CHMP positive opinion for ZS-9 in hyperkalaemia

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ZS-9 (sodium zirconium cyclosilicate) RECEIVES POSITIVE CHMP OPINION FOR THE TREATMENT OF HYPERKALAEMIA

AstraZeneca today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending the approval of ZS-9 (sodium zirconium cyclosilicate) for the treatment of hyperkalaemia, a serious condition characterised by high potassium levels in the blood serum caused by cardiovascular, renal and metabolic diseases.

The recommendation is based on data from three double-blind placebo-controlled trials and one ongoing 12-month open-label trial in adults with hyperkalaemia, representing over 1,600 patients treated to date.

Results from a pivotal Phase III study showed that in patients with hyperkalaemia, sodium zirconium cyclosilicate (oral suspension) significantly reduced blood serum potassium to normal levels (normokalaemia) within 48 hours, which was maintained during 12 days of maintenance therapy. Normal levels of potassium in the blood serum were also achieved within 48 hours in an additional study, with a higher proportion of patients maintaining normokalaemia for up to 28 days on treatment versus placebo.

In these trials, sodium zirconium cyclosilicate was shown to significantly lower serum potassium levels quickly and effectively in patients with acute and chronic hyperkalaemia.[1,2]

The condition occurs in 23 to 47% of patients with chronic kidney disease and/or chronic heart failure, both key strategic areas of focus for AstraZeneca, and may lead to cardiac arrest and death; with mortality being up to 30% in patients with severe hyperkalaemia if not treated rapidly[1]. As current therapy options are limited, sodium zirconium cyclosilicate has the potential to address a long-standing unmet need for the fast, safe and effective long-term treatment of hyperkalaemia.[2,3]

The CHMP's opinion will now be advanced to the European Commission (EC) for adoption of a decision on EU-wide marketing authorisation of the medicine. The final decision will be applicable to all 28 European Union member countries plus Iceland, Norway and Liechtenstein.

Sodium zirconium cyclosilicate is being developed by ZS Pharma, a subsidiary of AstraZeneca. It is currently also under regulatory review in Australia and by the FDA in the US, with decisions expected in the first half of 2017.

About ZS-9 (sodium zirconium cyclosilicate)
ZS-9 (sodium zirconium cyclosilicate) is an insoluble, non-absorbed zirconium silicate compound and acts as a highly selective potassium-removing agent.[4] It is odourless and tasteless. It is non-systemically absorbed, preferentially captures potassium, and is administered orally in 5 to 10g doses mixed with three tablespoons of water and is excreted in faeces. Clinical trials indicate that it is stable at room temperature and has a rapid onset of action. It has been studied in three double-blind, placebo-controlled trials and in one ongoing 12-month open label clinical trial in patients with hyperkalaemia, which represents over 1,600 patients treated to date.

About Hyperkalaemia
Hyperkalaemia (high potassium levels in the blood serum) occurs in 23 to 47% of patients with chronic kidney disease and/or chronic heart failure, and may lead to cardiac arrest and death (mortality up to 30% in patients with severe hyperkalaemia if not treated rapidly).[1] Treatment with common heart medicines can also be responsible for increases in hyperkalaemia. Current therapeutic options are limited, leaving a high unmet medical need, in particular for treatments with rapid onset of action, chronic use, and no significant drug to drug interaction risk.

About AstraZeneca in Chronic Kidney Disease
Chronic kidney disease (CKD) is a key strategic area of focus within AstraZeneca's Cardiovascular and Metabolic Diseases (CVMD) therapy area. By leveraging our expertise in diabetes and cardiovascular disease, AstraZeneca is able to better understand the interplay of these conditions and CKD to advance our scientific leadership in the cardio-renal space. Through novel therapies and therapy combinations that target both the complications of CKD and the underlying mechanisms of CKD progression, we are building a portfolio to aggressively prevent, treat, manage and modify this global public health issue.

About ZS Pharma
ZS Pharma, founded in 2008, was a publicly traded biopharmaceutical company until it entered into an agreement with AstraZeneca in November 2015 to be fully acquired. The transaction completed in December 2015. ZS Pharma has been focused on using its proprietary ion-trap technology to develop new treatments for kidney and liver diseases that are focused on addressing unmet needs in the medical community. For more information, please visit: www.zspharma.com.

About AstraZeneca in Cardiovascular and Metabolic Diseases
Cardiovascular, renal and metabolic diseases are key areas of focus for AstraZeneca as part of the company's strategy for achieving scientific leadership and returning to growth. By collaborating across therapeutic disciplines within the CVMD therapy area, we are addressing the underlying disorders that drive CVMD risk, with the goal of reducing morbidity, mortality and organ damage through innovative therapies.

About AstraZeneca
AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of Autoimmunity, Neuroscience and Infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit www.astrazeneca.com and follow us on Twitter @AstraZeneca.

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