



Advicenne Reports Full Year 2018 Financial Results and Confirms Operational Outlook for 2019

Nîmes, France, March 21, 2019 (5:45 p.m. CET) – Advicenne (Euronext: ADVIC - FR0013296746), a pharmaceutical company specializing in the development of adult and pediatric therapeutic products for the treatment of orphan renal and neurological diseases, announces its financial results for the full year ended December 31, 2018. The late-stage French biopharmaceutical company also confirms its operational outlook for 2019.

2018 Highlights

- ✓ **European marketing authorization (AMM) granted for Ozalin® (ADV6209), licensed to Primex Pharmaceuticals**
 - This approval allows Primex to commercialize Ozalin® in several European countries.
 - As provided for in the licensing agreement with Primex, the AMM also triggered a second milestone payment of 3 million euros as well as the definitive payment status of 2 million euros previously accounted for as an advance received.

- ✓ **Significant clinical progress in the development of Advicenne’s lead drug candidate, ADV7103**
 - The company received authorization from the French National Agency for Medicines and Health Products Safety (*Agence nationale de sécurité du médicament et des produits de santé* (ANSM)) to begin pivotal Phase II/III CORAL trials of ADV7103 for the treatment of cystinuria.
 - Advicenne also announced preliminary results of the drug candidate’s European Phase III extension study (B22CS) for the treatment of distal renal tubular acidosis (dRTA): the open-label clinical trial confirmed, after twenty-four months of treatment, the positive B21CS study results.
 - In North America, ADV7103 was granted investigational new drug (IND) status by the U.S. Food and Drug Administration (FDA), making it possible for the company to advance to pivotal Phase II/III ARENA-2 trials for patients with dRTA in the United States.
 - Also in North America, Advicenne received a No Objection Letter (NOL) from the Health Canada Office of Clinical Trials, making it possible to extend a pivotal Phase III ARENA-2 study of ADV7103 for patients with dRTA in Canada.

- ✓ **Product sales grew 72% to reach 963,000€ net**

- ✓ **Advicenne is poised for accelerated growth**
 - The company's staff grew 36% in 2018, with notable appointments including:



- Dr. Linda Law, who will serve as U.S. Vice President of Clinical Development and Medical Affairs, and who will supervise clinical trials in the U.S. beginning in March
 - Charlotte Sibley, who joined the Board of Directors as an American Independent Director in September
 - Paul Michalet, who was appointed to the post of Chief Financial Officer, also in September
- ✓ **Advicenne's burn rate has stabilized**, and a cash position of 26.2 million euros on December 31, 2018 – to which 3 million euros forthcoming from partner Primex Pharmaceuticals can be added – offering the company a financial visibility of two years.

Recent Highlights

- ✓ In January of 2019, Advicenne received authorization from the Belgian health authority (FAMHP) to extend to Belgium its pivotal Phase II/III CORAL clinical trial in cystinuria with its lead drug candidate, ADV7103.
- ✓ In March of 2019, the company submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) for ADV7103 as a treatment for distal renal tubular acidosis (dRTA).

2019 Outlook

- ✓ **Accelerated recruitment for two pivotal studies of ADV7103 in:**
 - Pivotal Phase II/III ARENA-2 trials for patients with dRTA (United States).
 - Pivotal Phase II/III CORAL trials for patients with cystinuria (Europe).
- ✓ **Preparation for commercial launch of ADV7103 in five European countries** (Germany, Spain, France, Italy, United Kingdom) including the establishment of field structures and “market access” initiatives.
- ✓ **Conclusion of agreements for distribution outside these five European countries**
- ✓ **Receipt of orphan designation for ADV7103 by regulatory authorities in the United States (dRTA, cystinuria) and in Europe (cystinuria)**
- ✓ **Continued new product development with a goal of expanding the company's portfolio**
- ✓ **Industrial and logistical deployment**



Key Financial Data for 2018

The Advicenne Board of Directors met on March 20, 2019, under the chairmanship of Dr. Luc-André Granier, and approved the company's consolidated financial statements for the year ended December 31, 2018. Audit work has been completed by approved independent auditors whose report is ongoing.

IFRS Income Statement

INCOME STATEMENT (K€)	December 31, 2018	December 31, 2017
Revenue	963	557
Partnership revenue	5,000	1,091
Other operating revenue	961	924
Total revenue from current activity	6,924	2,572
Operating expenses	-12,216	-8,546
Operating loss	-5,292	-5,974
Net loss	-5,015	-6,048
Loss per share (€/share)	-0.62	-1.01
Diluted loss per share (€/share)	-0.62	-1.01

Revenue in 2018 and 2017 was driven primarily by 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 with epilepsy. In 2018, Advicenne began its first sales of ADV7103 on a temporary authorization for use (ATU) basis.

Partnership revenue comprises milestone payments of 3 and 2 million euros under an agreement signed with Primex Pharmaceuticals in February 2016. As noted above, these payments were made as a result of Ozalin[®] having been granted European marketing authorization.

Other revenue derives from a research tax credit up to 0.8 million euros.

The increase in operating costs is due largely to investment in clinical trials for ADV7103, in particular for the preparation and launch of the pivotal Phase III ARENA-2 trials for patients with dRTA in the United States, and the pivotal Phase III CORAL trials for a second indication, cystinuria, in Europe. Costs incurred



in the preparation for the European commercial launch of ADV7103, as well as those relating to Advicenne's listing on Euronext, also contributed to the increase in operational expenses.

IFRS Balance Sheet

BALANCE SHEET (K€)	December 31, 2018	December 31, 2017
Non-current assets	254	226
Current assets	32,585	38,308
Cash and cash equivalents	26,232	36,183
Total assets	32,839	38,533
Total shareholders' equity	29,394	33,511
Non-current liabilities	321	560
Borrowings and financial debt	172	454
Current liabilities	3,123	4,463
Loans and financial debt	248	248
Suppliers	1,569	1,314
Other current liabilities	1,306	2,901
Total liabilities	32,839	38,533

At the close of 2018, Advicenne's burn rate had stabilized, and the company's cash and cash equivalents were at 26.2 million euros, ensuring strong financial visibility for two years.

IFRS Cash Flow Statement

CASH FLOW (K€)	December 31, 2018	December 31, 2017
Cash flow from operating activities	-10,181	-5,801
Self-financing capacity	-4,484	-5,032
Variation in working capital	-5,697	-769
Cash flow from investing activities	-342	-338
Cash flow from financing activities	571	40,739
Capital increase	744	40,830
Changes in loans and repayable advances	-	500
Change in cash	-9,951	34,600
Opening cash	36,183	1,583
Closing cash	26,232	36,183

In 2018, cash flow from operations was negative 10.2 million euros. This cash requirement can be explained by an operating loss and an increase in working capital needs, of which a sum of 3 million euros remained outstanding from Primex Pharmaceuticals on December 31, 2018, and by the need to establish inventory to sustain anticipated growth.

Cash flow of 0.7 million euros connected to financing activities was generated from the exercise of the over-allotment option following the initial public offering in December 2017.

Paul Michalet, Chief Financial Officer, states: *“We have controlled our spending while maintaining our operational objectives. We have good financial visibility and the trust of our partners should we further accelerate our development.”*

“2018 was a year of growth for Advicenne, in which we effectively accomplished everything we announced at our initial public offering” concludes **Dr. Luc-André Granier, Chief Executive Officer of Advicenne**, *“Our positive results were unaffected during a difficult financial period in which the market was disturbed by a considerable amount of bad news. We will persevere despite such a climate because the current and planned development of Advicenne makes it one of the most advanced companies in the biotech sector, and also perhaps one of the least risky. I have assembled an outstanding team of professionals that gives me confidence in our trajectory.”*



Contacts:

Advicenne

Luc-André Granier, Paul Michalet,
Julie Rachline
E-mail: investors@advicenne.com
+33 (0)4 66 05 54 20

Financial Communications

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

Press Relations

Alize RP
Caroline Carmagnol & Tatiana Vieira
E-mail: advicenne@alizerp.com
+33 (0)1 44 54 36 66

US Investor Relations

Rx Communications Group, LLC
Paula Schwartz
Email: pschwartz@rxir.com
+001 917-322-2216

About Advicenne

Advicenne (Euronext: ADVIC) specializes in pediatric-friendly therapeutics for the treatment of orphan renal and neurological diseases. The French pharmaceutical company's lead product, ADV7103, has achieved positive results in Europe in a pivotal Phase III study of distal Renal Tubular Acidosis (dRTA) in children and adults, leading to its recent submission for European marketing authorization. The commercial launch of ADV7103 in Europe is anticipated for late-2020.

In North America, ADV7103 has received clearance from the US FDA and Health Canada for a pivotal Phase III clinical trial for the treatment of dRTA patients. Commercial launch in the United States is anticipated for 2021.

In addition to dRTA, ADV7103 is currently in Phase III clinical studies for a second indication, cystinuria, an inherited renal tubulopathy.

Advicenne is listed on the Euronext Paris stock exchange (ISIN: FR0013296746; Euronext ticker: ADVIC). Established in 2007, the company is headquartered in Nîmes, France.

www.advicenne.com

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