## Tarpeyo® (budesonide) – Updated indication, accelerated approval converted to full approval

- On December 20, 2023, Calliditas Therapeutics announced the full FDA approval of Tarpeyo (budesonide), to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.
    - Tarpeyo was previously approved under accelerated approval, to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g.
- The full approval of Tarpeyo for the updated indication was based on NefIgArd, a randomized, double-blind, 2-part study in 364 adults with IgAN who were on a stable dose of maximally-tolerated renin-angiotensin system (RAS) inhibitor therapy. Patients were randomized to receive Tarpeyo or placebo. The primary endpoint for Part B of the study (final analysis) was a time-weighted average of the log ratio of estimated glomerular filtration rate (eGFR) at each time point over 2 years relative to baseline.
    - The study met the prespecified Part B primary endpoint ($p < 0.0001$). The favorable effect of Tarpeyo on eGFR was seen by month 3 (the earliest assessment) and did not appear to increase in magnitude over two years. At year 2, there was a 5.9 mL/min/1.73 $m^2$ difference in the mean change from baseline in eGFR between Tarpeyo and placebo (95% CI: 3.3, 8.5 mL/min/1.73 $m^2$; $p < 0.0001$).
- The recommended treatment duration with Tarpeyo is 9 months, with a dosage of 16 mg administered orally once daily. When discontinuing therapy, the dosage should be reduced to 8 mg once daily for the last 2 weeks of therapy.
- Safety and efficacy of treatment with subsequent courses of Tarpeyo have not been established.