Medinice S.A.
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29 APRIL 2026

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Title: Completion of the clinical investigation of the CoolCryo medical device

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

The Management Board of Medinice S.A., with its registered office in Warsaw (the "Issuer"), hereby announces the completion of the clinical investigation of the CoolCryo medical device. The conclusion of this stage confirms the completeness of the clinical dataset and enables the formal transition to the next phase, comprising results analysis and further regulatory activities

The completion of subject participation in the clinical investigation constitutes the basis for initiating the subsequent stage of regulatory work on CoolCryo, including the comprehensive analysis of clinical data and the preparation of documentation required for conformity assessment and CE marking in accordance with the requirements of the MDR Regulation.

A positive evaluation of the clinical investigation results will represent a key milestone in the process of obtaining CE marking, which would authorise the placing of the device on the European Union market. Securing CE marking would complement the regulatory approvals already obtained by the Issuer, including clearance from the U.S. Food and Drug Administration (FDA), thereby further strengthening the potential for international commercialization of the device.

The Issuer will inform of any further material developments concerning the CoolCryo project through relevant current reports.