Centessa Pharmaceuticals Announces New Data from an Additional 52-Weeks of Continuous Treatment from Third Year (Part 5) of Ongoing Phase 2a Study of SerpinPC for the Treatment of Hemophilia

December 10, 2023

- *Part 5 data reinforces favorable safety and tolerability profile and long-term efficacy results for SerpinPC:*
  - *Median all-bleed ABR of 1.0, a 96% reduction from prospective baseline*
  - *No thromboembolic events or treatment-related sustained elevations of D-dimer observed*
- *Poster presentation at American Society of Hematology (ASH) Annual meeting*
- *Registrational PRESent-2 and PRESent-3 studies of SerpinPC in hemophilia B are ongoing*

BOSTON and LONDON, Dec. 10, 2023 (GLOBE NEWSWIRE) -- Centessa Pharmaceuticals plc (Nasdaq: CNTA), today announced new data from an additional 52-weeks of continuous treatment from the third year (Part 5) of the ongoing Phase 2a study of SerpinPC for the treatment of hemophilia. The data were shared in a poster presentation at the American Society of Hematology (ASH) Annual Meeting on Sunday, December 10, 2023. SerpinPC is an investigational subcutaneously administered novel inhibitor of activated protein C (APC) in registrational studies for the treatment for hemophilia B, with or without inhibitors.

Part 5 data from the Phase 2a study (AP-0101) showed a continued favorable safety and tolerability profile for SerpinPC, as well as sustained long-term efficacy results, as measured by a 96% reduction in the median all-bleed annualized bleeding rate (ABR) from the prospective baseline. Consistent with data from earlier portions of the Phase 2a study, there were no thromboembolic events and no treatment-related sustained elevations of D-dimer observed throughout Part 5. D-dimer is a sensitive measure of excess thrombin generation. In addition, there were no SerpinPC-related adverse events observed during Part 5.

"We are excited to share additional data that further demonstrate the potential for SerpinPC to be a convenient subcutaneous treatment with a differentiated safety profile for people living with hemophilia," said Saurabh Saha, MD, PhD, Chief Executive Officer of Centessa. "Specifically, these data show that an additional 52-weeks of continuous treatment with SerpinPC further reduced the median all-bleed ABR to 1.0, representing a 96% reduction from the prospective baseline. These data highlight the strong foundation on which we are advancing SerpinPC in registrational studies for the treatment of hemophilia B. We would like to extend our sincere thanks to everyone involved in this study including the patients, investigators, and site coordinators."

Detailed ABR data from Part 5:

All bleed ABR

Part	Dose Tested (administered subcutaneously)	Median ABR from prospective baseline	Median ABR observed in this part	Median % change from baseline
Part 5 (n=20)	1.2 mg/kg once every 2 weeks for 52 weeks	35.63	1.0	-96%

Spontaneous joint bleed ABR

Part	Dose Tested (administered subcutaneously)	Median ABR from prospective baseline	Median ABR observed in this part	Median % change from baseline
Part 5 (n=20)	1.2 mg/kg once every 2 weeks for 52 weeks	30.28	1.0	-95%

All self-reported treated bleeds were recorded in subject diaries. The baseline ABR was determined from a prospective observation period of 2 to 6 months before exposure to SerpinPC, during which time subjects received usual on-demand clotting factor concentrate to treat breakthrough bleeds. During treatment with SerpinPC all breakthrough bleeds were treated on-demand with usual clotting factor concentrate, without dose reduction and without limitation of number of infusions.

Data from Part 5 were presented today at the ASH Annual Meeting in a poster titled: *SerpinPC in persons with severe hemophilia (PwH): Updated results from a multi-center, multi-part, first-in-human study*. A copy of the poster is available on the Company's website at https://investors.centessa.com/events-presentations.

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 AP-0101
AP-0101 is an ongoing first-in-human open-label multi-center study to investigate the safety, tolerability, pharmacokinetics, and efficacy of subcutaneous doses of SerpinPC in male participants with severe hemophilia. (https://clinicaltrials.gov/ct2/show/NCT04073498).

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 for executing on the Company's pipeline; the timing of commencement of new studies or clinical trials or clinical and preclinical data related to SerpinPC; its ability to identify, screen, recruit and maintain a sufficient number of or any subjects in its existing and anticipated studies or clinical trials including PRESent-5, the observational feeder study, PRESent-2 and PRESent-3 and its expectations on executing its research and clinical development plans and the timing thereof; the Company's ability to differentiate SerpinPC from other treatment options; the development and therapeutic potential of SerpinPC; 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 identify, screen and recruit a sufficient number of or any subjects in our existing and anticipated new studies or clinical trials including PRESent-2, PRESent-3, PRESent-5, or within anticipated timelines; 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 obtain adequate financing, including through our financing facility with Oberland, to fund our planned clinical trials and other expenses; 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; our operating costs and use of cash, including cash runway, cost of development activities and conducting clinical trials, future expenditures risks; the risk that any one or more of our product candidates will not be successfully developed and/or commercialized; the risk that the historical results of preclinical studies or clinical studies will not be predictive of future results in ongoing or future studies; economic risks to the United States and United Kingdom banking systems; and geo-political risks such as the Russia-Ukraine war or the Israeli-Palestinian conflict. 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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