LTX-315, a first in class oncolytic peptide, reshapes the tumor microenvironment in the patients with advanced metastatic tumors: Results from an ongoing study

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Aim
- Evaluate the safety and tolerability of intra-tumoral LTX-315 in monotherapy or in combination with either ipilimumab or pembrolizumab in patients with transgressively accessible tumors
- Determine the recommended phase II dose and schedule

LTX-315 is a first in class oncolytic peptide with unique “release and reshape” MoA

Study Design
Primary Endpoints
- Safety (including DLTs, AEs, SAEs, lab assessments) of LTX-315

Secondary Endpoints
- LTX-315 related immune parameters in tumor and peripheral blood
- Anti-tumor activity of LTX-315 by CT scan assessment (immune-related response criteria (irRC))

Patient population
- Advanced/metastatic disease (all tumor types)
- At least one transversely accessible lesion of ≤ 10 cm in diameter

LTX-315 converts cold tumors to hot
Increase in CD8 gene expression in tumors upon LTX-315 treatment

LTX-315 generates a systemic tumor specific immune response
Case study: patient 471-016, Breast cancer, Monotherapy

T cell clones expanded in blood are detected in post-treated tumors
- 128 T cell clones expanded in blood post treatment.
- Clones expanding in blood were predominantly detected in post-treatment tumor samples.

T cell clones expanded in blood are detected in post-treated tumors

Study Conclusions
- LTX-315 converts “cold” tumors to “hot”, as evidences by increase of tumor infiltrating lymphocytes (CD8+ T cells) and gene expression analysis.
- TCR clonality analysis of blood and tumors samples show that LTX-315 generates a systemic anti-Tumor T cell response.
- LTX-315 is generally safe and tolerable. No MTD has been reached.
- In contrast, the expansion of pre-treatment tumor associated clones is less in all but one patient; median 29%.
- Contracted clones in blood were not detected in the tumors in 2 of the 6 patients.

Hierarchical Clustering of Immunosign® 21 Immune Gene Signature (HalioDx) which profiles expressions of a pre-defined set of effector T cell, Th1, chemokine, and cytokine genes.