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## A RANDOMISED OPEN-LABEL PHASE I/II STUDY ADDING ONCOS-102 TO PEMETREXED/CISPLATIN IN PATIENTS WITH UNRESECTABLE MALIGNANT PLEURAL MESOTHELIOMA – 24 MONTH SURVIVAL DATA

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**Background** Malignant pleural mesothelioma (MPM) is an aggressive malignancy without curative treatment. Standard of care (SOC) include pemetrexed/cisplatin and nivolumab/ipilimumab with median overall survival in unresectable disease of 12.1 months and 18.1 months respectively.<sup>1 2</sup> ONCOS-102 is a granulocyte-macrophage colony stimulating factor (GM-CSF) expressing oncolytic adenovirus (Ad5/3-D24-GMCSF) with a unique ability to both prime and boost immune responses. The aim of the study was to assess efficacy and safety of ONCOS-102 in combination with SOC chemotherapy in 1st and 2nd line unresectable MPM.

**Methods** Twenty patients (experimental arm) were allocated to receive ONCOS-102 given intratumorally under CT or US guidance at a dose of 3 x 10<sup>11</sup> VP on Day 1, 4, 8, 36, 78 and 120 plus six cycles of SOC starting on Day 22. Eleven patients (control group) received SOC. Imaging was done at baseline, Day 43–64 and 127–148 with regular monitoring of blood and biopsy based immune markers. Primary objective was safety and tolerability. Secondary objectives were ORR, PFS and OS as well as immunological activation. An analysis of 24 month survival data compared randomised only patients excluding six patients in the single-arm safety lead-in.

**Results** 24-month survival rate for 1st line pts was 50% in the experimental group and 0% in the control group with mOS of 25.0 months and 13.5 months respectively (N.S). Based on censoring, mOS in the experimental group will be within 21.9 – 25.0 months range. mOS across both 1st and 2nd line was 19.3 and 18.3 months for experimental and control patients (N.S). mPFS was 9.8 months in the experimental group and 7.6 in the control group (N.S).

**Conclusions** The survival rate of patients receiving ONCOS-102 in combination with SOC was seen to be numerically higher than previously reported for SOC or nivolumab/ipilimumab. Improved survival was associated with ONCOS-102 induced immune activation with a favourable TME modulation providing scientific rationale for combination with checkpoint inhibition.

**Trial Registration** ClinicalTrials.gov NCT02879669

### REFERENCES

1. Vogelzang, et al, Phase III study of pemetrexed in combination with cisplatin versus cisplatin alone in patients with malignant pleural mesothelioma. *J Clin Oncol* 2003; **21**: 2636–44.
2. Baas P, et al, First-line nivolumab plus ipilimumab in unresectable pleural mesothelioma (CheckMate 743): a multicentre, randomised, open-label, phase 3 trial. *The Lancet* 2021; **397**: 375–386.

**Ethics Approval** This study was approved by the IRBs of all the participating sites in Madrid, Barcelona, Rennes and Poitiers.

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