Advicenne expects imminent marketing authorization for ADV7103 (Sibnayal™) for dRTA in Europe

Withdraws Orphan Drug Designation application to accelerate availability for patients

Paris, France, March 19, 2021 – 6.00 pm CET - Advicenne (Euronext: ADVIC) (the "Company"), a specialty pharmaceutical company dedicated to developing and commercializing innovative treatments for rare renal diseases, announced that it anticipates imminent European Marketing Authorization for its lead product, ADV7103 (Sibnayal™). Concurrently, and in order to prevent any delays to the potential patient availability of the product, the Company has decided to withdraw its application for the Orphan Drug Designation (ODD), as it was informed by EMA that additional data would be needed to grant /confirm ODD status.

As such, Advicenne will be able to make ADV7103 available to patients suffering from dRTA in Europe in the shortest possible timeframe. In Europe, dRTA is classified as an orphan condition affecting less than 2.1 per 10,000 people. The approval will make ADV7103 the first and only label-approved drug for the treatment of distal renal tubular acidosis (dRTA) in adults, adolescents and children aged one year and older. Given the debilitating consequences of the condition, the Company is convinced that with ADV7103 it has the opportunity to make a significant difference to patients sufferering from dRTA.

ADV7103 is developed as a multi-particulate formulation in 2mm granules, a novel pioneering delivery technology created by Advicenne that contains two active pharmaceutical ingredients. This approach not only has led to an excellent effectiveness in controlling metabolic acidosis, but also to ease the administration and aid compliance and quality of life in patients of all ages.

Peter Meeus, Chief Executive Officer of Advicenne, said: *"We are focused on bringing our treatments to patients as expediously as possibly and are delighted about the near-term prospects for Sibnayal™. This could bring life-changing benefits to patients with dRTA and we are excited to advance our medicine."*

About dRTA

Distal renal tubular acidosis dRTA is an orphan disease characterized by a failure in the renal excretion of acids generated through metabolism and for which there is no approved treatment. The excess of acids accumulated in the blood leads to an imbalance in pH (acidosis) as well as multiple other complications such as growth retardation and rickets (a disease affecting bone development) in children, and a series of metabolic disorders such as low potassium levels, elevated calcium in the urine resulting in kidney stones, the formation of calcium deposits in the kidneys (nephrocalcinosis) as well as possible kidney failure.
Whether genetic or acquired as a consequence of an immune disease, an estimated 30,000 patients with dRTA in Europe and approximately 20,000 in the United States could benefit from Sibnayal.

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: the renal tubular acidosis and cystinuria. ADV7103 has received a positive CHMP opinion for the treatment of dRTA in December 2020. 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 reference document, filed with the latter on December 19, 2019, under number D.19-1036. 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.

Any information relating to the use of drug candidates contained in the present press release is based on the results of ongoing studies at the time of the release’s publication. A drug candidate is a product that has not yet received marketing authorization from a health agency.