

Calliditas' partner Everest Medicines announces China NMPA's approval of Nefecon® for the treatment of primary IgA nephropathy

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced that its partner Everest Medicines (HKEX: 1952.HK) ("Everest") announced that China's National Medical Products Administration (NMPA) has approved Nefecon® for the treatment of primary immunoglobulin A nephropathy (IgAN) in adults at risk of disease progression.

China has the highest prevalence of primary glomerular diseases in the world with an estimated five million IgAN patients. There is a very significant unmet medical need for novel therapies among IgAN patients in China and other Asian countries. Everest also announced that, in addition to Nefecon's approval in mainland China and Macau, it expects a decision on New Drug Application (NDA) approval in Singapore and Hong Kong in the near term.

"We are very excited about Nefecon's approval in China. There is clearly a very significant need amongst IgAN patients in China to have access to an approved medication specifically designed to target the origin of the disease and which provides hope of disease modification," says CEO Renée Aguiar-Lucander.

Results from the Chinese subpopulation analysis of the Phase 3 NefIgArd trial, presented at the American Society of Nephrology (ASN) Kidney Week 2023, provided evidence that the treatment effect of Nefecon in the Chinese cohort was greater than in the global data set with regards to kidney function, proteinuria and microhematuria. In the Chinese cohort, the mean absolute change from baseline in eGFR at 24 months showed an approximately 66% reduction in loss of this measure of kidney function with Nefecon compared with a 50% reduction in loss of eGFR in the global data set.

This approval triggers a milestone payment of five million USD to Calliditas, which will be included as revenue in the fourth quarter.

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About Calliditas

Calliditas Therapeutics is a commercial stage biopharma company based in Stockholm; Sweden focused on identifying, developing and commercializing novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs. Calliditas' lead product, developed under the name Nefecon®, has been granted accelerated approval by the US FDA under the trade name TARPEYO® and conditional marketing authorisation by the European Commission under the trade name Kinpeygo®. Kinpeygo is being commercialized in the European Union Member States by Calliditas' partner, STADA Arzneimittel AG. Additionally, Calliditas is conducting a Phase 2b clinical trial in primary biliary cholangitis and a Phase 2 proof-of-concept trial in head and neck cancer with its NOX inhibitor product candidate, setanaxib. Calliditas' common shares are listed on Nasdaq Stockholm (ticker: CALTX) and its American Depositary Shares are listed on the Nasdaq Global Select Market (ticker: CALT).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' or Everest's strategy, commercialization efforts and potential, regulatory submissions and anticipated timelines and outcomes, including anticipated timing of NDA approval in Singapore and Hong Kong. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, any related to Calliditas' or Everest's business, operations, continued and additional regulatory approvals, market acceptance of products, goals and anticipated timelines, and other risks identified in the section entitled "Risk Factors" in Calliditas' reports filed with the Securities and Exchange Commission. Calliditas cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Calliditas disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent Calliditas' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.