Centessa Pharmaceuticals Announces Dosing of First Subject in Registrational PRESent-2 Study Evaluating SerpinPC for the Treatment of Hemophilia B without Inhibitors

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Enrollment progressing toward interim analysis planned when 36 subjects reach 12 weeks on treatment in Part 1 of study

BOSTON and LONDON, July 10, 2023 (GLOBE NEWSWIRE) -- Centessa Pharmaceuticals plc (Nasdaq: CNTA), a clinical-stage pharmaceutical company focused on discovering and developing medicines that are transformational for patients, today announced the dosing of the first subject in its registrational PRESent-2 study of SerpinPC for the treatment of hemophilia B without inhibitors. The dosing phase of PRESent-2 follows a minimum 12-week observation period during which prospective baseline data of the subject's disease status under their current therapy are collected to support regulatory review of the benefit and risk profile of SerpinPC. SerpinPC is an investigational subcutaneously administered novel inhibitor of activated protein C (APC) being developed as a potential treatment for hemophilia B, with or without inhibitors.

"There remains a significant global need for new treatment options for persons with hemophilia B," said Antoine Yver MD MSc, Chairman of Development of Centessa. "Based on encouraging clinical data from our ongoing Phase 2a study, we believe SerpinPC has the potential to be a first-in-class subcutaneously administered therapy with a differentiated safety profile for persons with hemophilia B, subject to regulatory review and approval. We are excited to be evaluating the potential of SerpinPC's novel mechanism of action in the registrational PRESent-2 study. We expect to enroll and dose additional patients across our clinical trial sites and advance toward the interim analysis planned when 36 subjects reach 12 weeks on treatment in Part 1 of the study."

The PRESent-2 study (AP-0102) is a Phase 2b, global, open-label, seamless adaptive design study to investigate the efficacy and safety of subcutaneous dosing of SerpinPC every week, every 2 weeks, or every 4 weeks in approximately 120 adult (aged 18 to ≤65 years) or adolescent (aged ≥12 to <18 years) male subjects with severe hemophilia A (with or without inhibitors) or moderately severe to severe hemophilia B (without inhibitors). PRESent-2 consists of 3 parts: a 24-week randomized dose-justification phase (Part 1), a 24-week dose-confirmatory phase (Part 2), and a further 24-week extension phase (Part 3) for subjects who complete either Part 1 or Part 2. Subjects must have undergone a minimum period of prospective observation (at least 12 weeks for Part 1 or 24 weeks for Part 2) under their current therapy (either on-demand or prophylaxis factor replacement) before switching to SerpinPC treatment. The primary efficacy endpoint for the study is the rate of treated bleeds (expressed as an annualized bleeding rate (ABR)) in the observation period compared to the first 24 weeks treated with SerpinPC. The Company expects to begin dosing in its registrational PRESent-3 (AP-0103) study for subjects with hemophilia B with inhibitors this year.

About SerpinPC
SerpinPC is a subcutaneously administered novel inhibitor of APC being developed as a potential treatment for hemophilia, regardless of severity or inhibitor status, and which may also be developed to prevent bleeding associated with other bleeding disorders. The registrational program for SerpinPC in hemophilia B includes a set of clinical studies with multiple components. PRESent-5 is an observational feeder study to collect prospective observational data for minimum defined periods before switching to dosing subjects in the interventional studies. The interventional studies include PRESent-2 (moderately severe to severe hemophilia B without inhibitors, and severe hemophilia A with or without inhibitors) and PRESent-3 (hemophilia B with inhibitors). Additional information on the trials can be accessed at www.clinicaltrials.gov (NCT05605678, NCT05789524, NCT05789537). The U.S. Food and Drug Administration (FDA) has granted Fast Track designation to SerpinPC for the treatment of hemophilia B, with or without inhibitors. SerpinPC is an investigational agent that has not been approved by the FDA or any other regulatory authority.

About Centessa Pharmaceuticals
Centessa Pharmaceuticals plc is a clinical-stage pharmaceutical company that aims to discover and develop medicines that are transformational for patients. Our programs span discovery-stage to late-stage development and cover a range of high-value indications. We operate with the conviction that each one of our programs has the potential to change the current treatment paradigm and establish a new standard of care. For more information, visit http://www.centessa.com/, which does not form part of this release.

Forward Looking Statements
This press release contains forward-looking statements. These statements may be identified by words such as "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "potential," "continue," "ongoing," "aim," "seek," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements, including statements related to the Company's ability to discover and develop transformational medicines for patients; its expectations regarding the timing of the interim analysis, the commencement of new studies or clinical trials or clinical and preclinical data related to SerpinPC, and other Company programs (if any); its ability to continue to meet the criteria for Fast Track designation; its ability to be eligible for Accelerated Approval, Priority Review, or Rolling Review; its ability to identify, screen, recruit and register a sufficient number of or any subjects in its anticipated new studies or clinical trials including PRESent-5, the observational feeder study, PRESent-2 and PRESent-3; its expectations on executing its research and clinical development plans and the timing thereof; the Company's ability to differentiate SerpinPC and other Company programs (if any) from other treatment options; the development and therapeutic potential of SerpinPC and other Company programs (if any); the Company's ability to present profiles or data of any of the Company's products at scientific meetings and conferences and regulatory matters, including the timing and likelihood of success of obtaining authorizations to initiate or continue clinical trials. Any forward-looking statements in this press release are based on our current expectations, estimates, assumptions and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, risks related to the safety and tolerability profile of our product candidates; our ability to maintain Fast Track designation; our ability to identify, screen and recruit a sufficient number of or any subjects in our anticipated new studies or clinical trials including PRESent-2, PRESent-3, PRESent-5; our ability to execute

IND-enabling activities in a timely manner or at all; our ability to protect and maintain our intellectual property position; business (including commercial viability), regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about the Company; risks inherent in developing product candidates and technologies; future results from our ongoing and planned clinical trials; our ability to maintain our cash runway and obtain adequate financing, including through our financing facility with Oberland, to fund our planned clinical trials and other expenses into 2026; trends in the industry; the legal and regulatory framework for the industry, including the receipt and maintenance of clearances to conduct or continue clinical testing; future expenditures risks related to our asset-centric corporate model; the risk that any one or more of our product candidates will not be successfully developed and/or commercialized; the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies; economic risks to the United States and United Kingdom banking systems; and geo-political risks such as the Russia-Ukraine war. These and other risks concerning our programs and operations are described in additional detail in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and our other reports, which are on file with the U.S. Securities and Exchange Commission (SEC). We explicitly disclaim any obligation to update any forward-looking statements except to the extent required by law.

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