

## Calliditas announces filing with UK MHRA for Kinpeygo in IgA nephropathy

**Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”) today announced that its partner STADA Arzneimittel AG (“STADA”) has submitted a request to the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom to convert the conditional marketing authorization for Kinpeygo®, a treatment for primary IgA nephropathy (IgAN), to standard, or “full”, marketing authorization.**

Kinpeygo is an orphan medicinal product and the first and only treatment approved in the UK for IgAN, a rare, progressive autoimmune disease of the kidney with a high unmet need. Kinpeygo is currently approved under conditional approval to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$  g/gram. STADA, which holds the commercial rights in the European Economic Area (EEA) member states, Switzerland and the UK, has already launched the IgAN medicine in Germany in September 2022 and is working to extend patient access to other countries.

The submission to the MHRA for full approval, made by STADA’s affiliate Britannia Pharmaceuticals Ltd., is based on the full two-year data set from the Phase 3 NeflgArd clinical trial, as recently published in leading medical journal *The Lancet*<sup>1</sup>. The trial met its primary endpoint, with Kinpeygo demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in estimated glomerular filtration rate (eGFR) over the two-year period of nine months of treatment with Kinpeygo or placebo and 15 months of follow-up off drug.

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*The information was sent for publication, through the agency of the contact persons set out above, on October 3, 2023 at 09:20 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 US 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 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’ and STADA’s strategy, commercialization efforts, business plans, regulatory submissions, and clinical development plans. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,”

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<sup>1</sup> Efficacy and safety of a targeted-release formulation of budesonide in patients with primary IgA nephropathy (NeflgArd): 2-year results from a randomised phase 3 trial - The Lancet

“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 and additional regulatory approvals for TARPEYO and Kinpeygo, market acceptance of TARPEYO and Kinpeygo, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, revenue and product sales projections or forecasts 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.