FDA grants Orphan Drug Designation to ADV7103 for the treatment of cystinuria.

- **After distal Renal Tubular Acidosis (dRTA) in December 2022, ADV7103 is granted "orphan drug" status in the United States in cystinuria.**
- **A long-awaited milestone for the Company and its flagship product has now been reached**
- **Cystinuria, a hereditary kidney disorder, is a major unmet medical need, affecting some 30,000 patients in the U.S.**
- **The Company is now looking forward to signing a partnership to pursue the development and prepare the marketing of ADV7103 in the U.S in its two indications: cystinuria and dRTA.**

Paris (France), March 25, 2024 – 7.30am 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, today announced that its proprietary drug ADV7103 has been granted Orphan Drug Designation (ODD) status for the treatment of cystinuria. This designation was issued by the US Food and Drug Administration (US FDA). ADV7103 is one of the few drugs to obtain orphan designation in the USA for both indications, cystinuria and distal Renal Tubular Acidosis (dRTA).

Didier Laurens, Chief Executive Officer of Advicenne, declared: *"After receiving an initial orphan designation of ADV7103 in dRTA in 2022, we are absolutely delighted to announce today that we have obtained orphan drug status in cystinuria. After months of intense discussions with the FDA, this is fantastic news for Advicenne and a major element of value creation. I am very proud of the teams who worked hard for this success, especially in the USA. I am also very proud that the first clinical data obtained in France have convinced the FDA of the benefit of ADV7103 in the treatment of cystinuria. The treatment of this condition with simplified alkalinization is a major unmet medical need with a very significant market potential with more than 30,000 patients in the USA. Obtaining this ODD in cystinuria is the powerful lever we have been waiting for to accelerate and finalize discussions with potential partners in the United States".*

Cystinuria is a genetic disease characterized by a buildup of the amino acid cystine in the kidneys and bladder. These high levels of cystine lead to the formation of cystine stones in the kidneys, ureter, and bladder. These stones generate various complications, such as hypertension, intense abdominal pain, recurrent urinary tract infections, renal function impairment in up to 70% of patients and chronic renal insufficiency. These complications can ultimately lead to chronic renal failure.

To date, 40,000 patients suffer from cystinuria in Europe and around 30,000 in the USA. The treatment of this pathology is based primarily on the alkalinization of urine combined with significant fluid intake and a low-protein diet to limit the recurring formation of kidney stones. ADV7103, an innovative and proprietary fixed combination of sustained-release potassium citrate and potassium bicarbonate, has the potential to become the first major drug in the treatment of cystinuria in North America, as well as in Europe, where ADV7103 is also designated an orphan drug since December 2022.

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 Sibnayal® 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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Disclaimer

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