Advicenne receives positive CHMP opinion recommending approval of ADV7103 (Sibnayal®) for the treatment of distal renal tubular acidosis (dRTA)

Paris, France, December 10, 2020 (6.00 pm CET) - Advicenne (Euronext: ADVIC) today announces the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending approval of its lead product ADV7103 (Sibnayal®) as therapy for distal renal tubular acidosis (dRTA). The European Commission (EC) will now review the CHMP recommendation and a final decision on the Marketing Authorisation of ADV7103 in the European Union is expected in the coming weeks/months.

"*The positive opinion issued by the CHMP for our lead medicine ADV7103 (Sibnayal®) in dRTA demonstrates Advicenne's unique expertise in clinical development and innovative formulations and continues our dedication to patients with this disease. While awaiting the decision of the European Commission, we are already preparing the commercialization of our medicine in Europe, which will be carried out through targeted partnerships to ensure rapid and broad market access. I also want to take this opportunity to thank all Advicenne colleagues, past and present, who have made this Sibnayal® registration possible.*" states **Dr. André ULMANN, Advicenne's Interim Chief Executive Officer**.

This CHMP positive opinion is based on results of a pivotal Phase III trial (B21CS) and its twenty-four-month extension study (B22CS) conducted in adult and pediatric patients with dRTA demonstrating the clinically relevant therapeutic effect of ADV7103.

While the standard of care (SoC) medicine today requires three to six daily intakes including during night, ADV7103 treatment consists of only two doses per day and provides complete night-time coverage for patients. In addition, gastrointestinal tolerability was improved. Plasma potassium and urinary calcium was normalized.

In order to make ADV7103 quickly and broadly available in all EU countries, Advicenne has decided to set up partnerships with specialized distributors. This approach will allow Advicenne to allocate its resources on the clinical development of ADV7103 in the United States and to develop its second indication for the medicine in cystinuria.

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 by Dr. L.A. Granier and C. Roussel-Maupetit 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: the renal tubular acidosis and cystinuria. ADV7103 has been granted orphan drug designation by the European Commission in the treatment of both conditions and has just received a positive CHMP opinion for the treatment of ATRd.

This is the second time Advicenne obtains a Marketing Authorization for an innovative pediatric product it has entirely developed: OZALIN a midazolam formulation for children for use in conscious sedation was registered in 2018 and is now commercialized in Europe by Primex.

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: https://advicenne.com/

Contacts:

Advicenne
David Solomon, Chairman
André Ulmann, iCEO

+33 (0)4 66 05 54 20

Email: investors@advicenne.com

Financial Communications
NewCap
Dusan Oresansky & Emmanuel Huynh
+33 (0)1 44 71 94 92

Press Relations
NewCap
Nicolas Merigeau
+33 (0)1 44 71 94 98

Email: advicenne@newcap.eu