

## **Calliditas partner STADA receives positive CHMP opinion recommending full approval for Kinpeygo® for the treatment of IgA nephropathy**

**Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the granting of full marketing authorisation for Kinpeygo for the treatment of adults with primary immunoglobulin A nephropathy (IgAN).**

Kinpeygo, which was granted conditional marketing authorisation in EU on 15 July 2022, was the first ever approved treatment for IgAN in the EU and UK. The full approval results in a significantly broader label for patients with primary IgAN, moving from a urine protein excretion (UPCR) limitation of > 1.5g/g to encompassing the entire study population, defined as UPCR of  $\geq 0.8$ g/g, or proteinuria of  $\geq 1.0$  g/g over 24 hours. Kinpeygo is marketed in the EU and UK exclusively by Calliditas’ commercial partner, STADA Arzneimittel AG.

“This is an important day for patients suffering from IgAN in Europe as Kinpeygo represents the first ever fully approved medication for this rare kidney disease. The long-term confirmatory trial met its eGFR endpoint with high statistical significance and we are delighted that EMA now has issued a positive opinion,” said Renee Aguiar-Lucander, CEO.

The CHMP’s positive opinion will now be forwarded to the European Commission (EC), which has the authority to grant this full marketing authorisation for Kinpeygo in the European Union (EU) member states, and which will be adopted by Iceland, Norway and Liechtenstein. A final decision by the EC on granting a marketing authorisation is anticipated in August 2024.

### **For further information, please contact:**

Åsa Hillsten, Head of IR & Sustainability, Calliditas  
Tel.: +46 76 403 35 43, Email: [asa.hillsten@calliditas.com](mailto:asa.hillsten@calliditas.com)

*The information in the report is information that Calliditas is obliged to make public pursuant to the EU Market Abuse Regulation. The information was sent for publication, through the agency of the contact person set out above, on May 30, 2024, at 8:00 p.m. CET.*

### **About Calliditas**

Calliditas Therapeutics is a biopharma company headquartered in Stockholm, Sweden, focused on identifying, developing, and commercializing novel treatments in orphan indications with significant unmet medical needs. 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). Visit [Calliditas.com](https://www.calliditas.com) for further information.

### **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’ strategy, commercialization efforts, business plans, regulatory submissions, clinical development plans, revenue and product sales projections or forecasts and focus. 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, EC authorization for full approval of Kinpeygo, 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.