



Advicenne reaches a significant milestone with the US FDA in the development of ADV7103 in cystinuria

Paris, France, January 29, 2025 – 7.00AM (CET) – Advicenne (Euronext Growth Paris ALDVI – FR0013296746) a specialty pharmaceutical company dedicated to the development and commercialization of innovative treatments for those suffering from rare renal diseases, provides an update on recent exchanges with the U.S. FDA (Food and Drug Administration) about the development of ADV7103 in cystinuria, and announces that it has reached an important milestone.

As previously stated, the company has engaged in a new round of discussions with the US FDA to finalize the development plan for ADV7103 in cystinuria in the United States. During the latest meeting, Advicenne has presented a set of data, with the active presence of American opinion leaders, and the “International Cystinuria Foundation”, the main cystinuria patient group, specifically:

- The preliminary clinical results obtained in Europe in cystinuria patients,
- The European and American expert opinions on medical needs in this rare kidney disease,
- A proposed clinical development plan with a biological endpoint.

Following this meeting, the FDA accepted Advicenne’s proposition of a biological primary endpoint for the evaluation of ADV7103 in cystinuria; a significant step in preparing for a clinical trial of limited duration and number of patients.

Advicenne is now preparing the submission of the final draft of the pivotal trial in cystinuria to the FDA. The choice of the biological primary endpoint should enable the company to enroll patients both in the United States and Europe, and to consider filing simultaneously registration applications in both territories.

ADV7103 has orphan drug status in the cystinuria indication in both Europe and the USA. Cystinuria affects around 30,000 patients in the US and 40,000 in Europe and represents a significant potential market for ADV7103.

Didier Laurens, CEO of Advicenne, stated: *“This major milestone reflects the quality of our discussions with the US Food and Drug Administration, which is demonstrating its pragmatism in accelerating the development of treatments for rare diseases and their access to the US market. After the orphan designations for distal Renal Tubular Acidosis (dRTA) and cystinuria, and the decision to file a registration application to the FDA based on European clinical data for dRTA, this milestone highlights further the interest of ADV7103 in the treatment of kidney diseases with high therapeutic needs and the building a solid future for this asset in the United States.”*



ABOUT ADVICENNE

Advicenne (Euronext: ALDVI) is a specialty pharmaceutical company founded in 2007, specializing in the development of innovative treatments in Nephrology. Its lead product Sibnaya[®] has received Marketing Approval for distal renal tubular acidosis (dRTA) in EU and GB. ADV7103 is currently in late stage development in cystinuria in Europe and in dRTA and cystinuria in the US and Canada. Headquartered in Paris, Advicenne, listed on the Euronext Paris stock exchange since 2017, has now been listed on Euronext Growth Paris since its transfer on March 30, 2022. For additional information, see: <https://advicenne.com/>.

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