Advicenne has submitted to the US FDA the registration application (NDA) for Sibnayal® in dRTA treatment

Paris (France), November 4, 2025 – 7.00AM (CET) – Advicenne (Euronext Growth Paris - FR0013296746 - ALDVI), a pharmaceutical company specializing in the development and marketing of innovative treatments for people suffering from rare kidney diseases, announces the submission of the registration application for Sibnayal® (fixed-dose combination of potassium citrate and potassium bicarbonate) for the treatment of distal Renal Tubular Acidosis (dRTA) to the US Food and Drug Administration (US FDA). Sibnayal® has been designated an orphan drug in dRTA in the USA.

The evaluation of the dossier should take approximately 12 months. The company will communicate on the main stages of the evaluation process as well as on the expected date of the US authorities' decision (PDUFA date), which should be known within a few weeks.

The company's management is organizing a conference call on **November 5, 2025** at **5.45PM (CET)**, accessible via the following link: Web-conference Advicenne | Join meeting | Microsoft Teams

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About Advicenne
Advicenne (Euronext Growth Paris ALDVI - FR0013296746) is a specialty pharmaceutical company founded in 2007, specializing in the development of innovative treatments in Nephrology. Its lead product Sibnayal® (ADV7103) has received its Marketing Approval for distal renal tubular acidosis in EU and GB. ADV7103 is currently in late-stage development in cystinuria in Europe and in dRTA and cystinuria in the US and in Canada. Headquartered in Paris, Advicenne, listed on the Euronext Paris stock exchange since 2017, has now been listed on Euronext Growth Paris since its transfer on March 30, 2022.

For additional information, see: https://advicenne.com/.

CONTACTS

Advicenne
Didier Laurens, Directeur Général
+33 (0) 1 87 44 40 17
Email: investors@advicenne.com

Ulysse Communication
Media relations
Bruno Arabian
+33 (0)6 87 88 47 26
Email: advicenne@ulysse-communication.com

Disclaimer

This press release contains certain forward-looking statements concerning Advicenne group and its business, including its prospects and product candidate development. Such forward-looking statements are based on assumptions that Advicenne considers to be reasonable. However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the 2024 Universal Registration Document filed with the French financial market authority on April 29, 2025 (a copy of which is available on www.advicenne.com) and to the development of economic conditions, financial markets and the markets in which Advicenne operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Advicenne or not currently considered material by Advicenne. The occurrence of all or part of such risks could cause actual results, financial conditions, performance, or achievements of Advicenne to be materially different from such forward-looking statements. Advicenne expressly declines any obligation to update such forward-looking statements.