Press release

STADA welcomes EU approval of Kinpeygo® for adults with primary IgA nephropathy

- The European Commission (EC) has granted conditional marketing authorization for Kinpeygo® for the treatment of primary immunoglobulin A (IgA) nephropathy (IgAN) in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram
- Initial launches in European markets by STADA are scheduled during the second half of 2022
- STADA's CEO Peter Goldschmidt: "The impending launch of STADA's first orphan Specialty medicine is testament to the growing breadth of our portfolio."

Bad Vilbel, Germany. 18 July 2022 – The European Commission (EC) has granted conditional marketing authorization for Kinpeygo® (budesonide) capsules for the treatment of primary immunoglobulin A (IgA) nephropathy (IgAN) in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram.

Kinpeygo is an orphan medicinal product and the first and only approved treatment for 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). Through a partnership with developer Calliditas Therapeutics, Kinpeygo will be marketed in the European Economic Area (EEA) exclusively by STADA.

The conditional marketing authorization applies in all 27 European Union member states, as well as Iceland, Norway and Liechtenstein. STADA intends to initiate launches in European markets during the second half of 2022.

STADA CEO Peter Goldschmidt commented: "Approval of Kinpeygo is a crucial milestone in STADA bringing a therapeutic option to an under-served patient

population across Europe. The impending launch of STADA's first orphan Specialty medicine is testament to the growing breadth of our portfolio."

The Kinpeygo approval is based on the efficacy and safety data of Part A of the NeflgArd pivotal Phase 3 study, an ongoing, randomized, double-blind, placebo-controlled, multicentre study conducted to evaluate Kinpeygo 16 mg once daily oral dose vs placebo in adult patients with primary IgAN. The effect of Kinpeygo, which was developed under the name Nefecon, was assessed in patients with biopsy-proven IgAN, eGFR ≥35 mL/min/1.73 m2, and proteinuria (defined as ≥1 g/day) who were on a stable dose of recommended or maximum tolerated RAS blockade. 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. After 9 months of treatment, Kinpeygo 16 mg once daily provided a statistically significant and clinically relevant 7% treatment benefit on eGFR compared to placebo (p=0.0014). This 3.87 mL/min/1.73 m2 treatment benefit at 9 months corresponded to a slight reduction from baseline of 0.17 mL/min/1.73 m2 in patients who received Kinpeygo 16 mg once daily and a deterioration from baseline of 4.04 mL/min/1.73 m2 in patients who received placebo.

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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