AVEROA receives European marketing authorization for XOANACYL®, an Oral Therapy for Chronic Kidney Disease (CKD)

- ***XOANACYL is an oral therapy designed to address critical challenges in CKD, including Iron deficiency and hyperphosphatemia***
- ***Averoa submitted XOANACYL for UK approval via MHRA's International Recognition Procedure***
- ***AVEROA actively seeking strategic partners and investors to bring XOANACYL to European patients and unlock full market potential***

Grenoble, France, 16th June 2025 - Averoa, a biopharmaceutical company bringing innovative therapeutic solutions to people with renal diseases, today announced that the European Commission (EC) has granted marketing authorization for XOANACYL. This follows the positive opinion issued in March by the committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), making XOANACYL the only approved treatment for iron deficiency in patients with elevated serum phosphorus levels – a significant unmet need in the European CKD market.

XOANACYL (Ferric Citrate as Coordination Complex) is a single oral therapy that addresses two common and co-occurring complications in adult patients with chronic kidney disease (CKD): iron deficiency and elevated serum phosphorus levels (hyperphosphatemia). Its dual mechanism of action allows for effective ferric iron supplementation while simultaneously reducing phosphorus absorption, helping to simplify treatment regimens, improve outcomes for patients with CKD.

In December 2022, Averoa strategically licensed XOANACYL from Akebia Therapeutics, Inc. (Akebia) with the goal of bringing this therapy to patients across Europe. The European marketing authorization was supported by data from three pivotal clinical trials conducted by Akebia, which demonstrated XOANACYL's efficacy in increasing iron levels while reducing serum phosphorus in patients with CKD. Since acquiring the rights, Averoa has re-engineered the clinical package and developed a comprehensive European dossier to support the dual indication, with a clear focus on addressing the needs of European CKD patients and securing EU-wide approval.

In Europe, more than 10 million CKD patients suffer from iron deficiency and phosphate dysregulation - two under- treated complications that drive disease progression and poor outcomes. Oral iron therapies are often ineffective while elevated serum phosphate is often addressed only at advanced CKD stages, despite phosphate dysregulation being detectable much earlier in the disease. If not appropriately treated, these complications significantly worsen clinical outcomes, contributing to vascular calcification, cardiovascular disease and increased mortality. XOANACYL offers a novel opportunity to address both complications earlier and more effectively.

Luc-André Granier, President and Medical Director at Averoa, said: *"This approval represents a major strategic milestone for our company, opening the door to one of Europe's most important healthcare markets, where tens of millions of people are living with chronic kidney disease. It underscores AVEROA's ability to translate scientific excellence into real-world patient impact. We are deeply grateful to all our partners who made this milestone possible, and we are proud to bring this novel therapy to CKD patients across Europe.*
"We look forward to working with strategic partners to drive the commercial potential of XOANACYL across Europe."

Averoa has submitted its marketing authorization application to the UK Medicines and Healthcare products Regulatory Agency (MHRA) under the International Recognition Procedure (IRP).

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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 induces two common debilitating disorders, Iron Deficiency Anemia (IDA) and Mineral Bone Disorders (MBD) that in turn is linked to an increase of FGF23 as a compensatory mechanism. 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 a kidney transplant.

About XOANACYL®
Akebia Therapeutics granted to Averoa an exclusive license to develop and commercialize XOANACYL® in the European Economic Area, Switzerland, the United Kingdom, Turkey, Israel and additional selected countries in eastern Europe.

Ferric citrate has been approved and is being commercialized 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 commercialize 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 and on our LinkedIn page

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