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31st, August 2026

CURRENT REPORT NO. 40/2026

DATED 31st August 2026

Subject: Positive Clinical Trial Results for the CoolCryo Cryoablation System

Legal basis: Article 17(1) of the MAR Regulation – inside information

Content of the report:

The Management Board of Medinice S.A. the "Company" announces that the Clinical Trial Report for the CoolCryo medical device was finalized. The clinical trial was conducted in accordance with the approved trial protocol and the requirements of Regulation EU 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices the "MDR".

The results of the CoolCryo system clinical trial demonstrate positive and clinically significant therapeutic effects of the investigated medical device in patients undergoing mitral valve surgery mitral valve repair or mitral valve replacement, with or without left atrial appendage closure who had documented concomitant paroxysmal or persistent atrial fibrillation AF. Clinical efficacy was demonstrated with respect to the occurrence of recurrent atrial fibrillation during the 6-month follow-up period.

The assessment of documented recurrence of atrial fibrillation constituted the primary endpoint of the clinical trial.

The trial also confirmed a favorable safety profile of the investigated medical device. No adverse events, including serious adverse events, related to the investigated medical device were reported during the trial.

The predefined level of statistical significance was achieved, and the clinical trial was successfully completed.

The report further indicates that the results obtained are consistent with results published for comparable surgical cryoablation procedures and provide clinical evidence supporting the safety and clinical performance of the CoolCryo system.

The document will form part of the clinical and technical documentation of the medical device and will be used in the Company's further regulatory activities conducted in accordance with applicable requirements, including as part of the conformity assessment process for the device.

The Management Board of the Company has classified the above information as inside information within the meaning of Article 7 of Regulation EU No. 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse the "MAR", as it directly concerns the Company, is of a precise nature and may be material to the assessment of the development and commercialization prospects of the CoolCryo device and, consequently, to the assessment of the Company by market participants.

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