NEWS RELEASE

NICE recommends Vifor Pharma's Veltassa® ▼ (patiromer) for adults with hyperkalaemia in England[1]

- A positive final appraisal determination (FAD) for Veltassa® (patiromer) recommends patients in England have access to a new treatment option for treating hyperkalaemia (raised serum potassium levels) in adults[1]
- Hyperkalaemia is a serious condition, which has a negative impact on quality of life and can lead to sudden death[2]
- Up to 73 percent of advanced Chronic Kidney Disease (CKD) and 40 percent of chronic Heart Failure (HF) patients may be at risk of hyperkalaemia[3]
- Traditionally, persistent hyperkalaemia has been managed by discontinuing or reducing potentially life saving medications (RAAS inhibitors) for CKD and HF[4]
- Patiromer should be started in hospital

SURREY, UK – MONDAY 16th DECEMBER, 2019 – THE NATIONAL INSTITUTE FOR HEALTH AND
CARE EXCELLENCE (NICE) HAS PUBLISHED A FINAL APPRAISAL DETERMINATION (FAD) RECOMMENDING VELTASSA® (PATIROMER) FOR THE TREATMENT OF HYPERKALAEMIA IN ADULTS, WITHIN THE NATIONAL HEALTH SERVICE (NHS) IN ENGLAND.

Hyperkalaemia remains a persistent challenge for clinicians treating approximately four million people in the UK living with chronic kidney disease (CKD) and heart failure (HF). [5,6]

Hyperkalaemia is a potentially life-threatening condition, which can cause fatal cardiac arrest and muscle paralysis, due to elevated levels of potassium in the blood.[2] Hyperkalaemia is often a consequence of the use of important blood pressure treatments, known as RAAS inhibitors. Historically persistent hyperkalaemia has been managed by reducing the dosage or by discontinuing these medicines, despite evidence of improvement of cardiovascular deaths and worsening of renal function.[3,4]

Professor Iain Squire, Professor of Cardiovascular Medicine, University Hospitals of Leicester NHS Trusts, said, "this is as great a result for us as clinicians as it is for our patients. For decades we have lacked effective drugs to treat hyperkalaemia, which has left us in a treatment paradox, confusing patients and leaving them in 'limbo'. We have a robust array of life-preserving drugs for heart failure and chronic kidney disease, but the adverse effect on potassium levels of the use of some of these drugs in some patients has prevented us from using them to their full life-saving effect in many of the patients who need them the most"

The announcement by NICE recognises the need for new options to treat patients with persistent hyperkalaemia as well as those in emergency care for acute life-threatening hyperkalaemia alongside standard care. The NICE approval follows data from multiple phase II and III trials which have shown patiromer lowers serum potassium and that it may allow people to stay on RAAS inhibitors for longer or at a higher dose.[7,8,9,10] NICE acknowledged the value of RAAS inhibitors in treating CKD and HF patients as they may extend life and improve quality of life.[5,11]

Nick Hartshorne-Evans, CEO of the national heart failure charity, the Pumping Marvellous Foundation, said "It's hard enough living with a long term condition like CKD or Heart Failure. However having the concern that medicines like RAAS inhibitors, which we know are helping to keep us alive, may have had to be taken

away due to hyperkalaemia was a burden carried by all patients taking RAAS inhibitors. In a recent Pumping Marvellous Foundation survey of patients with heart failure, over 70% of responders were aware that their Heart Failure medications could affect potassium levels. Of the responders, 35% had their Heart Failure medications changed or stopped, and 88% of that subset felt the immediate effects of this action. Importantly, further treatment options that will allow patients to stay on RAAS inhibitors is a positive development and welcoming, considering the positive impact on proven, guideline appropriate, prognostic medicine. We all stand to benefit from today's decision and hopefully, this will improve both the management and quality of life for people with heart failure like me."

NICE recommends patiromer as an option for treating hyperkalaemia in adults only if used:

- **in emergency care for acute life-threatening hyperkalaemia alongside standard care or**
- **for people with persistent hyperkalaemia and stages 3b to 5 chronic kidney disease or heart failure, if they:**
  - **have a confirmed serum potassium level of at least 6.0 mmol/litre and**
  - **are not taking, or are taking a reduced dosage of, a renin-angiotensinaldosterone system (RAAS) inhibitor because of hyperkalaemia and**
  - **are not on dialysis.**

This guidance from NICE does not affect treatment with patiromer that was started in the NHS before it was published. People having treatment outside of this recommendation may continue without change to the funding arrangements currently in place for them, until they and their NHS clinician consider it appropriate to stop.

Further, primary care and patient access to patiromer should be facilitated through establishment of local shared care protocols.

Patiromer is indicated for the treatment of hyperkalaemia in adults.[12]

FURTHER INFORMATION

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Notes to Editors:

Hyperkalaemia Patient Safety Alert:
The NHS has previously issued a Patient Safety Alert urging clinicians to be vigilant of hyperkalaemia due to the number of preventable deaths caused by the condition.[12,13] Yet symptoms of hyperkalaemia can be difficult for patients to recognise as they can be general to many other conditions e.g. fatigue and weakness.[7]

About patiromer: Patiromer is a non-absorbed, cation exchange polymer that contains a calcium-sorbitol complex as a counterion. Patiromer should not replace emergency treatment for life-threatening hyperkalaemia. Patiromer increases faecal potassium excretion through binding of potassium in the lumen of the gastrointestinal tract.

Binding of potassium reduces the concentration of free potassium in the gastrointestinal lumen, resulting in a reduction of serum potassium levels. The recommended starting dose is 8.4 g patiromer once daily, orally. The daily dose may be adjusted in intervals of one week or longer, based on the serum potassium level and the desired target range. The daily dose may be increased or decreased by 8.4 g as necessary to reach the desired target range, up to a maximum dose of 25.2 g daily.[12]

Vifor Pharma Group: is a global pharmaceuticals company headquartered in Switzerland. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is the partner of choice for pharmaceuticals and innovative patient-focused solutions. The 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. The 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. The Vifor Pharma Group is listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348).

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