# Advicenne Reports Full-Year 2019 Financial Results and Confirms Operational Outlook for 2020

**Nîmes, France, March 13, 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 its financial results for the year ended December 31, 2019 and confirmed its 2020 operational outlook.

## 2019 Highlights

2019 was a year of significant development for Advicenne as the company approaches the European commercialization of its lead drug candidate, ADV7103, in the treatment of distal renal tubular acidosis (dRTA). Preparations for the candidate's anticipated 2020 market launch, as well as ongoing Phase III clinical trials for dRTA in the United States and Canada, and for cystinuria in Europe, were the main investment items impacting the year's income statement.

### Financial and Commercial Developments

In 2019, Advicenne as:

- Announced a successful cross-listing on the Euronext Brussels, making shares of the company available on the two largest Euronext markets in the life sciences sector.
- Signed a financing agreement with the European Investment Bank (EIB) in the amount of €20 million, structured in three tranches of €7.5 million, €5 million and €7.5 million, respectively.
- In another major step, Advicenne secured the commercial production of its lead drug candidate, ADV7103, through a long-term manufacturing supply agreement with Elaiapharm Lundbeck.

### Scientific, Clinical and Regulatory Developments

Advicenne has also:

- Announced that it had received authorization from Belgium's Federal Agency for Medicines and Health Products (FAMHP) to begin a pivotal Phase II/III CORAL clinical trial for cystinuria with ADV7103.
- Filed the submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for ADV7103 in the treatment of dRTA.

- With three posters presented at the annual conference of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), Advicenne confirmed prevalence figures for dRTA and cystinuria.
- Announced the enrollment of the first patient in its United States pivotal Phase III Arena-2 clinical trial evaluating ADV7103 in the treatment of dRTA.
- Presented additional European efficacy data on ADV7103 in the treatment of dRTA through oral and poster presentations at the 18th annual congress of the International Pediatric Nephrology Association (IPNA).
- Announced that ADV7103 had been approved for orphan drug designation by the European Medicines Agency (EMA) for the treatment of cystinuria in Europe.

**Corporate Governance and Oversight Developments**

- In 2019 Advicenne named Implid Audit a co-auditor in addition to KPMG, whose mandate was renewed. This choice was made in anticipation of the consolidation of accounts planned as part of the company's international deployment.
- In the interest of corporate governance best practices, Advicenne separated the functions of Chief Executive Officer and Chairman of the Board of Directors, naming David Horn Solomon Chairman in an important step for the company's international strategy.
- The company appointed Dr. André Ulmann interim CEO on March 12, 2020.

## 2020 and 2021 Outlook

For Advicenne, 2020 will primarily be devoted to preparing the European launch of ADV7103, whose application for marketing authorization is under review with the EMA's Committee for Medicinal Products for Human Use (CHMP). A decision is expected in 2020.

In 2020 Advicenne will also continue to pursue its investment in Phase III clinical trials in Europe, Canada and in the United States in the treatment of dRTA and cystinuria.

The company has also submitted its first requests for orphan drug designation in the United States.

## Key Financial Data for 2019

The Advicenne Board of Directors met on March 12, 2020, under the chairmanship of David Horn Solomon, and approved the company's consolidated financial statements for the year ended December 31, 2019. Audit work has been undertaken by approved independent auditors whose report is ongoing.

**IFRS Income Statement**
(in thousands of euros)

| INCOME STATEMENT (€ thousands) | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Revenue | 1,663 | 963 |
| Income from partnership | - | 5,000 |
| Other operating income | 921 | 961 |
| **Total revenue and other income** | **2,584** | **6,924** |
| Operating expenses | -16,832 | -12,216 |
| **Operating loss** | **-14,248** | **-5,292** |
| **Net loss** | **-14,198** | **-5,015** |
| Loss per share (€/share) | -1.74 | -0.62 |
| Diluted loss per share (€/share) | -1.74 | -0.62 |

Revenue in 2019 and 2018 was driven primarily by sales of Likozam® and Levidcen®, two in-licensed products for the treatment of epilepsy. Advicenne has commercialized these medications in order to respond to the requests of physicians for alternative treatments for children suffering from the condition. Revenue from Likozam® and Levidcen® is up 35% since 2018.

At the close of 2018, sales of Advicenne's lead drug candidate, ADV7103, began within the framework of European Early Access Programs (EAP). Sales reached €460 thousand in 2019.

Other revenue derives from a research tax credit of €0.9 million. 2018 partnership revenue is tied to a second milestone payment of € 5 million following the September 2018 European marketing authorization for Ozalin®, sold to Primex Pharmaceuticals in 2016.

Operating costs, and their increase relative to 2018, are due primarily to investment in ADV7103 Phase III clinical trials for dRTA in the United States, and for cystinuria in Europe. Operating costs are also tied to preparations for the European commercial launch of ADV7103.

**IFRS Balance Sheet**
(in thousands of euros)

| BALANCE SHEET (€ thousands) | December 31, 2019 | December 31, 2018 |
|---|---|---|
| | | |
| **Non-current assets** | **2,241** | **254** |
| | | |
| **Current assets** | **21,638** | **32,585** |
| of which cash and cash equivalents | 16,629 | 26,232 |
| **Total assets** | **23,879** | **32,839** |
| | | |
| **Total shareholders' equity** | **16,720** | **29,394** |
| | | |
| **Non-current liabilities** | **1,536** | **321** |
| of which borrowings and financial debt | 1,324 | 172 |
| **Current liabilities** | **5,623** | **3,123** |
| of which borrowings and financial debt | 288 | 248 |
| of which trade payables | 3,907 | 1,569 |
| of which other current liabilities | 1,427 | 1,306 |
| **Total liabilities** | **23,879** | **32,839** |

At the close of 2019, Advicenne's cash and cash equivalents were at €16.6 million, reflecting limited consumption of €9.6 million for the year.

**IFRS Cash Flow Statement**
(in thousands of euros)

| CASH FLOW (€ thousands) | December 31, 2019 | December 31, 2018 |
|---|---|---|
| | | |
| **Cash flow from operations** | **-9,475** | **-10,181** |
| of which self-financing capacity | -13,303 | -4,484 |
| of which variation in working capital | 3,828 | -5,697 |
| **Cash flow from investing activities** | **-1,112** | **-342** |
| | | |
| **Cash flow from financing activities** | **983** | **571** |
| of which capital increase | 1,009 | 744 |
| of which variation of borrowings and refundable advances | 26 | - |
| **Change in cash** | **-9,603** | **-9,951** |
| Opening cash | 26,232 | 36,183 |
| Closing cash | 16,629 | 26,232 |

In 2019, cash flow from operations was negative €9.5 million due to an operating loss partially offset by a positive impact from working capital.

Cash flow connected to investing activities was mainly related to the automation of the packaging line for ADV7103 in preparation for its commercial launch.

Investing flow is covered by flows from financing activities with a positive variation of €1 million due to the capital increase that took place in 2019 following the exercise of warrants, primarily by company management.

“For Advicenne, 2019 was a year punctuated by the achievement of many key milestones,” explains **Dr. David Horn Solomon, the company’s Chairman of the Board**. “We have moved closer to bringing our lead drug candidate to market while preparing for its operational launch in Europe. The company has also improved its financial visibility by signing a financing agreement of €20 million with the EIB, which it has not yet used.”

**About Advicenne**

Advicenne (Euronext ADVIC) is a specialty pharmaceutical company 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.

ADV7103 was granted orphan drug designation by the European Commission in the treatment of Cystinuria in late 2019 and distal renal tubular acidosis (dRTA) in 2017, two rare renal diseases.

Cystinuria is a genetic disease characterized by cystine accumulation in the kidneys, leading to the recurrent formation of cystine stones.

dRTA is 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.

In 2019, ADV7103 received the same designation for the treatment of cystinuria, a genetic disease characterized by a buildup of the amino acid cystine in the kidneys and bladder, leading to the recurrent formation of kidney stones, among other complications.

ADV7103 is currently in Phase III clinical trials for dRTA in the United States and Canada, and for cystinuria in Europe. 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

**Contacts:**


**Advicenne**
David Horn Solomon, Paul Michalet,
Julie Rachline
Email: investors@advicenne.com
+33 (0)4 66 05 54 20

**Press Relations**
Alize RP
Caroline Carmagnol
Email: advicenne@alizerp.com
+33 (0)6 64 18 99 59

**Financial Communications**
NewCap
Emmanuel Huynh & Alexia Faure
E-mail: advicenne@newcap.eu
+33 (0)1 44 71 94 94

**US Investor Relations**
Rx Communications Group, LLC
Paula Schwartz
E-mail: pschwartz@rxir.com
+001 917-322-2216


**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.