Advicenne announces FDA clearance of IND to commence pivotal Phase 3 trial of ADV7103 for distal Renal Tubular Acidosis

Nîmes, France, September 5, 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 the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for ADV7103, allowing the Company to formally initiate its ARENA-2 pivotal Phase 3 trial for the treatment of distal Renal Tubular Acidosis (dRTA) in the United States.

"*FDA clearance of our IND for ADV7103 represents a very significant milestone for Advicenne as it validates our clinical and regulatory strategy for entering the U.S. market,"* stated Dr. Luc-Andre Granier, Advicenne's Chief Executive and Chief Medical Officer. "*Patients with dRTA have a poor quality of life and are often burdened with significant complications from the disease. ADV7103 clinical programs allow us to address a chronic, debilitating disease for which there is no approved treatment, neither by the FDA, nor by the EU*."

ARENA-2 is a pivotal phase 3, prospective, multicenter, randomized, double-blinded, placebo-controlled study expected to enroll approximately 40 patients in the United States. 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 trigger 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 (hypokalaemia) 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 US.

About Advicenne

Advicenne (Euronext: ADVIC) is a 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 3 study in children and adults with distal Tubular Renal Acidosis (dTRA), 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 H2 2018 and anticipates its commercial launch in 2020 in Europe. In the United States, FDA has cleared its Investigational New Drug (IND) application to commence pivotal phase 3 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.

http://www.advicenne.com

Contacts:

Advicenne
Luc-André Granier, Sarah Delbaere, Julie Rachline
Email: investors@advicenne.com
+33 (0)4 66 05 54 20

Investors Relations
NewCap
Emmanuel Huynh & Alexia Faure
advicenne@newcap.eu
+33 (0)1 44 71 94 94

Press Relations
Alize RP
Caroline Carmagnol & Tatiana Vieira
advicenne@alizerp.com
+33 (0)1 44 54 36 66