

Calliditas Receives Conditional Marketing Authorization from UK MHRA for Kinpeygo in IgA nephropathy

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”) today announced that the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom has granted Conditional Marketing Authorization (CMA) for Kinpeygo® for the treatment of primary immunoglobulin A (IgA) nephropathy (IgAN) in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/gram.

Kinpeygo is the first and only approved treatment for IgAN, a rare, progressive autoimmune disease of the kidney with a high unmet need, with more than 50% of patients potentially progressing to end-stage renal disease (ESRD). The MHRA authorization follows the European Commission (EC) authorization in July of 2022. Calliditas will transfer the CMA to its partner STADA Arzneimittel AG, which is commercializing Kinpeygo in the European Economic Area (EEA) member states, Switzerland and the UK. STADA launched Kinpeygo in its lead launch market, Germany, in October 2022.

“We are happy to be able to add another approval in a European territory, which will lead to patient access to Kinpeygo, a drug developed specifically to target this disease,” said CEO Renée Aguiar-Lucander.

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The information was sent for publication, through the agency of the contact persons set out above, on February 2, 2023 at 9:15 a.m. CET.

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 FDA under the trade name TARPEYO® and conditional marketing authorization by the European Commission under the trade name KINPEYGO®. KINPEYGO is being commercialized in the European Union Member States and will be commercialized in the UK by Calliditas’ partner, STADA Arzneimittel AG. Additionally, Calliditas is conducting a Phase 2b/3 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 regulatory approval and marketing of Kinpeygo in UK, Calliditas’ strategy, commercialization efforts, business plans, regulatory submissions, clinical development plans and focus, the planned transfer of the CMA to STADA, improved patient access to Kinpeygo and the potential therapeutic benefits of Kinpeygo. 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' business, operations, continued regulatory approvals for TARPEYO and Kinpeygo and additional regulatory approvals for Nefecon, market acceptance thereof, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, 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.