

melanoma and other skin tumours

10870 EFFICACY, SAFETY, AND QUALITY OF LIFE (QOL) DATA FROM THE EORTC 18071 PHASE III TRIAL OF IPILIMUMAB (IPI) VERSUS PLACEBO AFTER COMPLETE RESECTION OF STAGE III MELANOMA

A.M.M. Eggermont¹, V. Chiarion-Sileni², J.-. Grob³, R. Dummer⁴, J.D. Wolchok⁵, H. Schmidt⁶, O. Hamid⁷, C. Robert⁸, P.A. Ascierto⁹, J.M. Richards¹⁰, C. Lebbé¹¹, V. Ferraresi¹², M. Smylie¹³, J.S. Weber¹⁴, M. Maio¹⁵, C. Konto¹⁶, R. Karra Gurunath¹⁷, V. De Pril¹⁸, S. Suciù¹⁹, A. Testori²⁰

¹Direction, Gustave Roussy Cancer Campus Grand Paris, Villejuif, FRANCE

²Melanoma Oncology Unit, IOV-IRCCS, Padua, ITALY

³Dermatology and Skin Cancers, Hopital de la Timone, Marseille, FRANCE

⁴Department of Dermatology, University of Zürich Hospital, Zurich, SWITZERLAND

⁵Melanoma and Immunotherapeutics Service, Memorial Sloan-Kettering Cancer Center, New York, NY, USA

⁶Oncology, Aarhus University Hospital, Aarhus, DENMARK

⁷Department of Medical Oncology, The Angeles Clinic and Research Institute, Los Angeles, CA, USA

⁸Dermatology, Institut Gustave Roussy, Villejuif, FRANCE

⁹Unit of Medical Oncology and Innovative Therapy, Istituto Nazionale Tumori Fondazione "G. Pascale", Naples, ITALY

¹⁰Oncology Hematology, Oncology Specialists S.C., Park Ridge, IL, USA

¹¹Dermatology, APHP U976, Hôpital Saint-Louis, University Paris 7 Diderot, Paris, FRANCE

¹²Department of Medical Oncology, Istituti Fisioterapici Ospitalieri, Rome, ITALY

¹³Department of Oncology, Cross Cancer Institute, Edmonton, AB, CANADA

¹⁴Immunology, H Lee Moffitt Cancer Center, Tampa, FL, USA

¹⁵Medical Oncology and Immunotherapy, University Hospital of Siena, Istituto Toscano Tumori, Siena, ITALY

¹⁶Global Clinical Research Oncology, Bristol-Myers Squibb, Wallingford, CT, USA

¹⁷Melanoma Group, EORTC Headquarters, Brussels, BELGIUM

¹⁸Statistics, Bristol-Myers Squibb, Braine-l'Alleud, BELGIUM

¹⁹BioStatistics, EORTC Headquarters, Brussels, BELGIUM

²⁰Melanoma Division, European Institute of Oncology, Milan, ITALY

Aim: Ipi, a fully human monoclonal antibody that blocks cytotoxic T-lymphocyte antigen-4 to augment antitumor immune responses, is an approved treatment for advanced melanoma. We report primary efficacy data and ongoing analyses from a phase III trial to evaluate Ipi as an adjuvant therapy for resected stage III melanoma at high risk of recurrence.

Methods: In this randomized, double-blind trial, eligible patients (pts) included those ≥ 18 yrs of age who underwent complete resection of stage III cutaneous melanoma (excluding lymph node metastasis ≤ 1 mm or in-transit metastasis). 951 pts were randomized (stratified by stage and region) 1:1 to Ipi 10 mg/kg (n = 475) or placebo (Pbo, n = 476) q3w for 4 doses, then every 3 mos for up to 3 yrs until

completion, disease recurrence, or unacceptable toxicity. The primary endpoint was recurrence-free survival (RFS). Secondary endpoints included safety and health-related QoL.

Results: Overall, 20%/44%/36% of pts had stage IIIA/IIIB/IIIC, 42% ulcerated primary, and 58% macroscopic lymph node involvement. At a median follow-up of 2.7 yrs, Ipi significantly improved RFS vs Pbo (234/475 vs 294/476 events): median RFS 26.1 mos for Ipi vs 17.1 mos for Pbo (HR 0.75, 0.64–0.90; log-rank P = 0.0013). 3-yr RFS rates were 46.5% and 34.8%, respectively. RFS benefit was consistent across subgroups (e.g., stage IIIB or IIIC, ulcerated primary). Most common grade 3/4 immune-related adverse events (irAEs) in the Ipi and Pbo arms were gastrointestinal (15.9% vs 0.8%), hepatic (10.6% vs 0.2%), and endocrine (8.5% vs 0%). Most irAEs were managed and resolved using established algorithms. Of 471 pts who started Ipi, 245 (52%) discontinued treatment due to AEs (182 [38.6%] within 12 weeks); 5 (1.1%) died due to drug-related AEs. RFS analyses adjusted for prognostic factors and key HRQoL data will be presented.

Conclusions: In this phase III trial, Ipi as adjuvant therapy provided a clinically and statistically significant improvement in RFS vs Pbo for pts with stage III melanoma at high risk of recurrence. AE profile was generally consistent with that observed in advanced melanoma, although with a higher incidence of endocrinopathies.

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