



Advicenne decides to withdraw its ADV7103 New Drug Application in the USA

Paris (France), August 31, 2026 – 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 today the voluntary withdrawal of the New Drug Application (NDA) for ADV7103 in the treatment of primary distal Renal Tubular Acidosis (dRTA) in the USA.

During the review process and ongoing communications between Advicenne and the U.S. Food and Drug Administration (FDA), it was recognized that additional Chemistry, Manufacturing and Controls (CMC)-related work will need to be implemented, which cannot be completed within the current review cycle.

ADV7103 (Sibnaya[®]), approved in 2021, is currently marketed in the European Union and the United Kingdom. It is also approved in the Kingdom of Saudi Arabia (KSA) and United Arab Emirates (UAE).

The Company is hosting a webinar for shareholders, in French, on Tuesday September 1st, 2026 at 6:00PM, which can be accessed via the following link:

[ADVICENNE WEBCAST](#)

This webcast will be recorded and posted on Advicenne's website.

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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 Sibnaya[®] (ADV7103) has received its Marketing Approval for distal renal tubular acidosis in EU, the UK, KSA and UAE, and is marketed in more than 25 countries in Europe. 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 2025 Universal Registration Document filed with the French financial market authority on April 26, 2026 (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.