Press release

STADA set to expand Specialty portfolio after positive CHMP opinion on Kinpeygo™ orphan medicine for IgA nephropathy

- CHMP within the European Medicines Agency issues positive opinion on Kinpeygo™, a novel oral formulation of budesonide, for adults with primary immunoglobulin A nephropathy (IgAN)
- If confirmed by the European Commission (EC), Kinpeygo will be exclusively marketed by STADA as the EU's first and only treatment approved to treat IgAN, a rare, progressive autoimmune disease of the kidney with a high unmet need
- STADA CEO Peter Goldschmidt: "We are confident of bringing a specialty therapeutic option to an under-served patient population with what would be STADA's first orphan medicine."

Bad Vilbel, 20 May 2022 – STADA has taken a significant step towards expanding its Specialty portfolio after the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending a marketing authorisation for Kinpeygo™ for adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram.

If confirmed by the European Commission (EC), Kinpeygo will be the first and only treatment approved to treat IgAN, a rare, progressive autoimmune disease of the kidney with a high unmet need, with more than 50% of patients potentially progressing to end-stage renal disease (ESRD). Under a licensing agreement with Calliditas Therapeutics announced in July 2021, Kinpeygo will be exclusively marketed by STADA in European Economic Area (EEA) member states, Switzerland and the UK.[1]

[1] Calliditas Therapeutics and STADA partner | STADA

STADA CEO Peter Goldschmidt commented: “By combining through this partnership Calliditas’ drug-delivery expertise and clinical data with STADA’s pan-European commercial and supply-chain expertise, we are optimistic of bringing a specialty therapeutic option to an under-served patient population with what would be STADA’s first orphan medicine. We look forward to further serving Europe’s nephrology community, including through the epoetin zeta biosimilar that we have marketed for well over a decade.”

In May 2021, Calliditas announced that it had submitted a Marketing Authorisation Application (MAA) to the EMA, which had previously granted Orphan Medicinal Product status to this drug candidate in the treatment of IgAN. The CHMP’s positive opinion will now be forwarded to the EC, which has the authority to issue a marketing authorisation for Kinpeygo in the European Union (EU) member states, and which will be adopted by Iceland, Norway and Lichtenstein. A final decision by the EC on granting a marketing authorisation is anticipated in Q3 2022. The same formulation, which was developed under the name ‘Nefecon’, is already approved and marketed by Calliditas in the United States under the brand name Tarpeyo™.

“This is a great outcome, which reflects the strong clinical results from our Phase 3 trial. We are delighted that patients suffering from IgAN in Europe will hopefully soon be able to access a drug developed specifically to target this disease,” said Calliditas CEO Renée Aguiar-Lucander.

If confirmed by the EC, Kinpeygo will be granted a conditional marketing authorisation that is based on achievement of the primary endpoint of reduction in proteinuria in Part A of the NeflgArd pivotal Phase 3 study. Patients taking 16mg of Kinpeygo once daily showed a statistically significant 31% reduction in proteinuria from baseline vs 5% in the placebo arm after 9 months of treatment.

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 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.

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