FIRST PATIENTS ENROLLED INTO EUROPEAN PHASE III PROGRAMME FOR POTENTIAL FIRST IN CLASS ORAL TREATMENT FOR ANAEMIA ASSOCIATED WITH CHRONIC KIDNEY DISEASE (CKD)

Roxadustat could change treatment of anaemia associated with CKD and remove the need for multiple injections

Chertsey, UK, Monday 17th March, 2014. Astellas Pharma Europe Ltd. today announced that the first European patients have been enrolled into the global ALPINE programme being conducted in collaboration with FibroGen, Inc to investigate the safety and efficacy of roxadustat (also known as ASP1517/FG-4592), a potential new oral treatment for anaemia in people with chronic kidney disease (CKD). In Europe, Astellas will conduct three Phase III studies as part of this programme, ALPS, DOLOMITES and PYRENEES, encompassing both non-dialysis and dialysis patients. Approximately 1,800 patients will be enrolled in Europe and the studies will compare roxadustat to both current treatment and placebo. Roxadustat is not currently licensed for use in any country.

Treatments for anaemia aim to raise haemoglobin (Hb) levels in the blood to help the body transport oxygen more effectively.1 Current treatment options often involve a combination of injectable ESAs and iron supplements which can be delivered either orally or intravenously.2 There are some safety concerns regarding current treatments (known as erythropoiesis-stimulating agents, or ESAs), which have been shown to increase blood pressure2 and to be associated with an increased risk of cardiovascular events when used to target high Hb levels.3 Dosing guidance for ESAs has been revised as a result of these concerns.4

In Phase II studies roxadustat was well tolerated, and was seen to correct and maintain Hb levels in people with anaemia associated with CKD.5 Of key interest, no increase in blood pressure was detected and there was no need for additional intravenous infusions of iron (a common requirement associated with currently used ESAs).5 The ALPINE study programme is being conducted alongside other global Phase III studies to investigate whether roxadustat can offer patients with anaemia associated with CKD effective oral treatment without the need for additional injections or increasing patients’ cardiovascular risk profile.

“For years we have had to give people with CKD two injections to treat their anaemia”, said Dr Ashraf Mikhail, Senior Clinical Tutor at Swansea University and UK Coordinating Investigator for the ALPS study. “Firstly we give intravenous iron, the building blocks for haemoglobin, and ESA, which processes these building blocks into blood elements. This requires a lot of time, monitoring, testing and patient visits. Roxadustat could allow us to replace all this with one tablet, and potentially transfer management of this condition from secondary to primary care.”

Roxadustat is the first compound in a potential new therapeutic class known as hypoxia-inducible factor (HIF) prolyl hydroxylase inhibitors (or HIF-PHIs) to enter Phase III studies.6 Roxadustat raises Hb levels via a mechanism which mimics the natural effects of high altitude.6 It has long been known that Hb production increases at high altitude, and HIF promotes generation of the red blood cells which carry Hb.6 By increasing HIF levels, roxadustat increases Hb levels through utilising the body’s own iron stores, leading to Hb control without the need for supplementary iron.5
"Roxadustat has the potential to change the treatment of anaemia associated with CKD", said Dr Michael Allen, Therapeutic Area Head, Urology and Nephrology, Astellas Pharma Global Development. "We are very pleased to mark this milestone in roxadustat’s development, which is also an important one for Astellas. We are looking forward to working with the nephrology community as we establish ourselves in the area, and hope to make contributions similar to those Astellas has made in areas such as transplantation and urology.”

Astellas has licensed certain rights to roxadustat from FibroGen in territories that include Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa. Astellas will be responsible for regulatory filings to the EMA when appropriate.

CKD is a growing worldwide public health issue, and can lead to patients requiring dialysis. The European Kidney Health Alliance estimate that over 10% of people in Europe have CKD. As CKD gets more severe it is more likely to cause anaemia, a debilitating condition which can cause fatigue and breathlessness to the extent that normal daily activities become challenging or impossible. Studies suggest that around 12% of people with CKD also have anaemia. CKD is responsible for a large financial burden on European healthcare systems, with dialysis alone accounting for up to around 2% of the European health care budgets, although only a small proportion (<0.1%) of the population need treatment.

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About Anaemia
Anaemia is the condition of having fewer red blood cells and/or lower haemoglobin levels than is normal. The prevalence of anaemia increases with the progression of CKD and is a demonstrated risk multiplier in patients with pre-existing cardiovascular disease. Anaemia has been associated with adverse outcomes in CKD patients, increased hospitalisation rates, increased mortality, and reduced quality of life, but the condition tends to be undertreated due in part to the cost and complexity of treatment with injectable erythropoiesis-stimulating agents (ESAs) and intravenous iron supplements.

About Astellas Pharma Europe Ltd.
Astellas Pharma Europe Ltd., located in the UK, is the European headquarters of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative pharmaceuticals. The organisation’s focus is to deliver outstanding R&D and marketing to continue growing in the world pharmaceutical market. Astellas Pharma Europe Ltd. is responsible for 21 affiliate offices located across Europe, the Middle East and Africa, an R&D site and three manufacturing plants. The company employs approximately 4,300 staff across these regions. For more information about Astellas Pharma Europe, please visit www.astellas.eu.

References