Advicenne Receives European Commission Approval to Market ADV7103 (Sibnayal™) and announces Leadership Changes to support Commercialisation

ADV7103 becomes 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

Didier Laurens to join Advicenne as new CEO

Resumption of trading at the opening of the stock market on 4 May 2021

Paris, France, 3 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, is pleased to announce that the European Commission (EC) has granted marketing authorisation to ADV7103 (Sibnayal™), for the treatment of distal renal tubular acidosis (dRTA).

This approval makes ADV7103 the first and only label-approved drug for the treatment of dRTA in adults, adolescents and children aged one year and older. With the approval, Advicenne has the opportunity to make a significant difference to patients suffering from dRTA, classified as an orphan condition affecting no more than 1 to 2 individuals per 10,000 people in Europe.

The EC marketing authorisation will be valid in all EU Member States, in the United Kingdom as well as in the European Economic Area (EEA) countries (Iceland, Liechtenstein and Norway).

Dr. David Horn Solomon, Chairman at Advicenne, commented: "*We are delighted for the approval of ADV7103 by the European Commission. Advicenne will now focus on making the product available to patients as rapidly as possible. This approval marks a major milestone for the Company as it endeavours to bring to market therapeutics in areas of high unmet need. Kidney diseases are the 10th leading cause of mortality in the world which highlights the urgent need to develop innovative therapies for severe renal rare diseases.*"

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.

In addition to the approval of ADV7103 by the European Commission, Advicenne announces today several changes in governance and in its senior leadership team. Peter Meeus is leaving his position as Chief Executive Officer for personal reasons with immediate effect. In his place, the Board has appointed Mr Didier Laurens. Mr Laurens is a highly experienced executive who is currently serving as Chief Financial Officer of surgical robotics company eCential Robotics. Prior to this, he served as Chief Financial Officer for Pixium Vision and as Investor Relations, Treasury and Financing Director for Korian, a company specialized in care for the elderly. Advicenne's Chairman David Solomon will also assume an expanded role including new reponsibilities to ensure a smooth transition of CEO duties from Peter to Didier.

Dr. David Horn Solomon, Chairman at Advicenne, concluded: *"A new phase has started for Advicenne with the approval of our lead candidate, ADV7103, by the European Commission. My thanks go to Peter*

for his hard work over the past few months and for helping us achieve this outstanding result. I am also delighted to welcome Didier to Advicenne: his experience will no doubt enable us to progress our trials for ADV7103 for cystinuria in Europe and dRTA and cystinuria the US, to the benefit of an increasing number of patients affected by rare renal conditions."

The company has requested that Euronext suspend the listing of its shares during the trading session of 3 May 2021. The Advicenne share will resume trading at the opening of the stock market on 4 May 2021, following the publication of this press release.

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 the Phase III European program in dRTA (B21CS pivotal study & B22CS extension study)

B21CS was a multicenter pivotal study that enrolled 37 patients suffering from dRTA, including adults, adolescents, children and infants and aimed to assess the efficacy of ADV7103 compared to Standard of Care (SoC) on blood and urine biomarkers of metabolic acidosis. Patients took the SoC treatment for five consecutive days followed by five days of two daily doses of ADV7103, an innovative prolonged-release granule combination of potassium citrate and potassium bicarbonate. Based on the blood and urine parameters, the study results demonstrated the effectiveness and suggested clinical benefit of ADV7103 in dRTA patients in comparison with the SoC. The B22CS extension study was an open-label clinical study that confirmed the efficacy and safety of ADV7103 after 24 months of treatment. ADV7103 has successfully met the primary and secondary endpoints of the study and demonstrated its ability to treat biological disorders caused by dRTA.

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.