

Calliditas announces an additional seven year orphan drug exclusivity period for TARPEYO®

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”) today announced that the FDA has granted an orphan drug exclusivity period of seven years for TARPEYO®, expiring in December 2030 based on when the company obtained full approval with a new indication for this drug product.

Following full approval in December 2023, TARPEYO® (budesonide) is indicated “to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression”. The exclusivity period reflects the new indication covering all adult patients with primary IgAN at risk of disease progression based on a confirmed reduction of kidney loss reflecting a clinical benefit on kidney function for adult patients with primary IgAN.

“We are delighted to have seven years of market exclusivity expiring in December 2030 for TARPEYO in the US, reflecting the new indication based on the long-term data generated,” said CEO Renée Aguiar-Lucander.

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 in the press release 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 persons set out above, on March 6, 2024 at 08:15 a.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 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 the orphan drug exclusivity period of TARPEYO® and the therapeutic benefits of TARPEYO®. 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, clinical trials, intellectual property of the NEFECON franchise globally, 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.