Observational Study Report Synopsis

Study Code	D133HR00004
Version	1.0
Date	23 September 2020

KINDLE - A multi-centre, observational, retrospective study to reveal the patient characteristics, disease burden, treatment patterns and patient journey of stage III non-small cell lung cancer patients

Study dates:	**First Subject In:** 26th November 2018 **Last Subject Last Visit:** 30th September 2019

Background/Rationale:

Stage III Non-Small Cell Lung Cancer (NSCLC) is a heterogenous condition. Treatment practices vary by country and region, based on local practices and guidelines. KINDLE, a large multinational, non-interventional study (NIS), collected retrospective data from established patient medical records over a period of approximately 6 years (2013 to 2018). A centralized platform was built to capture and consolidate data on Stage III NSCLC treatment patterns, patient overall survival (OS), and treatment efficacy in real-world settings. Existing research on this disease is particularly limited within less affluent healthcare systems. This study offers a more comprehensive understanding of stage III NSCLC, compiling datasets to capture the entire patient journey – including patient demographics, disease characteristics, treatment options, and patient outcomes.

Methods:

This study used a multi-centre, multi-country, longitudinal cohort of patients with primary stage III NSCLC. Participants were identified through the review of established patient medical records. Patients diagnosed with primary stage III NSCLC between 01 January 2013 and 31 December 2017 were targeted for inclusion in the study. The enrolment window was such that living patients who participated in the study received, at minimum, 9 months of follow-up.

Patients were followed from the index date (i.e., date of initial diagnosis of locally advanced stage III NSCLC) until the earliest incidence of one of the following events: death, last available medical record or formal conclusion of the observation period (defined as the date of the data extraction).

Eligible patients (both living and deceased) had their data anonymously extracted from their medical records into a centrally designed electronic case report form (eCRF). Where a waiver of consent was not possible, patients (or next of kin/legal representative) were asked to provide informed consent prior to the data extraction. Statistical analysis was used to (1) describe patient demographics, disease characteristics and treatment patterns; and (2) understand their correlation with progression-free survival (PFS) and overall survival (OS).

Results

3151 patients were enrolled at 125 centres in three geographical regions; 1046 pts in Middle East and North Africa, 1874 pts in Asia and 231 pts in Latin America. Median age was 63 years (range 21-92); 76.5% were male; 69.2% with a smoking history; 55.9% were staged as IIIA (AJCC 7th ed.); 53.7% had adenocarcinoma and 36.6% squamous cell, and 31.7% were known to have an EGFR mutation. 21.4% of patients underwent curative surgical resection. First line therapy included more than 25 different regimens, the most common being concurrent chemo-radiotherapy (cCRT) in 29.4%, chemotherapy (CT) alone in 17%, sequential chemo-radiotherapy (sCRT) in 10.4%, and radiotherapy (RT)

alone in 8.5%. Median PFS for the whole cohort was 12.5 mos (95% CI; 12.06 – 13.14) and median OS 34.9 mos (95% CI; 32.00 – 38.01). Stage IIIA patients who were eligible for and underwent surgery + CT, had longer OS than patients who did not undergo surgery, receiving other treatments. Non-surgical approaches included CT, RT, and CRT. In stage IIIB, OS was significantly improved for cCRT vs. CT alone (p = 0.0015) or RT alone (p = < 0.0001) or sCRT (p = 0.0216). Improved survival was observed with sCRT compared with RT alone and chemotherapy vs RT alone.

Conclusion:

KINDLE, a large multi-country observational study, reveals the diversity of treatment practices that exist in stage III NSCLC and provides insights on the outcomes in a real-world setting. The unmet medical need remains high and approaches are required to optimize patient outcomes including implementation of guidelines, physician education and improved access to innovative medicines and quality care.