

# **Advicenne Provides an Update as its Operations Evolve**

**Paris, France, February 18, 2021 (6:00 pm CET)** - Advicenne (Euronext: ADVIC) provides an update on the overall progress of the Company.

In Europe, with the recent positive CHMP Opinion for our lead medicine ADV7103—Sibnayal™, Advicenne should receive the EMA Marketing Authorization (MAA) for Sibnayal™ soon. The company is currently pursuing discussions with several partners for its commercialization in most countries of the European Community.

Meanwhile the clinical program in cystinuria in the EU is progressing. In spite of the hurdles encountered due to the ongoing COVID-19 crisis, the submission for Marketing Authorization is expected by late 2022.

Advicenne has been able to maintain a satisfactory level of activity, and the team has been doing a great job in all the aspects of the Sibnayal pre-launch, from market access to manufacturing and securement of the supply chain .

In the US, Advicenne Inc, Advicenne's US affiliate, has made significant progress in building a team of highly qualified professionals. The pivotal Phase III ARENA trial of ADV7103 for distal Renal Tubular Acidosis (dRTA) is resuming. The submission for Marketing Authorization is expected in late 2022.

Meanwhile the launch of Ozalin<sup>™</sup> by Primex under an exclusive license is progressing. Advicenne is confident in the continuous positive execution of the €40 million licensing deal signed in 2016.

Focus and streamlining, as well as effective cost management are practices put in place by the Company during these difficult times. The Company was able to secure €4.3 million of non-dilutive financing through a PGE (French state guaranteed loan) at the end of 2020.

Thanks to the positive evolution of the company a number of financing options are now open to secure the development of the Company in the mid term.

With the recent appointment of Peter Meeus as Chief Executive Officer of Advicenne (effective February 15, 2021), the Company will continue to develop strategies and operations to increase its footprint on rare kidney diseases.

"I am very pleased with the progress of the Company in the past year. Important milestones have been met, setting the ground for our new incoming CEO Peter Meeus whose great business experience in the industry will serve Advicenne extremely well to bring the company to its next stage of growth", said **Dr. David Horn Solomon, Chairman of the Board of Directors.** 

"It gives me great pleasure to join Advicenne at this pivotal moment for the Company with the imminent launches of Sibnayal™ in dRTA in Europe. dRTA is a rare debilitating condition, leading to numerous complications such as softening of bones, kidney stones, and renal dysfunction. Sibnayal™ will be the first and only label-approved drug providing 24 hour coverage with just two doses, thus providing significant clinical outcome as well as an improved quality of life. Being able to address cystinuria as well, strengthens



my belief that Advicenne can make a strong difference for patients. Sibnayal™ has a very strong profile and clearly fills an unmet need. It will be particularly useful in children: its low intake frequency, tastelessness and positive tolerance profile will ensure better compliance", said Peter Meeus, newly appointed Chief Executive Officer.

"I have been honored to lead Advicenne for almost a year. With the positive CHMP opinion as well as with the strong development of our clinical strategy, I am proud of what the team have realized", said **Dr**. **André Ulmann,** who now will continue in the company as Chief Medical Officer.

## **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 acid 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 Advicenne**

Advicenne (Euronext: ADVIC) is a pharmaceutical company founded 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 dRTA.

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 see: https://advicenne.com/

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