Annual Progress Report

Study title: An open label, observational, prospective, longitudinal cohort study to evaluate safety, clinical and radiographic outcomes

Protocol ID: H-34

STRICTLY CONFIDENTIAL

CIP Number:	H-34
CIP Version:	2.0 05 November 2024

Sponsor:	Lima Corporate S.p.A.
Sponsor Address:	Via Nazionale, 52 33038 Villanova di San Daniele Udine, Italy
Sponsor Contact:	Francesca Citossi Manager Company Initiated Studies Europe & APAC francesca.citossi@enovis.com
Principal Investigator Name and Title:	Dr. Jerzy Bialecki

Principal Investigator Contact:	jerzybialecki@pro.onet.pl

Principal Investigator and site details

Site N°	Principal Investigator	Hospital / Address
	Dr. Jerzy Bialecki	Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP Księdza Stanisława Konarskiego 13, 05-400 Otwock, Poland

Annual Progress Report Approval Page

We, the undersigned, have read and approve this clinical study report and agree on its content:

Signature/Electronic Signature of Chief Investigator or Sponsor representative:	Firmato da: Francesca Citossi Nome firmatario: Francesca Citossi Motivo per la firma: Approvo il documento Ora firma: 24/2/2025 | 15:11 CET 10372FDFF8B54BDE8D56FA131AAAF8CA
Print name	Francesca Citossi
Date of submission	24th February 2025

1. CURRENT STATUS OF CLINICAL TRIAL GLOBALLY

Planned Number of Sites	1
Planned Number of Subjects	49
Number of Active Sites	1
Number of Subjects Included	28
Number of Subjects Ended	0
If you expect the study to overrun the planned completion date, what are the reasons for this?	Slow enrollment rate

2. SITE INFORMATION

Date of Authorization	9th September 2020
Current status	Enrollment
Early Termination? (YES/NO) If yes, please indicate Date and Cause	NO N/A

Number of Subjects Included	28
Do you plan to increase the total number of sites proposed for the study? (YES/NO)	NO

3. RECRUITMENT OF PARTICIPANTS

Number of participants recruited to date:	28
Number of participants completing trial:	9
Number of withdrawals from trial:	1 drop-out in 2024: - Pt 101/10: patient death. Causality of the adverse event was deemed not related to study medical device nor to study procedure.

4. SAFETY REPORTS

Have there been any Suspected Unexpected Serious Adverse Reactions (SUSARs) in this trial and have they been notified to the Committee? (YES/NO)	NO

5. AMENDMENTS

Have any substantial amendments been made to the trial during the year? (YES/NO)	YES

If yes, please give the date and amendment number for each substantial amendment made.	Substantial amendment Nr 7/2025 approved on 12 February 2025: - Extension of study enrollment phase from 30 to 60 months - Elimination of survival follow-up visits at 3-, 4- and 5-year follow-up

6. SERIOUS BREACHES OF THE PROTOCOL OR GOOD CLINICAL PRACTICE

Have any serious breaches of the protocol or GCP occurred in relation to this trial during the year? (YES/NO)	YES
If YES, please explain	- With reference to 2024 annual progress report "Pt 101/02, 101/3, 101/4, 101/5, 101/6, 101/7: date of signature on the Informed Consent Form was written by the SubI, not by the subject. The site was retrained and asked to collect a statement at a follow-up visit", the issue is partially resolved. - Pt 101/21, 101/24 follow-up visit out of window. - Pt 101/06, 101/10, 101/16 no visit due to lack of contact

7. OTHER ISSUES

Are there any other developments in the trial that you wish to report to the Committee? (YES/NO)	NO