Abstract #9090: Subgroup Analysis of Non-Squamous EGFR Wild-Type (WT) 2nd/3rd Line NSCLC Patients from the Global Phase 3 Trial DUBLIN-3 (BPI-2358-103) with the Plinabulin/Docetaxel Combination vs. Docetaxel Alone

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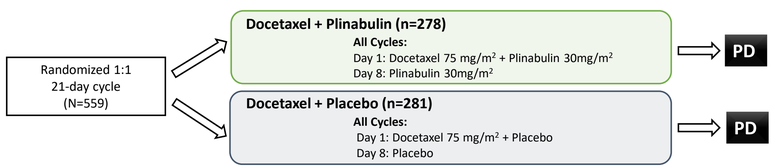
BACKGROUND

- With PD-1/PD-L1 inhibitors moving to 1st line for the treatment of NSCLC, 2nd and 3rd line treatment is a severe unmet medical need, which is dominated by docetaxel-based therapies and associated with >40% severe neutropenia and limited survival.
- Plinabulin, a novel immune-enhancing small molecule, enhances dendritic cell maturation and T-cell proliferation.
- DUBLIN-3 (NCT02504489) was a randomized, single-blind (patients only), active controlled, phase 3 study in 2nd/3rd line stage IIIB/IV EGFR wt NSCLC patients.
- Among the ITT population, the plinabulin + docetaxel combination had superior efficacy, safety and quality of life (mOS: p=0.0399, Gr3/4 AE rate/pt/year: p=0.038, and p=0.026 respectively) vs standard of care docetaxel alone.[1]
- Here we report on the non-squamous subgroup of DUBLIN-3.

METHODS

- In the DUBLIN-3 trial, patients had a measurable lesion (RECIST 1.1) in the lung and an ECOG ≤ 2. The trial was conducted in US, Australia and China. See below for the study overview.



- A post-hoc analysis of median overall survival (mOS), restricted mean survival time (RMST) from K-M curves, OS rate at 24-, 36- and 48-months, and grade 4 neutropenia rates were evaluated for non-squamous NSCLC patients of the DUBLIN-3 trial.

RESULTS

- Baseline characteristics were balanced between both groups.
- Primary and key secondary objectives in the ITT population were met (**Figures 1-3**).[1]

Non-squamous EGFR wild-type NSCLC patients treated with plinabulin + docetaxel in 2nd or 3rd line had superior efficacy and safety over standard of care docetaxel in the DUBLIN-3 trial.

There are limited treatment options for 2nd and 3rd line NSCLC patients, the plinabulin and docetaxel combination offers a safe and effective option.

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RESULTS CONTINUED

- The median OS was 11.4 months (plinabulin + docetaxel) vs 8.8 months (docetaxel), with 2.6 months mOS benefit.
- Non-squamous subgroup results (**Figures 4, 5 and 7**) and safety data (**Figures 6 and 8**) are summarized to the right.

CONCLUSION

The addition of plinabulin to docetaxel was superior to standard of care docetaxel alone for efficacy and safety in the clinically relevant subgroup of non-squamous EGFR wild-type, 2nd/3rd line NSCLC patients. Although total AE frequency was similar between treatment arms, AE-grade was shifted to the left, thus less grade 4 AEs and more grade 1-3 AEs. It's notable that at 48 months, the OS is 12% vs 0% (plinabulin + docetaxel vs docetaxel alone).

REFERENCES

[1] Han, ESMO 2021

ITT POPULATION DATA

Figure 1. ITT survival rates

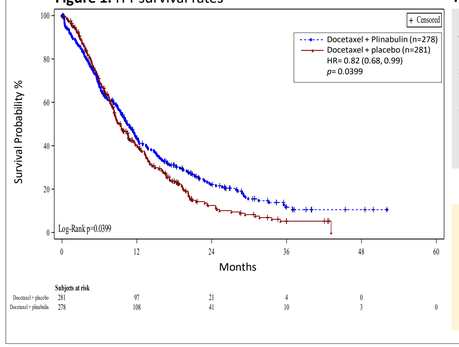


Figure 2. ITT 24, 36 & 48-month survival rates

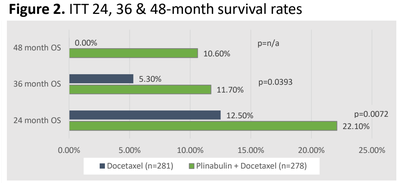
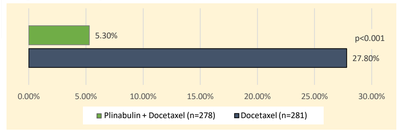


Figure 3. ITT grade 4 neutropenia rates



NON-SQUAMOUS POPULATION DATA

Figure 4. OS KM plot for non-squamous NSCLC (ITT population)

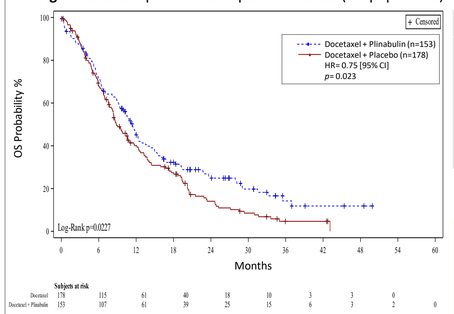


Figure 5. Non-squamous 24, 36, & 48-month survival rates

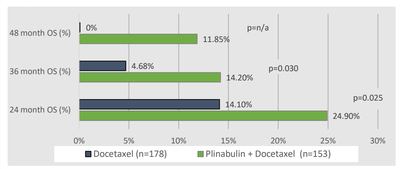


Figure 6. Non-squamous grade 4 neutropenia rate

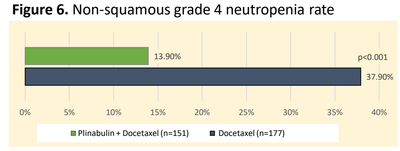


Figure 7. Non-squamous restricted mean survival time (RMST) months

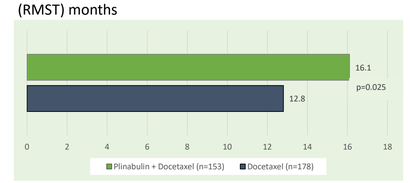
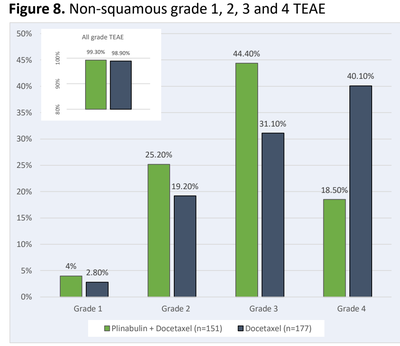


Figure 8. Non-squamous grade 1, 2, 3 and 4 TEAE



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