



Medinice S.A.  
Ul. Stefana Hankiewiczza 2  
02-103 Warsaw

6 MARCH 2026

**CURRENT REPORT NO. 8/2026**  
**DATED 6 MARCH 2026**

**Title: Submission to the FDA of a pre-submission (Q-Sub) request in the AtriClamp project**

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

The Management Board of Medinice S.A. (the “Company”) hereby informs that on 06 March 2026 the Company submitted to the U.S. Food and Drug Administration (FDA) a pre-submission request under the Q-Submission (Q-Sub) program concerning the AtriClamp project. Together with the request, the Company provided the FDA with documentation intended for preliminary review prior to the meeting.

The purpose of the meeting under the pre-submission is to obtain feedback from the FDA with respect to the submitted documentation, in particular regarding the scope and manner of conducting the planned preclinical studies and their adequacy for the purposes of the subsequent stages of the regulatory process for the AtriClamp project.

In accordance with FDA procedures, the date of the meeting is set by the Agency within standard timeframes, generally within 75 days from submission of the request.

The Company will inform about further material events concerning the AtriClamp project in accordance with its disclosure obligations.

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therapies for quality of life*

Medinice S.A.  
biuro@medinice.pl  
www.medinice.pl