may be a registration endpoint in FSGS and whether the ADVOCATE trial design will enable the drug candidate's commercial opportunity. 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 March 14, 2016 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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