EudraCT Results Form

Trial Information

A. Trial Identification

Full title of the trial

A Phase 2, Randomized, Open-label Platform Trial Utilizing a Master Protocol to Study Novel Regimens Versus Standard of Care Treatment in NSCLC Participants

EudraCT Number	2018-001316-29
Sponsor Protocol Code	205801
ISRCTN Number	
ClinicalTrials.gov identifier (NCT Number)	NCT03739710
WHO Universal Trial Reference Number (UTRN)	

Other trial identifiers

Other identifier name	Other identifier code

B. Paediatric Regulatory Details

Is the trial part of an agreed Paediatric Investigation Plan (PIP)?	No
Paediatric Investigation Plan(s)	EMA Decision number of Paediatric Investigation Plan(s)
Enter the EMA paediatric Investigation plan	

number(s) (PIP) using the following format: EMEA-999999-PIP99-99, where 9 is a number (0-9 inclusive).

Does Article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does Article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

C. Sponsor Details

Name	Scientific Contact	Public Contact
Organisation name: GlaxoSmithKline	**Functional contact name:** GSK Response Center	**Functional contact name:** GSK Response Center
Street Address: 79 New Oxford Street	**Organisation name:** GlaxoSmithKline	**Organisation name:** GlaxoSmithKline
Town/City: London	**Country code:** 1	**Country code:** 1
Country: United Kingdom	**Phone Number:** 8664357343	**Phone Number:** 8664357343
Post code: WC1A 1DG	**Email address:** GSKClinicalSupportHD@gsk.com	**Email address:** GSKClinicalSupportHD@gsk.com

D. Results Analysis Stage

Analysis Stage	Final
Date of interim/Final Analysis	2024-10-24
Is this the analysis of the primary completion data?	No

Primary completion date

Global end of trial date reached?	Yes
Global end of trial date	2024-05-02
Was the trial ended prematurely?	No

E. General Information About Trial

Main objective of Trial	To determine the safety and tolerability of novel regimen(s)

The actual start date of recruitment must be the current date or a date in the past.

Actual Start date of Recruitment	2019-01-24
Long term follow up planned?	No
Long term follow up rationale	
Long term follow up duration	
Independent data monitoring committee (IDMC) involvement?	No
Protection of trial subjects	NA
Background therapy	
Evidence of comparator(s)	

F. Population of Trial Subjects

Subject number per country

Country	Actual number of subjects enrolled
Canada	44
France	38
Germany	16
Italy	33
Korea, Republic of	10
Netherlands	6
Poland	9
Romania	15
Russian Federation	8
Spain	40
Sweden	4
United States	33
Total: worldwide	256
Total: EEA	161

Age group breakdown for Trial

Age Range	Actual number of subjects enrolled
In Utero	0
Pre-term newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Age Range	Actual number of subjects enrolled
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	127
From 65 years	
Elderly (From 65-84 years)	128
Elderly 85 years and over	1
Total	256

Subject Disposition

Subject Disposition

Recruitment Details

Pre-Assignment

Screening Details

This master record includes data of screened participants for its sub-studies, 205801-001 (NCT05553808), 205801-002 (NCT06790303) and 205801-003 (NCT06926673) and only contains data during screening phase (Day -28 to Day 0). Results are presented separately for each sub study.

Pre-Assignment Period

Periods

Overall Study
(overall period)

Blinding Implementation Details:

Is this the baseline period? true

Mutually exclusive arms? true

Non-Mutual Exclusive Number of Subjects:

Allocation: Not Applicable

Blinding Used: Not-blind

Roles Blinded:

Started

All Screened Participants (No intervention) Participants with Non-Small Cell Lung Cancer (NSCLC) were screened to be enrolled in sub-studies of this master protocol.	Total *(=sum per row)*
256	256 *(calculated)*

Completed

All Screened Participants (No intervention) Participants with Non-Small Cell Lung Cancer (NSCLC) were screened to be enrolled in sub-studies of this master protocol.	Total *(=sum per row)*
175	175 *(calculated)*

Reasons Not Completed

Other Reason: Screen Failed

All Screened Participants (No intervention) Participants with Non-Small Cell Lung Cancer (NSCLC) were screened to be enrolled in sub-studies of this master protocol.	Total *(=sum per row)*
81	81 *(calculated)*

Reasons Joined

Products

Arm	Product Name	Product Code	Product Other Name	Dosage and Administration Details	Pharmaceutical Forms	Routes of Administration

Baseline Characteristics

Baseline Characteristics Information

The baseline Period is : Overall Study

How are baseline characteristics being reported?

Per Arm in the baseline period

Subject Analysis Sets

Reporting Groups

Reporting Group Title	Number of subjects	Description	Options
All Screened Participants	256	Participants with Non-Small Cell Lung Cancer (NSCLC) were screened to be enrolled in sub-studies of this master protocol.	

Age Characteristics

Title: Age Categorical

Description:

Unit: Participants

Reporting Group Values	All Screened Participants	Total
Overall number of baseline subjects	256	256 (calculated)
18-64 years	127	127
Over 64 years	129	129
Total	256 (calculated)	256 (calculated)

Title: Age continuous

Description:

Unit:

Central Tendency Type:

Dispersion Type:

Reporting Group Values	All Screened Participants	
Unit of measure ()		Low () High ()

Gender Characteristics

Title: Sex: Female, Male

Description:

Unit: Participants

Reporting Group Values	All Screened Participants	Total
Overall number of baseline subjects	256	256
Female	86	86
Male	170	170

Study Categorical Characteristics

Title: Race/Ethnicity, Customized

Description: Race categories ('Asian', 'Black or African American' and 'Native Hawaiian or Other Pacific Islander' where 0<n<11) are combined into 'All other races' category to maintain participant confidentiality and privacy.

Unit: Participants

Reporting Group Values	All Screened Participants	Total

Overall number of baseline subjects	256	256 (calculated)
White	216	216
Unknown or Not Reported	12	12
All other races	28	28

Study Continuous Characteristics

End Points

Reporting Groups

Periods	Arms
Overall Study (overall period)	All Screened Participants

End Points

Primary: Number of Participants Randomized Across Sub-studies

Countable or measurable? Countable

Description: Number of Participants randomized across sub studies are presented.

Time Frame: Day 1

Units: Participants

Percentage:

Arm Reporting Groups	
	Overall Study **All Screened Participants**
Number of subjects that started the Arm:	256
Number of Subjects Analyzed:	175
Comment: (The comment is mandatory when the number of subjects analysed is zero)	
	Countable
Sub Study 1	105
Sub Study 2	8
Sub Study 3	62

Adverse Events

Adverse Events

Adverse Events Information

Timeframe for adverse event reporting Screening (-28 to 0 days)

Adverse events reporting additional description

Adverse event(s) of special interest [AESIs] and Serious Adverse Event(s) [SAEs] assessed as related to study participation, were not reported during the screening phase

Assessment Type Systematic

Frequency threshold for reporting non-serious adverse events:	0
Dictionary name	Other
Dictionary name - if other	NA
Dictionary version	NA

Adverse Events Reporting Groups

Reporting Group Totals	**All Screened Participants** Participants with Non-Small Cell Lung Cancer (NSCLC) were screened to be enrolled in sub-studies of this master protocol.
Total # Subjects Exposed	256
Total # Subjects Affected by Serious Adverse Events	0
Total # Subjects Affected by Non Serious Adverse Events	0
Total # of Deaths (all causes)	0
Total # of Deaths Resulting From Adverse Events	

Serious Adverse Events

Reporting Groups	**All Screened Participants**

Non Serious Adverse Events

Threshold for non-serious adverse event reporting is: 0%

Reporting Groups	**All Screened Participants**

More Information

More Information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Amendment Date	Description
20-Sep-2018	Protocol was amended at the request of the regulatory authority to provide additional clarification and guidance on specific aspects of the protocol
15-Jul-2019	Protocol was amended based on regulatory and ethics committee feedback to provide additional clarification and guidance on specific aspects of the protocol
29-Oct-2020	The protocol has been amended to introduce three new sub-studies into Section 12.1.3, Section 12.1.4, and Section 12.1.5 of the protocol.
02-Feb-2021	The protocol has been amended to clarify substudies included in previous amendment and to align with updates to study strategy
02-Sep-2021	The protocol has been amended to introduce a new arm under Section 12.1 (subsection 12.1.4). In addition, changes were made in line with study design
19-Nov-2021	The protocol has been amended to introduce a new arm under Section 12.1 (subSection 12.1.5). In addition, changes were made in line with study design
08-Mar-2022	The protocol has been amended to include additional safety assessments for cardiac monitoring in the Schedule of Activities under Section 12.1 (subsection 12.1.4 and 12.1.5).
23-May-2022	The protocol has been amended to include additional safety assessments for cardiac monitoring in the Schedule of Activities under Section 12.1 (sub Section 12.1.4 and Section 12.1.5).
30-Mar-2023	Amendment 09 provides additional cardiac risk mitigation measures, including updated requirements for mandatory cardiology or locally appropriate specialist consultation in the event of specified cardiac indicators.
26-Apr-2023	Amendment 10 provides updated eligibility requirements with regards to toxicity from previous immunotherapy treatment.

Interruptions (globally)

For any interruption, the restart date must not be before the interruption date.

Were there any global interruptions to the trial? No

Interruption Date	Description	Restart Date

Limitations and caveats

Limitations and caveats applicable to this summary of the results

Online References

Provide identifiers to retrieve publications of interest in regards to the results of this clinical trial.

Enter PubMed Identifier (PMID)