Press Release

STADA receives European Commission approval to expand label and patient group for IgA Nephropathy orphan medicine

- The European Commission has extended the approval of STADA's orphan drug Kinpeygo®, a medicine for the treatment of adults with the rare disease immunoglobulin A nephropathy (IgAN), to a far broader group of patients – those with a urinary protein excretion of ≥1.0 g/day (or a urinary protein to creatinine ratio of ≥0.8 g/g)
- The full approval of the medicine with the expanded indication was based on the complete two-year data from the NefIgArd Phase 3 clinical trial, published in the leading medical journal *The Lancet*
- Kinpeygo is the first and only approved disease-modifying treatment in Europe for IgAN, a rare, progressive autoimmune disease of the kidney with a high unmet need

Bad Vilbel, Germany – 26 July 2024 – STADA has received approval from the European Commission for an extension of the marketing authorization of its orphan drug for the treatment of primary immunoglobulin A nephropathy (IgAN; Kinpeygo®). The extension is based on the full two-year data of the Phase 3 clinical trial NefIgArd, published in the leading medical journal *The Lancet.*[1]

In granting a full marketing authorization for the treatment of a significantly larger patient population, the European Commission is following a positive opinion issued by the European Medicines Agency (EMA) earlier this year. The scope of the approval has been extended from a restriction of the urinary protein creatinine ratio (UPCR) to ≥1.5 g/g to the entire NefIgArd study population, defined as proteinuria of ≥1.0 g over 24 hours or UPCR of ≥0.8 g/g.

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

The medicine is the first and only approved treatment for IgAN in Europe that works at the source of the disease thanks to a targeted formulation. For several decades, people suffering from IgA nephropathy have had limited treatment options while facing the progression of renal insufficiency. The majority of patients are young men diagnosed in their thirties. Before IgAN specific treatment was available, these patients often needed renal replacement therapy (dialysis or kidney transplant) before the age of 50.

STADA, holder of the European marketing rights, already in September 2022 launched the orphan medicine in Germany following European conditional approval under the Kinpeygo® name. Marketing authorization has already been granted in other countries, including the United Kingdom, and the company is striving to provide access to additional patients in other countries in the near future.

A detailed description of the instructions for use can be found in the updated Summary of Product Characteristics (SmPC), which was published in the revised European Public Assessment Report (EPAR) and is available in all languages of the European Union.[2] At the same time, the status as an orphan medicinal product was confirmed, for which a ten-year period of market exclusivity applies until 2032.

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.

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

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.

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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