AVEROA Receives Positive Opinion from the European Medicines Agency for XOANACYL®, an Oral Therapy for Chronic Kidney Disease (CKD)

- ***CHMP recommends approval for XOANACYL, an oral therapy for use in the following therapeutic areas: Iron deficiency, chronic renal failure and hyperphosphatemia***

- ***Final European Commission decision expected by June 2025; UK regulatory submission foreseen via MHRA's international recognition procedure***

- ***AVEROA seeking strategic commercial partners to bring XOANACYL to market across Europe***

Grenoble, France, April 2nd, 2025 - Averoa, a biopharmaceutical company bringing innovative therapeutic solutions to people with renal diseases, today announces a positive opinion from the European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) for XOANACYL®, an oral therapy for chronic kidney disease (CKD). This milestone represents a key step toward a potential EU-approval.

XOANACYL (Ferric Citrate as Coordination Complex) is an oral therapy offering a dual mechanism of action for patients with CKD. This new treatment provides an effective source of ferric iron for addressing iron deficiency and plays a pivotal role in controlling phosphorus absorption. XOANACYL offers a comprehensive approach to improving patient outcomes in CKD.

XOANACYL was licensed from Akebia Therapeutics, Inc. (Akebia) in December 2022. Since then, Averoa has created an appropriate dossier, in particular by re-engineering the clinical package, to support the dual indication for the benefit of the European patients.

The marketing authorization application (MAA) was filed in March 2024 through the centralized European procedure, supported by three pivotal clinical studies performed by Akebia Therapeutics.
The positive opinion will now be reviewed by the European Committee (EC), which has the authority to approve medicines for European Union member states. The EC has approximately two months from the CHMP opinion to issue the final decision. Additionally, Averoa will submit a marketing authorization application to the Medicines and Healthcare products Regulatory Agency (MHRA), following the international recognition procedure (IRP) which has the authority to approve medicines for the UK market. A final MHRA decision is anticipated in the coming months.

Luc-André Granier, President and Medical Director at Averoa, said: *"This positive CHMP opinion is a pivotal moment for Averoa. It validates our ability to successfully navigate European regulatory pathways and brings us one step closer to offering a novel therapy to CKD patients. We are now focused on securing the right commercial partners to bring XOANACYL to market and accelerate patient access."*

With EU approval expected in the coming months, Averoa is actively pursuing strategic commercial partnerships to support the launch and distribution of XOANACYL across Europe. The company is focused on collaboration models that can accelerate access to this innovative therapy and maximize its clinical and commercial impact.

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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, Turkey, Switzerland and the United Kingdom.

Xoanacyl® 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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