



Centessa Pharmaceuticals Receives Fast Track Designation from the U.S. FDA for SerpinPC for Hemophilia B

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BOSTON and LONDON, May 22, 2023 (GLOBE NEWSWIRE) -- [Centessa Pharmaceuticals plc](#) (Nasdaq: CNTA), a clinical-stage pharmaceutical company that aims to discover and develop medicines that are transformational for patients, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to SerpinPC, an investigational novel inhibitor of activated protein C (APC) being developed for the treatment of hemophilia B, with or without inhibitors.

"We are pleased with the FDA's decision to grant Fast Track designation for SerpinPC as we continue to advance the PRESENT registrational studies for SerpinPC in hemophilia B," said Saurabh Saha MD PhD, Chief Executive Officer of Centessa. "This designation is important recognition of SerpinPC's novel mechanism of action and underscores the critical need for new treatment options for persons with hemophilia B. 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 review and approval."

According to the FDA, Fast Track is a process designed to facilitate the development and expedite the review of drug candidates to treat serious conditions and fulfill an unmet medical need. A therapeutic candidate that receives Fast Track designation may be eligible for more frequent interactions with the FDA to discuss the candidate's development plan and, if relevant criteria are met, eligibility for Accelerated Approval, Priority Review, or Rolling Review.

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. Centessa is advancing the registrational program for SerpinPC in hemophilia B, which includes a set of clinical studies with multiple components. PRESENT-5, initiated in late 2022, 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 and without inhibitors) and PRESENT-3 (hemophilia B with inhibitors). Additional information on the trials can be accessed at www.clinicaltrials.gov ([NCT05605678](#), [NCT05789524](#), [NCT05789537](#)). 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 implications of Fast Track designation; its expectations regarding the timing of 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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