Harald Enzmann, MD
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

22 January 2019

Subject: Conditional Marketing Authorisation Application withdrawal-avacopan (INN), 10 mg hard capsules, EMEA/H/C/004487

Dear Dr. Enzmann:

We would like to inform you that ChemoCentryx, Ltd. has taken the decision to withdraw the application for a Conditional Marketing Authorisation (CMA) of avacopan (INN) 10 mg hard capsules which was intended to be used for treatment of adult patients with organ or life threatening granulomatosis with polyangiitis (Wegener's) (GPA) or microscopic polyangiitis (MPA) in combination with cyclophosphamide (CYC) or rituximab (RTX).

The CMA application was based on data obtained from a 12-week dosing regimen in a Phase II study enrolling over 60 patients. Given the near-term availability of pivotal Phase III data from an ongoing trial comprising a one-year dosing regimen with avacopan in over 300 patients with MPA and GPA (now expected in the fourth quarter of this year), we have decided to focus our efforts on a full Marketing Authorisation Application which we believe will support a positive benefit / risk assessment.

ChemoCentryx believes that there is an urgent unmet need in patients with GPA or MPA, and looks forward to submitting the 52-week data from the ongoing Phase III pivotal study in this patient population. We also note that the manufacturing guidance received during the CMA procedure will be integrated into the full Marketing Authorisation Application, at the time of submission.

The present withdrawal does not have an impact on ongoing clinical trials, any compassionate use programs with avacopan, or anticipated timelines for filing a full Marketing Authorisation Application for avacopan in patients with GPA or MPA in combination with CYC or RTX.

The applicant would like to express sincere gratitude to the (Co) Rapporteurs, PRAC and the CHMP for their time dedicated to reviewing this application, and the valuable support and helpful guidance provided during the review process.

We remain fully committed to the development of avacopan in granulomatosis with polyangiitis (Wegener's) (GPA) or microscopic polyangiitis (MPA) as well as other indications and reserve the right to make further submissions at a future date.

I agree for this letter to be published on the EMA website.

Yours sincerely,