

Stockholm, Sweden

July 26, 2024

Calliditas partner STADA receives European Commission decision for full approval of Kinpeygo® for the treatment of IgA Nephropathy

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”) today announced that the European Commission has granted a full marketing authorization for Kinpeygo for the treatment of adults with primary immunoglobulin A nephropathy (IgAN).

The European Commission has granted a full marketing authorization of Kinpeygo®. The granting of 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 ≥ 0.8g/g, or proteinuria of ≥1.0 g/g over 24 hours. This expanded label is based on full two-year data set from the Phase 3 NeflgArd clinical trial, published in leading medical journal *The Lancet* ⁽¹⁾.

“This is an important event 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 the European Commission has granted a full approval for the broader population” said Renee Aguiar-Lucander, CEO.

Kinpeygo is marketed in the EU and UK exclusively by Calliditas’ commercial partner, STADA Arzneimittel AG. The full marketing authorization for Kinpeygo covers the European Union (EU) member states as well as Iceland, Norway and Liechtenstein. Also, Kinpeygo’s status as an orphan drug for a rare disease, subject to 10-year market exclusivity running until 2032, was confirmed by the Commission.

This approval triggers a milestone payment of ten million EUR to Calliditas, which will be recognized as revenue in the third quarter.

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

For further information, please contact:

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

The information was sent for publication, through the agency of the contact person set out above, on July 26, 2024 at 5 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 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, continued market acceptance of Kinpeygo, 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.