Advicenne Announces Submission of European Marketing Authorization Application (MAA) for ADV7103 as Treatment for Distal Renal Tubular Acidosis (dRTA)

Nîmes, France, March 12, 2019 (6:15 p.m. CET) – Advicenne (Euronext: ADVIC – FR0013296746), specializing in the development of adult and pediatric therapeutic products for the treatment of orphan renal and neurological diseases, announces today that it has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for its lead drug candidate, ADV7103, as a treatment for distal renal tubular acidosis (dRTA).

The application comes after positive results in a pivotal Phase III clinical trial (B21CS) and its twenty-four-month extension study (B22CS). In view of patient numbers and the absence of approved treatments for dRTA, ADV7103 had previously received orphan medicinal product designation in Europe in 2017.

Marketing authorization for ADV7103 is anticipated in mid-2020. This schedule is in keeping with the late-2020 commercial launch strategy announced by Advicenne at its IPO: directly in the five principal European markets (France, Germany, Italy, Spain, United Kingdom) and through partnerships in other European Union countries.

With Ozalin® (ADV6209), which received authorization in September of 2018, approval for ADV7103 would make Advicenne one of the very rare French biotechnology companies to obtain two marketing authorizations for innovative products developed in-house.

“This European marketing authorization application represents a major step in Advicenne’s growth,” observes Caroline Roussel, Advicenne Co-Founder and Director of Operations, “one made possible by the outstanding work of our teams.”

“This application fulfills the milestones announced at Advicenne’s initial public offering. In addition to its first obtained MAA, this application promotes the company to a quite advanced development stage” concludes Dr. Luc-André Granier, Chief Executive Officer of Advicenne, “We are delighted to be actively preparing the commercial launch of ADV7103.”

About Distal Renal Tubular Acidosis (dRTA)

dRTA is an orphan disease characterized by a failure in the renal excretion of the acids generated through metabolism. The excess of acids thus accumulated in the blood leads to an imbalance in pH (acidosis) as well as multiple other complications. These include growth retardation and rickets (a disease affecting bone development) in children, and a series of metabolic disorders such as low potassium levels (hypokalemia), high calcium levels (hypercalcemia), elevated calcium in the urine (hypercalciuria)

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 autoimmune disease, dRTA affects an estimated 30,000 patients in Europe and approximately 20,000 in the United States.

About Advicenne

Advicenne (Euronext: ADVIC) specializes in pediatric-friendly therapeutics for the treatment of orphan renal and neurological diseases. The French pharmaceutical company's lead product, ADV7103, has achieved positive results in Europe in a pivotal Phase III study of distal Renal Tubular Acidosis (dRTA) in children and adults, leading to its recent submission for European marketing authorization. The commercial launch of ADV7103 in Europe is anticipated for late-2020.

In North America, ADV7103 has received clearance from the US Food and Drug Administration and Health Canada for a pivotal Phase III clinical trial for the treatment of dRTA patients. Commercial launch in the United States is anticipated for 2021.

In addition to dRTA, ADV7103 is currently in Phase III clinical studies for a second indication, cystinuria, an inherited renal tubulopathy.

Advicenne is listed on the Euronext Paris stock exchange (ISIN: FR0013296746; Euronext ticker: ADVIC). Established in 2007, the company is headquartered in Nîmes, France.

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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 estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements and needs for additional financing. 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, they are based largely on the current expectations of Advicenne as of the date of this press release and 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 3, 2018, under number R.18-073. 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.