



Advicenne announces positive opinion from the French Transparency Commission (HAS) for its drug SibnayaTM in dRTA

- **SibnayaTM eligible for reimbursement by the French public health insurance system**
- **ASMR IV: Recognition of the contribution of SibnayaTM in the treatment of dRTA**

Paris, France, 20 December 2021 – 7:00 am CEST – Advicenne (Euronext: ADVIC), a specialty pharmaceutical company dedicated to developing and commercializing innovative treatments for those suffering from rare renal diseases, announces it has received a positive opinion from the French Transparency Commission (HAS) with its lead asset, SibnayaTM eligible for reimbursement with a Moderate Level SMR (Medical Rendered Service) and a Level IV ASMR (Medical Rendered Service Improvement), in the treatment of distal Renal Tubular Acidosis (dRTA) in adults, adolescents and children over the age of 1.

This decision makes SibnayaTM the only specialty pharmaceutical product reimbursed in the treatment of dRTA in France, which will significantly ease access to treatment of the disease for both patients and their doctors. The French Transparency Commission (HAS – Haute Autorité de Santé), in its opinion, acknowledges the contribution of the twice-daily dosing formulation of SibnayaTM which significantly improves the quality of life of patients as well as compliance to long-term treatment plans. These factors contribute to the continuous improvement of disease indicators, particularly bone mineral density, as shown by the clinical development of SibnayaTM over a period of at least 4 years.

Didier Laurens, Chief Executive Officer of Advicenne, comments: *“We are particularly pleased and proud of the opinion delivered by the French Transparency Commission. The reimbursement of SibnayaTM is a major step forward for patients and their physicians. This opinion also recognizes the benefit of a form of SibnayaTM that makes it easier to administer with a positive impact on the long-term disease indicators. This notice is an additional step towards the commercialization of SibnayaTM, following the recent commercial announcements.”*

Distal renal tubular acidosis (dRTA) is an orphan disease characterized by the inability of the kidney to excrete acids from metabolism. The excess of acids in the blood leads to pH imbalance (acidosis) and multiple other complications: growth retardation, bone development and rickets, metabolic abnormalities (decreased blood potassium, elevated urinary calcium), kidney stone formation, calcium deposits in the kidney (calcinosis), renal failure. Whether genetic or acquired, as a consequence of an immunological disease, dRTA is a chronic pathology that affects approximately 30,000 patients in Europe and 20,000 in the United States.

About Advicenne

Advicenne (Euronext: ADVIC) is a pharmaceutical company founded in 2007, specializing in the development of innovative treatments in Nephrology. Its lead drug candidate is currently in late-stage clinical trials for two kidney diseases: distal renal tubular acidosis and cystinuria. ADV7103 has just received a positive CHMP opinion for the treatment of dRTA. Headquartered in Paris, Advicenne has been listed on the Euronext Paris stock exchange since 2017 and was cross listed on the Euronext Brussels stock exchange in 2019. For additional information see: <https://advicenne.com/>

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Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Advicenne, which shall not be considered per se as historical facts. Such statements include projections and estimates, and the hypotheses on which these are based, as well as observations relating to operations, ongoing projects, objectives, the development of products and their future performance, and expectations regarding financial results.

In some cases, forward-looking statements can be identified by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets" or similar words. Although the management of Advicenne believes that these forward-looking statements are reasonably made, investors should be aware that they are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. In particular, the expectations of Advicenne could be affected by, among other things, uncertainties involved in the placing on the market and commercialization of Advicenne products or any other risks and uncertainties developed or identified in any public documents filed by Advicenne with the French Financial Markets Authority (*Autorité des marchés financiers* (AMF)), including those listed in Chapter 4, "Risk Factors," of its universal registration document, filed with the latter on December 22, 2020. Notwithstanding the compliance with article 223-1 of the General Regulation of the AMF (the information disclosed must be "accurate, precise and fairly presented"), Advicenne disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.