VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA

VIFOR PHARMA

PRESS RELEASE

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CHMP RECOMMENDS VELTASSA® FOR THE TREATMENT OF HYPERKALAEMIA IN THE EU

- **Opinion includes treatment of patients who develop hyperkalaemia while on RAAS inhibitors**
- **Currently expected to be marketed as Veltassa® in EU/EAA countries**
- **Final EU commission decision expected in Q3 2017**

THE COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP) OF THE EUROPEAN MEDICINES AGENCY (EMA) HAS RECOMMENDED MARKETING AUTHORISATION FOR PATIROMER (BRAND NAME VELTASSA®) IN ALL 31 EU/EEA COUNTRIES FOR THE CONTROL OF ELEVATED SERUM POTASSIUM LEVELS (HYPERKALAEMIA) IN ADULT PATIENTS.

The recommendation specifies Veltassa® for the treatment of hyperkalaemia in adult patients. This includes patients who develop hyperkalaemia while being treated with renin angiotensin aldosterone system (RAAS) inhibitor therapy. Nearly 100% of patients treated with Veltassa® in the phase II-III clinical program were on RAASi at baseline.

The CHMP's recommendation to approve Veltassa® for the treatment of hyperkalaemia in adults is based on a comprehensive clinical development program that included the following studies:

- Pivotal Phase III OPAL-HK study, which evaluated Veltassa® treatment in hyperkalaemic patients with CKD who were taking renin angiotensin aldosterone system (RAAS) inhibitors.[1]
- Phase II AMETHYST-DN trial, which evaluated the use of Veltassa® over 52 weeks in hyperkalaemic patients with CKD and type 2 diabetes who were taking RAAS inhibitors.[2]
- An open-label, uncontrolled, Phase I study that evaluated the onset-of-action of Veltassa® in hyperkalaemic CKD patients.[3]

"We are very pleased with CHMP's decision. This positive opinion means that we are much closer in our efforts to give hyperkalaemia patients in Europe an option for the long-term treatment of their life-threatening condition," said Dr. Behruz Eslami, Head of Global Regulatory Affairs at Vifor Pharma.

Developed by Relypsa, Veltassa® was approved by the US Food and Drug Administration (FDA) for the treatment of hyperkalaemia in the US in October 2015, becoming the first new therapy in more than 50 years to be available for chronic use in patients with elevated serum potassium. Marketing applications for Veltassa® have been submitted and under review in Switzerland and Australia and are planned in other markets worldwide.

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Vifor Pharma Group, formerly **Galenica Group**, is a global specialty pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is the partner of choice for specialty pharmaceuticals and innovative patient-focused solutions. Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The company develops, manufactures and markets pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma; Vifor Fresenius Medical Care Renal Pharma, a joint company with Fresenius Medical Care; Relypsa; and OM Pharma. Vifor Pharma Group is listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN). For more information, visit www.viforpharma.com.

Vifor Pharma, a company of the Vifor Pharma Group, is a world leader in the discovery, development, manufacturing and marketing of pharmaceutical products for the treatment of iron deficiency. The company also offers a diversified portfolio of prescription medicines as well as over-the-counter (OTC) products. Vifor Pharma, headquartered in Zurich, Switzerland, has an increasingly global presence and a broad network of affiliates and partners around the world. For more information about Vifor Pharma, please visit www.viforpharma.com.

Vifor Fresenius Medical Care Renal Pharma Ltd., a common company of Vifor Pharma Group and Fresenius Medical Care, develops and commercialises innovative and high quality therapies to improve the life of patients suffering from chronic kidney disease (CKD) worldwide. The company was founded at the end of 2010 and is owned 55% by Vifor Pharma Group and 45% by Fresenius Medical Care. For more information about Vifor Fresenius Medical Care Renal Pharma and its parent companies, please visit www.viforpharma.com and www.freseniusmedicalcare.com.

References

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