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ChemoCentryx Reports Improvement in Renal Physiology and Stabilization of Kidney Function Following Treatment with Orally Administered Complement Inhibitor CCX168 (Avacopan) in Patient with Refractory C3 Glomerulopathy

Kidney transplant patient treated under a "Special Needs" protocol for previously intractable C3G disease is stable after avacopan treatment; avacopan now continued for more than 13 months

MOUNTAIN VIEW, Calif., Oct. 27, 2016 (GLOBE NEWSWIRE) -- ChemoCentryx, Inc., (Nasdaq:CCXI), today announced that its orally administered complement 5a receptor inhibitor CCX168 (newly designated "avacopan") has shown a beneficial effect on disease in a patient with C3 glomerulopathy (C3G). C3G is a rare disease of the kidney characterized by deposition of the protein known as C3 (a component of the body's complement system) in the filtration units (the glomeruli) of the kidney, leading to profound kidney damage and eventual renal failure. There is currently no approved effective standard therapy for C3G.

Under the Special Needs program in the United Kingdom (similar to compassionate use protocols in the United States), a C3G renal transplant recipient with deteriorating kidney function has responded well to treatment with the orally administered complement inhibitor CCX168 (avacopan). After only one month of initial treatment with avacopan, renal function (based on estimated glomerular filtration rate, or eGFR) stabilized. Moreover, sequential kidney biopsies taken after the patient had been on avacopan for two and seven months showed continued improvement in kidney histology based on a decrease in glomerular endocapillary proliferation and a marked reduction in the number of glomerular inflammatory macrophages, as compared to the pre-treatment biopsy.

Prior to receiving treatment with CCX168 (avacopan), the C3G patient had received treatment with a wide spectrum of immunosuppressant drugs including rituximab, cyclophosphamide, mycophenolate mofetil, tacrolimus and glucocorticosteroids. All of these previous treatments had failed to prevent disease recurrence and progression, including new disease in the patient's transplanted kidney. The patient has now had over 13 months of treatment with avacopan and continues to enjoy stabilized kidney function, and to tolerate the agent well with no serious adverse events. These findings provide the first evidence that avacopan may be effective in treating patients with this rare and debilitating disorder.

"This devastating disease, frequently targeting young people, is called ‘C3' glomerulopathy, but there is strong evidence that the production of C5a in the terminal complement pathway is a major driver of the pathology," said Thomas J. Schall, Ph.D., President and Chief Executive Officer of ChemoCentryx. "Accordingly, there is a clear scientific rationale to treat C3G patients with the C5aR inhibitor avacopan with the goal of offering an effective treatment option otherwise not available to these individuals. This is particularly encouraging since we recently announced positive Phase II clinical data for avacopan in another rare disease that typically involves the kidney, ANCA associated vasculitis, or AAV. The positive results in AAV provide additional validation of the use of avacopan in important rare diseases for which current care approaches are simply not satisfactory. Based on these findings, we plan to initiate a multi-center clinical endpoint study to further investigate avacopan in the treatment of C3G in the first half of 2017."

About CCX168 (avacopan)

CCX168 (avacopan) 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. The U.S. Food and Drug Administration granted orphan-drug designation for CCX168 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 CCX168 for the treatment of microscopic polyangiitis and granulomatosis with polyangiitis (formerly known as Wegener's granulomatosis). Both conditions are forms of ANCA-associated vasculitis (AAV). CCX168 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 Complement 3 Glomerulopathy (C3G)

C3 glomerulopathy is characterized by evidence of alternative complement activation based on C3 deposition in the glomeruli. There are two forms of the disease: dense deposit disease (DDD, formerly called membranoproliferative glomerulonephritis (MPGN) Type II) and C3 glomerulonephritis (C3GN, formerly called idiopathic MPGN). Genetic lesions leading to defective complement regulation, including mutations in complement factor H (CFH) have been described in these patients. Patients with C3 glomerulopathy often have high proteinuria and progressive deterioration in renal function. Without treatment, C3G invariably leads to kidney failure, and kidney transplant is frequently the only option. Even after transplantation, the new kidney will frequently manifest the disease. There is no approved effective standard therapy for C3G; non-specific immunosuppressants are frequently employed. The estimated prevalence of C3G is two-to-three per one million people.

Phase II study data in patients with ANCA-associated vasculitis showed a significant anti-proteinuric effect of CCX168 in the majority of treated patients in addition to marked improvements in the Birmingham Vasculitis Activity Score, or BVAS. This treatment effect was observed in patients receiving CCX168 plus glucocorticoids, but also in patients receiving CCX168 with no glucocorticoids.

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. CCX168 (avacopan), a C5aR inhibitor, is in Phase II development for the treatment of anti-neutrophil cytoplasmic antibody-associated vasculitis (AAV). CCX168 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, without compromising efficacy or safety during a 12-week treatment period. CCX168 is also in Phase II studies for the treatment of atypical hemolytic uremic syndrome (aHUS) and Immunoglobulin A nephropathy, or IgA nephropathy (IgAN). ChemoCentryx has licensed exclusive rights to Vifor Pharma to commercialize CCX168 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 improvements in kidney function in patients with diabetic nephropathy. 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 which has been tested in Crohn's 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 whether CCX168 (avacopan) will be shown to be safe and effective in in the treatment of C3 glomerulopathy and other rare diseases and the Company's statement regarding the timing of initiating additional clinical trials to further investigate CCX168 in the treatment of C3G. 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 13, 2015 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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