Presentation of ATLAS-IT-05 ESMO poster

Interim data and ATLAS-IT-05 Update

Webinar

October 23rd 2023

Lytix Biopharma

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LYTIX BIOPHARMA IN BRIEF

Company overview

- A listed, Norwegian, clinical-stage, immuno-oncology company
- Broad technology platform derived from world leading research on host defense peptides
- International management team with presence in both US and Europe
- US Life Science specialist as largest shareholder
- Strategy to bring multiple projects forward and partner for late-stage development and commercialization
- Nasdaq-listed Verrica Pharmaceuticals Inc. has licensed Lytix's LTX-315 for certain dermatologic oncology indications

Key Highlights

1. Positioned in the fastest growing segment in pharma, with revenue potential estimated to USD 120 bn
2. First in class molecules with potential to overcome the major challenge in current cancer therapy
3. Science validated by our strategic advisor, Nobel prize winner and founder of modern immunotherapy, Jim Allison
4. Two Proof of Concept Phase II studies ongoing, in basal cell carcinoma and melanoma
5. Lytix`s molecules can work in many different cancer indications, both as mono- and combination therapy
6. The versatility of our technology platform opens for a number of different types of commercial avenues

ATLAS-IT-05 DATA SNAPSHOT - ESMO 2023 POSTER PRESENTATION

INTRATUMORAL INJECTION OF LTX-315 IN COMBINATION WITH PEMBROLIZUMAB IN PATIENTS WITH ADVANCED MELANOMA REFRACTORY TO PRIOR PD-1/PD-L1 THERAPY: INTERIM RESULTS FROM THE ATLAS-IT-05 TRIAL

1051P

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BACKGROUND

LTX-315 is a first-in-class oncolytic peptide of non-viral origin that is in development for intratumoral treatment of solid tumors (1,2)

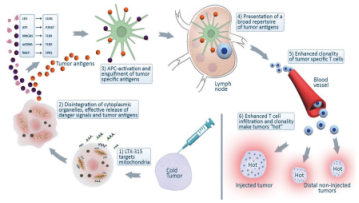
Pre-clinical studies of LTX-315 demonstrate:

- Unique immunogenic cell death mode of action by causing mitochondrial lysis and disintegration of cytoplasmic organelles resulting in effective release of danger signals and a broad repertoire of tumor antigens (3-6)
- Reduced number of immunosuppressive cells (T reg and myeloid derived suppressor cells) (7)
- Enhanced infiltration of T cells and T cell clonality (8)
- Complete regression of injected and non-injected tumors (i.e. systemic immune response) (8-10)

Clinical studies of LTX-315 demonstrate:

- Enhanced infiltration of T cells and T cell clonality (11, 12)
- Regression of injected and non-injected tumors (i.e. systemic immune response) (12)
- Generation of tumor-specific T cells (13)

LTX-315 - UNIQUE MODE OF ACTION RESULTS IN EFFECTIVE RELEASE OF POTENT IMMUNOSTIMULANTS AND ANTIGENS



STUDY OBJECTIVES AND ENDPOINTS

Objectives

Evaluate the efficacy and safety of intratumoral LTX-315 in combination with pembrolizumab in patients with Stage IIIB-IVm1b melanoma, who have progressed on or after prior treatment with a PD-1/PD-L1 inhibitor

Primary Efficacy Endpoint

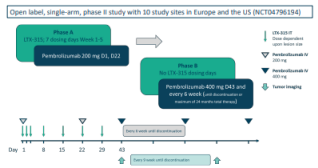
- Objective Response Rate (ORR) using RECIST v1.1 criteria assessed by investigators
- Disease Control Rate (DCR) using RECIST v1.1 criteria assessed by investigators

Secondary Efficacy Endpoint

- Regression of injected lesions assessed by CT/MRI or ultrasound measurements by investigators
- Incidence and severity of treatment emergent adverse events related to LTX-315

STUDY DESIGN

Open label, single-arm, phase II study with 10 study sites in Europe and the US (NCT04796194)



KEY INCLUSION AND EXCLUSION CRITERIA

- Histologically confirmed, Stage IIIB-IVm1b unresectable melanoma
- Confirmed disease progression on or after prior treatment with PD-1/PD-L1 inhibitor
- ≤3 prior lines of systemic treatment for metastatic disease
- ECOG performance status of 0-1
- At least 1 superficial, non-visceral tumor lesion accessible for injection - superficial lymph nodes with metastatic disease can also be injected
- LDH ≤ 2 x ULN
- No ocular or mucosal melanoma diagnosis

PATIENT DISPOSITION

	Number of patients
Patients with available data at cutoff date (13 September 2023)	20
Patients with melanoma diagnosis	19
Patients included in Safety Analysis Set (SAS)	20
Patients included in Efficacy Analysis Set (EAS)	14
Reasons for exclusion from EAS • No available post-baseline scan at cutoff date yet • Patient withdrew consent prior to first post-baseline scan • Only 1 available post-baseline scan and insufficient follow-up • No melanoma diagnosis*	3 1 1 1

*Patient with acinic cell carcinoma enrolled under earlier protocol version

Median duration on study was 15 weeks at cutoff date

BASELINE CHARACTERISTICS

Baseline characteristic	All patients (N=20)
Mean age (range)	68 years (42-91)
Sex Female Male	 9 (45%) 11 (55%)
ECOG 0 1	 16 (80%) 4 (20%)
Melanoma stage Stage IIIB Stage IIIC Stage IVM1a Stage IVM1b Stage IVM1c	 1 (5%) 4 (20%) 7 (35%) 3 (15%) 5 (25%)
Prior systemic treatment for metastatic disease* BRAF+MEK PD-(L)1+ monotherapy PD-(L)1+ CTLA-4 PD-(L)1 + other CTLA-4+ other	 4 (20%) 10 (50%) 8 (40%) 6 (30%) 1 (5%)

Baseline characteristic	All patients (N=20)
Prior systemic treatment lines in metastatic setting 0 1 2 3	 1 (5%)** 11 (55%) 6 (30%) 2 (10%)
Prior lines of treatment with checkpoint inhibitor 0 1 ≥2	 1 (5%)** 6 (30%) 13 (65%)
BRAF status Positive Negative	 5 (25%) 15 (75%)
LDH Normal >ULN	 9 (45%) 11 (55%)

*More than 100% as some patients received >1 systemic metastatic treatment line
**Patient with acinic cell carcinoma
All melanoma patients had prior surgery

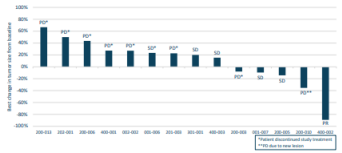
BEST OVERALL RESPONSE - RECIST V1.1

Best overall response (RECIST v1.1)	N (%)
Complete response	0 (0%)
Partial Response*	1 (7%)
Stable Disease	5 (36%)
Progressive Disease	8 (57%)

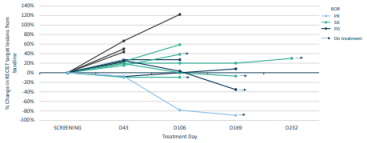
Objective Response Rate (ORR) = 7% (95% CI 1-30%)
Disease Control Rate (DCR)= 43% (95% CI 20-70%)

*Confirmed PR

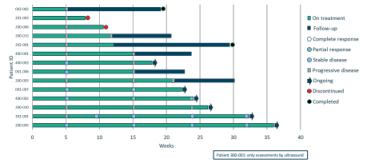
BEST CHANGE IN RECIST TARGET LESIONS



CHANGE IN RECIST TARGET LESIONS



RESPONSE ASSESSMENTS PER RECIST V1.1



RESPONSE IN INJECTED LESIONS

- 9 out of 21 (43%) evaluable injected lesions showed complete regression by CT scan as best response after start of treatment*
- Complete regression was shown in 3 out of 11 (27%) evaluable patients by CT scan

*Analysis includes 3X5 population, except:
- Injected lesions that were not injected per injection plan
- Injected lesions without baseline assessment of lesion size

OVERVIEW OF TREATMENT EMERGENT ADVERSE EVENTS (>10%) IN SAS

Preferred AE term	Patients n (%)
Injection site pain	15 (75%)
Asthenia	5 (25%)
Pruritus	5 (25%)
Anemia	5 (25%)
Fatigue	4 (20%)
Injection site erythema	4 (20%)
Injection site swelling	3 (15%)
Hypertension	3 (15%)

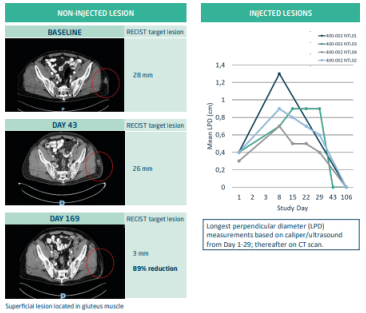
LTX-315 TREATMENT-RELATED ADVERSE EVENTS (>10%) IN SAS

Preferred AE term	Grade 1-2	Grade 3	Grade 4	Grade 5	Patients - n (%)
Injection site pain	10 (50%)	5 (25%)	0	0	15 (75%)
Injection site erythema	3 (15%)	1 (5%)	0	0	4 (20%)
Injection site swelling	3 (15%)	0	0	0	3 (15%)

- The most common (>10%) LTX-315 treatment-related adverse events were related to injections and mostly mild, self-limiting and manageable in clinical practice.
- There was no increase in immune-related adverse events.
- No grade 4-5 treatment-related adverse events were reported

CASE – MELANOMA PATIENT WITH CLINICALLY RELEVANT SYSTEMIC RESPONSE

- 75-year-old male with Stage IVm1a, nodular melanoma (BRAF positive)
- Multiple metastases in lymph nodes and gluteal muscle at baseline
- Prior treatment with nivolumab (adjuvant setting) and BRAF/MEK inhibitor (metastatic setting)
- Treated with in total 20 intratumoral LTX-315 injections in 4 lesions on pre-scribed dosing days and 2 cycles (200 mg) + 3 cycles (400 mg) pembrolizumab
- Non-injected RECIST target lesion in left gluteal muscle
- Partial response as best overall response at cutoff date with RECIST target lesion shrinkage of 89%



CONCLUSION

- The combination regimen demonstrates preliminary signs of tumor shrinkage and prolonged stabilization in heavily pre-treated patients with PD-1/PD-L1 inhibitor refractory metastatic melanoma.
  - Enrolled patients had generally poor prognostic factors and some patients had also failed BRAF/MEK inhibition.
- The efficacy signal is encouraging with a disease control rate of 43% and 1 patient achieving a partial response to date.
- There is evidence of tumor shrinkage in both injected and in non-injected lesions.
- Intratumoral treatment with LTX-315 is well-tolerated with mild to moderate treatment-related adverse events.
- Adverse events related to the intratumoral injections were generally self-limited and easily manageable in clinical practice.
- The trial is currently ongoing and data are considered immature - further details will be shared in a future presentation.

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Patient accrual (SAS): CHU Lyon 5; UPMC 3; MD Anderson 3; CU Navarra 3; CHRU Lille 2; Radiumhospital 2; Gustave Roussy 1; Mount Sinai 1.

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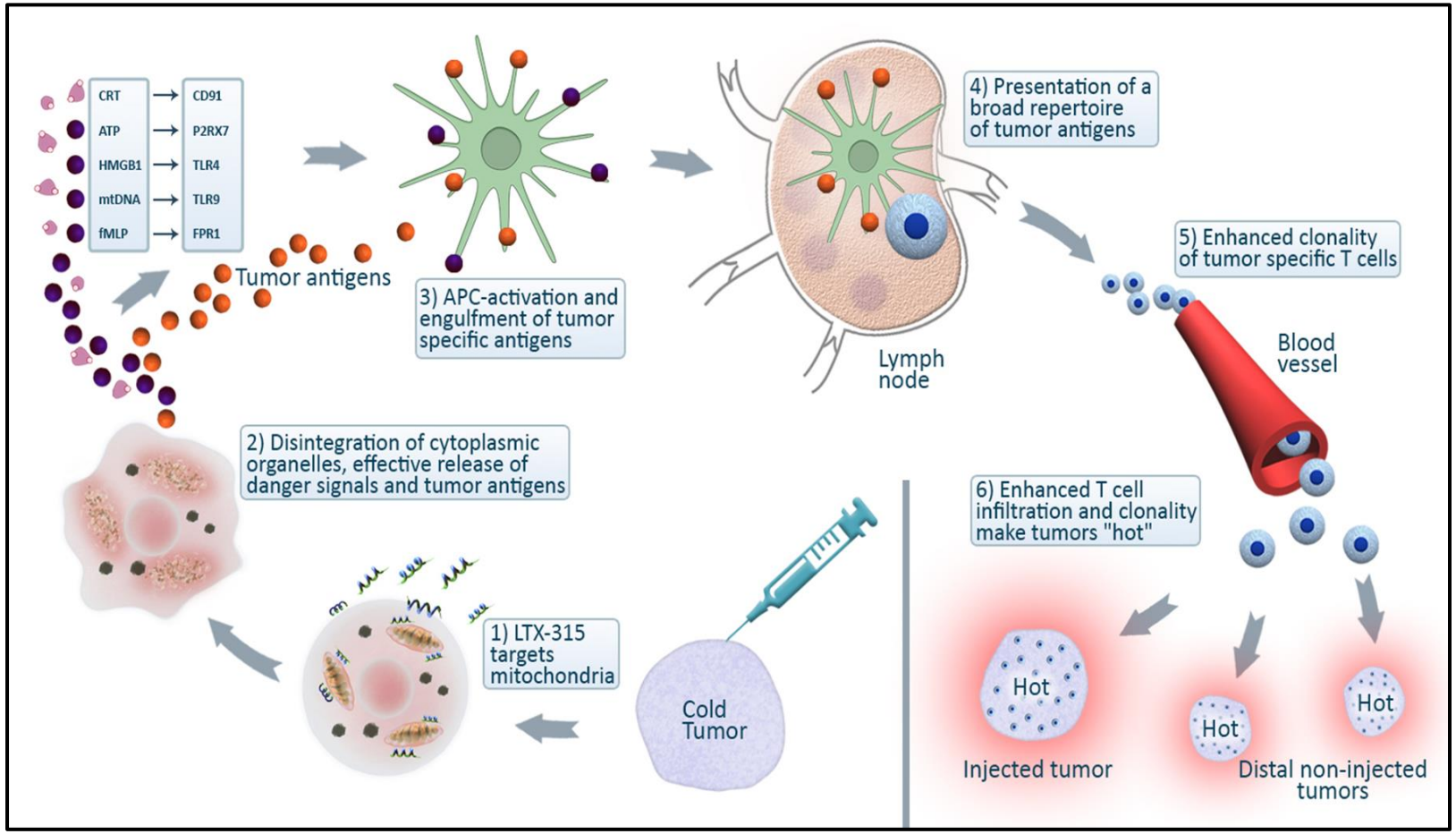
LTX-315 - UNIQUE MODE OF ACTION RESULTS IN EFFECTIVE RELEASE OF POTENT IMMUNOSTIMULANTS AND ANTIGENS



RECIST VERSION 1.1 - DEFINITIONS

- **Complete response:** disappearance of all tumor lesions
- **Partial response:** ≥30% decrease of target lesion(s)
- **Progressive disease:** ≥20% increase of target lesion(s) or presence of new lesion(s)
- **Stable disease:** neither partial response nor progressive disease

- **Objective Response Rate (ORR):** patients with complete or partial response
- **Disease Control Rate (DCR):** patients with complete/partial response or stable disease

STUDY OBJECTIVES AND ENDPOINTS

Objectives

- Evaluate the efficacy and safety of intratumoral LTX-315 in combination with pembrolizumab in patients with Stage IIIB-IVm1b melanoma, who have progressed on or after prior treatment with a PD-1/PD-L1 inhibitor

Primary Efficacy Endpoint

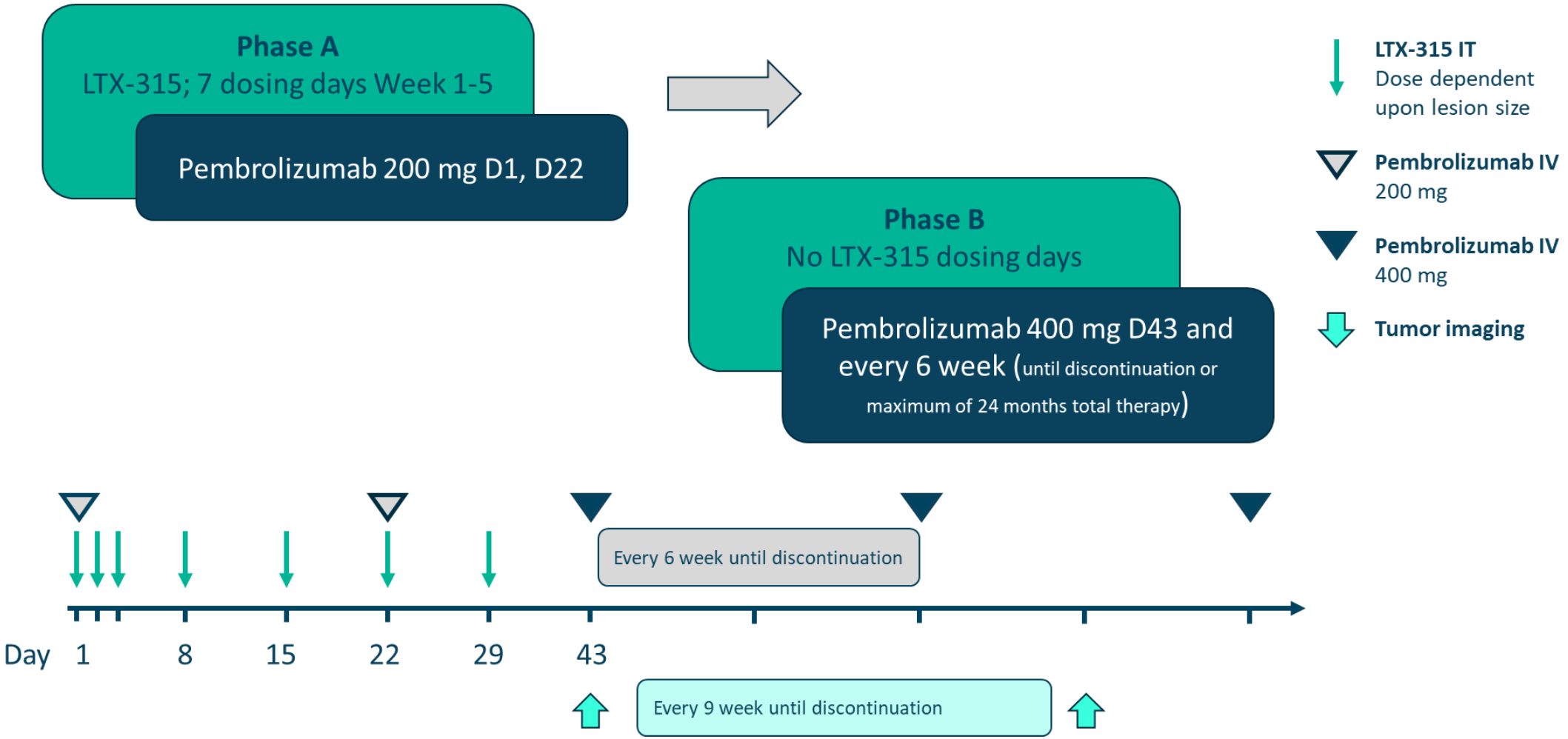
- Objective Response Rate (ORR) using RECIST v1.1 criteria assessed by investigators
- Disease Control Rate (DCR) using RECIST v1.1 criteria assessed by investigators

Secondary Efficacy Endpoint Objectives

- Regression of injected lesions assessed by CT or ultrasound measurements by investigators
- Incidence and severity of adverse events related to LTX-315

ATLAS-IT-05 STUDY DESIGN

Open label, single-arm, Phase II study with 10 study sites in Europe and the US (NCT04796194)



KEY INCLUSION AND EXCLUSION CRITERIA

- Stage IIIB-IVm1b unresectable melanoma
- Confirmed disease progression on or after prior treatment with PD-1/PD-L1 inhibitor
- ≤3 prior lines of systemic treatment for metastatic disease
- At least 1 superficial tumor lesion accessible for injection

ATLAS-IT-05 enrolled patients with very advanced disease, who were resistant or refractory to prior standard-of-care treatments (PD-[L]1 and/or CTLA-4 inhibitors) and in addition some to BRAF/Mek inhibitors

There is currently no approved treatment and limited options for the patients that were enrolled into the trial

PATIENT DISPOSITION IN FIRST DATA SNAPSHOT

	Number of patients
Patients included in Safety Analysis Set (SAS)	20
Patients included in Efficacy Analysis Set (EAS)	14

- The cutoff date for this data snapshot was 13 September 2023
- Median duration of follow-up was limited at the cutoff date - only 15 weeks

PATIENT POPULATION WITH VERY ADVANCED MELANOMA DISEASE AND POOR PROGNOSTIC BASELINE FACTORS

- Majority of patients (60%) had Stage IV disease and relatively high tumor burden
- 40% of patients had received 2 or more prior anti-cancer treatments in an advanced, metastatic disease setting – *including some patients with previous treatment with BRAF/MEK inhibitor, who are known to progress rapidly*
- 65% of patients had disease progression on at least two prior lines of checkpoint inhibitor therapy – *very heavily pre-treated patient population*
- 55% of patients had increased lactate dehydrogenase (LDH) levels at baseline – *well known factor associated with a poor prognosis*

BEST OVERALL RESPONSE - RECIST VERSION 1.1

Best overall response in EAS (n=14)	n (%)
Complete response	0 (0%)
Partial Response*	1 (7%)
Stable Disease	5 (36%)
Progressive Disease	8 (57%)

- Objective Response Rate (ORR) = 7% (95% CI 1-30%)
- Disease Control Rate (DCR)= 43% (95% CI 20-70%)

*Response was confirmed on subsequent CT scan indicating a durable response

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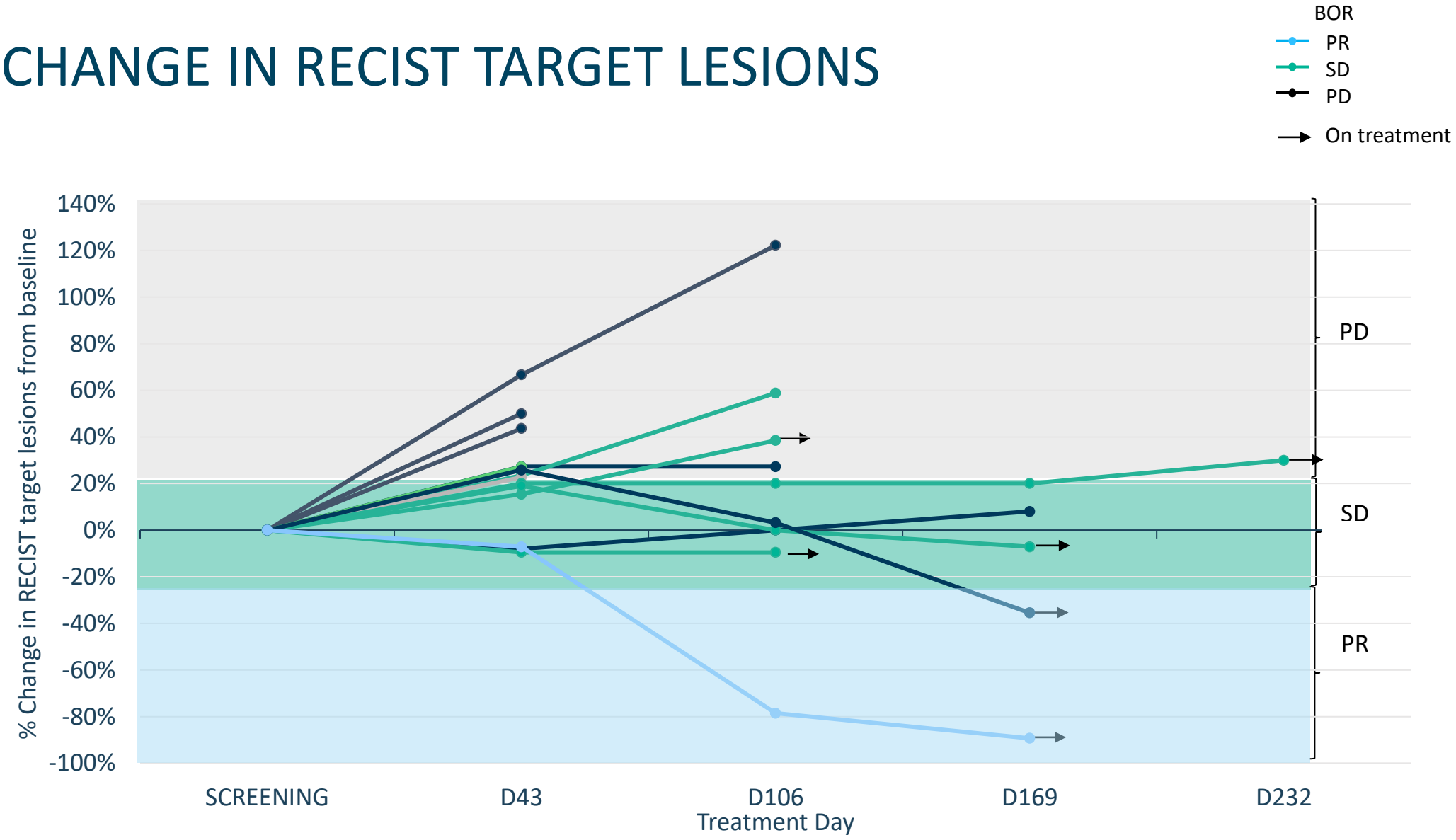
CHANGE IN RECIST TARGET LESIONS

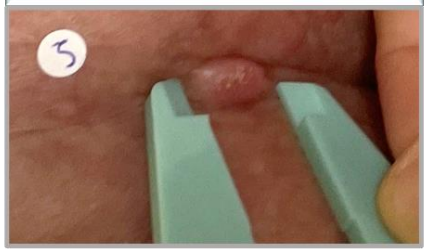


43% of patients included in this analysis are still on study treatment and still have the potential to respond in future assessment

RESPONSE IN INJECTED LESIONS

- 9 out of 21 (43%) **evaluable injected lesions** showed **100% complete regression** by CT scan after start of treatment
- Any **partial responses** were not captured in this assessment by CT
- Updated and more mature data on responses in injected lesions will be presented in the future

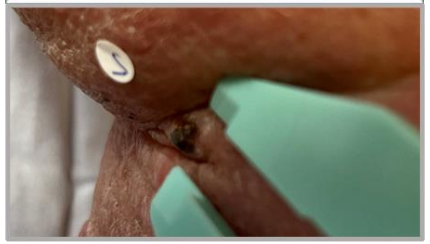
BASELINE



Mean of two longest perpendicular diameters

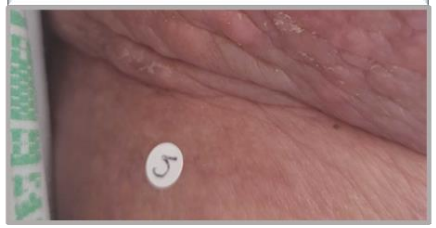
12mm

DAY 8- post LTX-315 dosing



NE

DAY43

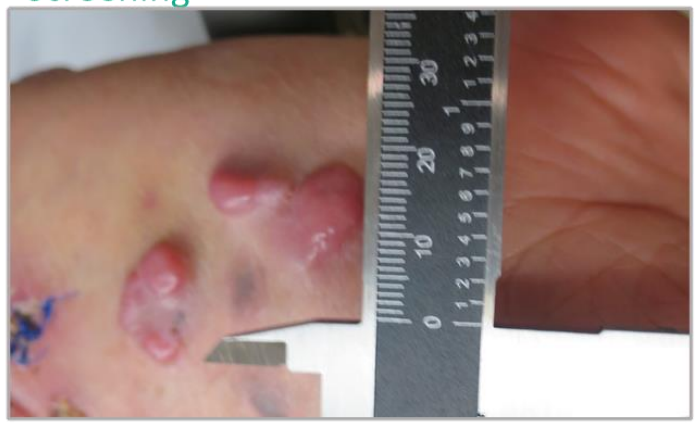


0 mm

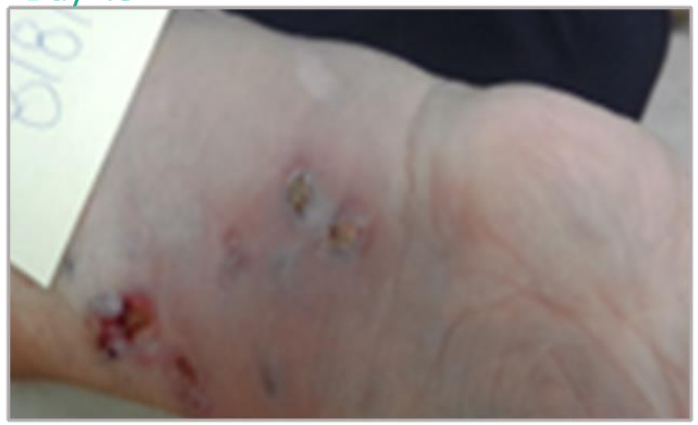
RESPONSE IN INJECTED LESIONS

- Patient with multiple large tumor lesions on right forearm that were injected with LTX-315*
- Clear signs of necrosis and regression of injected tumor lesions on Day 43

Screening



Day 43



*Patient was technically classified as PD due to emergence of a small lesion in the finger

LTX-315-RELATED ADVERSE EVENTS

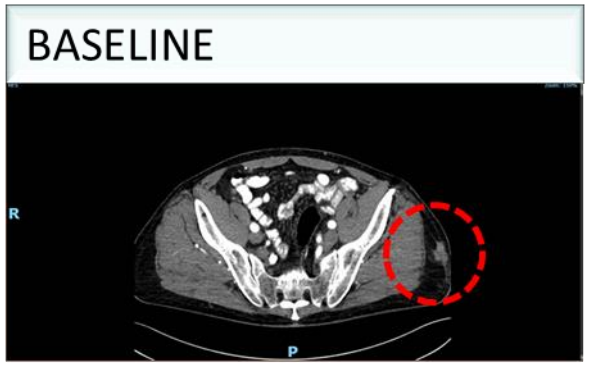
Adverse event	Mild	Moderate	Severe	Death	Patients - n (%)
Injection site pain	10 (50%)	5 (25%)	0	0	15 (75%)
Injection site erythema	3 (15%)	1 (5%)	0	0	4 (20%)
Injection site swelling	3 (15%)	0	0	0	3 (15%)

- The most common (>10%) LTX-315-related adverse events were local and mostly mild, self-limited and easily manageable in clinical practice.
- There was no increase in immune-related adverse events.
- No severe or lethal adverse events have been reported.

CASE #1 – MELANOMA PATIENT WITH CLINICALLY RELEVANT LOCAL AND SYSTEMIC RESPONSE

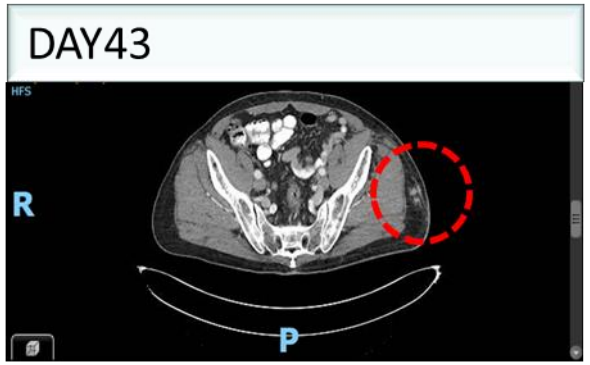
- 75-year-old male with Stage IVm1a, nodular melanoma (BRAF positive)
- Multiple metastases in lymph nodes and gluteal muscle at baseline
- Prior treatment with nivolumab (adjuvant setting) and BRAF/Mek inhibitor (metastatic setting)
- Treated with in total 20 intratumoral LTX-315 injections in 4 lesions on prescribed dosing days and 2 cycles (200 mg) + 3 cycles (400 mg) pembrolizumab
- Non-injected RECIST target lesion in left gluteal muscle
- Partial response as best overall response at cutoff date with RECIST target lesion shrinkage of 89%

NON-INJECTED LESION

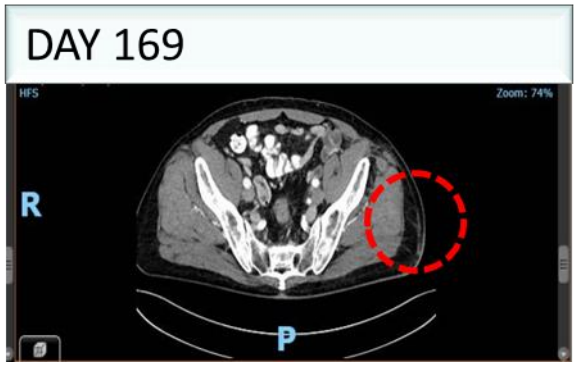


Target lesion size

28 mm



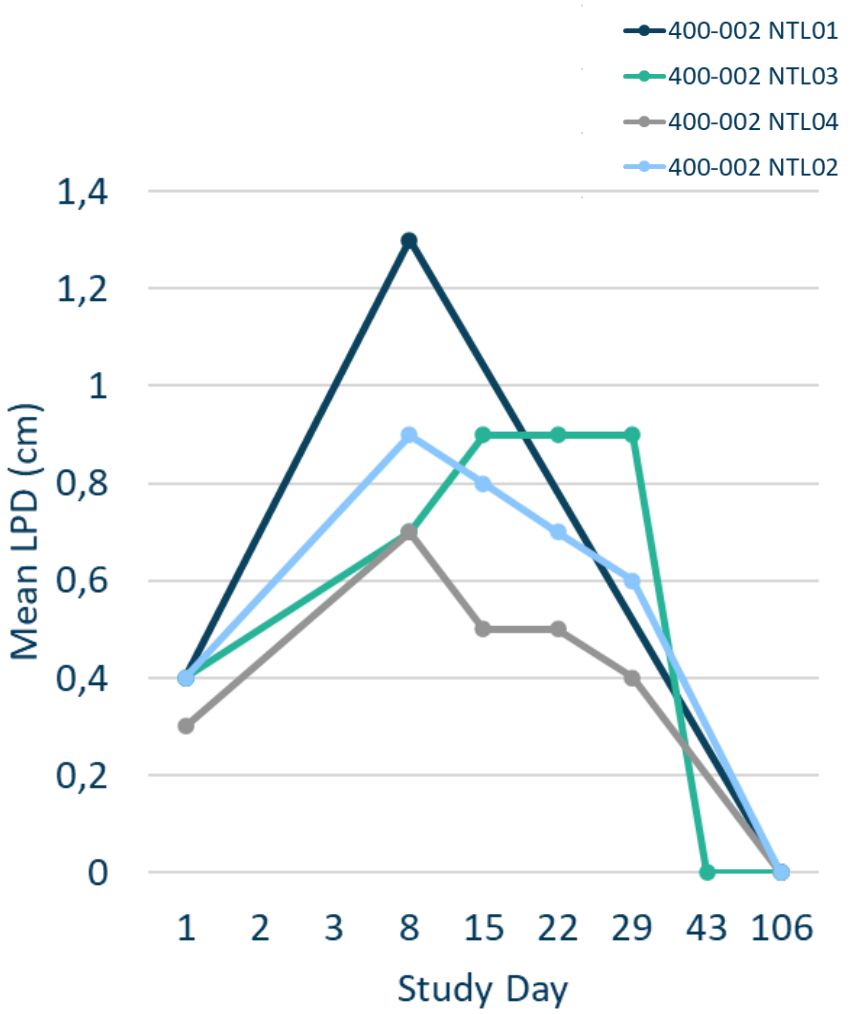
26 mm



3 mm

89% tumor shrinkage

INJECTED LESIONS

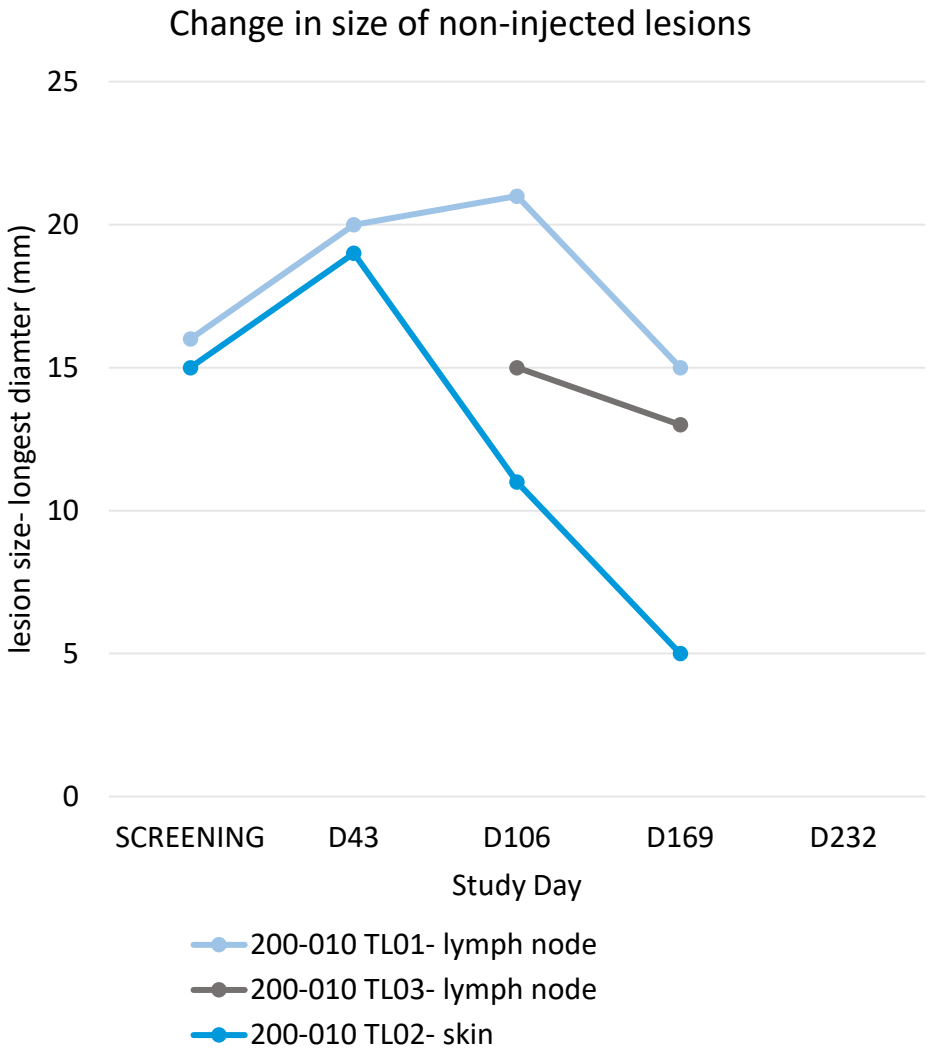


- **Complete regression of all injected lesions**

CASE #2 – MELANOMA PATIENT WITH CLINICALLY RELEVANT SYSTEMIC RESPONSE BUT PD DUE TO NEW LESION

- 77-year-old female patient with stage IVm1a melanoma
- Prior treatment with nivolumab in metastatic setting – disease progression while on treatment
- Treated with in total 30 intratumoral LTX-315 injections in 1 lesion on 6 prescribed dosing days and 2 cycles (200 mg) + 4 cycles (400 mg) pembrolizumab
- Non-injected RECIST target lesions in lymph node and skin
- Shrinkage of RECIST target lesions by -36% but appearance of new lesion, so not assessed as partial responder by RECIST v1.1. criteria

CASE #2 – MELANOMA PATIENT WITH CLINICALLY RELEVANT SYSTEMIC RESPONSE BUT PD DUE TO NEW LESION



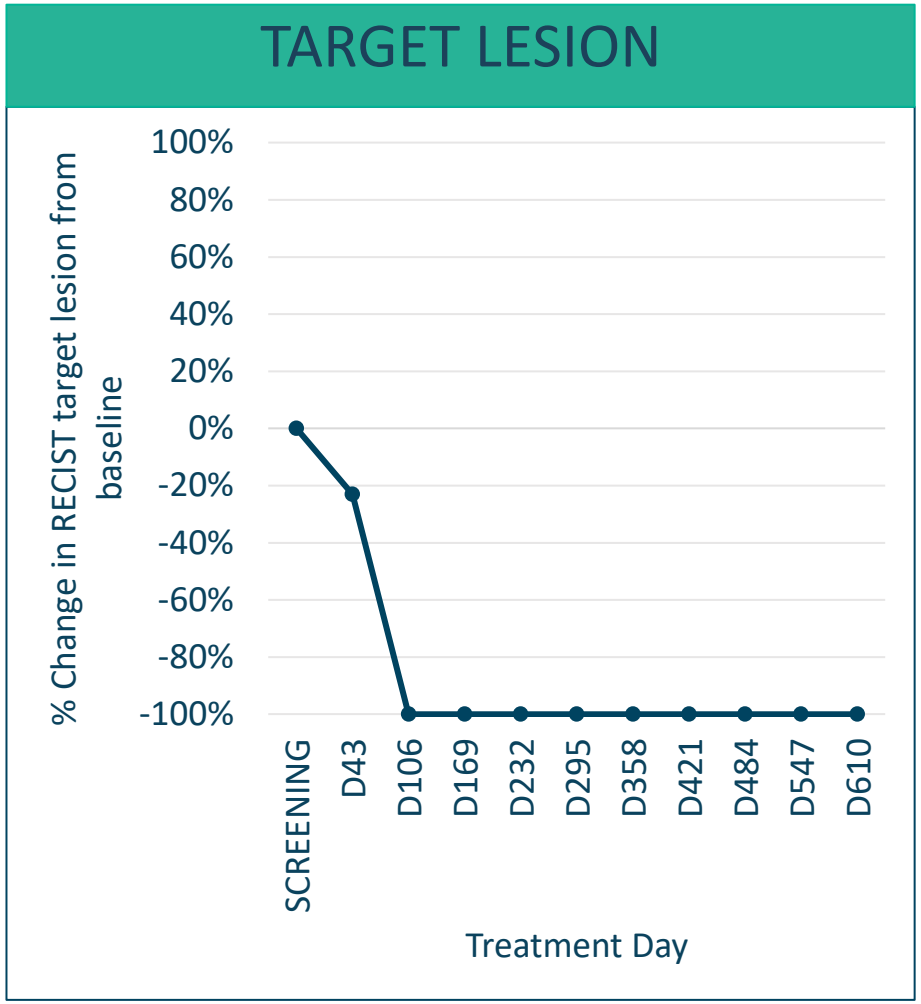
- Two non-injected lesions (TL01 and TL02) reduced in size (-36%)
- One new lesion (TL03 - lymph node) appeared at day 106
- By RECIST 1.1 criteria the patient has a progressive disease

CASE #3 – ACINIC CELL CARCINOMA PATIENT WITH DEEP AND DURABLE RESPONSE (NOT PRESENTED AT ESMO)

- 62-year-old female with stage IV acinic cell carcinoma was enrolled under a prior version of the study protocol
- Multiple metastases in bone, peritoneum, breast, adrenal gland and lung
- No prior treatment with checkpoint inhibitor
- Treated 7 dosing days with intratumoral injections of LTX-315 and 2 cycles (200 mg) + 15 cycles (400 mg) pembrolizumab
- Non-injected intramuscular RECIST target lesion
- Partial response as best overall response at cutoff date with durable RECIST target lesion shrinkage of -100% and complete regression in 4 out of 7 RECIST non-target lesions

CASE #3 – ACINIC CELL CARCINOMA PATIENT WITH DEEP AND DURABLE RESPONSE (NOT PRESENTED AT ESMO)

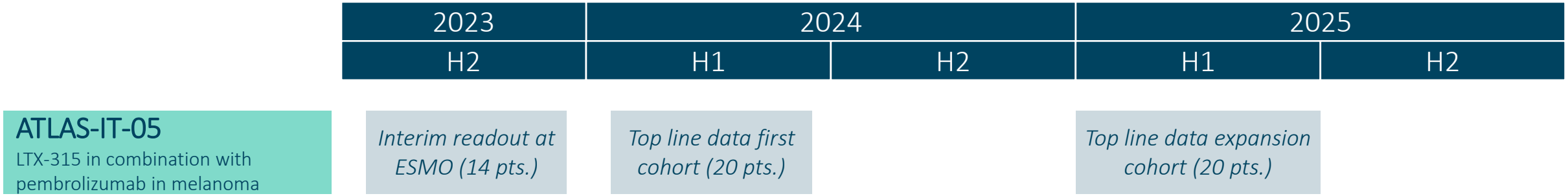
- Complete regression of non-injected target lesion (100% shrinkage)
- Very durable response **(>1.5 years**) suggesting a long lasting immune response
- Patients with acinic cell carcinoma tend to respond very poorly to monotherapy with PD-(L)1 inhibitor with response rates <5%



CONCLUSIONS BASED ON FIRST DATA SNAPSHOT

- The combination regimen demonstrates preliminary signs of tumor shrinkage and prolonged stabilization in heavily pre-treated patients with PD-1/PD-L1 inhibitor refractory metastatic melanoma.
  - Enrolled patients had generally poor prognostic factors and some patients had also failed BRAF/Mek inhibition.
- The efficacy signal is encouraging with a disease control rate of 43% and 1 patient achieving a partial response so far.
- There is evidence of tumor shrinkage in both injected and in non-injected lesions.
- Intratumoral treatment with LTX-315 is well-tolerated with generally mild to moderate adverse events.
- The trial is currently ongoing, this is a very early report and data are considered immature – further details will be shared in a future presentation.

ATLAS-IT-05 - NEXT STEPS



- Top line data from first cohort - H1 2024
- New amendment for initiation expansion cohort –Q4 2023
- Top line data expansion cohort – H1 2025

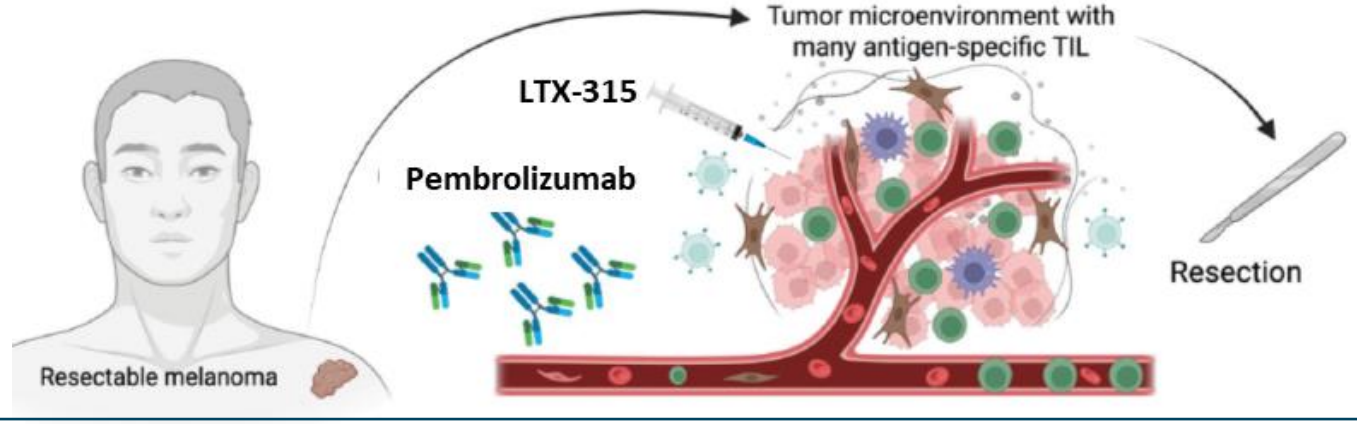
- Final readouts of first and second cohort depend on how long last patient is treated with pembrolizumab (until discontinuation or 24 months)

PLANNED NEOADJUVANT STUDY:
-LTX-315 IN EARLIER STAGE MELANOMA PATIENTS

- Neoadjuvant LTX-315 added to standard of care immune checkpoint inhibitor (pembrolizumab) in resectable stage III/IV melanoma
- Principal investigator, dr. Henrik Jespersen, Head of melanoma oncology, Oslo University Hospital - Radiumhospitalet
- Study start: 1H 2024
- Rationale:
  - Investigate any added clinical effect of LTX-315 in earlier stage patients with a stronger immune system
  - Expected to result in more effective T-cell priming and reduce risk of relapse compared with pembrolizumab monotherapy

Neoadjuvant therapy: Treatment before surgery

Lytix molecules may have a potential in neoadjuvant setting in several cancer indication



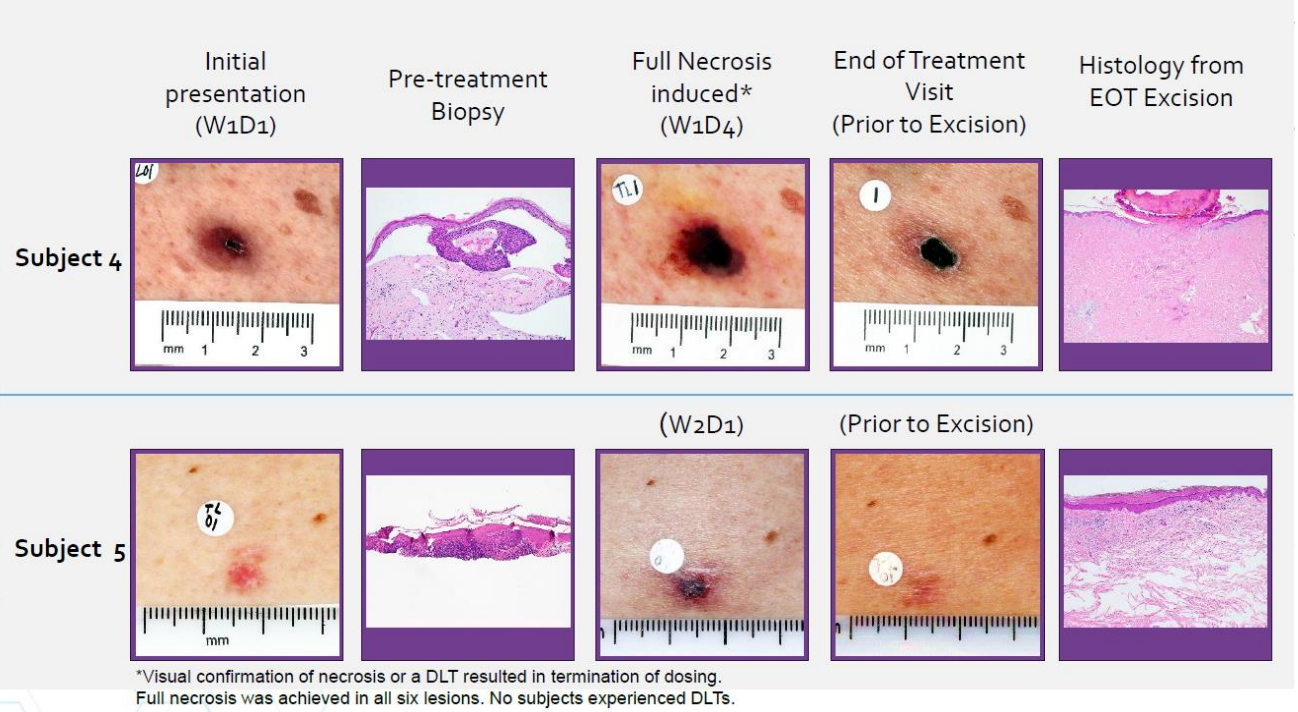
Source: Figure adapted and modified from Saad & Tarhini, Current Oncology Reports 2023

POSITIVE EARLY RESULTS FROM ONGOING PHASE II STUDY IN BASAL CELL CARCINOMA

- Of the six patients treated with LTX-315 at the highest dose, complete clearance was observed in four injected lesions, 95% and 30% clearance in two other injected lesions

Subject 4 presented with BCC and received three consecutive daily doses of 8 mg VP-315. Complete lesion clearance achieved.

Subject 5 presented with BCC and received three consecutive daily doses of 8 mg VP-315. Complete lesion clearance achieved.

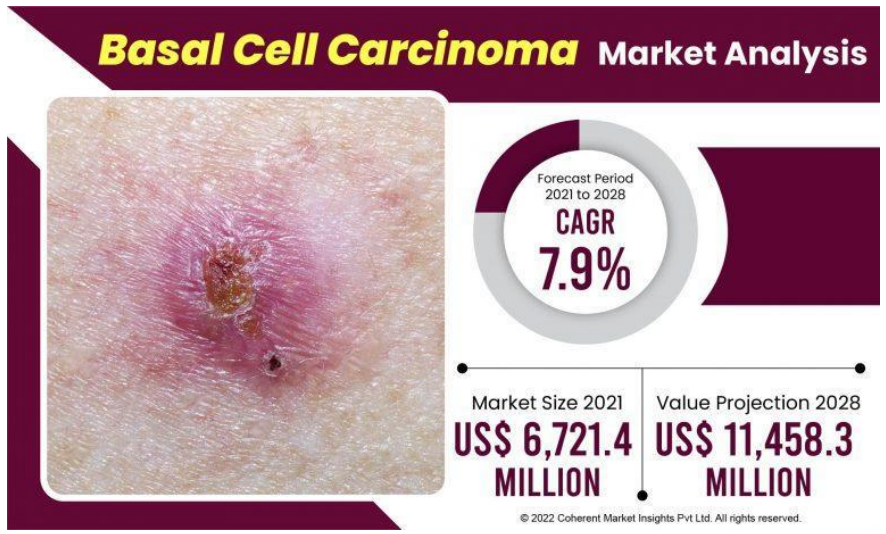


*Visual confirmation of necrosis or a DLT resulted in termination of dosing.
Full necrosis was achieved in all six lesions. No subjects experienced DLTs.

Phase II study expected to be completed mid 2024

Source: Dr. Neal Bhatia; AAD INNOVATION ACADEMY 2023, August 10-13th, Tampa Florida

BASAL CELL CARCINOMA MARKET



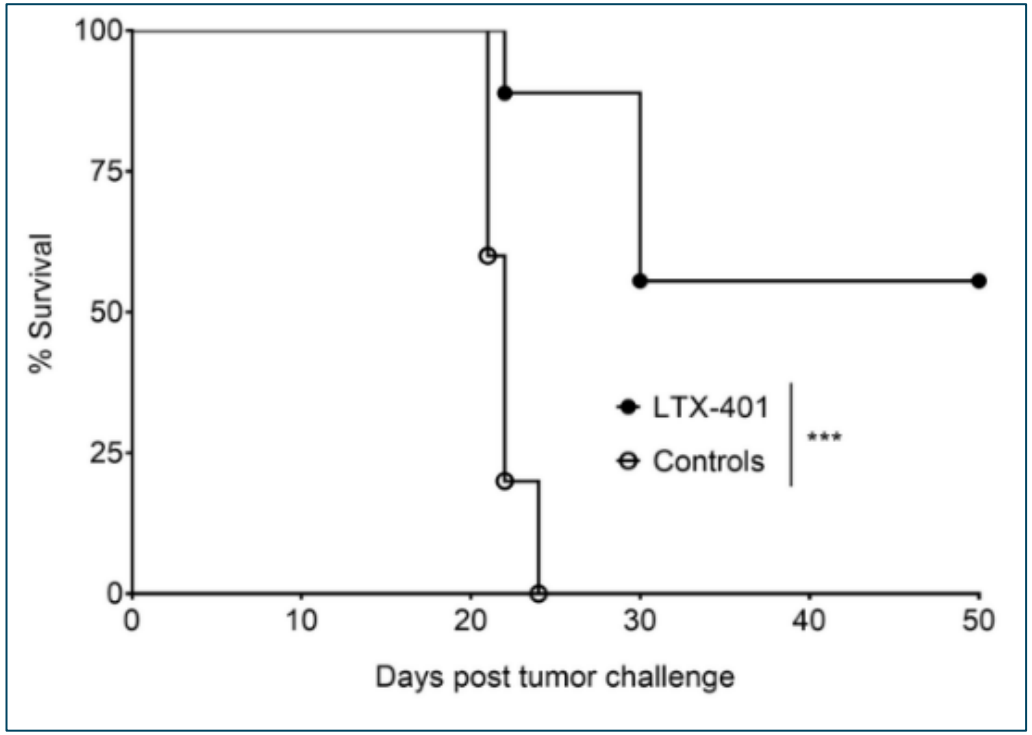
Verrica has also global **rights** to enter into squamous cell carcinoma

- Current treatment(s) for BCC are invasive, painful, disfiguring, and may require destruction of healthy tissue
  - LTX-315 represent a non-surgical alternative for patients suffering from skin cancer
- The BCC market size is expected to increase from 6.7 billion USD in 2021 to 11.4 billion USD by 2028
- Worldwide license agreement with LTX-315 for specific types of skin cancer
  - Regulatory and sales milestones at >100 mill. USD
- Royalty rates from low double-digits to mid-teens (net sales)

LTX-401: OPTIMIZED FOR DEEP-SEATED SOLID TUMORS

- Superior effects in several different pre-clinical cancer models, including liver cancer
- Strong synergy with checkpoint inhibitors
- Favorable safety profile
- Phase I ready
- Fully owned
- Ideal for deep seated tumors with a large commercial potential

LTX-401 cured 50% of the animals with liver cancer



SUMMARY

- The combination with LTX-315 and pembrolizumab demonstrates encouraging preliminary result in heavily pre-treated melanoma patient with one partial response and a disease control rate of 43%
- Top line data from all 20 patients in cohort 1 will be presented in Q1 2024.
- An amendment for the initiation of an expansion cohort with up to 20 additional patients in process to be submitted
- A neoadjuvant study in early-stage melanoma with LTX-315 and standard of care pembrolizumab planned to start early 2024
- Promising early results from Verrica`s Phase II study in basal cell carcinoma
- Lytix`s molecules can work in several different cancer indications, both as mono- and combination therapy
- The versatility of our technology platform opens for a number of different types of commercial avenues