



## **Advicenne Makes ADV7103 8 mEq and 24 mEq Prolonged-Release Granules Available Within Framework of French Temporary Authorization for Use (TAU) Scheme**

**Nîmes, France, March 10, 2020 (7:45 a.m. CET)** - Advicenne (Euronext Paris & Brussels: ADVIC - FR0013296746), a specialty pharmaceutical company focused on the development and commercialization of therapeutic products for rare kidney diseases, today announced that it has made its lead drug candidate, ADV7103, available for use within the framework of the Temporary Authorization for Use (TAU) scheme established by France's National Agency of Medicine and Health Products Safety (*Agence Nationale de Sécurité du Médicament et des Produits de Santé* (ANSM)).

This authorization allows for the exceptional use of coated 8 mEq and 24 mEq granules in sachet for the treatment of distal renal tubular acidosis (dRTA) in France. Its prescription is reserved for physicians specializing in nephrology.

The follow-up and monitoring procedures for efficacy and security obtained in patients treated within the framework of this TAU are defined in the Protocol for Therapeutic Use and the collection of information available on the ANSM website. <https://www.ansm.sante.fr/Activites/Autorisations-temporaires-d-utilisation-ATU/ATU-de-cohorte-en-cours/Liste-des-ATU-de-cohorte-en-cours/ADV7103-8-meq-granules-a-liberation-prolongee>

### **About Distal Renal Tubular Acidosis (dRTA)**

dRTA is an orphan disease characterized by a failure in the renal excretion of the acids generated through metabolism. The excess of acids thus accumulated in the blood leads to an imbalance in pH (acidosis) as well as multiple other complications. These include growth retardation and rickets (a disease affecting bone development) in children, and a series of metabolic disorders such as low potassium levels (hypokalemia), high blood calcium levels (hypercalcemia), elevated calcium in the urine (hypercalciuria) 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 autoimmune disease, dRTA affects an estimated 30,000 patients in Europe and approximately 20,000 in the United States.

### **About Advicenne**

Advicenne (Euronext ADVIC) is a specialty pharmaceutical company dedicated to developing and commercializing innovative treatments for those suffering from rare kidney disease.

In 2017, ADV7103 was granted orphan drug designation by the European Commission in the treatment of distal renal tubular acidosis (dRTA), a serious condition that occurs when the kidneys are unable to effectively remove the buildup of circulating acids in the blood, resulting in metabolic imbalance.

ADV7103 is currently in Phase III clinical trials for dRTA in the United States and Canada. In 2019, a European marketing authorization application for the drug candidate in the treatment of dRTA was submitted for centralized review.

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.

[www.advicenne.com](http://www.advicenne.com)

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#### **Forward-Looking Statements**

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 19, 2019, under number D.19-1036. 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.