Phase II LAPACT trial of nab-paclitaxel (nab-P) plus gemcitabine (G) for patients with locally advanced pancreatic cancer (LAPC).

Sub-category: **Multidisciplinary Treatment**

Category: **Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract**

Meeting: **2018 Gastrointestinal Cancers Symposium**

Abstract No: 204

Poster Board Number: Poster Session B (Board #A1)

Citation: J Clin Oncol 36, 2018 (suppl 4S; abstr 204)

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**Abstract Disclosures**

Abstract:

**Background:** In the phase 3 MPACT study, treatment with nab-P + G resulted in a > 3-fold reduction in primary pancreatic tumor burden vs G in patients with metastatic PC, suggesting the potential for activity against LAPC. This international, multicenter single arm, phase 2 trial (LAPACT) was designed to evaluate the efficacy and safety of an induction phase regimen of nab-P + G in previously untreated patients with LAPC. **Methods:** Treatment-naïve patients with unresectable LAPC and Eastern Cooperative Oncology Group (ECOG) performance status ≤ 1 were enrolled. The induction phase was designed as 6 cycles of nab-P 125 mg/m² + G 1000 mg/m² on D 1, 8, and 15 of each 28-day cycle. After induction, patients without progressive disease or unacceptable adverse events were eligible for continued treatment with nab-P + G, chemoradiation, or surgery per investigator’s choice (IC). Surgery could occur prior to completing 6 induction cycles if the investigator deemed there had been a sufficient tumor response. The primary endpoint was time to treatment failure (TTF) in patients treated with nab-P + G as induction therapy followed by IC treatment. Key secondary endpoints included
disease control rate (DCR), overall response rate (ORR), progression-free survival (PFS), and overall survival (OS). **Results:** Of 107 patients enrolled, 106 were evaluable for the safety analysis. No new toxicities were identified. The most common grade ≥ 3 treatment-emergent adverse events during induction were neutropenia (42%), anemia (11%), and fatigue (10%); grade 3 peripheral neuropathy occurred in 4% of patients. The most frequent reasons for discontinuing induction were adverse events (18%) and progressive disease (7%). Forty-six (43%) patients received IC treatment after induction: 13 (12%) continued nab-P + G, 17 (16%) received chemoradiation, and 16 (15%) underwent surgical resection (R0, n = 7; R1, n = 9). DCR and ORR during induction were 78% and 35%, respectively; with a median TTF of 8.6 months and median PFS of 10.2 months. **Conclusion:** A nab-P + G induction regimen in LAPC appears tolerable and feasible and is associated with encouraging antitumor activity and promising TTF and PFS. NCT02301143. Clinical trial information: NCT02301143