

Calliditas' partner STADA launches the first medicine authorized in the EU for treating primary IgA nephropathy

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced that its European commercial partner, STADA Arzneimittel AG, has launched the first and only approved treatment in the EU for primary immunoglobulin A nephropathy (IgAN), a rare, progressive disease of the kidneys with a high unmet need. STADA will initially launch in Germany with additional European countries to follow.

"We are excited that STADA is in the position to swiftly launch this product in Europe, starting with the German market. To bring an approved medication to patients suffering from this rare disease has been our focus since we started this endeavor well over a decade ago," said Calliditas CEO Renée Aguiar-Lucander.

Calliditas received conditional approval in July from the European Commission for the development candidate Nefecon, providing the first and only approved treatment alternative for adult patients with IgAN at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/gram. The conditional marketing authorization, which has now been transferred to STADA, applies in all 27 European Union Member States as well as Iceland, Norway, and Liechtenstein. This is the first orphan medicine introduced through STADA's Specialty Care business unit.

"Making this product available to primary IgAN patients in Europe brings for the first time a therapeutic option to an under-served patient population," commented STADA CEO Peter Goldschmidt. "The launch of STADA's first orphan Specialty medicine is evidence of how STADA is bringing additional value to patients, healthcare professionals and health systems through a broad portfolio of Specialty, Generics and Consumer Healthcare products."

In Germany, the lead launch market, 3.1 people per 100,000 develop IgAN each year, a frequency slightly higher than the 2.5 per 100,000 which is the estimated global incidence.¹

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The information was sent for publication, through the agency of the contact persons set out above, on September 20, 2022 at 2:00 p.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 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).

¹ O'Shaughnessy MM et al. Glomerular disease frequencies by race, sex and region: Results from the International Kidney Biopsy Survey. *Nephrol Dial Transplant* 2011; 26(2): 414-430

About STADA Arzneimittel AG

STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of generics, specialty pharma and non-prescription consumer healthcare products. Worldwide, STADA Arzneimittel AG sells its products in approximately 120 countries. In financial year 2021, STADA achieved group sales of EUR 3,249.5 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 776.5 million. As of 31 December 2021, STADA employed 12,520 people worldwide.

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 EC approval for Kinpeygo, 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.