STADA sets standard in Specialty by launching the first medicine authorized in the EU for treating rare kidney disease

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BAD VILBEL, HESSE, GERMANY, September 20, 2022 /EINPresswire.com/ -- STADA sets the standard in Specialty by launching the first medicine authorized in the EU for treating rare kidney disease

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• Orphan medicine launch with exclusivity gives STADA Specialty Care a strong foothold in nephrology, adding to Parkinson's franchise and biosimilars portfolio

• STADA CEO Peter Goldschmidt: "The launch of STADA's first orphan Specialty medicine is evidence of how STADA is bringing added value to patients, healthcare professionals, and health systems through a broad portfolio of Specialty, Generics, and Consumer Healthcare products."

STADA has achieved a major milestone in expanding its Specialty Care business by introducing in the European Union (EU) the region's first authorized treatment for the rare kidney disease immunoglobulin A nephropathy (IgAN). STADA has selected Germany as the lead launch market, with launches in additional European countries planned in the future.

Designated as an orphan medicinal product qualifying for 10-year market exclusivity, the modified-release budesonide capsules are the first and only approved treatment in the EU for primary IgAN, a rare, progressive autoimmune disease of the kidney with a high unmet need, with more than 25%-30% of patients over time developing terminal kidney insufficiency that requires dialysis or kidney transplantation. Developed with Calliditas Therapeutics, the prescription-only medicine will be marketed in the European Economic Area (EEA) exclusively by STADA.

“Making this medicine available to primary IgAN patients in Europe brings for the first time a therapeutic option to an under-served patient population,” commented STADA CEO Peter Goldschmidt. “The launch of STADA’s first orphan Specialty medicine is evidence of how STADA is bringing added value to patients, healthcare professionals and health systems through a broad portfolio of Specialty, Generics, and Consumer Healthcare products.“
In Specialty Care, the nephrology drug complements STADA’s existing epoetin zeta kidney drug, one of the first biosimilars approved in the EU and a central element of STADA’s nephrology portfolio. STADA also offers a range of Specialty Parkinson’s disease therapies, as well as a range of other added-value products in therapeutic categories such as oncology and cardiology.

Primary IgAN, also known as Berger’s disease, is a chronic, debilitating, and life-threatening kidney disease. It is the most prevalent primary chronic glomerulonephritis worldwide. An orphan disease, IgAN is estimated to affect approximately 200,000 people in the EU and United Kingdom.

“The problem with IgA nephropathy is that most patients do not know that they have this disease, and a large proportion of patients are diagnosed by coincidence,” explained Professor Jonathan Barratt, Mayer Professor of Renal Medicine at the University of Leicester. “There is a significant unmet need in the treatments we can offer our patients.”

In the lead launch market, Germany, 3.1 people per 100,000 develop IgAN each year, an incidence somewhat higher than 2.5 per 100,000 globally. Men are twice as likely as women to suffer from IgAN, while the disease is most likely to first manifest itself in the 16-35 years age group.

STADA’s Head of Germany and Europe, Stephan Eder, commented: "It is a great honor for our team that this new orphan drug will be launched in Germany first. After all, this marks the beginning of a new chapter for STADA. We are expanding the range of our portfolio enormously and are underpinning our claim to live up to our purpose in the Specialty area of caring for people's health as a trusted partner."

In granting conditional marketing authorization for the budesonide 4mg delayed-release 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, the European Medicines Agency determined that the medicine “was shown to be effective at lowering the level of excess protein in the urine in patients with IgAN, indicating an improvement in kidney function”.

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3 Thiass F, Stahl RAK. IgA-Nephropathy. Klinik, Pathogenese und Therapie der häufigsten Glomerulonephritis. Dt Ärztebl 2000; 97(41): A 2708-2711
4 Kinpeygo | European Medicines Agency (europa.eu)

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