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:	2024-12-30
Visit Type:	On-Site
CRA:	CRA-116

SUMMARY OF MONITORING VISIT

This Interim Monitoring Visit (IMV) was conducted at CRU Hungary Egeszsegugyi Kft. (SITE-074) on 30-Dec-2024 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 of 20 subjects since activation in September 2024.

During the visit, 100% Source Document Verification (SDV) was performed for all randomized subjects. The monitor reviewed medical records, including pathology reports, concomitant medications, and adverse event logs. All data entered into the eCRF matched the source documents perfectly. There were no queries generated during this visit, and no data discrepancies were identified. The Investigator Site File (ISF) was reviewed and found to be complete and up-to-date with all essential documents filed correctly. All versions of the ICF were present, and all subjects were consented using the correct version prior to any study procedures.

Investigational Product accountability was reviewed for all dispensed kits. The temperature logs showed no excursions, and storage conditions remain within the protocol-defined range. The pharmacy binder was organized, and drug dispensing logs matched the IVRS confirmations exactly. Safety reporting was reviewed; all Adverse Events have been documented and reported within the required timelines. There are no unreported SAEs. The site staff is well-trained and delegated tasks appropriately. The Delegation of Authority log is current. The PI remains highly involved in the study oversight. No concerns noted during this monitoring visit.

Overall Impression:

Site performing well.

Exit Interview Comments:

The CRA met with Dr. Kovacs and Ms. Nagy. The findings of the visit were discussed. No issues were raised. The PI acknowledged the visit findings and confirmed continued oversight.

URGENT ISSUES

No

PERSONS PRESENT

Name	Position/Title
Dr. Laszlo Kovacs	Principal Investigator

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Eva Nagy	Study Coordinator

ENROLLMENT STATUS

Screened:	29
Consented:	22
Pre Randomization Failure:	7
Randomized:	20
Completed:	17
Ongoing:	3
Withdrawn:	0

Recruitment Plan Notes:

The site has achieved the target enrollment of 20 subjects ahead of schedule. Recruitment is now closed for this site.

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 the ICF signed prior to any study-specific procedures?	Yes	
3	Did the subject/LAR personally sign and date the ICF?	Yes	
4	Is the process of obtaining consent adequately documented in source?	Yes	

Site Staff/Facilities

5	Is the Principal Investigator available for supervision?	Yes	
6	Are Sub-Investigators qualified and trained?	Yes	
7	Is the Study Coordinator adequately trained on the protocol?	Yes	
8	Are pharmacy facilities adequate and secure?	Yes	
9	Are laboratory certifications current and valid?	Yes	
10	Is site equipment properly calibrated and maintained?	Yes	
11	Is the Delegation of Authority Log current and signed?	Yes	
12	Is the Site Training Log complete for all staff?	Yes	
13	Are CVs current for all active study staff?	Yes	

Investigator Site File

14	Is the Investigator Site File (ISF) complete and organized?	Yes	
15	Are all essential documents current and filed?	Yes	
16	Is the Site Monitoring Log signed by site staff and CRA?	Yes	
17	Have action items from the prior visit been resolved?	Yes	

Research Ethics Board

18	Is the 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 as required?	Yes	
21	Is the annual renewal/continuing review current?	Yes	
22	Has the site-specific consent form been approved?	Yes	
23	Is SAE reporting to the IRB/EC compliant with local requirements?	Yes	

Safety

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

Compliance

32	Is overall 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 current and accurate?	Yes	
37	Is IP dispensing performed correctly per protocol?	Yes	
38	Are IP returns documented correctly?	Yes	
39	Is temperature monitoring compliant with no excursions?	Yes	

Study Supplies/Vendors

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40	Are lab kits and study supplies adequate?	Yes	
Source Document Verification			
41	Are source documents available for all subjects?	Yes	
42	Was SDV completed according to 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 appropriately?	Yes	

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
SUBJ-001	Visit 1 - Visit 4	All source data verified, no discrepanci	
SUBJ-002	Visit 1 - Visit 4	All source data verified, no discrepanci	
SUBJ-003	Visit 1 - Visit 3	All source data verified, no discrepanci	
SUBJ-004	Visit 1 - Visit 3	All source data verified, no discrepanci	
SUBJ-005	Visit 1 - Visit 2	All source data verified, no discrepanci	

CRA ASSESSMENT

Site continues to demonstrate excellent compliance with protocol requirements. No corrective actions needed at this time.