



Advicenne Receives MHRA Approval to Market Sibnaya[™] (ADV7103) in the UK for the Treatment of dRTA

Paris, France, 2nd July 2021 – 7 am CEST – Advicenne (Euronext: ADVIC), a specialty pharmaceutical company dedicated to developing and commercializing innovative treatments for those suffering from rare renal diseases, is pleased to announce that the Medicines & Healthcare products Regulatory Agency (MHRA) has today granted marketing authorisation for Sibnaya[™] (ADV7103) in the UK, for the treatment of distal renal tubular acidosis (dRTA).

With this authorization, and following the recent approval by the European Commission to market Sibnaya[™] for the treatment of dRTA in the European Union, Advicenne is now able to bring to market in the EU and the UK the first and only label-approved drug for the treatment of dRTA in adults, adolescents and children aged one year and older. Advicenne now has the opportunity to make a significant difference to patients suffering from dRTA, classified as an orphan condition in Europe.

Didier Laurens, Chief Executive Officer of Advicenne said: *“We welcome the approval by the MHRA of Sibnaya[™] which enables us to provide a much needed treatment to patients in the United Kingdom affected by dRTA. With this approval, and following the marketing authorization by the European Commission earlier this year, we are now able to make a difference to the lives of the thousands of people affected by this rare disease. Our first priority is now to finalize a distribution agreement for Sibnaya[™] in Europe.”*

Sibnaya[™] is 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.

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 thus 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 (calcinosis) as well as possible kidney failure.

Whether genetic or acquired as a consequence of an immune disease, dRTA affects an estimated 30,000 patients in Europe and approximately 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.