Lokelma approved in the US for the treatment of adults with hyperkalaemia

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Lokelma provides rapid and sustained potassium control for patients in a condition with high unmet need

The US Food and Drug Administration (FDA) has approved *Lokelma* (sodium zirconium cyclosilicate), formerly ZS-9, for the treatment of adults with hyperkalaemia,[1] a serious condition characterised by elevated potassium levels in the blood associated with cardiovascular, renal and metabolic diseases.[2]

The risk of hyperkalaemia increases significantly for patients with chronic kidney disease (CKD) and for those who take common medications for heart failure (HF), such as renin-angiotensin-

aldosterone system (RAAS) inhibitors, which can increase potassium in the blood.[2,3] To help prevent the recurrence of hyperkalaemia, RAAS-inhibitor therapy is often modified or discontinued, which can compromise cardio-renal outcomes and increase the risk of death.[3,4]

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: “We are pleased by today’s FDA approval of *Lokelma* as it enables us to help address a long-standing clinical need with a new medicine that offers rapid and sustained treatment for adults with hyperkalaemia. The consequences of hyperkalaemia can be very serious and it’s reassuring for treating physicians that *Lokelma* has demonstrated lowering of potassium levels in patients with chronic kidney disease, heart failure, diabetes and those taking RAAS inhibitors.”

Lokelma is a highly-selective, oral potassium-removing agent.[1] The FDA approval is supported by data from three double-blind, placebo-controlled trials and two open-label trials, which showed that for patients receiving *Lokelma* the onset of action was at 1.0 hour and the median time to achieving normal potassium levels in the blood was 2.2 hours, with 92% of patients achieving normal potassium levels within 48 hours from baseline.[1,8] The treatment effect was maintained for up to 12 months.[1,5,6,7,8]

Steven Fishbane, MD, Professor, Donald and Barbara Zucker School of Medicine at Hofstra Northwell, New York, said: “This FDA approval represents an exciting milestone, as it stands to deliver a rapid, effective and generally well-tolerated treatment option to patients suffering from hyperkalaemia in the US.”

The European Commission granted marketing authorisation for *Lokelma* in the European Union on 22 March 2018.

NOTES TO EDITORS

About Hyperkalaemia

The risk of hyperkalaemia increases significantly for patients with CKD and for those who take common medications for HF, such as RAAS inhibitors, which can increase potassium in the blood. Hyperkalaemia occurs in 23% to 47% of patients with CKD and/or HF, with an estimated 200 million and 38 million people, respectively, living with each condition worldwide. Hyperkalaemia may lead to cardiac arrest and death, with mortality being up to 30% in patients with severe hyperkalaemia, if not treated rapidly.

About *Lokelma*

Lokelma is an insoluble, non-absorbed sodium zirconium silicate, formulated as a powder for oral suspension, that acts as a highly-selective potassium-removing agent. It is administered orally, is odourless, tasteless and stable at room temperature. It has been studied in three double-blind, placebo-controlled trials and in two 12-month open label clinical trials in adult patients with hyperkalaemia.

About AstraZeneca in Cardiovascular, Renal & Metabolism

Cardiovascular and metabolic diseases are a main therapy area and a key growth platform for AstraZeneca, which is now called Cardiovascular, Renal & Metabolism (CVRM), following the addition of *Lokelma* to our portfolio of medicines.

By following the science to understand more clearly the underlying links between the heart, kidney and pancreas, AstraZeneca is investing in a portfolio of medicines to protect organs and improve outcomes by slowing disease progression, reducing risks and tackling co-morbidities. Our ambition