**Overall survival results from the randomized phase II study of palbociclib (P) in combination with letrozole (L) vs letrozole alone for frontline treatment of ER+/HER2– advanced breast cancer (PALOMA-1; TRIO-18).**

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**1001**

**Background:** Preclinical data identified a synergistic role for P and hormone blockade in blocking growth of ER+ breast cancer (BC) cell lines. PALOMA-1 was an open-label phase II trial comparing progression-free survival (PFS) in patients (pts) with advanced ER+/HER2– BC treated with P+L or L alone. Median PFS increased with addition of P to L to 20.2 mos (vs 10.2 mos with L alone; HR = 0.488), with an acceptable safety profile, leading to accelerated approval by the US FDA. These results were confirmed in the phase 3 PALOMA-2 trial. At the time of the final PFS analysis, overall survival (OS) data were immature with only 61 events in both arms and a median follow-up of < 30 mos with a trend in favor of P+L vs L (37.5 vs 33.3 mos; HR = 0.813; *P*= 0.211). Here we present final OS results. **Methods:** PALOMA-1 was a 2-part study evaluating P+L in ER+/HER2– advanced BC. Part 1 enrolled postmenopausal pts with this subtype using only ER+/HER2– while Part 2 enrolled pts of this subtype additionally screened for CCND1 amplification and/or loss of p16. The primary endpoint was investigator-assessed PFS. Secondary endpoints included objective response rate, OS, safety, and correlative biomarker studies. A total of 165 pts were randomized; 66 in Part 1 and 99 in Part 2. Baseline characteristics were balanced between treatment arms. In both parts, pts were randomized 1:1 to receive P+L or L alone. OS data were collected as well as post-study therapy. **Results:** As of Dec 2016, there were 116 OS events. Median OS was 37.5 mos (95% CI: 31.4, 47.8) with P+L vs 34.5 mos (95% CI: 27.4, 42.6) for L (HR = 0.897 [95% CI: 0.623, 1.294]; *P*= 0.281). Median OS was 37.5 vs 33.3 mos (HR = 0.837; *P*= 0.280) for Part 1 and 35.1 vs 35.7 mos (HR = 0.935; *P*= 0.388) for Part 2. 78.6% of pts in the P+L arm received post-study systemic therapy vs 86.4% in the L arm. More pts in the L arm received ≥3 lines of therapy (37% vs 18%). Further subgroup analyses and details on post-study therapies will be presented. **Conclusions:** In PALOMA-1, P+L provided a statistically non-significant trend towards an improvement in OS. Survival data from the phase III, PALOMA-2 study is awaited. Sponsor: Pfizer; [Clinical trial information: NCT00721409.](http://clinicaltrials.gov/show/NCT00721409" \t "_blank)