2021 ESMO congress

LBA66

Efficacy and safety of nivolumab for patients with pre-treated type B3 thymoma and thymic carcinoma: Results from the EORTC-ETOP NIVOTHYM phase II trial

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Background

Thymic malignancies are rare intrathoracic tumors which still represent a therapeutic challenge in the advanced/metastatic setting, with limited treatment options after the failure of platinum-based chemotherapy.

Methods

NIVOTHYM is the first international multicenter phase II, 2-cohort, single-arm trial evaluating the use of nivolumab (240 mg IV Q2 weeks) +/- ipilimumab (1mg /kg IV Q6 weeks) in patients (pts) with advanced/relapsed type B3 thymoma or thymic carcinoma, after exposure of platinum-based chemotherapy. Primary endpoint is progression-free survival rate at 6 months (PFSR6, binary) based on RECIST 1.1 per independent radiological review. A two-stage design was used (H1 60%, H0 40%, α 10%, power 90%). We report the final results of the nivolumab monotherapy cohort.

Results

From Apr 2018 to Feb 2020, 55 pts were enrolled in 15 centers/5 countries, including 35 (64%) males, 27 (49%) never-smokers and 53 (96%) PS0-1 pts. Median age was 58 years. Histology was thymoma in 10 (18%) pts and thymic carcinoma in 45 (82%) pts; 16 (29%) pts underwent prior surgical resection. After a median follow-up of 13.3 months, nivolumab had been discontinued in 45 pts, related to progression in 30, toxicity in 9, patient or investigator decision in 4, occurrence of other malignancy in 1, and completion in 1 case. In the safety population of 54 pts, adverse events (AEs) of grade 1/2 were observed in 22 (41%) pts and for grade 3/4 AEs in 31 (57%) pts; grade 5 toxicity was reported in 1 patient (respiratory failure). Grade ≥3 immune-related AEs included 2 myocarditis, 4 hepatitis/elevated transaminases, 2 colitis and 1 pneumonitis. Among the 49 eligible pts who started treatment, PFSR6 by central review was 35% (95%CI 22-50) and 39% by local assessment (95%CI 25-54). ORR and DCR were 12% (95%CI 5-25) and 63% (95%CI 48-77), respectively. Using the Kaplan-Meier method, median PFS (local) and OS were 6.0 (95% CI 3.1-10.4) and 21.3 (95% CI 11.6-NE) months, respectively.

Conclusions

Nivolumab monotherapy is demonstrating a manageable safety profile and objective activity, however insufficient to meet the trial primary objective. The second cohort is currently ongoing to assess combination of nivolumab plus ipilimumab.

Clinical trial identification

NCT03134118.

Legal entity responsible for the study

EORTC.

Funding

BMS.

Disclosure

N. Girard: Financial Interests, Personal, Invited Speaker: AstraZeneca; Financial Interests, Personal, Invited Speaker: BMS; Financial Interests, Personal, Invited Speaker: MSD; Financial Interests, Personal, Invited Speaker: Roche; Financial Interests, Personal, Invited Speaker: Pfizer; Financial Interests, Personal, Invited Speaker: Boehringer; Financial Interests, Personal, Invited Speaker: Amgen; Financial Interests, Personal, Advisory Board: AstraZeneca; Financial Interests, Personal, Advisory Board: BMS; Financial Interests, Personal, Advisory Board: MSD; Financial Interests, Personal, Advisory Board: Roche; Financial Interests, Personal, Advisory Board: Pfizer; Financial Interests, Institutional, Advisory Board: Sivan; Financial Interests, Personal, Advisory Board: Janssen; Financial Interests, Personal, Advisory Board: Boehringer; Financial Interests, Personal, Advisory Board: Novartis; Financial Interests, Personal, Advisory Board: Sanofi; Financial Interests, Personal, Advisory Board: AbbVie; Financial Interests, Personal, Advisory Board: Amgen; Financial Interests, Personal, Advisory Board: Lilly; Financial Interests, Personal, Advisory Board: Seagen; Financial Interests, Personal, Advisory Board: Grunenthal; Financial Interests, Personal, Advisory Board: Takeda; Financial Interests, Institutional, Research Grant, Local: Roche; Financial Interests, Institutional, Research Grant, Local: Sivan; Financial Interests, Institutional, Research Grant, Local: Janssen; Non-Financial Interests, Invited Speaker, French Thoracic Cancer Intergroup, Treasurer: IFCT; Non-Financial Interests, Officer, International Thymic malignancy interest group, president: ITMIG; Other, My partner is an employee: AstraZeneca. All other authors have declared no conflicts of interest.