



Advicenne Presented Additional Efficacy Data on ADV7103 in the Treatment of dRTA at International Pediatric Nephrology Association Congress

Nîmes, France, October 28, 2019 (7:45 a.m. CEST) – Advicenne (Euronext: ADVIC - FR0013296746), a specialty pharmaceutical company focused on the development and commercialization of therapeutic products for rare kidney disease, is pleased to announce oral and poster presentations on its lead drug candidate, ADV7103, given at the 18th congress of the International Pediatric Nephrology Association (IPNA). Advicenne also organized a symposium at the October congress.

During an oral session, **Professor Pierre Cochat, Head of Pediatric Nephrology at the University Hospitals of Lyon (*Hospices Civils de Lyon (CHU)*) and Chairman of the Advicenne Advisory Board**, presented an analysis of patients responsive to treatment with ADV7103 in comparison to patients treated with the standard of care (SoC).

During another session, **Dr. Aurelia Bertholet, also of the University Hospitals of Lyon, where she is a team member of the Reference Center for Rare Kidney and Phosphocalcic Diseases**, presented a poster entitled “Improved Management of Urine Parameters in Distal Renal Tubular Acidosis with ADV7103 Versus Current Treatments.”

The related clinical study, B21CS, was conducted to assess the efficacy of ADV7103 compared to the SoC in dRTA patients based on blood and urine biomarkers of metabolic acidosis.

In particular, the results on plasma bicarbonate showed that 82.4% (14/17) of the Non Responder (i.e. patient unable to achieve adequate correct ion of plasma bicarbonate) became Responder when switching from SoC to ADV7103.

The multicenter pivotal study enrolled 37 patients suffering from dRTA, including adults, adolescents, children and infants. Patients took the SoC treatment for 5 consecutive days followed by 5 days of 2 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.

Several urine parameters relating to dRTA were measured in the study. No significant difference was observed on calciuria – measured using urine ratios of calcium/creatinine – between the two treatments. Hypocitraturia, a low urinary citrate excretion, is a well-known risk factor for the development of kidney stones and was observed in 94.1% of patients on the SoC treatment, while only 58.8% of patients treated with ADV7103 were affected. Calcium/citrate ratios suggested a reduced risk of lithogenesis with ADV7103. The number of patients not responsive to a normalization of urine ratios was reduced when switching to ADV7103, suggesting a noticeable benefit achieved with this new formulation compared to current SoC treatments.

Professor Cochat, commented: *“Most patients with distal renal tubular acidosis (dRTA) develop nephrocalcinosis from infancy as well as nephrolithiasis which may later lead to deleterious consequences and potentially to chronic kidney disease. It was therefore very important in this study to evaluate the effects of the compound on the blood and urine parameters of patients and we are glad to see that the switch from a ‘standard of care treatment’ to ADV7103 leads to the reduction of the number of non-responders for plasma bicarbonate normalization showing improvement for the patient, with a better quality of life due to fewer doses per day.”*

Dr Luc-André Granier, CEO and co-founder of Advicenne concluded: *“These additional results reinforce our first results, in particular the stone event rate, and will be added to the registration dossier during the procedure.”*

Advicenne also organised a symposium on dRTA at the IPNA congress, entitled “Optimum Care in Pediatrics to Avoid Long-Term Issues in Adulthood” with Pr Pierre Cochat (Fr), Pr Fernando Santos (Sp), Pr Sabrina Giglio (It) and Dr Stephen Walsh (UK).

About Advicenne

Advicenne (Euronext - ADVIC) is dedicated to developing and commercializing innovative treatments for those suffering from rare kidney disease. Our lead drug candidate, is currently in late-stage clinical trials for two indications.

In 2017, ADV7103 was granted orphan drug designation by the European Commission in the treatment of distal renal tubular acidosis (dRTA), a rare kidney disorder that occurs when the kidneys are unable to effectively remove the buildup of circulating acids in the blood. ADV7103 is currently in Phase III clinical trials for this indication in Europe, the United States and Canada, and a marketing application for the drug candidate has been submitted for centralized European review.

While we prepare its European commercial launch for dRTA, we are simultaneously conducting trials for ADV7103 in the treatment of cystinuria, a genetic disease characterized by a buildup of the amino acid cystine in the kidneys and bladder. ADV7103’s Phase II/III European clinical trials for this second indication were recently expanded to Belgium.

At Advicenne, we are committed to innovating in the areas of formulation and dosage. Tasteless and easy to administer, our products are commercialized in small-size formats that offer flexible, personalized dosing – because path-breaking treatments for rare diseases should be available to patients of all ages.

Headquartered in Nîmes, France, Advicenne has been listed on the Euronext Paris stock exchange since 2017 and was cross-listed on the Euronext Brussels stock exchange in 2019.

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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 projections and estimates, and the hypotheses on which these are based, as well as observations relating to operations, ongoing projects, objectives, the development of products and their future performance, and expectations regarding financial results.

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, investors should be aware that they 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, and in Section 8 of its annual financial report published on April 30, 2019. 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.

Any information relating to the use of drug candidates contained in the present press release is based on the results of ongoing studies at the time of the release's publication. A drug candidate is a product that has not yet received marketing authorization from a health agency.