Efficacy and safety of varlitinib, a reversible pan-HER tyrosine kinase inhibitor, in combination with platinum-based regimens in biliary tract cancers: A pooled analysis from three phase 1 studies

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Background
- Advanced biliary tract cancer (BTC) encompasses cholangiocarcinoma (CCA), gallbladder cancer (GBC) and cancers of the ampulla of Vater. These tumours have a highly aggressive disease course and a poor prognosis. Molecularly distinct entities exist between tumour and geographical origin.
- The doublet chemotherapy of gemcitabine with cisplatin or S-1 are standard first line regimens for ABTC.

Methods
- To conduct a pooled analysis of ABTC patients from three phase 1 studies (ASLAN001-002, ASLAN001-007, and ASLAN01-07), assessing the safety and efficacy of varlitinib in combination with platinum-based chemotherapy.
- The depth of tumour response, investigator-assessed objective response rate (dORR), disease control rate (DCR), and treatment-related adverse events were analysed.

Results
- Of the 27 patients evaluable for efficacy assessment, 9 patients (33.3%) experienced a PR. Disease control rate (DCR) was 74.0% (9/12). Median PFS and OS were 6.0 and 11.7 months, respectively. Most common treatment-related adverse events were:
  - Gastrointestinal: vomiting (14.8%), nausea (14.8%), diarrhea (14.8%), decreased appetite (14.8%), constipation (14.8%), anorexia (14.8%), fatigue (14.8%), decreased appetite (14.8%), and constipation (14.8%).

Conclusions
- Varlitinib was tolerable in combination with platinum-based chemotherapy in BTC. A phase 2/3 study is ongoing.

Safety and tolerability profile
- Most common treatment-related adverse events (>10%) included:
  - Anorexia: 14.8%
  - Vomiting: 14.8%
  - Fatigue: 14.8%

References