Advicenne receives positive feedback from the US FDA on pathway to approval and amended Phase III study protocol for its treatment of distal renal tubular acidosis (dRTA)

- *FDA accepts amended protocol and Advicenne will resume Phase III trial of its lead product ADV7103 (Sibnayal™) in the US in June 2021*

- *FDA guidance provides clear path for market approval of ADV7103 in the United States*

Paris, France, 17 May 2021 – 6 pm CEST – Advicenne (Euronext: ADVIC), a specialty pharmaceutical company dedicated to developing and commercializing innovative treatments for those suffering from rare renal diseases, announces US Food and Drug Administration (FDA) acceptance of the amended protocol of the Company's US-based Phase III pivotal trial of ADV7103 (Sibnayal™) for the treatment of primary distal renal tubular acidosis (dRTA).

dRTA is an orphan disease of the kidney affecting an estimated 30,000 patients in Europe and 20,000 in the US for which no approved treatments currently exist.

Following the FDA's written feedback, Advicenne is moving forward with the ongoing restart of its pivotal dRTA clinical Study (ARENA-2) in the US and Canada, with a clear plan for study execution and regulatory strategy to ensure a clear path for the market approval of ADV7103 in the United States. The trial was halted last year due to challenges to its execution posed by COVID-19.

Advicenne's lead product, ADV7103, is developed as a multi-particulate formulation in 2mm microtablets, a novel pioneering delivery technology created by Advicenne that contains two active pharmaceutical ingredients to ease its administration and aid compliance and quality of life in patients of all ages.

Critically, the FDA has agreed that the proposed primary endpoint of its Phase III pivotal trial of ADV7103 (Sibnayal™) for the treatment of dRTA in the US could serve as the basis for full approval in patients with hereditary dRTA.

Dr. David Horn Solomon, Chairman at Advicenne, commented: "*We welcome the positive feedback by the FDA which provides important clarity on the clinical roadmap for ADV7103 in the United States and enables us to overcome the challenges to its execution posed by the COVID-19 pandemic. Following the recent approval by the European Commission to market ADV7103 for the treatment of dRTA in Europe, Advicenne is on course to commercialize a product with the potential of benefitting the lives of patients in an area of high unmet need.*"

Dr. André Ulmann, Chief Medical Officer of Advicenne, said: "*The feedback by the FDA represents another very important milestone for Advicenne, providing key information as we ultimately intend to commercialize ADV7103 in the United States. With the approval of the amended study protocol, which enables us to resume our pivotal Phase III trial, we are optimistic that thousands of patients in the US will also be able to benefit from this potentially life-changing treatment.*"

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 Marketing Approval (MAA) 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.