Advicenne receives authorisation from French regulation authorities to initiate pivotal phase II/III trial of ADV7103 in Cystinuria

Nîmes, France, May 4th 2017 – Advicenne (Euronext : ADVIC), a specialist biopharmaceutical company focused on the development of pediatric-friendly therapeutics for the treatment of orphan renal diseases, announces today that it has received approval from the French National Agency of Medicine and Health Products Safety (ANSM) to initiate a pivotal phase II/III trial in Europe with its lead candidate ADV7103 in Cystinuria.

ADV7103 is an innovative product that has been designed to address two orphan nephrological indications: dRTA (distal renal tubular acidosis) and Cystinuria.

Cystinuria is a rare hereditary disease associated with the abnormal transport of amino acids in the renal tubule which leads to the recurrent formation of large kidney stones. The disease can develop at any age, but clinical symptoms usually appear during the first 20 years of life, affecting one in every 7,000 people in Europe. The Company estimates that these patients represent a population of approximately 70,000[1] in Europe. There is currently no registered first-line treatment in Europe for Cystinuria.

The forthcoming pivotal European phase II/III clinical trial is designed to evaluate the efficacy and safety of ADV7103 in patients with Cystinuria. This study follows positive pivotal phase III data of ADV7103 in dRTA in Europe, an indication for which Advicenne is currently preparing its registration with the European Medicines Agency (EMA) which it expects to file by the end of 2018.

Dr Luc André Granier, co-founder and CEO of Advicenne, comments: "*We are delighted to have gained the authorization to initiate this pivotal clinical trial in Cystinuria. ADV7103 has been designed to address critical unmet medical needs in two renal orphan indications, and we strongly believe there is a real potential for this new drug candidate to improve the treatment and quality of life of patients with Cystinuria and as was shown in patients with dRTA.*"

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 shown positive results in a European pivotal phase III study in children and adults with distal Tubular Renal Acidosis (dTRA), is also being developed in a second indication, Cystinuria, an inherited renal tubulopathy. 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 Nimes (France).

For more information please visit: http://advicenne.com

[1] Eggermann T. and al, Cystinuria: an inborn cause of urolithiasis, Orphanet Journal of Rare Diseases 2012; 7:19

For further information, please contact:

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

International media
Citigate Dewe Rogerson
David Dible, Sylvie Berrebi, Marine Perrier
advicenne@citigatedewerogerson.com
+44 (0) 20 7638 9571

Forward-Looking Statements – Advicenne

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 estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements, needs for additional financing.

In some cases, you can identify forward-looking statements 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, they are based largely on the current expectations of Advicenne as of the date of this press release and 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 achievement 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 commercialisation of Advicenne products or any other risk and uncertainties developed or identified in any public documents filed by Advicenne with the AMF, included those listed in chapter 4 "Risk factors" of its document de base filed with the French financial market authority (the Autorité des marchés financiers) on October 31, 2017 under number I.17-071. 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.