

**ASCO 2017 Gastrointestinal Cancers Symposium: summary of key guidelines for abstracts**

**TITLE:** Titles should be in sentence case. There is no character limit for the title, but characters in the title will count towards the overall character count

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**Note: This draft has not been copy-edited nor fact-checked**

**A phase 1b/2 study of INCB039110 in combination with nab-paclitaxel (N) and gemcitabine (G) in patients (pts) with advanced solid tumors and pancreatic cancer (PC)**

**BACKGROUND:** JAK-STAT activity has been associated with the malignant cell proliferation and the production of proinflammatory cytokines involved in cancer progression. INCB039110, a potent and selective inhibitor of JAK1, was evaluated in pts with advanced solid tumors and PC.

**METHODS:** This was a 2-part phase 1b/2 open-label study evaluating INCB039110 in combination with N and G ( $\pm$  GCSF) in pts with advanced or metastatic solid tumors (Part 1, dose optimization phase) and pts with advanced or metastatic PC who had not received prior chemotherapy (Part 2 and 2A). Pts in P2 received the P1 tolerated dose regimen [INCB039110 (300 mg QD) + N (125 mg/m<sup>2</sup> QW) + G (1000 mg/m<sup>2</sup> QW)]. Pts in P2A underwent a 7-day induction phase with INCB039110 (200 mg QD) prior to receiving INCB039110 (200 mg QD) + N (125 mg/m<sup>2</sup> QW) + G (1000 mg/m<sup>2</sup> QW).

**RESULTS:** A total of 27 pts enrolled in P1, 20 in P2 and 8 in P2A. Median age was 65 (P1), 67 (P2), and 66 years (P2A). Prior therapy: 67% in P1, 30% in P2 (2 pts for advanced disease, 4 pts for (neo)adjuvant therapy), and 0% in P2A. The most common reasons for treatment discontinuation were: AEs (41% P1, 20% P2, 38% P2A), disease progression (37% P1 and 45% P2), and study termination by the sponsor (38% P2A). Median treatment durations were 84 d (P1), 121 d (P2), and 47 d (P2A). The most common non-hematologic adverse events (AEs) overall were fatigue (59% P1, 75% P2, 88% P2A), nausea (41% P1, 50% P2, 38% P2A), pyrexia (37% P1, 40% P2, 13% P2A), and peripheral edema (30% P1, 50% P2, 25% P2A). There were few grade 3 or 4 non-hematologic AEs. The most common grade 3 or 4 hematologic AEs (laboratory values) overall were neutropenia (33% P1, 60% P2, 13% P2A), lymphopenia (30% P1, 30% P2, 13% P2A), and leukopenia (30% P1, 45% P2, 0% P2A). Serious AEs (SAEs) occurring in  $\geq 3$  pts in P1 or P2 or P2A were pneumonia (n=4 P1 and n=2 P2) and anemia (n=3 P1, n=2 P2, n=2 P2A). ORRs (all PRs) were 5/27 (19%) in P1, 7/20 (35%) in P2, and 1/8 (13%) in P2A.

**CONCLUSIONS:** INCB039110 had an acceptable safety profile in combination with nab-paclitaxel/gemcitabine in pts with advanced pancreatic cancer. . Partial responses were seen across the trial.