# H21

## IPILIMUMAB EXPANDED ACCESS PROGRAMME (EAP): 50% OF CLINICAL BENEFIT IN 16 EVALUABLE ADVANCED MELANOMA PATIENTS.

Stefania V.L. Nicoletti[1], Massimo Guidoboni[1], Laura Ridolfi[1],Alberto Farolfi[2], Alessandro Passardi[2], Linda Valmorri[3], Angela Ragazzini[3], Ruggero Ridolfi[1].

[1]Immunotherapy Unit;[2] Medical Oncology; [3]Biostatistics Unit; IRST Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori. Via Maroncelli 40, 47014 Meldola- Forlì.

BACKGROUND: Ipilimumab is a fully human monoclonal antibody (IgG1) that blocks CTLA-4 to promote antitumor immunity and has shown to improve Overall Survival (OS) in patients with metastatic Melanoma. Recently Food and Drug (FDA) Administration has approved its use for advanced melanoma. In Eastern Countries, while waiting for European Medicines Agency's (EMA) approval, clinical trials using Ipilimumab or an expanded access programme are available. We report the preliminary results obtained using the latter programme in our Institute.

METHODS: Thirty-five advanced melanoma patients (5 ocular melanomas), 16 males and 19 females, median age 56.5 (range 26-83), entered the study and received at least one administration of Ipilimumab 3 mg/kg (given by Bristol Meyers Squibb Italy). All the patients were pretreated, 28 (80%) of them had received more than one line of chemotherapy.
The first disease evaluation with Total Body CT Scan was performed at week 12; Progressive Disease (PD) had to be confirmed with a second assessment after 4-6 weeks, whereas Clinical Benefit (CB= Responses + Stabilizations) after further 12 weeks.

RESULTS: Of 16 (46%) evaluable patients, 3 had Partial Remission (PR), 1 Mixed Response (MR), 4 Stable Disease(SD), and 8 had PD. The Overall Response (OR) is 25% and CB 50% .
At second assessment performed in 8 (23%) patients, 2 were in PR (one in further response, and one in response after PD).
Two (6%) of the 35 patients experienced Adverse Events (AE) and had to interrupt treatment prior to week 12. Of the 16 patients evaluated 3 experienced coetaneous rash G2-G3, 2 diarrhea G2, 1 Hypothyriditis G2, the remaining 10 did not have drug related toxicities.

CONCUSIONS: These data further support the increasing relevance of Ipilimumab in the treatment of advanced melanoma even when heavily pretreated. A 50% CB seemingly forecasts even better results if an adequate preselection of patients participating to EAP is performed.