

Title: First-in-Human Study of INCB062079, a Fibroblast Growth Factor Receptor 4 Inhibitor, in Patients with Advanced Hepatobiliary Cancers and Other Solid Tumors

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Online Supplementary Table 2 Definition of dose-limiting toxicity^a

Toxicity	Definition
Nonhematologic	- Any grade ≥ 3 nonhematologic toxicity, except: - Transient (≤ 72 hours) abnormal laboratory values without associated clinically significant signs or symptoms^{b,c} - Grade 3 nausea, vomiting, and diarrhea adequately controlled with medical therapy within 48 hours^d - Changes in cholesterol and triglycerides - An event clearly associated with the underlying disease, disease progression, a concomitant medication, or comorbidity^e
Chemistry	- AST and/or ALT elevation: - AST and or ALT elevation $>5.0 \times \text{ULN}$ and $<20 \times \text{ULN}$ for >7 days or recurring on rechallenge - AST and/or ALT $\geq 20 \times \text{ULN}$ - Hy's Law: ALT $>3 \times \text{ULN}$, concurrent with serum total bilirubin elevation to $>2 \times \text{ULN}$, without findings of cholestasis (serum ALP $<2 \times \text{ULN}$) and no other reason can be found to explain the combination of increased ALT and total bilirubin
Hematology	- Grade 3 thrombocytopenia with bleeding - Grade 4 thrombocytopenia - Febrile neutropenia (ANC $<1.0 \times 10^9$ cells/L and fever $>101^\circ\text{F}/38.5^\circ\text{C}$) - Grade 4 neutropenia - Grade 4 anemia

^aTransient abnormal laboratory values (duration ≤ 72 hours) without associated clinically significant signs or symptoms based on investigator determination were not considered a DLT. ^bBased on investigator determination.

^cAll grade 4 electrolyte abnormalities were considered a DLT regardless of duration. ^dAll grade 4 vomiting and diarrhea were considered DLTs regardless of prophylactic treatment, response to management, or duration. ^eAll grade 4 systemic reaction symptoms were be considered DLTs.

ALP alkaline phosphatase, *ALT* alanine aminotransferase, *ANC* absolute neutrophil count, *AST* aspartate aminotransferase, *DLT* dose-limiting toxicity *ULN* upper limit of normal.