Centessa Pharmaceuticals Announces Orphan Drug Designation Granted to SerpinPC for the Treatment of Hemophilia B

September 14, 2022

- Registrational studies planned to start in 4Q 2022 -

- Two-year data from Phase 2a Open Label Extension study expected in 4Q 2022 -

BOSTON and LONDON, Sept. 14, 2022 (GLOBE NEWSWIRE) -- Centessa Pharmaceuticals plc (Nasdaq: CNTA), a clinical-stage pharmaceutical company with a Research & Development ("R&D") innovation engine that aims to discover, develop, and ultimately deliver impactful medicines to patients, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to SerpinPC, a novel inhibitor of activated protein C ("APC"), for the treatment of hemophilia B. Centessa plans to begin registrational studies of SerpinPC in the fourth quarter of 2022.

SerpinPC is a biological drug candidate, based on the serpin family of proteins that is designed to allow more thrombin to be generated by inhibiting APC, thus rebalancing coagulation in hemophilia patients. In September 2021, Centessa announced positive topline data from its proof-of-concept Phase 2a study of SerpinPC in severe hemophilia A and B patients not on prophylaxis. In the highest dose cohort, SerpinPC demonstrated an 88% reduction in median Annualized Bleeding Rate (ABR) for all bleeds and a 94% reduction in median ABR for spontaneous joint bleeds. SerpinPC was observed to be well-tolerated with no thrombosis and no instances of sustained D-dimer elevations.

"We believe SerpinPC has the potential to offer patients with hemophilia B a convenient subcutaneous option that is designed to prevent and reduce bleeds without the risk of thrombosis," said Saurabh Saha, MD, PhD, Chief Executive Officer of Centessa. "This designation from the FDA is an important milestone in the development of SerpinPC and underscores the need for new, innovative treatment options for patients with hemophilia B. We look forward to initiating registrational studies for SerpinPC later this year, as well as reporting the two-year follow-up data from the SerpinPC Phase 2a open label extension study in the fourth quarter."

Orphan Drug Designation is granted by the FDA to drugs or biologics intended to treat a rare disease or condition, defined as one that affects fewer than 200,000 people in the U.S. Orphan Drug Designation provides certain financial incentives to support clinical development, and the potential for up to seven years of marketing exclusivity for the product for the designated orphan indication in the U.S. if the product is ultimately approved for its designated indication.

About Centessa Pharmaceuticals

Centessa Pharmaceuticals plc is a clinical-stage pharmaceutical company with an R&D innovation engine that aims to discover, develop, and ultimately deliver impactful medicines to patients. Our programs span discovery-stage to late-stage development and cover a range of high-value indications in rare diseases and immuno-oncology. We are led by a management team with extensive R&D experience, providing direct guidance to our program teams to rapidly advance our candidates from research through all stages of development. For more information, visit 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 deliver impactful medicines to patients; the ability of our management team and board to drive execution of the Company's portfolio of programs; our asset-centric business model and the intended advantages and benefits thereof; research and clinical development plans and the timing thereof; the scope, progress, results and costs of developing our product candidates or any other future product candidates; the development and therapeutic potential of our product candidates, including SerpinPC; strategy; regulatory matters, including the timing and likelihood of initiating clinical trials, reporting clinical trial results, submitting an IND and the success of obtaining authorizations to initiate or continue clinical trials or market any products; and the market size and opportunity for our product candidates. Any forward-looking statements in this press release are based on our current expectations, estimates 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 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; 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 non-clinical studies or clinical studies will not be predictive of future results in connection with future studies; geo-political risks such as the Russia-Ukraine war and risks related to the ongoing COVID-19 pandemic including the effects of the Delta, Omicron and any other variants. 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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