Official Title of Study:

A Phase 3, Randomized, Blinded, Placebo-Controlled Study of Tislelizumab (Bgb-A317) Plus Chemoradiotherapy Followed by Tislelizumab Monotherapy in Newly Diagnosed, Stage III Subjects with Locally Advanced, Unresectable Non-Small Cell Lung Cancer

EudraCT Number: 2018-001132-22

Final Results Disclosure

Results Registration Form
NCT03745222

Point of Contact

Name or Official Title:	Bristol-Myers Squibb Study Director
Organization Name:	Bristol-Myers Squibb
Phone:	Please email
Email:	Clinical.Trials@bms.com

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.
Results from a center cannot be submitted for publication before results of multicenter study are published unless it is > 1 year since study completion. Then, Investigator can publish if manuscript is submitted to Celgene 60 days prior to submission. If Celgene decides publication would hinder drug development, Investigator must delay submission for up to 90 additional days. Investigator must delete confidential information before submission and defer publication to permit patent applications.

Participant Flow

Recruitment Details	One participant was enrolled in the United States before the study was terminated.
Pre-assignment Details	

Type of Units Assigned:

Period: Overall Study

	Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Total** *(=sum per row)*
Started	Participants 0	Participants 1	Participants 0	1 *(calculated)*

Completed	Participants 0	Participants 0	Participants 0	0 *(calculated)*
Not Completed: *(=Started - Completed)*	0 *(calculated)*	1 *(calculated)*	0 *(calculated)*	1 *(calculated)*
Reason for Not Completed				
Total: *(=sum per column)*	0 *(calculated)*	1 *(calculated)*	0 *(calculated)*	1 *(calculated)*
Withdrawal by Subject	0	1	0	1 *(calculated)*

Baseline Characteristics

Overall Number of Baseline Participants				
	Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Total(=sum across Arm/Groups)**
Overall Number of Baseline Participants	0	1	0	1 *(calculated)*
Overall Number Of Units Analyzed **Type Of Units Analyzed**:				Unknown *(calculated)*
Baseline Analysis Population Description	Intent to Treat Population included all randomized participants regardless of whether the participant received any study drug or had any efficacy assessments performed.			
NOTE: A Study Specific Baseline Measure for an Outcome Measure has not been entered.				

Baseline measure title = "Age Categorical"

Age Categorical

Units: Participants

Parameter type: Count of Participants

Dispersion type: Not Applicable

Row	Category	**Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching	**Total** *(=sum per row)*

		tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	
	Number Analyzed:	0 Participants	1 Participants	0 Participants	1 *(calculated)* Participants
	<=18 years		0		Unknown *(calculated)*
	Between 18 and 65 years		1		Unknown *(calculated)*
	>=65 years		0		Unknown *(calculated)*

Baseline measure title = "Sex: Female, Male"

Sex: Female, Male
Units: Participants
Parameter type: Count of Participants
Dispersion type: Not Applicable

Row	Category	**Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Total** *(=sum per row)*
	Number Analyzed:	0 Participants	1 Participants	0 Participants	1 *(calculated)* Participants
	Female	0	1	0	1 *(calculated)*
	Male	0	0	0	0 *(calculated)*

Baseline measure title = "Ethnicity (NIH/OMB)"

Ethnicity (NIH/OMB)

Units: Participants

Parameter type: Count of Participants

Dispersion type: Not Applicable

Row	Category	**Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Total** *(=sum per row)*
	Number Analyzed:	0 Participants	1 Participants	0 Participants	1 *(calculated)* Participants
	Hispanic or Latino	0	0	0	0 *(calculated)*
	Not Hispanic or Latino	0	1	0	1 *(calculated)*
	Unknown or Not Reported	0	0	0	0 *(calculated)*

Baseline measure title = "Race/Ethnicity, Customized"

Race/Ethnicity, Customized

Units: Participants

Parameter type: Count of Participants

HINT: Number is the preferred Measure Type for Race/Ethnicity, Customized

Dispersion type: Not Applicable

Row	Category	**Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Total** *(=sum per row)*

		discontinuation for another reason.			
	Number Analyzed:	0 Participants	1 Participants	0 Participants	1 *(calculated)* Participants
	Caucasian	0	1	0	1 *(calculated)*
HINT: Number is the preferred Measure Type for Race/Ethnicity, Customized					

Outcome Measures

ALERT: Outcome measures from protocol are not used when records include results.

1. Primary: Progression-Free Survival (PFS)

Reporting Status:

Description: Progression-free survival was defined as the time from the date of randomization to the date of the first objectively tumor progression as assessed by the blinded independent central review per Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1 criteria (documented by radiological assessment) or death (any cause) on or prior to the clinical cut-off date, which ever occurred first. Stable disease-neither sufficient shrinkage to qualify for PR nor sufficient increase of lesions to qualify for Progressive disease (PD)• Progressive Disease- At least a 20% increase in the sum of diameters of target lesions from nadir.

Time Frame: Up to approximately 5 years; date of randomization to the date of tumor progression or death; until study withdrawal date of 26 June 2019

Safety Issue:

Measure Type:

Method of Dispersion:

Unit of Measure:

Type of Units Analyzed:

Analysis Population Description: The study was terminated. The number of participants and the data collection period were not sufficient for statistical analysis. The patient withdrew consent.

		Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.
	Number of Participants Analyzed:	0	0	0

Progression-Free Survival (PFS) Units:	Category						
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	0 Participants		0 Participants		0 Participants	

2. Secondary: Overall Survival (OS)

Reporting Status:

Description: Overall survival was defined as the time between randomization of treatment and death from any cause.

Time Frame: Up to approximately 5 years; date of randomization to date of death from any cause.

Safety Issue:

Measure Type:

Method of Dispersion:

Unit of Measure:

Type of Units Analyzed:

Analysis Population Description: The study was terminated. The number of participants and the data collection period were not sufficient for statistical analysis. The patient withdrew consent.

		Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.		**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.		**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	
	Number of Participants Analyzed:	0		0		0	
Overall Survival (OS) Units:	Category						
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS	0 Participants		0 Participants		0 Participants	

	when single Measure Row.			

3. Secondary: Overall Survival at 24 months

Reporting Status:

Description: Overall survival was defined as the time between randomization of treatment and death from any cause.

Time Frame: Up to approximately 24 months

Safety Issue:

Measure Type:

Method of Dispersion:

Unit of Measure:

Type of Units Analyzed:

Analysis Population Description: The study was terminated. The number of participants and the data collection period were not sufficient for statistical analysis. The patient withdrew consent.

		Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.
	Number of Participants Analyzed:	0	0	0
Overall Survival at 24 months Units:	Category			
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	0 Participants	0 Participants	0 Participants

4. Secondary: Percentage of Participants Who Achieved a Best Overall Response of Complete Response or Partial Response

Reporting Status:

Description: Overall Response was defined as percentage of participants who had a radiologic confirmed complete response (CR) or partial response (PR) according to Response Evaluation Criteria in Solid Tumors (RECIST 1.1) guidelines, between Day 1 of treatment and subsequent anti-cancer therapy, death or study discontinuation. Complete response was defined as the disappearance of all target lesions; partial response (PR) is defined as at least a 30% decrease in the sum of diameters of target lesions from baseline; stable disease-neither sufficient shrinkage to qualify for PR nor sufficient increase of lesions to qualify for progressive disease (PD).

Time Frame: Up to approximately 5 years

Safety Issue:

Measure Type:

Method of Dispersion:

Unit of Measure:

Type of Units Analyzed:

Analysis Population Description: The study was terminated. The number of participants and the data collection period were not sufficient for statistical analysis. The patient withdrew consent.

		Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.
	Number of Participants Analyzed:	0	0	0
Percentage of Participants Who Achieved a Best Overall Response of Complete Response or Partial Response Units:	Category			
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	0 Participants	0 Participants	0 Participants

5. Secondary: Duration of Response

Reporting Status:

Description: Duration of Response is defined as the time from the first occurrence of a documented objective response to the time of relapse, as determined by blinded independent central review per RECIST v1.1, or death from any cause, whichever comes first.

Time Frame: Up to approximately 5 years

Safety Issue:

Measure Type:

Method of Dispersion:

Unit of Measure:

Type of Units Analyzed:

Analysis Population Description: The study was terminated. The number of participants and the data collection period were not sufficient for statistical analysis. The patient withdrew consent.

		Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.
	Number of Participants Analyzed:	0	0	0
Duration of Response Units:	Category			
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	0 Participants	0 Participants	0 Participants

6. Secondary: Percentage of Participants Alive and Progression-Free at 12 months (APF12)

Reporting Status:

Description: Progression-free survival was defined as the time from the date of randomization to the date of the first objectively tumor progression as assessed by the blinded independent central review per Response

Evaluation Criteria in Solid Tumors (RECIST) Version 1.1 criteria (documented by radiological assessment) or death (any cause) on or prior to the clinical cut-off date, which ever occurred first

Time Frame: Up to 12 months

Safety Issue:

Measure Type:

Method of Dispersion:

Unit of Measure:

Type of Units Analyzed:

Analysis Population Description: The study was terminated. The number of participants and the data collection period were not sufficient for statistical analysis. The patient withdrew consent.

		Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.
	Number of Participants Analyzed:	0	0	0
Percentage of Participants Alive and Progression-Free at 12 months (APF12) Units:	Category			
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	0 Participants	0 Participants	0 Participants

7. Secondary: Percentage of Participants Alive and Progression-free at 18 months (APF18)

Reporting Status:

Description: Progression-free survival was defined as the time from the date of randomization to the date of the first objectively tumor progression as assessed by the blinded independent central review per Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1 criteria (documented by radiological assessment) or death (any cause) on or prior to the clinical cut-off date, which ever occurred first

Time Frame: Up to approximately 18 months

Safety Issue:

Measure Type:

Method of Dispersion:

Unit of Measure:

Type of Units Analyzed:

Analysis Population Description: The study was terminated. The number of participants and the data collection period were not sufficient for statistical analysis. The patient withdrew consent.

		Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.
	Number of Participants Analyzed:	0	0	0
Percentage of Participants Alive and Progression-free at 18 months (APF18) Units:	Category			
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	0 Participants	0 Participants	0 Participants

8. Secondary: Time to Distant Metastasis (TTDM)

Reporting Status:

Description: TTDM was defined as the time from the date of randomization until the first date of distant metastasis or death in the absence of distant metastasis. Distant metastasis was defined as any new lesion that is

outside of the radiation field according to RECIST v1.1 or proven by biopsy.

Time Frame: Up to approximately 5 years

Safety Issue:

Measure Type:

Method of Dispersion:

Unit of Measure:

Type of Units Analyzed:

Analysis Population Description: The study was terminated. The number of participants and the data collection period were not sufficient for statistical analysis. The patient withdrew consent.

		Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.
	Number of Participants Analyzed:	0	0	0
Time to Distant Metastasis (TTDM) Units:	Category			
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	0 Participants	0 Participants	0 Participants

9. Secondary: Number of Participants with Treatment Emergent Adverse Events (TEAEs)

Reporting Status:

Description: TEAEs include any adverse events (AEs) that had an onset date or a worsening in severity from baseline on or after the first dose of study drug up to 30 days following study drug discontinuation or initiation of new anticancer therapy, whichever occurred first. TEAEs also included all immune-related AEs recorded up to 90 days after the last dose of tislelizumab or placebo, regardless of whether or not the particpant started a new anticancer therapy. In addition, any serious AE with an onset date more than 30 days after the last dose of study drug that is assessed by the investigator as related to study drug were considered a TEAE."

Time Frame: From first dose of study drug up to study withdrawal date of 26 June 2019; 15 days.

Safety Issue:

Measure Type: Number

Method of Dispersion: Not Applicable

Unit of Measure: Participants

Type of Units Analyzed:

Analysis Population Description: Safety population includes participants who received at least 1 dose of study drug.

		Tislelizumab + Concurrent Chemoradiotherapy -Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy -Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.
	Number of Participants Analyzed:	0	1	0
Number of Participants with Treatment Emergent Adverse Events (TEAEs) Units: Participants	Category	Number	Number	Number
≥ 1 TEAE	Number Analyzed:	0 Participants	1 Participants	0 Participants
			1	
≥ 1 Treatment Related TEAE	Number Analyzed:	0 Participants	1 Participants	0 Participants
			1	

10. Secondary: Number of Participants with Lung Cancer Symptoms Assessed by the Corresponding Domains of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30 (EORTC-QLQ-C30) and Lung-Cancer Specific QLQ-LC13

Reporting Status:

Description: The EORTC QLQ-C30 is a 30-item, questionnaire assessing quality of life (QoL), psychosocial burden and physical symptoms. It is classified into 15 domains: 5 functional subscales (physical functioning, role functioning, emotional functioning, cognitive functioning, and social functioning); 3 multi-item symptom subscales (fatigue, nausea/vomiting, and pain); each item is measured on a 4 point response scale; (not at all, a little, quite a bit, very much), with the exception of the 2 items measuring global health and QoL, (measured on a 7-point response scale). Scores are linearly transformed to 0 to 100 scores. Scores vary from 0 (worst) to 100 (best) for the functional dimensions and GHS, and from 0 (best) to 100 (worst) for the symptom dimensions; higher scores = better QoL, better functioning, or more severe symptoms, respectively. The LC13 covers 13 typical symptoms of lung cancer patients, such as coughing, pain, dyspnea, sore mouth, peripheral neuropathy, and hair loss.

Time Frame: Up to approximately 5 years

Safety Issue:

Measure Type:

Method of Dispersion:

Unit of Measure:

Type of Units Analyzed:

Analysis Population Description: The study was terminated. The number of participants and the data collection period were not sufficient for statistical analysis. The patient withdrew consent.

		Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.
	Number of Participants Analyzed:	0	0	0
Number of Participants with Lung Cancer Symptoms Assessed by the Corresponding Domains of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30 (EORTC-QLQ-C30) and Lung-Cancer Specific QLQ-LC13 Units:	Category			
	Number Analyzed:	0 Participants	0 Participants	0 Participants

	NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.			

11. Secondary: Percentage of Participants who Would have Continued on to Monotherapy Phase

Reporting Status:

Description: Included the percentage of participants who would have received at least one dose of tislelizumab or placebo in the monotherapy phase before progression.

Time Frame: Up to approximately 5 years

Safety Issue:

Measure Type:

Method of Dispersion:

Unit of Measure:

Type of Units Analyzed:

Analysis Population Description: The study was terminated. The number of participants and the data collection period were not sufficient for statistical analysis. The patient withdrew consent.

		Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.		**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.		**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	
	Number of Participants Analyzed:	0		0		0	
Percentage of Participants who Would have Continued on to Monotherapy Phase Units:	Category						

	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	0 Participants	0 Participants	0 Participants

Limitations and Caveats

Description	

Adverse Events

Time Frame	From first dose of study drug up to study withdrawal date of 26 June 2019; 15 days.
Adverse Event Reporting Description	No serious adverse events or deaths occurred during the course of the study,
Source Vocabulary for Table Default	MedDRA 21.0
Collection Approach for Table Default	Systematic Assessment

All-Cause Mortality

	Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.
Total Number Affected	0	0	0
Total Number At Risk	0	1	0

Serious Adverse Events

	Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision,

	disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	withdrawal of consent or treatment discontinuation for another reason.
Total # Affected by any Serious Adverse Event	0	0	0
Total # at Risk by any Serious Adverse Event	0	1	0

†	Events were collected by systematic assessment
1	Term from vocabulary, MedDRA 21.0

Other Adverse Events

Frequency Threshold for reporting Other Adverse Events: 5

	Tislelizumab + Concurrent Chemoradiotherapy - Tislelizumab Participants were to receive 2 cycles of tislelizumab 200 mg by intravenous (IV) infusion every 3 weeks (Q3W) with concurrent chemoradiotherapy (cCRT), followed by monotherapy with tislelizumab 200 mg IV Q3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Tislelizumab** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with tislelizumab 200 mg IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.	**Placebo + Concurrent Chemoradiotherapy - Placebo** Participants were to receive 2 cycles of identically matching placebo by IV infusion Q 3 weeks with cCRT, followed by monotherapy with placebo IV Q 3W until disease progression, death, unacceptable toxicity, subject or physician decision, withdrawal of consent or treatment discontinuation for another reason.
Total # Affected by any Other Adverse Event	0	1	0
Total # at Risk by any Other Adverse Event	0	1	0

	Injury, poisoning and procedural complications		
Infusion Related Reaction[1, †]			
Number of participants affected	0	1	0
Number of events			
Number of participants at risk [blank=Total]	0	1	0

	Musculoskeletal and connective tissue disorders		
MUSCLE CRAMPING[1, †]			
Number of participants affected	0	1	0
Number of events			
Number of participants at risk [blank=Total]	0	1	0
NECK PAIN[1, †]			

Number of participants affected	0	1	0
Number of events			
Number of participants at risk [blank=Total]	0	1	0

	Respiratory, thoracic and mediastinal disorders		
Cough [1, †]			
Number of participants affected	0	1	0
Number of events			
Number of participants at risk [blank=Total]	0	1	0

†	Events were collected by systematic assessment
1	Term from vocabulary, *MedDRA 21.0*