BACKGROUND

Vast recruitment efforts and patient pre-enrolment (BICR) were included in the full safety and efficacy analysis.

TRIAL DESIGN

Multicentre, placebo-controlled, double-blind; 1:1 randomized Phase IIb study in female hormone receptor-positive metastatic breast cancer patients.

TREATMENT DESIGN

The treatment consists of a chemotherapeutics phase followed by a maintenance phase:

- Chemotherapeutics phase: 4 cycles of 8 weeks with weekly paclitaxel (cumulative administration allowed in 6, 8, 10 and 12 weeks).
- Maintenance phase: responding or stable patients will afterwards receive study agent (placebo or placebo) every 4 weeks for additional 12 injections (52 months).

OBJECTIVES AND ENDPOINTS

Primary efficacy results from AIPAC: A double-blind, placebo controlled, randomized multinational phase IIb trial comparing weekly paclitaxel plus efiltagimod alpha (soluble Lag-3 protein) vs. weekly paclitaxel plus placebo in HR-positive metastatic breast cancer patients

PATIENT DISPOSITION AND EXPOSURE

- In total, 237 patients were randomized to efti (n=114) and to placebo (n=123). At end of study, one patient randomized at least 1 treatment and were included in the full safety and efficacy analysis.

SAFETY

- 2 L1 pts in the efti group and 3 L1 pts in the placebo group had total treatment-emergent adverse events (TEAEs) = ± Grade 3 TEAEs.

EFFICACY

- Long-term, significant and sustained increase in number of circulating CD8 T cells in vitro-bred to efti/placebo was observed in the same subgroup.

CONCLUSION

Overall Population:

- Efti did not prolong median PFS in women with HR+ MBC resolving paclitaxel, but ORR on trend favorably
- Efti showed statistically significant, sustained long-term increase in peripheral CD8+ T cells.
- Efti in combination with weekly paclitaxel is well-tolerated

Subgroup:

- In pts with age < 65 yrs, low monocytes and luminal B, substantial and mostly statistically significant increase in all relevant efficacy parameters, i.e., OS were observed.
- Median OS was 11.9 months in the efti group and final OS data expected in 2021.
- Efti in combination with weekly paclitaxel warrants further late-stage clinical development in HR+ MBC, in particular in pts with age < 65 yrs

Efficacy—Overall population

At second interim analysis (61 %) events, cut-off was extended to 7th May 2020 for HR, DFS (HR 0.69 (0.42-0.98); p=0.02) for the overall group.
- PFS study treatment was similar with 80 % (effi) and 81 % (placebo) receiving any post study systemic anticancer therapies. No major difference in minor chemotherapy (46 % vs. 65 %) related to efti.

Subgroup analysis:

- In three pre-defined subgroups, clinically relevant and statistically significant differences were observed for pts 65 yrs and OS Survival (HR 0.83 for the overall group).
- CIM-04 had negative impact on OS in placebo group (median reduced from 20.5 to 21.9 months, re: which is not the case in the efti group (median OS 23.0 vs. 24.0 months).

Subgroup analysis by DFS:

- Median (IQR) DFS Efti 19.9 (17.6-22.4) months vs. Placebo 19.5 (17.1-22.2) months, re: which is not the case in the efti group (median OS 23.0 vs. 24.0 months).

Efficacy—Overall survival

- At median DFS (7.5 [6.4-8.4] vs. 7.4 [6.3-8.4] months).
- PFS 6 months: 57% vs. 54% (HR 0.87, 7.2 [5.9-8.5] vs. 7.1 [5.8-8.4] months).
- PFS 1 year: 29% vs. 27% (HR 0.74, 22.4 [19.5-25.3] vs. 22.2 [19.3-25.2] months).
- Placebo: 7.2 [5.7-8.7] vs. 5.6 [4.7-6.5] (p=0.0105)