AVEROA Submits Marketing Authorisation Application to the European Medicines Agency Seeking Approval of AVA1014 for Treating Complications Associated with Chronic Kidney Disease

Grenoble, France, 23rd April 2024 - Averoa, a biopharmaceutical company bringing innovative therapeutic solutions to people with renal diseases, announces the submission of a marketing authorisation application (MAA) to the European Medicines Agency (EMA) for Ferric Citrate Coordination Complex (AVA1014), an oral iron-based compound for patients suffering from Chronic Kidney disease (CKD).

Ferric Citrate Coordination Complex (AVA1014) was licensed from Akebia Therapeutics, Inc. (Akebia) in December 2022. Since then, Averoa has revised the clinical package and the regulatory strategy using all clinical studies and recent scientific publications to address the specific needs of the European market. The MAA submission is supported by three pivotal clinical studies performed by Akebia.

The EMA will review the accepted application under the centralised marketing authorisation procedure and a decision on a potential approval is expected in 2025. This centralised procedure means that a single marketing authorisation application can be submitted to the European Union (EU), and, if approved, allows Averoa to market and make Ferric Citrate Coordination Complex (AVA1014) available to patients and healthcare professionals throughout the EU.

"*The submission of Averoa's first product to the EMA is an exciting milestone as we seek to expand our portfolio of in-licenced products*," said **Luc-André Granier, President and Medical Director at Averoa**. *"Patients with chronic kidney diseases are faced with a significant burden of disease requiring long-term treatment and there remains a high unmet need."*

***

About CKD

Chronic Kidney Disease (CKD) describes the gradual loss of kidney function. It is a major public health problem resulting in an important burden for patients and healthcare systems. It affects millions of people with an estimated prevalence ranging from 3% to 17% in Europe. It is one of the ten leading causes of death in developed countries and can be due to multiple causes, including: high blood pressure, diabetes, high cholesterol, kidney infections, glomerulonephritis, polycystic kidney disease, genetic conditions, autoimmune diseases, kidney stones, smoking, age, and use of certain medicines.

CKD is commonly associated with two common debilitating disorders, Iron Deficiency Anaemia (IDA) and Mineral Bone Disorders (MBD). Depending on the stage of the disease, CKD can induce cardiovascular diseases. CKD can progress to end-stage kidney failure, which is fatal without dialysis or kidney transplant.

About AVA1014
Akebia Therapeutics granted to Averoa an exclusive license to develop and commercialise AVA1014 in the European Economic Area, Turkey, Switzerland and the United Kingdom.

AVA1014 has been approved and is being commercialised in different regions: in the United States (US) under the brand name Auryxia® (ferric citrate) by Akebia Therapeutics, Inc.; in Japan as Riona® (ferric citrate hydrate) by Japan Tobacco Inc.; in Taiwan as Nephoxil® by Panion & BF Biotech Inc.; and in South Korea as Nephoxil® by Kyowa Kirin Korea Co. Ltd.

About Averoa
Averoa is a biopharmaceutical company, founded in December 2021, bringing innovative therapeutic solutions to people with renal diseases. Averoa's goal is to build, advance and commercialise a strong pipeline of products to meet significant unmet medical needs of patients with kidney or metabolic diseases.

More information is available on our website www.averoa-pharma.org

Contacts:

Averoa
Luc-André Granier
President et Directeur Medical
Email: info@averoa-pharma.com

MEDiSTRAVA
Sandi Greenwood, Sylvie Berrebi
averoa@medistrava.com