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USFDA approves Proteostasis's triple combination program for CF

April 4, 2018 | News

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Singapore — Proteostasis Therapeutics, a clinical stage biopharmaceutical company dedicated to the discovery and development of ground-breaking therapies to treat cystic fibrosis (CF) and other diseases caused by dysfunctional protein processing, announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for the Company's triple combination program for the treatment of cystic fibrosis. The Company's proprietary triple combination

includes a novel cystic fibrosis transmembrane conductance regulator (CFTR) amplifier, third generation corrector and potentiator, known as PTI-428, PTI-801 and PTI-808, respectively. The Company announced in January that the protocol for its triple combination clinical study, which the Company plans to initiate in the current quarter, has received endorsement and a high strategic fit score from the Therapeutics Development Network (TDN) and the Clinical Trial Network (CTN), the drug development arms of the Cystic Fibrosis Foundation (CFF) and the European CF Society (ECFS), respectively.

"Fast Track designation represents another positive step for the development of our triple combination therapy and underscores the serious unmet need that remains for the vast majority of CF patients," said Meenu Chhabra, president and chief executive officer of Proteostasis Therapeutics.

The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. An investigational drug that receives Fast Track program designation is eligible for more frequent communications between the FDA and the company relating to the development plan and clinical trial design, and may be eligible for priority review if certain criteria are met.