Advicenne Presents 2020 Half-Year Financial Report and Provides Update on Outlook and Recent Developments

Objective of 2021 European launch of ADV7103 in the treatment of distal renal tubular acidosis (dRTA) maintained

Paris, France, September 25, 2020 (7:00 a.m. CEST) - Advicenne (Euronext: ADVIC) today announced the publication of its financial results for the six months ending on June 30, 2020, and provided an update on the company's activities and outlook.

In a statement, **Chief Executive Officer Dr. André Ulmann** reflected on the company's achievements in the difficult context of the COVID-19 health crisis, providing an overview of future developments and thanking the Advicenne team for its dedication:

"During this first half of 2020, Advicenne has continued to prepare the next phase of its development, namely the European launch of its lead drug candidate, ADV7103, in the treatment of a first indication, distal renal tubular acidosis (dRTA), planned for the beginning of 2021. In spite of the challenges brought about by COVID-19, we have also been able to lay the groundwork for our development in the United States, where we have created a subsidiary. Today we are producing the first consolidated accounts in Advicenne's history.

On the basis of my clinical and regulatory experience, I have asked our teams to make good use of the interruption imposed by the health crisis by conducting a thorough review of our American dRTA study protocol, as well as our European cystinuria protocol, with an aim of proposing simplified protocols to the American and European health authorities. These simplifications would allow us to facilitate recruitment and, more generally, an expedited implementation, thus limiting the delay these projects experienced due to the crisis.

We plan to extend the target indication in the United States from dRTA to all genetic forms of RTAs. This will enlarge the population that we target in the US.

Our goal is to obtain marketing authorization for cystinuria in Europe and for RTAs in the United States in H2 2022.

I would like to take this opportunity to express my sincere appreciation to the Advicenne teams in both France and the United States for their exemplary professionalism and engagement."

2020 Half-Year Highlights

Despite the context of the COVID-19 pandemic, Advicenne's structure was not impacted in the first half of 2020. Already accustomed to telecommuting, the company's teams pursued preparations for the 2021 commercial launch of Advicenne's lead drug candidate, ADV7103, in the treatment of dRTA, in keeping with previously established objectives.

Financial and Commercial Developments

During the course of the first semester of 2020 Advicenne has:

- Drawn down a first tranche of €7.5 million in the framework of a €20 million financing agreement with the European Investment Bank (EIB).
- Thus brought its cash in bank to €17.8 million as of June 30, 2020, compared with €16.6 million on December 31, 2019.
- Created a subsidiary in the Unites States to lead the company's clinical activities in this strategic market.
- Prepared the reinforcement of its team in the United States.

Scientific, Clinical and Regulatory Developments

In the first half of 2020, Advicenne has also:

- Made 8 and 24 mEq prolonged-release granules of ADV7103 available to patients suffering from dRTA in France within the framework of the country's Temporary Authorization for Use (TAU) scheme. The medication had previously received a nominative TAU.
- Added new 24-month clinical data to the marketing authorization application (MAA) for ADV7103 in the treatment of dRTA, currently under review with the European Medicines Agency (EMA).

Governance and Oversight Developments

In the first semester of 2020, Advicenne:

- On March 12 announced a change in leadership with the appointment of Dr. André Ulmann to the position of Interim Chief Executive Officer, replacing Dr. Luc-André Granier.
- Developed the competencies of its board of directors in keeping with the growth of the company with the appointment of Hege Hellstrom, a specialist in innovative product launch, as independent director. This nomination, as well as that of Dr. André Ulmann as a director, was approved by the general assembly at its May 26 closed-door meeting.

Outlook

The centralized registration procedure of ADV7103 in Europe in the treatment of dRTA is on course and has not been impacted by the COVID-19 context as it is based on completed clinical studies. An opinion on the application by the EMA's Committee for Medicinal Products for Human Use (CHMP) is expected in the beginning of 2021. Commercialization of ADV7103 in Europe will take place in 2021 as planned, with an approach optimized by territory.

Owing the Covid-19 pandemic, the modifications of the clinical trial strategy described above should allow Advicenne to maintain the clinical and regulatory timelines in Europe and limit the impact in the United States.

Key Financial Data for the First Half of 2020

The Advicenne Board of Directors met on September 24, 2020, under the chairmanship of David Horn Solomon, and approved the company's half-year financial statements through June 30, 2020. A limited review by approved independent auditors did not identify any accounting or presentation anomalies.

Income Statement
(in thousands of euros)

INCOME STATEMENT (€ thousands)	June 30, 2020	June 30, 2019
Revenue	1 096	757
Income from partnership	-	-
Other operating income	523	369
Total revenue and other income	**1 619**	**1 125**
Operating expenses	-9 334	-7 901
Operating loss	**-7 715**	**-6 776**
Net loss	**-7 696**	**-6 806**
Loss per share (€/share)	-0,92	-0,85
Diluted loss per share (€/share)	-0,92	-0,85

Revenue in the first half of 2020 rose to €1.1 million, or an increase of 44.8% relative to the first half of 2019. Recorded sales were driven primarily by Likozam® and Levidcen®, two in-licensed products for the treatment of epilepsy, as well as by ADV7103, commercialized under temporary use authorization (TUA) in France since March of 2020.

Operating costs, as well as their increase relative to the first half of 2019, are due largely to investment made in relation to Phase III clinical trials for ADV7103 in the treatment of dRTA in the United States and in trials for the treatment of cystinuria in Europe, as well as preparations for the European commercial launch of ADV7103. 7% of operating cost increase was due to non-recurring expenses.

Balance Sheet
(in thousands of euros)

BALANCE SHEET (€ thousands)	June 30, 2020	December 31, 2019
Non-current assets	**2 587**	**2 241**
Current assets	**22 307**	**21 638**
of which cash and cash equivalents	17 825	16 629
Total assets	**24 894**	**23 879**
Total shareholders' equity	**9 425**	**16 720**
Non-current liabilities	**8 952**	**1 536**
of which borrowings and financial debt	8 791	1 324
Current liabilities	**6 516**	**5 623**
of which borrowings and financial debt	288	288
of which trade payables	4 394	3 907
of which other current liabilities	1 834	1 427
Total liabilities	**24 894**	**23 879**

As of the close of June 2020, the company's cash and cash equivalents amounted to €17.8 million, as compared to €16.6 million on December 31, 2019. These figures take into account the receipt of a first tranche of €7.5 million, drawn down from Advicenne's EIB financing (of a total amount of €20 million). With the financing resources over which it has visibility, the company has financial capacity until the fourth quarter of 2021.

Cash and Cash Equivalents
(in thousands of euros)

CASH FLOW (€ thousands)	June 30, 2020	June 30, 2019
Cash flow from operations	**-5 728**	**-4 064**
of which self-financing capacity	-7 179	-6 328
of which variation in working capital	1 451	2 264
Cash flow from investing activities	**-473**	**-282**
Cash flow from financing activities	**7 398**	**-52**
of which capital increase	16	71
of which variation of borrowings and refundable advances	7 500	-
Change in cash	**1 198**	**-4 397**
Opening cash	16 628	26 232
Closing cash	17 825	21 835

In the first half of 2020, cash flow from operations was negative €5.7 million due to operating losses, partially offset by a positive impact on working capital.

Cash flow from investment activities is primarily related to the investment in an automated line for the primary packaging of the ADV7103 product.

Cash flow from financing activities showed a positive variation of €7.4 million as a result of the EIB financing drawdown of €7.5 million.

About Advicenne

Advicenne (Euronext: ADVIC) is a pharmaceutical company specializing in the development and commercialization of innovative treatments in the field of nephrology. Our lead drug candidate is currently in late-stage clinical trials for two kidney diseases: the renal tubular acidoses and cystinuria. ADV7103 has been granted orphan drug designation by the European Commission in the treatment of both conditions.

A European marketing authorization application for ADV7103 in the treatment of dRTA is currently under review with the European Medicines Agency.

Advicenne's ambition is to develop new medications based on an innovative formulation in order to respond to unmet medical needs, particularly in the field of nephrology.

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: https://advicenne.com/

Contacts:

Advicenne
David Solomon, André Ulmann,
Paul Michalet
+33 (0)4 66 05 54 20

Email: investors@advicenne.com

Financial Communications
NewCap
Dusan Oresansky & Emmanuel Huynh
+33 (0)1 44 71 94 92

Press Relations
NewCap
Nicolas Merigeau
+33 (0)1 44 71 94 98

Email: advicenne@newcap.eu

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 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.