

# 2015 EUROPEAN CANCER CONGRESS

25-29 September 2015

Vienna, Austria

## SUMMARY

The European Cancer Congress (ECC 2015) combined the 40th European Society for Medical Oncology (ESMO) congress with the 18th congress of the European CanCer Organisation (ECCO) and was held 25 to 29 September, 2015. The meeting was organised in partnership with the European Society of Radiation and Oncology (ESTRO), the European Society of Surgical Oncology (ESSO), the European Academy for Cancer Research (EACR), the European Oncology Nursing Society (EONS), and International Society of Paediatric Oncology (SIOPE). The efforts of all partner organisations were united to continue advancing multidisciplinary as the way forward to optimise the prevention, diagnosis, treatment, and care of cancer patients by encouraging participants to leverage knowledge, promote education and build awareness for patient-centred oncology.

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## HEAD AND NECK CANCER

### Cabazitaxel shows clinical benefit in patients with refractory recurrent or metastatic squamous cell carcinoma of the head and neck: Final results of UNICANCER ORL03

Patients with recurrent or metastatic (R/M) squamous cell carcinoma of the head and neck (SCCHN) who progress on platinum, anti-EGFR, and taxanes are considered as refractory and offered methotrexate as palliative care. Jerome Fayette, Centre Léon Bérard, Lyon, France, and colleagues evaluated whether cabazitaxel, which has been reported to prolong survival in patients with hormone – refractory metastatic prostate cancer that fail docetaxel, could benefit patients with R/M SCCHN. UNICANCER ORL03 was a multicentre, phase II trial that enrolled 31 patients with R/M SCCHN, ECOG PS 0–2 who progressed after sequential and/or combined platinum, cetuximab and taxanes. All patients received cabazitaxel at 25mg/m<sup>2</sup> every 3 weeks for a maximum of 10 cycles, plus granulocyte colony stimulating factor (G-CSF) support with lenograstim 150µg/m<sup>2</sup>/day, which was administered after each cycle of chemotherapy. Response was assessed every 6 weeks, according to RECIST 1.1 (centralised review). The primary endpoint was non-progression at 6 weeks. Of 31 enrolled patients, data from 29 were evaluated for efficacy; 22 were male, median patient age was 60 (range: 30 to 71) years, 13 (45%) had oropharynx tumours, and 20 (69%) patients had metastatic disease. All had received at least 2 previous lines of chemotherapy and cetuximab.

A total of 81 cabazitaxel cycles were administered and toxicity assessments revealed that the maximum grade of toxicity was 1 to 2 for 31 cycles, grade 3 for 28 cycles, and grade 4 for 12 cycles. The overall toxicity was manageable, although one patient died of toxicity at the 6<sup>th</sup> cycle. The main grade 3/4 toxicity was neutropenia, with 8 (26%) patients having at least one event despite G-CSF use. Treatment-related serious adverse events occurred in 18 of 31 patients including febrile neutropenia in 6 patients resulting in one death.

Data from 29 patients were evaluable for the primary endpoint of non-progression of disease at 6 weeks; by central review, 21 patients had progressive disease but 8 (27.6%) 95%CI 12.7%, 47.2%) patients achieved stable disease, meeting the preplanned endpoint of a minimum of 6 non-progressive patients to consider the drug worthy of further study. Fayette *et al.* Abstract 2800.

#### Practice point and future research opportunities

This trial met its primary endpoint, demonstrating a 27.6% 6-week disease control rate in refractory patients with R/M SCCHN, warranting further investigation of cabazitaxel in this patient population. The toxicity seems acceptable for a heavily pretreated population primarily in poor medical condition.

## Pembrolizumab is safe and shows anti-tumour activity in patients with PD-L1-positive nasopharyngeal carcinoma

High expression of PD-1 has been observed in nasopharyngeal carcinoma (NPC) and PD-1/PD-L1 expression in these tumours is associated with poorer outcome, according to lead investigator Chiun Hsu, National Taiwan University Hospital in Taipei, China. He presented findings from the KEYNOTE-028 non-randomised, multicohort phase Ib trial of pembrolizumab in patients with PD-L1 positive advanced solid tumours showing that one-third of patients showed a measurable decrease in lesion size following pembrolizumab. The KEYNOTE-028 NPC cohort enrolled 27 patients with ECOG performance status 0–1, who had failed prior therapy and had advanced tumours that displayed PD-L1 expression in  $\geq 1\%$  of cells in tumour nests or PD-L1-positive bands in stroma, as determined by immunohistochemistry. Pembrolizumab was given at 10mg/kg every 2 weeks for up to 2 years or until confirmed progression or unacceptable toxicity. The median patient age was 52.0 (range: 18 to 68) years and 63% were Asian. In all, 92.5% of patients had received prior therapies for recurrent and/or metastatic disease and 33.3% had received  $\geq 5$  prior therapies. A preliminary efficacy assessment done after a median follow-up of 12.9 months demonstrated a best overall (confirmed and unconfirmed) response rate of 25.9% (95%CI 11.1, 46.3); one patient achieved complete response, 6 patients had partial response and 14 patients experienced stable disease, lasting a median duration of 5.6 months. The 6-month progression-free survival (PFS) rate was 49.7% and the 12-month PFS rate was 28.9%; median PFS was 5.6 months.

The most frequent all-grade adverse events (AEs) with pembrolizumab, occurring in more than 20% of patients, were fatigue (33%), pruritus (29.6%), nausea ((25.9%), and pyrexia (25.9%). Drug-related AEs occurred in 70.4% of patients and included pruritus (15.9%), fatigue (11.1%), rash (11.1%), maculopapular rash (11.1%), and hypothyroidism (11.1%). At the time of the conference, 8 patients remained on pembrolizumab treatment. (NCT02054806) Hsu *et al.* Abstract 2801.

### Practice point and future research opportunities

This study represents the first demonstration of robust clinical activity of a PD-1 inhibitor in patients with recurrent metastatic nasopharyngeal carcinoma, which, though rare in Western countries, is a

major cancer in parts of Asia. These data show the potential for new approaches to treat this type of cancer, where there are currently limited treatment options, and which carries a poor prognosis.

## RELATED INFORMATION

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## AFFILIATION AND DISCLOSURE

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### Disclosure

No conflicts of interest to disclose.

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