Press release

Calliditas Therapeutics and STADA partner to register and commercialize specialty therapy for IgA Nephropathy in Europe

- Calliditas and STADA partner to bring a specialty therapy focused on downregulating IgA1 to European patients. If approved, it would be the first-ever approved treatment in the EU for chronic autoimmune kidney disease IgA Nephropathy (IgAN)
- Partnership for this oral orphan-drug candidate combines Calliditas' drug-delivery expertise with STADA's go-to-partner strategy and pan-European marketing and sales expertise, including for specialty and nephrology medicines
- Deal covering European Economic Area (EEA) member states, Switzerland and the UK is valued at a total of EUR 97.5 million ($115m), plus royalties

Stockholm, Sweden; Bad Vilbel, Germany, 21 July 2021 – Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") and STADA Arzneimittel AG ("STADA") announced today that they have entered into a license agreement to register and commercialize a novel specialty drug candidate for the treatment of the chronic autoimmune kidney disease Immunoglobulin A Nephropathy (IgAN) in the European Economic Area (EEA) member states, Switzerland and the UK.

The partnership relates to a novel oral formulation, developed under the projectname Nefecon, of a potent and well-known active substance – budesonide – designed to target down regulation of IgA1 with a view to be disease-modifying. If approved, this value-added specialty medicine, which received an EU orphan-drug designation in 2016, would be the first treatment authorised in the European Union for IgAN, a rare autoimmune disease. IgAN, also known as Berger's disease, is a serious progressive autoimmune disease in which up to 50% of patients end up at risk of developing end-

stage renal disease and thus requiring dialysis or a kidney transplant.[1] Prevalence in Europe is estimated at 4 in 10,000, translating into approximately 200,000 patients.

“This partnership, which leverages Calliditas’ drug-delivery expertise and clinical data in this under-served patient population, further validates STADA’s position as a go-to-partner for specialty pharmaceuticals, as well as for generics and consumer health products,” commented STADA CEO Peter Goldschmidt. “This value-added novel formulation for a large orphan indication will complement STADA’s offerings in nephrology, where we have built strong expertise over more than a decade through our epoetin zeta biosimilar and where we continue to place a clear strategic focus on seeking further opportunities to bring new options to patients.”

“We are excited to be entering into this partnership with STADA to bring this IgAN therapy to market in Europe, where there is a significant unmet medical need for this patient population. We look forward to working in close collaboration with STADA to pursue marketing authorisation with the goal of bringing the first ever EU-approved medication in IgAN to patients as soon as possible, utilizing STADA’s extensive marketing and sales platform throughout Europe,” said Renée Aguiar-Lucander, CEO of Calliditas.

The novel formulation is designed to deliver the drug to the Peyer’s patch region of the lower small intestine, where the disease originates as per the predominant pathogenesis models. The formulation uses a unique two-step technology, which allows for the substance to pass through the stomach and intestine without being absorbed, and to be released in a pulse-like fashion only when it reaches the ilium in the lower small intestine.

[1] EU/3/16/1778 | European Medicines Agency (europa.eu)

In addition to its potent local effect, another advantage of using this active substance is that it has very low bioavailability, with around 90% being inactivated in the liver before it reaches the systemic circulation. This means that a high concentration can be applied locally where needed, whilst limiting systemic exposure.

On 28 May 2021, Calliditas announced that the company had, under the drug-development candidate name Nefecon, submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for a novel oral formulation of budesonide targeting down regulation of IgA1 for the treatment of primary IgAN. The company also filed an application for accelerated approval in the US on March 15, 2021 and was granted priority review in April 2021. The commercial brand name for this therapy in Europe will be determined and disclosed at a later date.

Calliditas' oral formulation has been granted Accelerated Assessment procedure by the Committee for Human Medicinal Products (CHMP) within the European Medicines Agency, which is intended to expedite access to drugs that the CHMP considers to be of major therapeutic interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Accelerated assessment reduces the maximum timeframe for review of the MAA to 150 days (excluding clock-stops)[2].

IgAN is designated as an orphan disease in both the US and Europe. In Europe, an orphan disease is defined as a disease or condition affecting no more than five in 10,000 European citizens with no satisfactory method of diagnosis, prevention or treatment[3]. Orphan incentives consist of 10 years of market exclusivity from the grant date of marketing approval in the EU, protocol assistance and scientific advice, fee reductions on EMA procedural activities and eligibility for EU grants.

[2] Accelerated assessment | European Medicines Agency (europa.eu)
[3] Orphan designation: Overview | European Medicines Agency (europa.eu)

If approved, the product could be available to patients in Europe in the first half of 2022 and would become the first therapy specifically designed and approved for the treatment of IgAN, and which has the potential to be disease-modifying.

Under the terms of the agreement, Calliditas is entitled receive an initial upfront payment of EUR 20m ($24m) upon signing and up to an additional EUR 77.5m ($91m) in future payments linked to pre-defined regulatory and commercialization milestones.

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 2020, STADA achieved group sales of EUR 3,010.3 million and adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 713.3 million. As of 31 December 2020, STADA employed 12,301 people worldwide.

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