INTRODUCTION

Nintedanib is an oral, triple angiokinase inhibitor of vascular endothelial growth factor receptors 1–3, as well as the oncogenic kinases FLT-3 and RET, which have been shown to display significant progression-free survival (PFS) benefit compared with placebo + docetaxel in patients with non-small-cell lung cancer (NSCLC) that had progressed on one previous line of chemotherapy.* Significant overall survival (OS) benefit was demonstrated in patients with tumours of adenocarcinoma histology.

These data have led to the approval of nintedanib in 31 countries worldwide for use with docetaxel in locally advanced adenocarcinoma or metastatic disease.

Since the approval of nintedanib, options for treatment of advanced NSCLC have increased with the introduction of immunotherapy. The addition of nintedanib to first-line pembrolizumab, by blocking immunity checkpoint proteins,** tumour-infiltrating lymphocytes and anti-angiogenic drugs have been approved for use in combination with immunotherapy** in advanced NSCLC.

Correspondingly, limited data are available regarding the effectiveness and safety of nintedanib + docetaxel after immunotherapy treatment. In the non-interventional VARGADO study, in which a similar response rate in third-line treatment of NSCLC was observed in a very similar patient population in the non-interventional VARGADO study, in which a similar DCR was attained.

METHODS

Nintedanib + docetaxel after immunotherapy in adenocarcinoma non-small cell lung cancer: first results from the non-interventional LUME-BioNIS study

INTRODUCTION

• Tumour biomarker status
• Demographics, medical history
• Line of prior immunotherapy, n (%)
• Location of metastatic sites at baseline, n (%)
• Stage IV disease at diagnosis, n (%)

RESULTS

Patient population

• 65 patients were enrolled between March 2019 and October 2019; 67 (20.5%) had previously received immunotherapy as well as chemotherapy and were included in the subgroup analysis

Baseline characteristics indicated a group with a relatively poor prognosis (Table 1)

The majority of patients (n=47; 72.3%) received nintedanib + docetaxel as second- or third-line treatment, with only 10 patients (14.6%) receiving this combination in the second line

Median duration of treatment with nintedanib was 2.6 months (range: 0.2–25.5)

A total of 22 patients (33.8%) received subsequent anticancer therapy, which included further chemotherapy in 21 patients (31.3%) and immunotherapy in two patients (3.1%)

Median OS was 8.8 months (95% CI: 7.0–11.5) (Figure 2)

At the time of the OS analysis, 54 patients (80.6%) had died

Median PFS was 4.6 months (95% CI: 3.5–5.7) (Figure 3)

At the time of the PFS analysis, 59 patients (88.1%) had progressed or died

Table 3. AEs/ADRs reported in ≥10% of patients during the on-treatment period in patients with prior immunotherapy (n=65)

CONCLUSIONS

• Used according to the approved nintedanib label in routine practice, nintedanib + docetaxel showed clinical effectiveness in patients with adenocarcinoma NSCLC previously treated with chemotherapy and one- or two-line immunotherapy.

The median PFS of 4.6 months, median OS of 8.8 months and ORR of 72.3% in the LUME-BioNIS study are consistent with the results of other non-interventional studies in the same disease setting.

These data provide independent confirmation of the safety profile of nintedanib + docetaxel compared favourably with reports from prior real-world observational studies in the same disease setting.

Safety

• Febrile neutropenia was the most frequently reported AE (9/67, 13.4%), which was reported as grade 3/4 in 0/67 (0.0%) patients.

• The most common Grade 3/4 AEs were diarrhoea (38/67, 56.7%), nausea (31/67, 46.3%), constipation (23/67, 34.3%) and vomiting (17/67, 25.4%) (Table 4).

• Among 65 patients with available adverse event data, the median duration of treatment with nintedanib + docetaxel was 2.6 months (range: 0.2–25.5) (Table 2).

Study design

• LUME-BioNIS (NCT03711942) is a prospective, European, multi-centre, non-interventional study of patients with adenocarcinoma NSCLC who initiated nintedanib + docetaxel in routine practice according to the approved Vargatef® (nintedanib) EU label (Figure 1).

• The worst intensity of AEs/ADRs was mild in four patients (6.2%), moderate in 13 patients (19.7%), and severe in 48 patients (73.1%).

• The majority of patients (n=57; 85.1%) received nintedanib + docetaxel as third- or fourth-line treatment.

• Among 55 patients with available tumour response data, best response was partial response in 10 patients (18.2%) and stable disease in 33 patients (60.0%), with 2 patients (3.6%) experiencing disease progression and 10 (18.2%) experiencing disease control.

• A total of 25 patients (37.3%) received subsequent anticancer therapy, which included further chemotherapy in 21 patients (31.3%) and immunotherapy in two patients (3.1%).

• There was no apparent relationship between the duration of prior therapy and response to nintedanib + docetaxel (Figure 4).

• Overall survival (OS) and disease progression-free survival (PFS) were assessed in patients with prior immunotherapy (n=65).

• No data were available for all patients due to data collection issues.

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• REFS:


