

Quality of Life (QoL) of OSE2101 in HLA-A2+ Non-Small Cell Lung Cancer (NSCLC) patients after failure to immune checkpoint inhibitors (IO): Final data of Phase 3 Atalante-1 randomized trial

Authors: B. Besse¹, R.G Campelo², M. Cobo-Dols³, E.A. Quoix⁴, A. Madroszyk⁵, E. Filip⁶, F. Cappuzzo⁷, F. Denis⁸, W. Hilgers⁹, G. Romano¹⁰, D. Debieuvre¹¹, D. Galetta¹², E. Baldini¹³, S. Viteri¹⁴, M.D. Phan¹⁵, W. Schuette¹⁶, A. Zer¹⁷, B. Vasseur¹⁸, R. Dziadziuszko¹⁹, G. Giaccone²⁰

¹Gustave Roussy Institute, Villejuif; ²Hospital Universitario A Coruña; ³Hospital Universitario Regional Málaga; ⁴Hôpitaux Universitaires de Strasbourg-Nouvel Hôpital Civil; ⁵Institut Paoli-Calmettes, Marseille; ⁶Vall d'Hebron University Hospital, Institute of Oncology, Barcelona; ⁷Istituto Nazionale Tumori "Regina Elena", Rome; ⁸Institut Inter-Regional de Cancérolgie Jean Bernard-Elsan, Le Mans; ⁹Institut Sainte Catherine, Avignon; ¹⁰Oncologia Medica, Lecce; ¹¹Groupe Hospitalier de la région Mulhouse Sud Alsace; ¹²IRCCS Istituto Tumori Giovanni Paolo II, Bari; ¹³Ospedale San Luca, Lucca; ¹⁴Instituto Oncológico Dr. Rosell, Hospital Universitario Dexeus, Grupo Quironsalud Cancer Center, Barcelona; ¹⁵University of Oklahoma Health Sciences Center; ¹⁶Martha-Maria City Hospital Halle-Doelau; ¹⁷Davidoff Cancer Center, Rabin Medical Center, Petah Tikva; ¹⁸OSE Immunotherapeutics, Paris; ¹⁹Medical University of Gdańsk; ²⁰Weill-Cornell Medical Center, New York

Background:

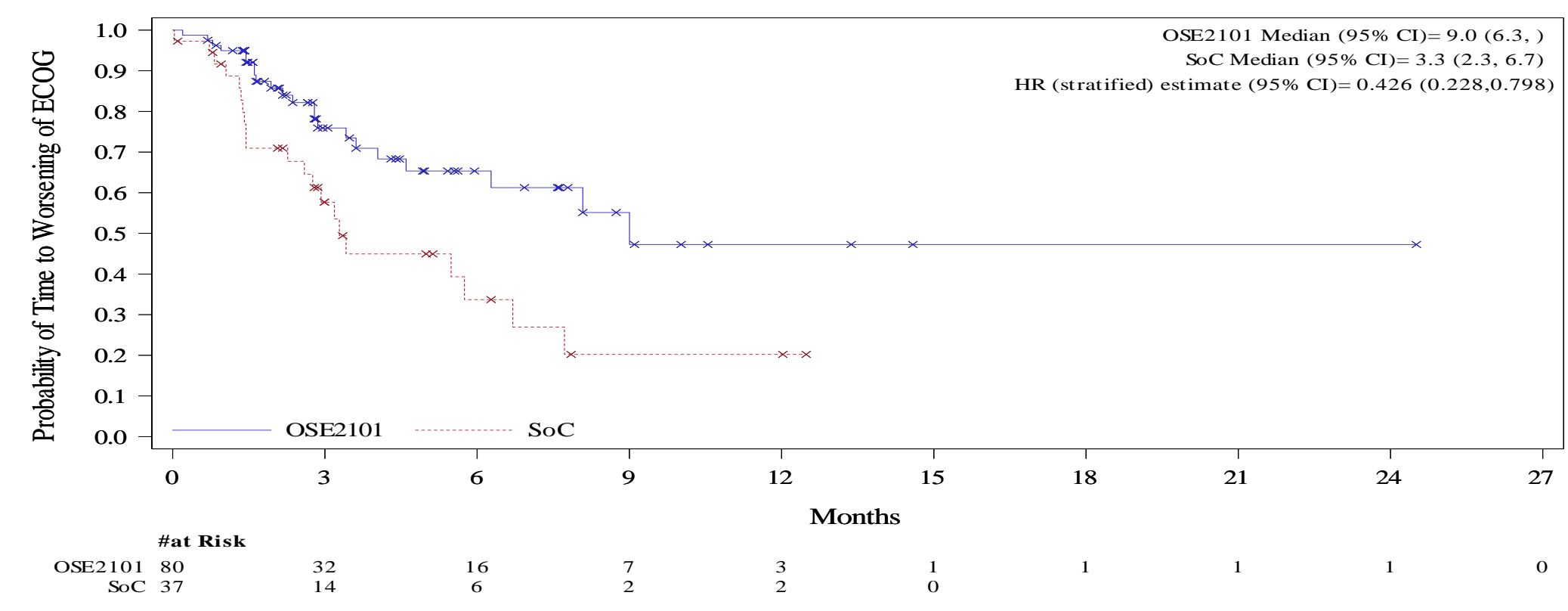
- OSE2101 (Tedopi) is a **cancer vaccine increasing median overall survival (OS) by 3.6 months with HR of 0.59 (p=0.017) versus chemotherapy (docetaxel or pemetrexed) in HLA-A2+ EGFR and ALK negative in NSCLC patients with IO secondary resistance after sequential CT-IO** (predefined Population of Interest (PoI) of 118 patients)¹. HR for OS in overall population of primary or secondary resistance after sequential or concomitant CT-IO (n=219) was 0.86 (ns)¹.
- Quality of Life (QoL) and time to worsening ECOG Performance Status (PS) were compared between groups.

Methods:

- **QoL by EORTC QLQ-C30/LC13** questionnaires and **ECOG PS** were collected at baseline and before each treatment administration until the end of treatment (EOT).
- **Changes in QLQ-C30/LC13 scores from baseline to EoT** were assessed using mixed-effects model for repeated measures (MMRM).
- **Time to worsening ECOG PS** was defined by the time from randomization to the earliest time **when the ECOG becomes > 1 using Kapan Meier method**.

Results:

Figure 1 Time to worsening ECOG PS > 1



- Median time to worsening of ECOG PS was **prolonged in OSE2101 arm with a difference of 5.3 months (p<0.01) compared to SoC in PoI (figure 1)**. Increase in ITT was of 3.3 months (p=0.02).

In advanced HLA-A2+ NSCLC patients with IO Secondary Resistance, cancer vaccine OSE2101 significantly increased OS, QoL and Time to worsening of ECOG PS compared to chemotherapy.



SCAN ME

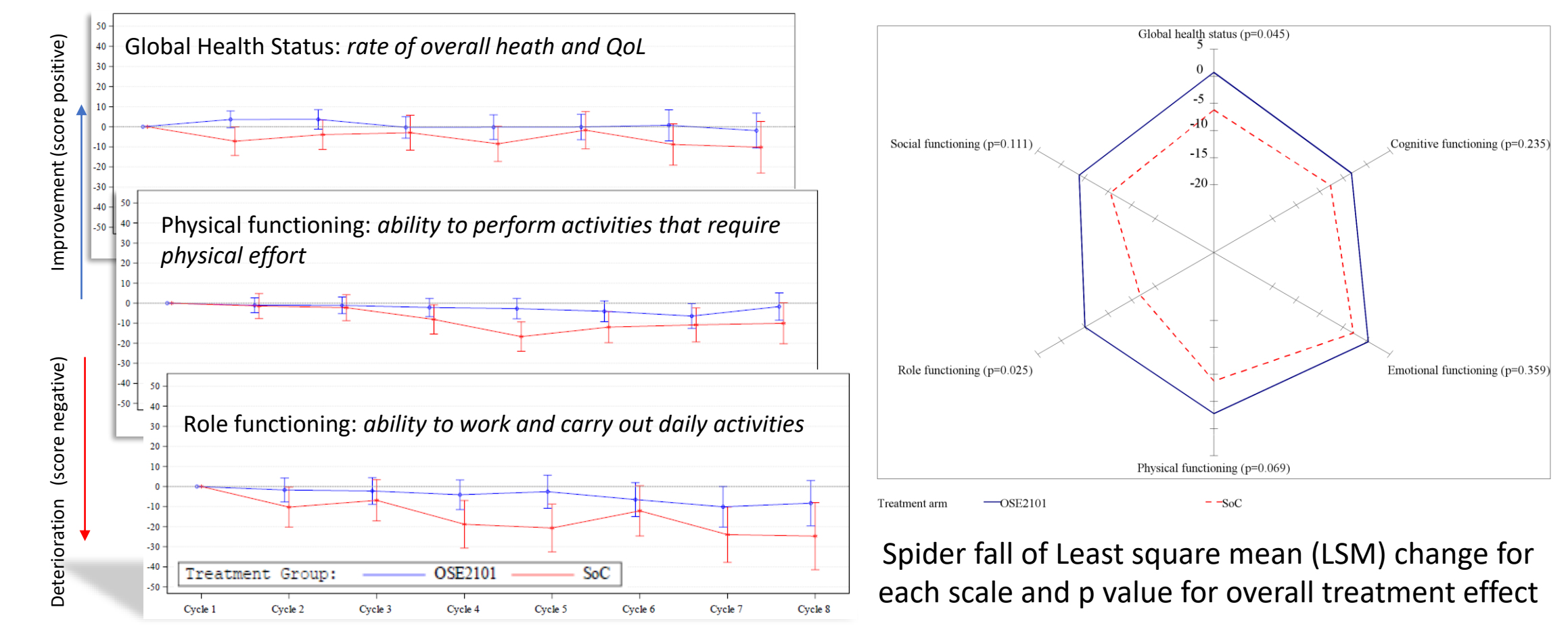
We thank all investigators and their study team, all patients and their families

Author Contact: benjamin.besse@gustaveroussy.fr

Reference: 1. B Besse et al; #47LBA ESMO 2021 in Annals of Oncology (2021) 32 (suppl_5): S1283-S1346. 0.1016/annonc/annonc741

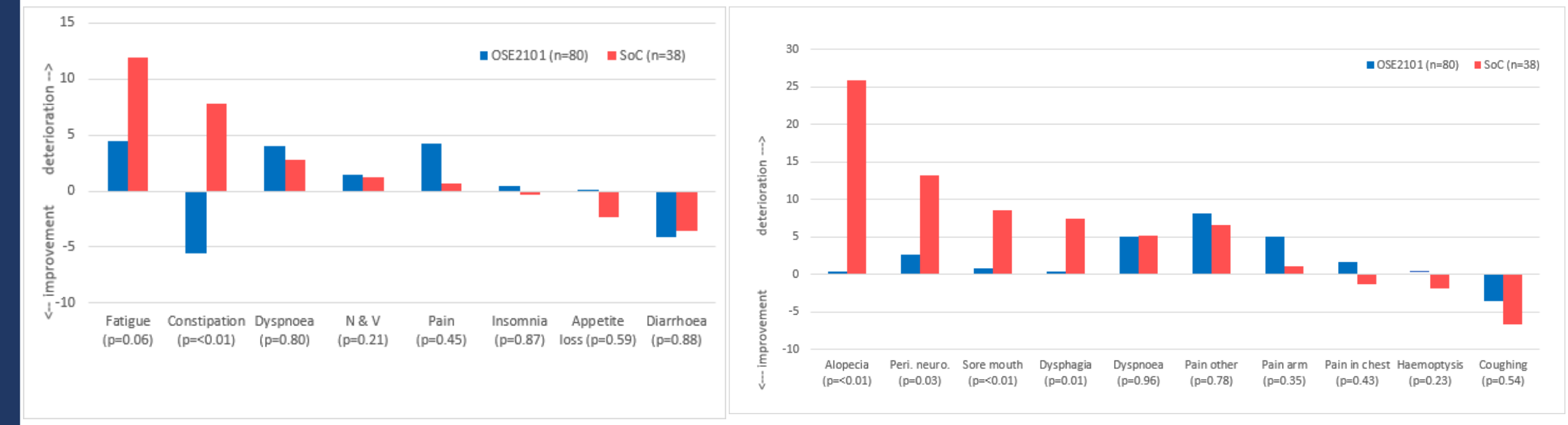
We thank P. Attali (MD) for his support in writing the abstract and J. Le Boulicaut, C. Hayem and F. Montestruc (eXYSTAT) for the QoL analysis
Copies of this poster obtained through Quick Response (QR) Code are for personal use only and may not be reproduced without permission from ASCO and the author of this poster

95 (80.5%) of patients filled questionnaires at baseline and during treatment. Figures 2a & 2b QLQ-C30 Functional Score change from Baseline to Cycle 8



- **Global Health Status, Physical and Role functioning remained stable with OSE2101 whereas it deteriorated from the 1st cycle with SoC in PoI (figure 2)**; Similar results were observed in ITT.

Figures 3a & 3b Change for Symptoms from Baseline to Cycle 8 QLQ-C30/LC13



- **Patients presented fewer symptoms typically related to adverse effects of chemotherapy (alopecia, mouth soreness, dysphagia, peripheral neuropathy) with OSE2101 than with SoC.**
- **Patient Reported Outcomes together with prior reported lower incidence of severe adverse events¹ confirm that OSE2101 is better tolerated than SoC.**