Press release

STADA welcomes CHMP positive opinion on extending indication for Kinpeygo

- The CHMP adopted a positive opinion recommending a change to the terms of the marketing authorization of Kinpeygo for the treatment of adults with primary immunoglobulin A, now covering patients with a UPCR of ≥0.8 g/g
- Submission to the CHMP for full approval was based on the full two-year data set from the Phase 3 NefIgArd clinical trial, published in leading medical journal *The Lancet*
- Kinpeygo is the first approved treatment in Europe for IgAN, a rare, progressive autoimmune disease of the kidney with a high unmet need

Bad Vilbel, Germany – 05 June 2024 – STADA welcomes the adoption by the Committee for Medicinal Products for Human Use (CHMP) within the European Medicines Agency (EMA) of a positive opinion regarding Kinpeygo®. This recommends granting Kinpeygo a standard, or "full", marketing authorization for a wider patient population group: adults with primary immunoglobulin A nephropathy (IgAN) with a urine protein excretion ≥1.0 g/day (or urine protein-to-creatinine ratio ≥0.8 g/g, rather than ≥1.5 g/g as in the previously-approved label)[1]. Thus, the expanded label would potentially make therapy available to affected patients earlier in their treatment.

Kinpeygo is the first approved treatment in Europe for IgAN, a rare, progressive autoimmune disease of the kidney with a high unmet need. For decades, people living with IgA

[1] https://www.ema.europa.eu/en/medicines/human/variation/kinpeygo

nephropathy have had limited treatment options while facing a progression toward kidney failure.

STADA, which holds European commercial rights, in September 2022 already introduced the IgAN treatment in Germany. Launches in other markets, including the UK, have followed, and the company is working to extend access to more patients.

"An extended authorization for Kinpeygo would expand options for the kidney diseases community, for patients and their loved ones. We will continue our collaboration with scientific societies and EU member states to bring this important, disease-modifying specialty therapy to more people with primary immunoglobulin A nephropathy in Europe," commented STADA's Head of Global Specialty, Bryan Kim.

The submission to the CHMP for full approval was based on the full two-year data set from the Phase 3 NefIgArd clinical trial, as recently published in leading medical journal *The Lancet*[2]. This randomized, double-blind, multicenter study assessed the efficacy and safety of Kinpeygo – developed under the project name Nefecon® – dosed at 16mg once-daily versus placebo on a background of optimized renin-angiotensin system inhibitor (RASi) therapy in adult patients with primary IgAN. The trial met its primary endpoint with high statistical significance, with Kinpeygo demonstrating ~50 % less kidney function deterioration vs. placebo after 2 years. This estimated Glomerular Filtration Rate (eGFR) benefit observed by the end of 9 months was maintained over the 15 months off-drug. The expanded indication proposed by the CHMP would cover the entire study population, which included more than 70 patients with a UPCR <0.8g/g while fulfilling <1.0g/d proteinuria.[3]

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[2] Efficacy and safety of a targeted-release formulation of budesonide in patients with primary IgA nephropathy (NefIgArd): 2-year results from a randomised phase 3 trial - The Lancet

[3] Nefecon-treatment-provides-kidney-benefits-for-patients-with-IgAN-that-extend-to-those-with-low-levels-of-UPCR_-A-subanalysis-of-the-Phase-3-NefIgArd-trial_e-poster-1.pdf (calliditas.se)

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR)[4] and made available in all official European Union languages, subject to the proposed change to the marketing authorization has been granted by the European Commission.

About Kinpeygo

Kinpeygo is an oral, modified-release formulation of budesonide, a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism. Kinpeygo is a 4 mg modified-release capsule and is enteric coated and designed to remain intact until it reaches the ileum. Each capsule contains coated beads of budesonide that target mucosal B-cells present in the ileum, including the Peyer's patches, which are responsible for the production of galactose-deficient IgA1 antibodies (Gd-Ag1) causing IgA nephropathy.

About the NeflgArd Study

The global clinical trial NefIgArd is a Phase 3, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of Kinpeygo 16 mg once daily vs placebo in adult patients with primary IgAN (N=364), as an addition to optimized RAS inhibitor therapy. Part A of the study included a 9-month blinded treatment period and a 3-month follow-up period. The primary endpoint was UPCR, and eGFR was a secondary endpoint. Part B included a 12-month observational period off drug and assessed eGFR over the entire 2-year period for patients who were treated with the Kinpeygo or placebo regimen in Part A. The full NefIgArd trial met its primary endpoint. Topline data from the full NefIgArd study were reported on 12 March 2023.

About Primary Immunoglobulin A Nephropathy

Primary immunoglobulin A nephropathy (IgA nephropathy or IgAN or Berger's Disease) is a rare, progressive, chronic autoimmune disease that attacks the kidneys and occurs when galactose-deficient IgA1 is recognized by autoantibodies, creating IgA1 immune complexes that become deposited in the glomerular mesangium of the kidney. This deposition in the kidney can lead to progressive kidney damage and potentially a clinical course resulting in end- stage renal disease. IgAN most often develops between late teens and late 30s.

[4] Kinpeygo | European Medicines Agency (europa.eu)

About STADA Arzneimittel AG

STADA Arzneimittel AG is headquartered in Bad Vilbel, Germany. The company focuses on a three-pillar strategy consisting of consumer healthcare products, generics and specialty pharma. Worldwide, STADA Arzneimittel AG sells its products in approximately 115 countries. In financial year 2023, STADA achieved group sales of EUR 3,734.8 million and reported earnings before interest, taxes, depreciation and amortization (EBITDA) of EUR 802.1 million. As of 31 December 2023, STADA employed 11,667 people worldwide.

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