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AstraZeneca’s Lokelma receives EU approval

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AstraZeneca is a global, science-led biopharmaceutical company, announced that the European Commission has granted marketing authorisation for Lokelma (formerly ZS-9, sodium zirconium cyclosilicate) for the treatment of adults with hyperkalaemia.

Hyperkalaemia is a serious condition characterised by elevated potassium levels in the blood associated with cardiovascular, renal and metabolic diseases.

Lokelma is a highly-selective, oral potassium-removing agent. The approval is supported by data from three double-blind, placebo-controlled trials and one open-label trial, where patients with hyperkalaemia were treated for up to 12 months. In these trials, for patients receiving Lokelma the median time to achieving normal potassium levels in the blood was 2.2 hours, with 98% achieving normal levels within 48 hours from baseline. Lokelma also demonstrated sustained potassium control for up to one year.

Elisabeth Björk, Vice President, Head of Cardiovascular, Renal and Metabolism, Global Medicines Development, AstraZeneca, said: “The consequences of hyperkalaemia can be serious, even life-threatening, and can occur in patients either with chronic kidney disease or as a result of taking some medications for heart failure. Today’s approval of Lokelmaaddresses a significant unmet need by bringing a rapid and sustained therapeutic option for patients with hyperkalaemia.”

Lokelma is currently under separate regulatory review in the US, with a decision expected in the first half of 2018.