



## **Advicenne secures production of ADV7103 through long-term manufacturing supply agreement with Elaiapharm Lundbeck**

**Nîmes, France, September 4<sup>th</sup>, 2019 (6:45 p.m. CEST)** - Advicenne (Euronext Paris & Brussels: ADVIC - FR0013296746), a specialty pharmaceutical company dedicated to developing and commercializing innovative treatments for those suffering from rare disease, announces that it has signed a supply agreement with the pharmaceutical CDMO Elaiapharm Lundbeck for the manufacturing of its lead product, with a view to its worldwide commercialization as a treatment for distal Renal Tubular Acidosis (dRTA).

Based in Sophia Antipolis, France, Elaiapharm, a wholly owned subsidiary of the renowned H. Lundbeck A/S, provides contract development and manufacturing services to the life science industry. Under the agreement, Elaiapharm will secure manufacturing for the global commercialization of ADV7103, in accordance with cGMP requirements. This agreement is the result of a fruitful eight-year collaboration for the pharmaceutical process development of Advicenne's lead drug candidate, ensuring an extensive knowledge of the product by Elaiapharm.

Alongside the manufacturing of batches for clinical trials conducted by Advicenne, Elaiapharm has scaled up the production process for commercial use and has already produced multiple GMP batches, thus limiting risks associated with industrial production.

ADV7103 is an innovative product with a prolonged-release formulation, designed to maintain sustained release over a twelve-hour period. The product was developed as a multi-particulate formulation in 2mm granules that contains two active pharmaceutical ingredients, to ease its administration in patients of all ages. This patented formulation combines state-of-the-art technology and the development of a substantial know-how for its manufacture. The experience of Elaiapharm is essential to ensuring that the 2020 commercial production of ADV7103 begins on schedule, and the agreement marks Advicenne's planned evolution into an industrial and commercial pharmaceutical company.

**Caroline Roussel, Co-Founder and Director of Operations at Advicenne, comments:** *"For years, our close working collaboration with Elaiapharm has pushed us past many challenges to make the innovative manufacturing process of ADV7103 a success. We are very pleased to continue working as a team with Elaiapharm. Their knowledge and high-quality industrial standards are a key advantage for the commercial production of our lead candidate."*

*"This agreement is a critical step forward in our defined go-to-market strategy,"* adds **Luc-André Granier, Co-founder and CEO of Advicenne.**

*"The Supply agreement is the result of a great collaboration between Advicenne and Elaiapharm. Both companies have invested significant resources and expertise in developing the manufacturing process for ADV 7103, and we are committed to support Advicenne in their efforts to successfully bring this new*

*and innovative treatment to patients in an area of significant unmet need,” says Bo Hilligsøe, SVP Pharmaceutical Production, H. Lundbeck A/S.*

## **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.

[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 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.