Press Release

Advicenne confirms ADV7103' safety and efficacy after 24 months in the Phase III Extension Study

These results will allow Advicenne to prepare and file a Marketing Authorization Application in Europe for ADV7103

Nîmes, France, July 2, 2018 (5:45pm CEST) – Advicenne (Euronext: ADVIC), a specialist pharmaceutical company focused on the development of pediatric-friendly therapeutics for the treatment of orphan renal and neurological diseases, announces preliminary results of the Phase III Extension Study (B22CS) with ADV7103 in Distal Renal Tubular Acidosis (dRTA). This open-label clinical study confirms the efficacy and safety of ADV7103 after 24 months of treatment.

Results from 90% of patients at 6 months, 12 months, 18 months, and 24 months demonstrate the ability of ADV7103 to normalize biological disorders caused by dRTA throughout the course of treatment. This efficacy, measured by blood bicarbonate levels and stabilized serum potassium, remains constant in about 80% of patients.

The safety profile of ADV7103 remains very favorable during the treatment, with only 15% of patients having reported digestive side effects considered as product-related, rated as mild for three patients and as medium for one patient.

Dr Luc André Granier, co-founder and CEO of Advicenne, says: *"We are delighted with the progress in this study, in line with the schedule and these first results, which confirm the ADV7103 6-month efficacy and safety data presented at the ASN (American Society of Nephrology) in November 2017 (press release). These positive results will enable us to file a Marketing Authorization Application in Europe for ADV7103 and to offer an alternative to patients suffering from Distal Renal Tubular Acidosis."*

This B22CS extension study which comes on the heels of the Phase III pivotal clinical trial (B21CS), confirms the positive results of the B21CS study. ADV7103 has successfully met the primary and secondary endpoints of the Phase II/III pivotal study and demonstrates its ability to treat biological disorders caused by dRTA.

The preliminary positive results of this study pave the way for the company to file an AMM application in Europe for ADV7103 in the dRTA, an indication for which the European Commission granted ADV7103 the orphan drug designation in June 2017.

About distal Renal Tubular Acidosis (dRTA)
dRTA is a disease that occurs when the kidneys do not properly remove acids from the blood into the urine. As a result, too much acid remains in the blood which generates an unbalanced pH in the blood that can generate 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 the blood serum which alters the function of several organs and most prominently affects the cardiovascular system; and a high concentration of calcium in the blood and urine (hypercalcemia and hypercalciuria respectively) which can lead to kidney stones and calcinosis that can potentially cause renal impairment, ultimately leading to renal failure. The disease, either genetic (usually occurring during childhood) or acquired as a result of autoimmune disease, 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 paediatric 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. A phase II/III clinical trial assessing ADV7103 in dRTA patients in the United States is expected to start in H2 2018. 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.
For more information please visit: http://advicenne.com

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