MONITORING VISIT REPORT

VISIT INFORMATION

Protocol Title:	A Randomized, Open-Label, Multicenter, Phase 3 Trial Comparing Veliparib Plus Carboplatin and Paclitaxel Versus Investigator's Choice of Standard Chemotherapy in Subjects Receiving First Cytotoxic Chemotherapy for Metastatic or Advanced Non-Squamous Non-Small Cell Lung Cancer (NSCLC) and Who Are Current or Former Smokers
Protocol Name:	M14-359
Site Name / Site #:	CRU Hungary Egeszsegugyi Kft. / SITE-074
Site Address:	Miskolc, HUN
Site Activation Date:	2024-09-23
Monitoring Visit Date:	2025-09-01
Visit Type:	On-Site
CRA:	CRA-117

SUMMARY OF MONITORING VISIT

This Interim Monitoring Visit (IMV) was conducted at CRU Hungary Egeszsegugyi Kft. (SITE-074) on 01-Sep-2025 to review study progress, verify source data, check investigational product (IP) accountability, and ensure compliance with Protocol M14-359, GCP, and local regulations. The monitor met with the Principal Investigator, Dr. Laszlo Kovacs, and the Study Coordinator, Eva Nagy, to discuss the study status. The site has shown remarkable recruitment performance, having already met the target enrollment. All source documents were verified against the eCRF, and no discrepancies were noted. The Investigator Site File (ISF) was reviewed and found to be complete and up to date. IP accountability was performed, and all records matched the physical inventory. No safety issues or protocol deviations were identified during this visit. The site staff continues to demonstrate excellent adherence to the protocol and GCP guidelines.

Overall Impression:

The site continues to perform excellently with no issues noted.

Exit Interview Comments:

Discussed visit findings with the PI and SC. No issues were raised. The PI acknowledged the findings.

URGENT ISSUES

No

PERSONS PRESENT

Name	Position/Title
Dr. Laszlo Kovacs	Principal Investigator
Eva Nagy	Study Coordinator

ENROLLMENT STATUS

Screened:	29
Consented:	22
Pre Randomization Failure:	7
Randomized:	20
Completed:	17

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Ongoing:	3
Withdrawn:	0

Recruitment Plan Notes:

Recruitment target met. No further recruitment activities required.

Recruitment Rate Adequate? Yes

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MONITORING CHECKLIST

Informed Consent

1	Is the current IRB/EC-approved ICF version being used?	Yes	
2	Was ICF signed prior to any study procedures?	Yes	
3	Is the correct version of the ICF filed in the subject binder?	Yes	
4	Was re-consent obtained if required?	Yes	

Site Staff/Facilities

5	Is the Principal Investigator available for supervision?	Yes	
6	Are Sub-Investigators qualified and delegated appropriately?	Yes	
7	Is the Study Coordinator trained on the current protocol?	Yes	
8	Are pharmacy facilities adequate for IP storage?	Yes	
9	Is the laboratory certified/accredited?	Yes	
10	Is relevant equipment calibrated and maintained?	Yes	
11	Is the Delegation of Authority Log current and signed?	Yes	
12	Is the Training Log complete for all staff?	Yes	
13	Are CVs current for all active staff?	Yes	

Investigator Site File / Monitoring Activities

14	Is the Investigator Site File (ISF) complete?	Yes	
15	Are all essential documents current and filed?	Yes	
16	Is the Site Visit Log signed by the monitor?	Yes	
17	Have prior visit follow-up items been completed?	Yes	

Research Ethics Board

18	Is IRB/EC approval current for the protocol?	Yes	
19	Have all protocol amendments been approved?	Yes	
20	Have safety reports been submitted to the IRB/EC?	Yes	
21	Is the annual renewal/progress report current?	Yes	
22	Is the site-specific consent form approved?	Yes	
23	Is SAE reporting to the IRB/EC compliant?	Yes	

Safety

24	Is Adverse Event (AE) reporting timely?	Yes	
25	Are SAEs followed to resolution?	Yes	
26	Is pregnancy reporting compliant with protocol?	Yes	
27	Are protocol deviations documented appropriately?	Yes	
28	Is the safety database reconciled with source?	Yes	
29	Are SUSAR notifications acknowledged/filed timely?	Yes	
30	Have DSMB recommendations been implemented?	Yes	
31	Is the risk-benefit assessment current?	Yes	

Compliance

32	Is protocol compliance acceptable?	Yes	
33	Is GCP compliance maintained?	Yes	
34	Is regulatory compliance current?	Yes	

Study Investigational Product

35	Is IP storage adequate and secure?	Yes	
36	Is IP accountability logs current?	Yes	
37	Is IP dispensing performed correctly?	Yes	
38	Are IP returns documented?	Yes	
39	Is temperature monitoring compliant?	Yes	

Study Supplies/Vendors

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40	Are lab kits and study supplies adequate?	Yes	
Source Document Verification & Review			
41	Are source documents available for all subjects?	Yes	
42	Was SDV completed per the monitoring plan?	Yes	
43	Were data discrepancies identified?	Yes	
44	Does CRF data match source documents?	Yes	
45	Is query resolution timely?	Yes	
46	Are data corrections documented properly?	Yes	

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
SUBJ-018	Visit 1-3	No discrepancies noted.	
SUBJ-019	Visit 1-3	No discrepancies noted.	
SUBJ-020	Visit 1-3	No discrepancies noted.	

CRA ASSESSMENT

The site is performing well. All study activities are being conducted in accordance with the protocol and GCP. Documentation is accurate and complete. No corrective actions are required at this time.