



November 7, 2016

## ChemoCentryx Reports Third Quarter 2016 Financial Results and Provides Corporate Update

*-- Preparing for the Initiation of Phase III Development with Complement 5a Receptor Inhibitor Avacopan (CCX168) for the Treatment of ANCA Vasculitis --*

*-- Reported Positive Data from Ongoing Pilot Phase II Trial of Avacopan in Patients with Atypical Hemolytic Uremic Syndrome --*

*-- Highlighted Positive Findings in Complement 3 Glomerulopathy Patient Treated with Avacopan; Plan to Initiate Multi-Center Clinical Trial in 2017 --*

*-- Conference Call Today at 5:00 p.m. Eastern Time --*

MOUNTAIN VIEW, Calif., Nov. 07, 2016 (GLOBE NEWSWIRE) -- ChemoCentryx, Inc., (Nasdaq:CCXI), today reported financial results for the third quarter ended September 30, 2016 and provided an update on the Company's clinical development activities.

"We have made significant progress in our orphan and rare diseases portfolio -- building upon our positive Phase II results in the CLEAR and CLASSIC trials in ANCA vasculitis earlier this year, we have also reported positive results in the aHUS pilot Phase II study, as well as improvement of renal function in a C3G patient who had few, if any, other treatment options. All of this provides mounting evidence that avacopan has the potential to change treatment paradigms in these rare and debilitating diseases," said Thomas J. Schall, Ph.D., President and Chief Executive Officer of ChemoCentryx. "With avacopan in AAV, we continue to make progress regarding our regulatory discussions and remain on track to initiate our Phase III development program by the end of this year. Our scientific approach forms the foundation of a broad pipeline of promising chemoattractant-based drug candidates which we believe will transform patient care."

### **Pipeline Developments Across Key Therapeutic Areas**

**Orphan and Rare Diseases:** Avacopan, an orally-administered complement inhibitor targeting the C5a receptor (C5aR), is the cornerstone of an orphan and rare diseases portfolio addressing multiple unmet medical needs. These diseases include ANCA vasculitis (AAV), atypical Hemolytic Uremic Syndrome (aHUS) and Complement 3 Glomerulopathy (C3G). Avacopan acts by blocking the destructive action of neutrophils that are activated as a consequence of the complement protein known as C5a binding to C5aR on neutrophils during autoimmune inflammatory events including the destruction of blood vessels in AAV.

- | Announced positive data from a pilot Phase II study designed to assess the effects of orally-administered avacopan on thrombus formation from the serum of aHUS patients with end-stage renal disease. The aHUS patients in the study are on stable chronic hemo-or peritoneal dialysis. Avacopan (30 mg) was administered twice daily for two weeks. Five patients have been treated to date. Highlights of the presentation that will take place at the American Society of Nephrology (ASN) Kidney Week 2016 include:
  - | After 14 days of dosing the mean decrease in thrombus size was 83%. Three patients showed 100% inhibition of thrombus formation and one patient showed greater than 30% inhibition. Additionally, one patient who received only two days of avacopan treatment showed greater than 30% inhibition at that time;
  - | Treatment appeared to be mechanism specific: when avacopan treatment was stopped, the thrombus size returned to pre-treatment levels; and
  - | Avacopan treatment appeared to be safe; there was one serious adverse event, not considered related to avacopan use, in a patient with long-standing cardiovascular and renal disease of cardiac asystole.
- | Reported improvement in renal physiology and stabilization in renal function following treatment with avacopan in a patient with refractory C3G. Under a "Special Needs" protocol (similar to the compassionate use program in the United States), a C3G renal transplant recipient with deteriorating kidney function responded well to treatment with avacopan. Prior to receiving treatment with avacopan, the C3G patient had received treatment with a wide spectrum

of immunosuppressant drugs including rituximab, cyclophosphamide, mycophenolate mofetil, tacrolimus and glucocorticosteroids, all of which had failed to prevent disease recurrence or progression. Highlights of the results are as follows:

- ┆ After one month of avacopan treatment, renal function, based on estimated glomerular filtration rate (eGFR) stabilized, and has remained stable for over a year. Decline in a patient's eGFR is a negative and often life-threatening effect of C3G;
  - ┆ 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; and
  - ┆ Avacopan was shown to be safe and well tolerated. The patient has now entered month 15 of treatment and continues to tolerate avacopan well with no serious adverse events.
- ┆ Conducted End-of-Phase II and scientific advice meetings with U.S. and EU regulatory agencies, respectively, regarding the avacopan AAV Phase III development plan.

**Immuno-Oncology and Other Therapeutic Areas:** CCX872 is a selective inhibitor of the chemokine receptor known as CCR2, and is designed to block the infiltration of immune suppressor cells in the tumor microenvironment. CCX872 is being evaluated in patients with non-resectable pancreatic cancer in an ongoing, multi-center clinical trial. The primary outcome measurement of the study is progression-free survival (PFS) after at least 24 weeks of treatment. The Company's immuno-oncology efforts include research to identify potential drug candidates targeting additional receptors that are believed to play an important role in the tumor microenvironment. Inhibiting CCR2 may be effective in therapeutic areas beyond immuno-oncology, including decreasing inflammatory macrophage infiltration into the liver, thus reducing hepatic inflammation and fibrosis.

- ┆ Presented data at the American College of Gastroenterology (ACG) 2016 Annual Meeting demonstrating that treatment with CCX872 reduced hepatic inflammation, steatosis, and scarring in models of non-alcoholic steatohepatitis (NASH). Highlights of the results are as follows:
  - ┆ Two models of NASH were used to determine the efficacy of CCX872 in reducing fibrosis; in both models, treatment with CCX872 achieved a statistically significant reduction in liver fibrosis as compared to placebo control;
  - ┆ CCX872 was more efficacious than a CCR2/CCR5 dual inhibitor, being advanced elsewhere in clinical development, in reducing liver fibrosis in a model which is known to induce NASH;
- ┆ Reported initial 12 week overall response rate (ORR) results from an ongoing open label, single arm Phase Ib clinical trial with CCX872 in patients with advanced pancreatic cancer; and
- ┆ Presented preclinical data at the CRI-CIMT-EATI-AAACR 2016 Annual Meeting demonstrating that blocking CCR2 with CCX872 decreases tumor burden by blocking monocyte infiltration, creating a microenvironment that is more favorable for CD8+ T-cell activity. This provides a mechanistic rationale for investigating the combination of CCX872 and an immune checkpoint inhibitor for the treatment of pancreatic cancer.

### **Corporate Development**

- ┆ Announced the appointment of Henry A. McKinnell, Jr., Ph.D., retired chairman and chief executive officer of Pfizer Inc., to our Board of Directors. Dr. McKinnell brings significant leadership in operations and international strategic alliances, as well as commercial experience to ChemoCentryx.

### **Anticipated Milestones**

#### **Orphan and Rare Diseases:**

- ┆ Present detailed results from the Phase II CLEAR and CLASSIC trials of avacopan in AAV in oral presentations at ASN Kidney Week and the American College of Rheumatology (ACR) 2016 Annual Meeting, respectively;
- ┆ Present results from the pilot Phase II study of avacopan in aHUS patients with end-stage renal disease at ASN Kidney Week;
- ┆ Present CRISPR-Cas9 data at ASN Kidney Week, which include details of the creation of a colony of genetically unique mice that are designed to assess the effects of inhibiting the C5aR with avacopan on diseases characterized by unregulated complement activation, such as aHUS and C3G;
- ┆ Finalize development plan and initiate Phase III development program of avacopan for the treatment of AAV by year end;
- ┆ Initiate a clinical endpoint study with avacopan in patients with C3G in the first half of 2017; and
- ┆ Initiate a clinical endpoint study with avacopan in patients with aHUS in 2017.

#### **Immuno-Oncology and Other Therapeutic Areas:**

- 1 Report PFS data from pancreatic cancer trial of CCX872 in combination with FOLFIRINOX early in the first quarter of 2017, potentially at a major medical meeting; and
- 1 Initiate a Phase II trial with CCX872 in combination with a checkpoint inhibitor in 2017.

### **Third Quarter 2016 Financial Results and Outlook**

Cash, cash equivalents and investments totaled \$131.6 million at September 30, 2016.

Revenue was \$4.1 million for the three months ended September 30, 2016 compared to zero in the same period in 2015. The increase in revenue from 2015 to 2016 was due to: (i) amortization of the upfront payment from Vifor Pharma pursuant to the avacopan agreement and (ii) grant revenue from the FDA to support the clinical development of avacopan for the treatment of patients with AAV.

Research and development expenses were \$8.4 million for the three months ended September 30, 2016 compared to \$7.9 million reported for the same period in 2015. The increase in research and development expenses from 2015 to 2016 was primarily attributable to higher expenses associated with avacopan for start-up activities related to the Phase III development program in patients with AAV. This increase was partially offset by lower expenses associated with Phase II development of avacopan, due to the completion of the CLEAR and CLASSIC Phase II clinical trials in 2016.

General and administrative expenses were \$3.2 million for the three months ended September 30, 2016 compared to \$3.8 million for the comparable period in 2015. The decrease from 2015 to 2016 was primarily due to lower stock-based compensation and intellectual property filing expenses.

Net loss was \$7.1 million for the second quarter ended September 30, 2016 compared to \$11.7 million in the same period in 2015.

Total shares outstanding at September 30, 2016 were approximately 47.8 million shares.

### **Conference Call and Webcast**

The Company will host a conference call and webcast today, November 7, 2016 at 5:00 p.m. Eastern Time / 2:00 p.m. Pacific Time. To participate by telephone, please dial 877-303-8028 (Domestic) or 760-536-5167 (International). The conference ID number is 7748243. A live and archived audio webcast can be accessed through the Investors section of the Company's website at [www.ChemoCentryx.com](http://www.ChemoCentryx.com). The archived webcast will remain available on the Company's website for fourteen (14) days following the conference call.

### **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, has successfully completed Phase II development for the treatment of anti-neutrophil cytoplasmic auto-antibody-associated vasculitis (AAV). Avacopan 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) and immunoglobulin A nephropathy, or IgA nephropathy (IgAN). 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. 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 achievement of anticipated goals and milestones 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 March 14, 2016 and its other reports which are available from the SEC's website ([www.sec.gov](http://www.sec.gov)) and on ChemoCentryx's website ([www.chemocentryx.com](http://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.

Source: ChemoCentryx, Inc.  
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**ChemoCentryx, Inc.**

**Consolidated Statement of Operations Data**

(in thousands, except per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
<b>Consolidated Statement of Operations Data:</b>				
Revenue:				
Collaboration and license revenue	\$ 4,131	\$ -	\$ 6,751	\$ -
Grant revenue	120	-	295	-
Total revenue	4,251	-	7,046	-
Operating expenses:				
Research and development	8,389	7,931	28,696	24,953
General and administrative	3,193	3,811	11,154	11,076
Total operating expenses	11,582	11,742	39,850	36,029
Loss from operations	(7,331)	(11,742)	(32,804)	(36,029)
Interest income	259	95	506	298
Net loss	\$ (7,072)	\$ (11,647)	\$ (32,298)	\$ (35,731)
Basic and diluted net loss per share	\$ (0.15)	\$ (0.26)	\$ (0.70)	\$ (0.82)
Shares used to compute basic and diluted net loss per share	47,763	44,070	45,942	43,804

	September 30,	December 31,
	2016	2015
(in thousands)		
<b>Consolidated Balance Sheet Data</b>		
Cash, cash equivalents and investments	\$ 131,611	\$ 76,289
Working capital	96,474	66,541
Total assets	133,747	78,155
Accumulated deficit	(299,394)	(267,096)
Total stockholders' equity	54,354	72,507

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