



Advicenne Receives Health Canada Clearance to Extend its Pivotal Phase III Trial of ADV7103 in Canada

Nîmes, France, October 15, 2018 (5:45pm CEST) – Advicenne (Euronext: ADVIC), a specialty pharmaceutical company focused on the development of pediatric-friendly therapeutics for the treatment of orphan renal and neurological diseases, announced today that it has received a No Objection Letter to extend its ARENA-2 pivotal Phase III trial for the treatment of distal Renal Tubular Acidosis (dRTA) in Canada from Health Canada’s Office of Clinical Trial.

“After clearance obtained in September from the United States FDA, this new milestone will allow Advicenne to accelerate the recruitment of patients for our ARENA-2 pivotal Phase III trial for ADV7103 in dRTA and enlarges the company’s perspective in North America,” stated Dr. Luc-André Granier, Chief Executive Officer of Advicenne.

About ARENA-2

ARENA-2 is a pivotal Phase III, prospective, multicenter, randomized, double-blinded, placebo-controlled study expected to enroll approximately 40 patients in the United States and now Canada. The primary objective of the study is to evaluate the safety and efficacy of ADV7103 versus placebo in preventing the development of metabolic acidosis defined by serum bicarbonate level in pediatric (6 months to < 18 years of age) and adult (18 to 65 years of age) subjects with primary dRTA.

About distal Renal Tubular Acidosis (dRTA)

dRTA is a disease that occurs when the kidneys do not properly remove acids from blood into urine. As a result, acid overload generates an unbalanced blood pH that triggers failure to thrive and rickets (a condition that affects bone development in children), as well as a range of additional clinical disorders such as a potassium deficiency (hypokalemia) in blood serum, thus altering the function of several organs and most prominently affecting the cardiovascular system. In addition, a high concentration of calcium in blood and urine (hypercalcemia and hypercalciuria, respectively) can lead to kidney stones and calcinosis which may potentially cause renal impairment and ultimately renal failure. Either genetic or acquired as a result of autoimmune disease, dRTA is estimated to affect 30,000 patients in Europe and 20,000 in the United States.

About Advicenne

Advicenne (Euronext: ADVIC) is a specialty pharmaceutical company developing pediatric-friendly therapeutics for the treatment of orphan renal and neurological diseases. The Company’s lead product is ADV7103 which has demonstrated positive results in a European pivotal Phase III study in children and adults with distal Renal Tubular Acidosis (dRTA), is also being developed for a second indication, Cystinuria, an inherited renal tubulopathy.

Advicenne is planning to file ADV7103 for market authorization for dRTA in Europe in the next coming months and anticipates its commercial launch in 2020 in Europe. In North America, the United States

FDA and Health Canada gave clearance to commence a pivotal Phase III clinical trial assessing ADV7103 in dRTA patients. Commercial launch in the United States is anticipated in 2021.

Advicenne is listed on the regulated market of Euronext in Paris (ISIN: FR0013296746; Euronext ticker: ADVIC). The Company, which was established in 2007, is headquartered in Nîmes, France.

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Forward-Looking Statement

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, needs for additional financing. In some cases, you can identify forward-looking statements 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 achievement 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 risk and uncertainties developed or identified in any public documents filed by Advicenne with the AMF, included those listed in chapter 4 "Risk factors" of its document de base filed with the French financial market authority (the Autorité des marchés financiers) on October 31, 2017 under number I.17-071. 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.