Advicenne: FDA has accepted for review the Marketing Authorization Application for Sibnayal® in the United States for the treatment of dRTA

- The US regulatory agency has set the target date for the final approval decision, known as the PDUFA date, as of September 3rd, 2026.

Paris (France), January 19, 2026 – 7.30AM (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 that the FDA (Food and Drug Administration) has accepted for review the New Drug Application (NDA) for Sibnayal® (ADV7103), a fixed combination of potassium citrate and potassium bicarbonate for the treatment of distal Renal Tubular Acidosis (dRTA). The FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) for September 3rd, 2026.

Following the submission of the New Drug Application (NDA) dossier on November 2, 2025, the U.S. FDA completed its standard 60-day filing review. During this period, Advicenne satisfactorily addressed several questions raised by the Agency. As we agreed with the FDA, the 505(b)(2) application incorporates the European clinical studies that also underpin the recently renewed Marketing Authorization dossier in Europe.

Didier Laurens, Chief Executive Officer of Advicenne, stated: *"This acceptance acknowledges the outstanding work accomplished by the entire Advicenne team, across clinical, regulatory, and CMC functions, both in France and the United States. It attests to the quality of our submission, which, I would like to emphasize, was filed precisely on schedule. We are now entering the substantive review phase, which is expected to continue through September 2026. During this time, we will remain fully committed to responding promptly and effectively to all FDA requests. Our main goal is to bring to U.S. patients, their families, and caregivers the only therapy specifically designed for the treatment of distal Renal Tubular Acidosis (dRTA)".*

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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/.

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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.