Real-world (RW) data from the sotorasib French pre-market authorization early access program in patients with KRAS\textsuperscript{G12C} driven metastatic non-small cell lung cancer (mNSCLC): clinical characteristics


Background

The KRAS\textsuperscript{G12C} mutation is an oncogenic driver identified in ~13% of NSCLC. Sotorasib is a first-in-class small molecule that specifically and irreversibly inhibits KRAS\textsuperscript{G12C} activation.

Pooled Phase 1, 2 data from CodeBreaK 100 reported an objective response rate of 40.7%, a 2-year overall survival rate of 32.5% and a well-tolerated safety profile with sotorasib.

Methods

Prior to the EMA approval in January 2022, French Health Authorities considered sotorasib an innovative drug and allowed a nominative Temporary Authorization of Use (nATU) in December 2020 and then approved a cohort ATU (cATU) in June 2021.

Eligible patients were adults with KRAS\textsuperscript{G12C} mutant driven non small cell lung cancer who progressed after at least one prior line of systemic therapy.

Results

From August 2021 to January 2022, data from 679 patients were collected in 197 French centers including 549 patients via cATU and 130 patients previously treated via nATU. 651 were exposed to sotorasib. Patients’ main characteristics are presented in Table 1. Across prior lines and before exposure to sotorasib, patients received Chemotherapy (CT) alone, CT and Immunotherapy (IO), IO alone in 14.6%, 80.8%, 4.6% of cases respectively. In 1\textsuperscript{st} line, 45.4% of patients received CT-IO (among them, 71.4% had sotorasib as a first-line), 35.2% CT, 13.7% IO and 5.4% CT-bevacizumab. In 51% of patients, the immediate prior line of therapy before sotorasib contained IO. The median duration of sotorasib treatment was 7.5 [1.5-11.3] months for patients from nATU (n=121/130) and 3.5 [0.2-5.7] months for new patients in cATU (n=152/549) for a median follow up of 7.7 [1.9-11.3] and 4.0 [0.2-5.7] months respectively.

Conclusions

Broad KRAS\textsuperscript{G12C} testing allowed 651 patients with KRAS\textsuperscript{G12C} driven mNSCLC ineligible to sotorasib clinical trials to be treated. Prior lines treatments received by cATU patients are in accordance with CodeBreaK trial patients.

Further RW data on efficacy and safety are the subject of an ongoing French study NCT05273047.

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