APACT: phase III, multicenter, international, open-label, randomized trial of adjuvant nab-paclitaxel plus gemcitabine (nab-P/G) vs gemcitabine (G) for surgically resected pancreatic adenocarcinoma.

Authors:
Margaret A. Tempero, Michele Reni, Hanno Riess, Uwe Pelzer, Eileen Mary O’Reilly, Jordan Michael Winter, Do-Youn Oh, Chung-Pin Li, Giampaolo Tortora, Heung-Moon Chang, Charles D. Lopez, Josep Tabernero, Eric Van Cutsem, Philip Agop Philip, David Goldstein, Jordan Berlin, Stefano Ferrara, Mingyu Li, Brian D. Lu, Andrew Blankin; University of California, San Francisco, San Francisco, CA;...View More

Background:
In metastatic pancreatic cancer (PC), nab-P/G demonstrated significantly longer overall survival (OS) vs G. APACT assessed efficacy & safety of nab-P/G vs G in surgically resected PC.

Methods:
Treatment (tx)-naive patients (pts) with histologically confirmed PC, macroscopic complete resection, ECOG PS 0/1, & CA19-9 < 100 U/mL were eligible. Stratification factors: resection status (R0/R1), lymph node status (LN+/−), & geographic region. Tx was initiated ≤ 12 wks postsurgery. Pts received nab-P 125 mg/m2 + G 1000 mg/m2 or G 1000 mg/m2 on days 1, 8, 15 of six 28-day cycles. Primary endpoint was disease-free survival (DFS) by independent reviewer (IR); IRs received baseline clinical data & scans. Secondary endpoints were OS & safety. ≈438 DFS events were needed for 90% power to detect an HR for disease recurrence or death of 0.73 with nab-P/G vs G at a 2-sided significance level of 0.05.

Results:
866 pts were randomized. Median age was 64 y (range, 34 - 86); most pts had ECOG PS 0 (60%), LN+ (72%), & R0 (76%). 69% of pts completed 6 tx cycles (nab-P/G, 66%; G, 71%). Median follow up for OS was 38.5 mo. Median IR-assessed DFS (439 events) was 19.4 mo (nab-P/G) vs 18.8 mo (G) (HR, 0.88; 95% CI, 0.729 - 1.063; stratified log-rank P = 0.1824). Investigator-assessed DFS (571 events) was 16.6 mo (nab-P/G) vs 13.7 mo (G) (HR, 0.82; 95% CI, 0.694 - 0.965; nominal P = 0.0168). Interim OS (427 events) was 40.5 mo (nab-P/G) vs 36.2 mo (G) (HR, 0.82; 95% CI, 0.680 - 0.996; nominal P = 0.045). Grade ≥ 3 TEAEs were reported in 86% vs 68% of pts with nab-P/G vs G. The most common grade ≥ 3 hematologic & nonhematologic TEAEs with nab-P/G vs G were neutropenia (49% vs 43%) & fatigue (10% vs 3%). TEAEs led to death in 2 pts in each arm.

Conclusions:
IR DFS with nab-P/G was not significantly longer vs G; median DFS with G was longer than historical data. DFS by investigator (sensitivity analysis) and interim OS were improved with nab-P/G vs G (HR 0.82 for both). Adjuvant nab-P/G may be an option for pts who are ineligible for FOLFIRINOX. Additional OS follow-up may better support nab-P/G as an option in the adjuvant setting. Clinical trial information: NCT01964430

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