LTX-315, a first in class oncolytic peptide reshapes the tumor microenvironment inducing a local and systemic effect in metastatic tumors: Results from an ongoing study.

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Background
LTX-315’s “Release and Reshape” MoA

- Unique immunogenic cell death mode of action by targeting the immunoprotective tumor microenvironment
- Induction of antitumor adaptive immune responses
- Systemic activation of antitumor adaptive immunity
- Conversion of cold tumors to hot

Summary of Phase 1-2 trials in 96 patients
- Phase 1: 30 patients
- Phase 2: 66 patients
- Treatment schedule:
  - Induction (6 w)
  - Maintenance (46 w)
- Median number of injected lesions per patient 1 (1 - 6)
- Median number of treatment weeks 6 (1 - 33)
- Treatment lasting 50 weeks (End of T)

Aim
The aim of this study is to evaluate the safety and tolerability of intra-tumor LTX-315 in a novel metastatic treatment setting.

Study design
Primary endpoints
- Safety (initial 3), efficacy (10 monotherapy efficacy), immunohistochemistry studies
- Secondary endpoints
- Efficacy (10 monotherapy efficacy), immunohistochemistry studies
- Immune-related response assessment

Treatment schedules - LTX-315

- Induction (6 w)
- Maintenance (46 w)
- Median number of injected lesions per patient 1 (1 - 6)
- Median number of treatment weeks 6 (1 - 33)
- Treatment lasting 50 weeks (End of T)

Safety study
- Safety of LTX-315 (N=28)
- Patients with at least one transdermally accessible lesion (in/ close to the skin) of ≤ 10 cm
- LTX-315 safety (N=28 patients)

Conclusion
- LTX-315 is generally safe and tolerable.
- The majority of AEs are grade ≤ 1 (19% of AEs)
- No grade ≥ 4 local or non-tumor related AEs
- Grade ≥ 3 LTX-315 related AEs: metastatic disease (2), pain on injection (2), and sepsis (1)
- 7 of 28 patients (25%) had CTC AE ≥ grade 3 related AEs including allergic reaction/anaphylaxis
- LTX-315 related adverse events (any grade) have been observed in 21 of 28 patients who received LTX-315 monotherapy (75%)
- LTX-315 monotherapy efficacy (suitable patients)
- BRIEF: observed in 15 evaluable patients
- Disease control rate: 53% (36/68 patients)
- Stable disease (median duration 11 weeks)
- Retrospective analyses (Phase 1-2) have been conducted
- Analyses are ongoing

References
2. Sveinbjørnsson, B et al.; Future Medicinal Chemistry (2017)