Spanish Real World Data on unresectable stage III NSCLC patients treated with durvalumab after chemoradiotherapy (S-REAL Study)

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Contact details

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EU PAS number
EUPAS38961

Study ID
38962

DARWIN EU® study
No
Study countries
Spain

Study description
Lung Cancer represent approximately 13% of total cancer diagnoses worldwide. Stage III represents between 25-30% of NSCLC and the majority of them are unresectable. The SOC in unresectable patients was chemoradiotherapy concurrently if possible. The PACIFIC study is a phase III study to evaluate the efficacy and safety of durvalumab as a sequential therapy concurrent platinum-based chemo and thoracic RT. The study was positive for both primary endpoints PFS and OS. After that, it was decided to open an early access program to provide access to durvalumab for patients with locally advanced, unresectable NSCLC (stage III) who have not progressed following chemoradiation. S-Real study is a non-interventional, observational, multicentre, one-arm, non-comparative, and retrospective study. This observational study is based on the collection of data about the patients treated with Durvalumab after chemoradiotherapy in the real world. The study will include all patients who have participated in the Pacific study between 1 September 2017 up to 21 December 2018 and have received at least 1 dose of durvalumab. The primary objective is to assess affectiveness of durvalumab in patients treated in real-life settings by evaluating Progression Free Survival. Secondary objectives are: To assess effectiveness of durvalumab in patients treated in real-life settings by evaluating 1-year survival rate, to describe adverse events of special interests, to stimate time and sites of disease progression or relapse in metastatic setting, to describe details on durvalumab treatment, to describe demographic and clinical characteristics of stage III unresectable NSCLC patients treated with Durvalumab, to describe previous chemoradiotherapy strategy, to describe the baseline staging status, to further assess subsequent treatments pattern at the time of disease progression including duration and type of therapy, and to explore healthcare resource utilization while on durvalumab treatment.

Study status
Ongoing

Research institution and networks

Institutions

Fundación Grupo Español de Cáncer de Pulmón (GECP)
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Study timelines
Date when funding contract was signed
Actual:
14/02/2020

Data collection
Actual:
25/05/2020

Start date of data analysis
Actual:
31/12/2020

Date of final study report
Planned:
31/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Other study registration identification numbers and links

GEC-DUR-2020-01

Methodological aspects

Study type list
Study type:
Non-interventional study

Scope of the study:
Effectiveness study (incl. comparative)

Main study objective:
Primary Objective of S-REAL study: To assess effectiveness of durvalumab in patients treated in real-life settings by evaluating PFS defined as time from the index date (date of the first dose of durvalumab received within the EAP) to the date of investigator-determined disease progression or death (if no progression) or the end of follow-up.

Study Design

Non-interventional study design
Other

Non-interventional study design, other
Non-PAS, non-interventional, observational, multicentre, one-arm, non-comparative, retrospective study.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
200000003483
durvalumab

Medical condition to be studied
100000015838
Non-small cell lung cancer stage III

Population studied

Age groups
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)
Study design details

Data analysis plan
PFS is calculated from the index date (date of the first dose of durvalumab received within the EAP) to the date of investigator-determined disease progression or death (if no progression) or the end of follow-up for censored patients. PFS S will be estimated and plotted using the Kaplan-Meier method. The median and associated 95% confidence interval will be estimated. The percentage of patients remaining event free at specific timepoints will be displayed: PFS at 12, 18 months. Clinical characteristics, previous and subsequent treatment patterns will be displayed descriptively. Patients with unknown progression status at the time of data collection will be censored at the date they were last known not to have radiologically and/or clinically progressed. Patients will be followed from the index date (date of the first dose of durvalumab received within the EAP) to the end of follow-up (date of death for patient, withdrawal from study drug, loss to follow-up, or end of study period).

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
The sample of patients identified for the current study will be based on a portion of patients enrolled into the durvalumab PACIFIC study and no hypothesis and power analysis will be conducted. The study will include all patients who have participated in the PACIFIC study between 1 September 2017 up to 21 December 2018 and have received at least 1 dose of durvalumab

Use of a Common Data Model (CDM)

CDM mapping
No

Data quality specifications
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**Data characterisation**

Data characterisation conducted
- No