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Early safety from a phase 1, multicenter, open-label clinical trial of talimogene laherparepvec (T-VEC) injected into liver tumors

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Purpose: T-VEC is a genetically modified HSV-1 oncolytic immunotherapy designed to preferentially replicate in tumors, produce GM-CSF, and stimulate anti-tumor immune responses. This study evaluates the safety of intrahepatic injection (inj) of T-VEC in patients (pts) with hepatocellular carcinoma (HCC) or liver metastases (mets).

Materials: The primary objective is to assess the maximum tolerated dose. Eligible pts were ≥ 18 years (y) old, had progressive HCC or breast cancer (BC), colorectal cancer (CRC), gastroesophageal cancer, melanoma, non-small cell lung cancer, or renal cell cancer with liver mets, with measurable liver tumors suitable for inj. This dose escalation study comprised 2 groups: A (non-HCC) and B (HCC). T-VEC was given initially at 10^6 plaque-forming units (PFU)/mL followed by up to 4 mL of 10^7 PFU/mL (cohort 1) or 10^8 PFU/mL (cohort 2) every 21(±3) days (Q21D), or up to 8 mL of the maximum tolerated concentration (MTC) Q21D (cohort 3). Inj volume was based on lesion size.

Results: Results from cohorts 1 and 2 of group A are reported. 14 pts were treated; 12 (3 BC, 9 CRC) were DLT-evaluable: Median age was 65.5 y (range: 33-73); median number of inj was 3; 1 pt received all 12 inj. MTC was 10^8 PFU/mL. There was 1 DLT, grade (G) 3 aspartate aminotransferase (AST)/G2 bilirubin increase (inc), after 1 dose. In all treated pts, 4 (28.6%) had G3/4 treatment-related adverse events (TRAEs): anemia and inc gamma-glutamyltransferase, alanine aminotransferase (ALT) and AST. There were 2 deaths, both attributable to disease. Incidence of serious AEs (SAEs) is shown (Table).

Conclusions: The MTC was 10^8 PFU/mL Q21D after initial inj at 10^6 PFU/mL. Repeated intrahepatic inj of T-VEC at the FDA-approved concentration for intralesional inj of melanoma was deemed tolerable and feasible in pts with liver mets. Additional investigation in combination with a PD-1 inhibitor is planned.

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DLT-Evaluable Pt Incidence of SAEs	
	n
Any SAE	6
Any TR SAE	2
Pyrexia	1
AST inc[a]	1
Hernial eventration	1
Syncope	1
ALT inc[a,b]	1
Nausea[a,b]	1
Pneumothorax[b,d]	1
Urinary tract infection[b,d]	1
Liver cholestasis due to hematoma[c]	1
Hepatic hemorrhage[c]	1
[a]TR SAEs; [b]1pt, [d]Not procedure-related; [c]Procedure-related, 1pt.	