

## Calliditas Announces Positive NeflgArd Open Label Extension Results

**Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”) today announced that the global open-label extension (OLE) study to the Phase 3 NeflgArd study showed a treatment response consistent with the NeflgArd study across endpoints of urine protein to creatinine ration (UPCR) and estimated glomerular filtration rate (eGFR) at 9 months across all IgAN patients, including those who had previously received Nefecon in the NeflgArd study.**

NeflgArd was a global, Phase 3, randomized, double-blind, placebo-controlled, multicenter study designed to evaluate the efficacy and safety of Nefecon 16 mg once daily vs placebo in adult patients with primary IgAN as an addition to optimized RASi therapy. Patients were randomized 1:1 to receive 16 mg/day of Nefecon or matching placebo for 9 months, followed by a 15-month observational follow-up period without the study drug. The NeflgArd study achieved both its primary and key secondary endpoints and was the basis for full approval by the FDA in December 2023. The full data set was published in [The Lancet](#).

The OLE study was designed to provide 9 months of treatment with Nefecon for all patients who completed the NeflgArd study and who at that time had > 1g/g of proteinuria over 24h and > 30 ml/min of eGFR. All enrolled OLE patients continued on optimized RAS inhibitor therapy (ACEs and/or ARBs) and were treated for 9 months with Nefecon 16mg per day, with a follow-up visit three months after completion of treatment. Primary assessment was based on UPCR and eGFR at 9 months. A total of 119 patients were enrolled, of whom 45 had previously had active treatment.

Topline data from the OLE study showed that the treatment response was consistent with the NeflgArd study's findings regarding the endpoints of UPCR and eGFR at nine months across all patients, irrespective of whether they had previously been treated with Nefecon or with placebo. The safety data after 9 months of treatment or retreatment with Nefecon in patients who completed the NeflgArd study were consistent with previously reported safety data.

“It is exciting to see these results on both proteinuria reduction and eGFR stabilization at 9 months across all patients irrespective of previous treatment regimen in the Phase 3 trial,”, said CEO Renée Aguiar-Lucander. “These topline results support the study thesis that the response to retreatment with Nefecon was unaffected by previous treatment cycles. We look forward to presenting data at the upcoming ERA EDTA symposium.”

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

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### **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](http://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 development of Calliditas' pipeline. 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, competition from other companies, pipeline development, revenue and product sales projections or forecasts, 2023 revenue guidance 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.