Advicenne obtains Orphan Drug Designation for ADV7103 in the United States for the treatment of distal Renal Tubular Acidosis (dRTA)

Paris, France, December 13, 2022 – 7.00 AM (CET) – Advicenne (Euronext Growth Paris ALDVI - FR0013296746), a specialty pharmaceutical company dedicated to developing and commercializing innovative treatments for those suffering from rare renal diseases, announced today that ADV7103, its proprietary drug currently in Phase III in the United States, has been granted Orphan Drug Designation (ODD) status for the treatment of distal Renal Tubular Acidosis (dRTA). This designation was issued by the US Food and Drug Administration (US FDA).

ADV7103 is a proprietary innovative combination of two active pharmaceutical ingredients (potassium citrate and potassium hydrogen carbonate) in the form of prolonged release coated granules. The specific formulation of ADV7103 aims to optimize the daily dosing of active ingredients and thus improve the adherence to treatment and quality of life of patients with dRTA.

Didier Laurens, Chief Executive Officer of Advicenne, stated: *"ADV7103 being granted orphan drug designation in dRTA is a major step for our drug candidate and Advicenne. This regulatory status is of critical importance in the ongoing discussions for the signing of a commercial partnership in North America. The real-world clinical data obtained from patients with dRTA, in European countries for more than 5 years, confirm both the therapeutic benefit of ADV7103 and its safety, and significantly strengthen the prospects for its development in the United States.*"

ADV7103 has the potential to become the first drug to treat dRTA in North America. This disease results in a decrease in blood pH that causes many complications such as growth retardation, rickets (a disease of bone development in children), lithiasis, nephrocalcinosis and, in some cases, hearing loss. This disease can ultimately lead to chronic kidney dysfunction.

In the United States, dRTA in its genetic and secondary forms affects between 20,000 and 30,000 patients. In Europe, it is estimated that between 30,000 and 50,000 patients are living with this condition.

With a view to creating additional value, Advicenne is also studying the possibility of applying for an orphan designation in the cystinuria indication 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 Sibnayal® (ADV 7103) has received its Marketing Approval for distal renal tubular acidosis in EU and the UK. ADV 7103 is currently in late-stage development in cystinuria in Europe and in dRTA and cystinuria in the US and in 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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