

# Lytix Biopharma AS

*At the forefront of innovative cancer therapy*

Fourth quarter 2021 presentation

February 17, 2022



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# Today's presenters



## Øystein Rekdal / CEO and co-founder

- Dr. Rekdal's post-doctoral research forms the basis of Lytix Biopharma's oncolytic molecule platform.
- Over the last years Rekdal has been instrumental in the development of intra-tumoral therapy of LTX-315 from preclinical to clinical 'proof of concept'-studies.
- He previously served Lytix in various roles including CSO, and Head of R&D.



## Graeme Currie / CDO

- Has 30 years of drug development experience in pharmaceutical, medium and small biotechnology companies .
- Most recently Chief Development Officer of Tolerion Inc.
- Has held senior leadership roles at both public and privately held biotech organizations.
- Dr. Currie has been integrally involved in the development of 8 approved new drugs.
- Dr. Currie holds a Ph.D. from Aston University in the UK.



## Gjest Breistein / CFO

- Mr. Breistein has eight years of experience from PwC as an auditor and consultant working with public and private companies across multiple industry sectors.
- Prior to joining Lytix Biopharma, he was in PwC's capital markets group advising clients in capital market transactions, financing and listing processes.

# Lytix Biopharma in brief

Lytix is a biotech company headquartered in Oslo, Norway.

The company was listed at Euronext Growth in June 2021.

Lytix has developed a unique and proprietary technology platform for *in situ vaccination*.

Lytix aims to accelerate progression of this unique platform, building a pipeline of oncolytic molecules for intratumoral injection.

The lead asset is in a clinical Phase II at MD Anderson Cancer Center, targeting several cancer indications.

A second clinical Phase II trial is expected to commence in Q1 2022, performed by our commercial partner Verrica Pharmaceuticals.



# Highlights of the quarter

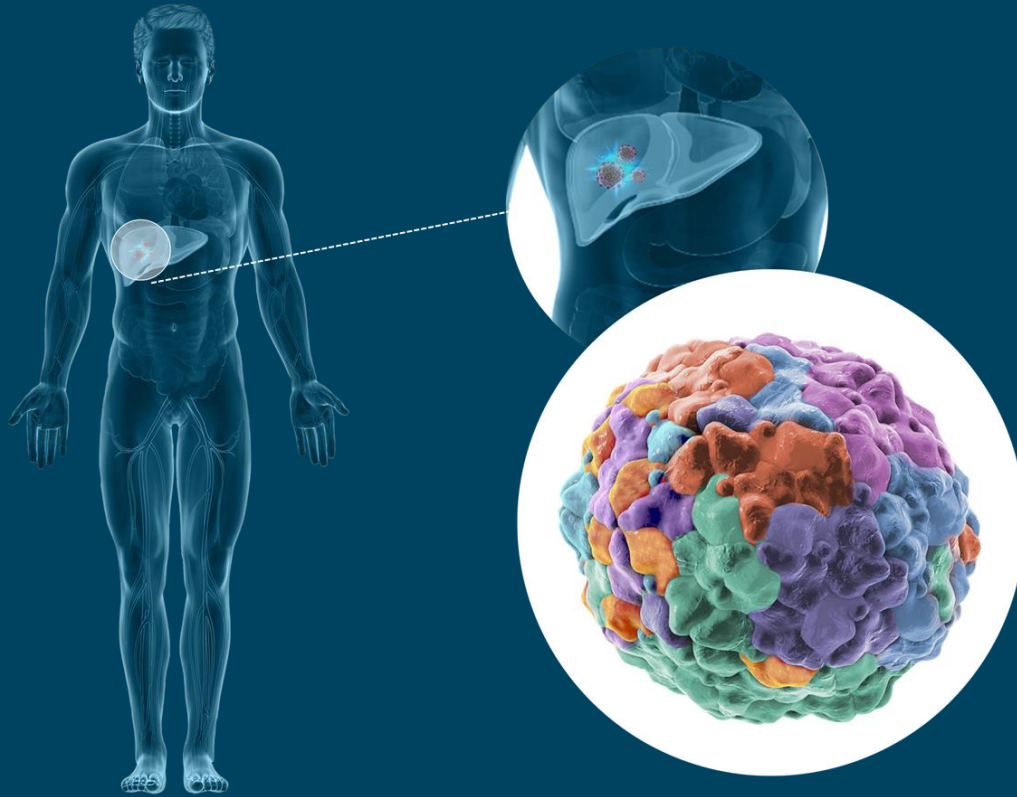
## Highlights of the fourth quarter 2021

- Lytix' partner Verrica Pharmaceutical's approval for Phase II study in the US for skin cancer diseases
  - Verrica received US FDA approval to initiate its Phase II study with LTX-315 for the treatment of basal cell carcinoma
  - First patient due to be dosed in the first quarter of 2022
- Kick-off for Phase II study in the US with our lead cancer drug candidate LTX-315
  - First patient dosed at MD Anderson Cancer Center in Texas (ATLAS-IT-05)

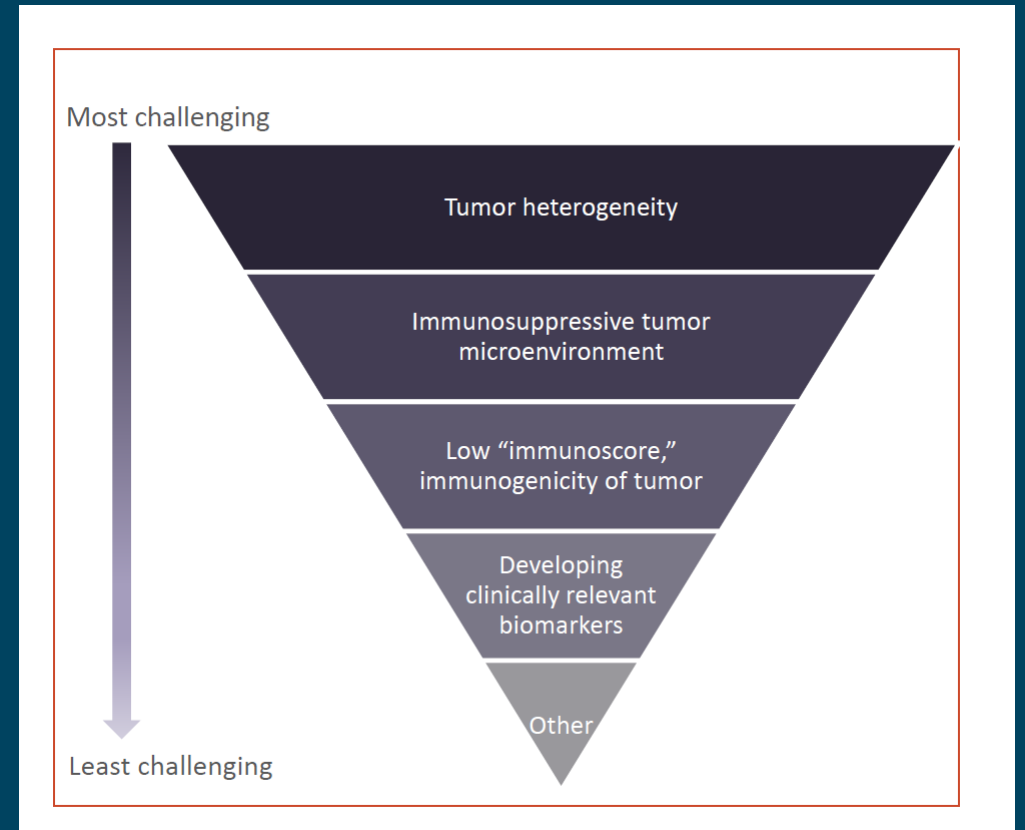
## Highlights of the fourth quarter 2021

- Treatment completed in Phase II study for patients with soft tissue sarcoma,
  - Data to be presented at international conference Q2/Q3
- Key pre-clinical data presented at SITC (Society for Immunotherapy of Cancer) annual meeting
- One additional patent granted in the EU
  - Strengthening Lytix' business case and long-term value generation

# Oncolytic molecules solve one of the major challenges in current cancer therapy



Tumors consist of many different cancer cells with different mutations

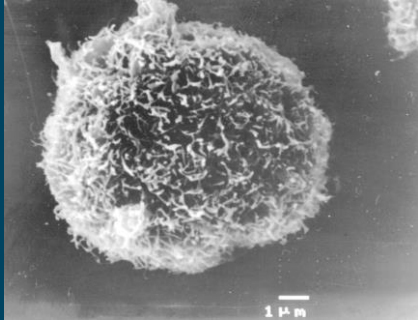


Source: GlobalData High-Prescriber Survey (December, 2020)

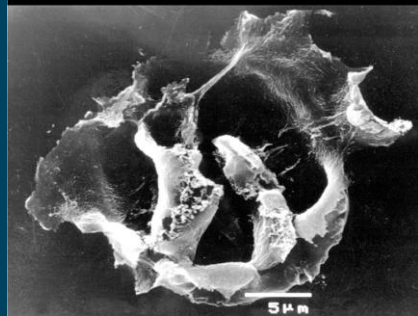


# Oncolytic molecules provide a new *in situ* vaccination principle

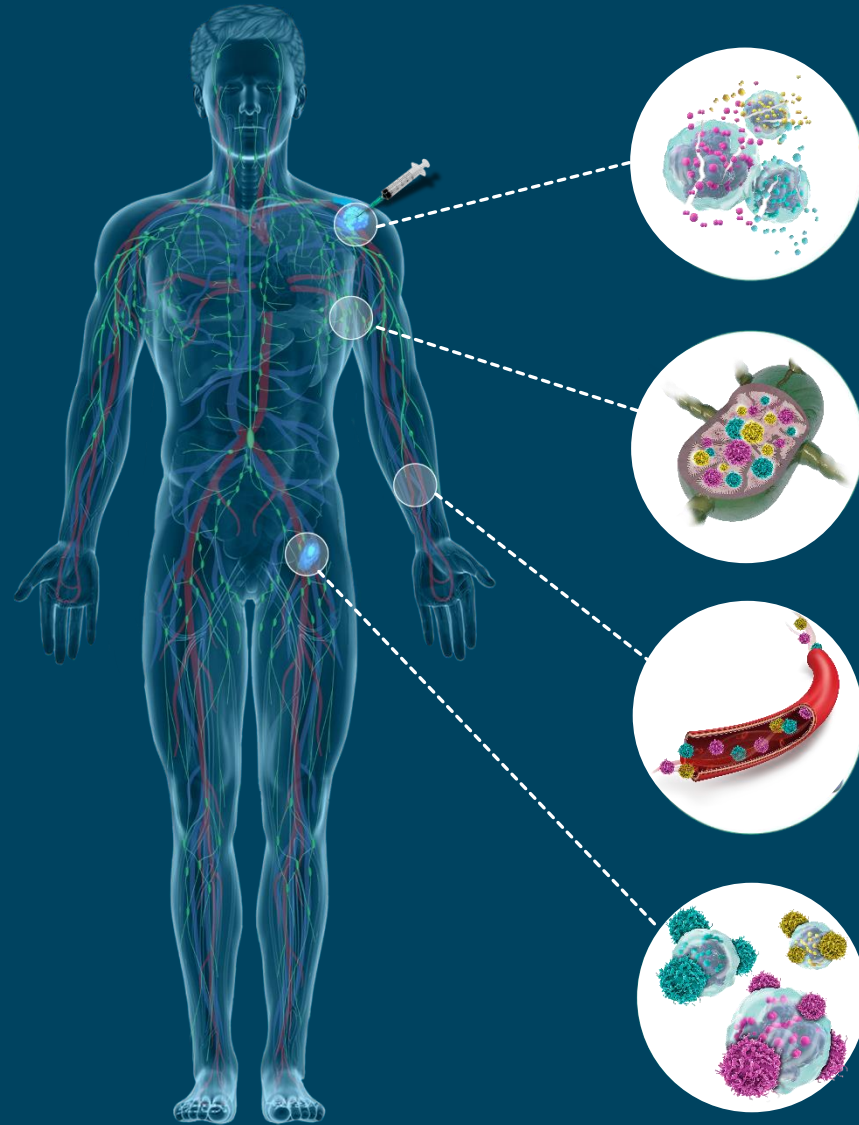
A cancer cell before treatment



A cancer cell after treatment



Immunogenic  
cell death



## TREATED TUMOR

Exposure of mutations (tumor antigens) from all dead cancer cells

## LYMPH NODE

Generating T cells that recognize the different mutations (tumor antigens)






## BLOOD VESSELS

T cells enter the blood stream searching for cancer cells

## NON-TREATED TUMOR

T cells infiltrate and eradicate distant cancer cells

# A unique technology platform with high commercial potential

Product candidate	Combination partner	Population	Preclinical	Phase I	Phase II	Phase III	Collaborations
LTX-315	ATLAS-IT-05 Pembrolizumab (Keytruda®)	Patients progressed on checkpoint inhibitors	→				    
	N/A (monotherapy)	Basal cell carcinoma	→				
	ATLAS-IT-04 Adoptive T-cell therapy	Advanced soft tissue sarcoma	→				
LTX-401	Monotherapy	Liver cancer	→				
LTX-122	Adoptive T-cell therapy	Dog lymphoma	→				
<b>A unique technology platform</b>	<b>Inspired by nature</b> Based on the scientific concepts of naturally occurring host defense proteins, scientifically improved for cancer therapy			<b>In situ vaccination platform</b> Candidate drugs to be directly injected into solid tumors priming the immune system for potent activation			

# Lytix targets large market opportunities

## HEAD AND NECK CANCER

**130.000\***  
new patients diagnosed

**3.7 Bn USD\***  
estimated indication value

## LIVER CANCER

**260.000\***  
new patients diagnosed

**5.3 Bn USD\***  
estimated indication value

## MALIGNANT MELANOMA

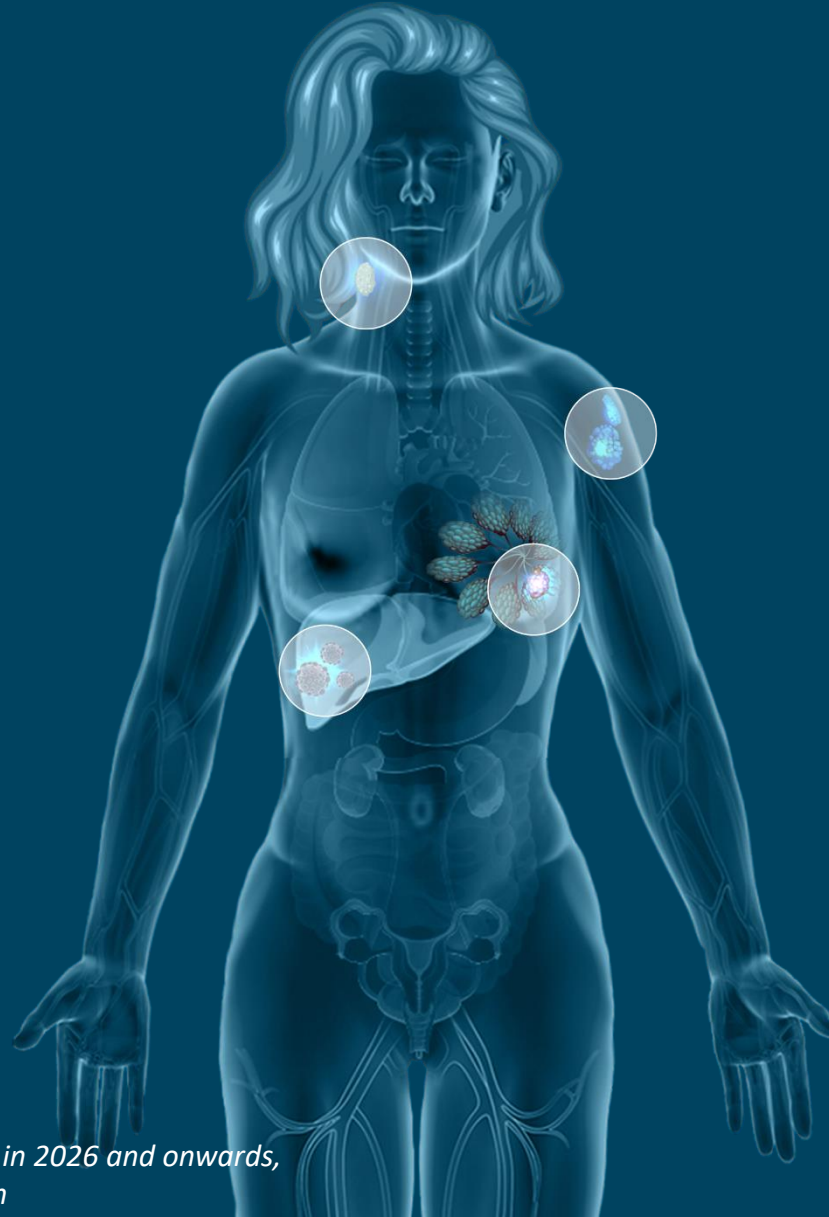
**200.000\***  
new patients diagnosed

**5.5 Bn USD\***  
estimated indication value

## BREAST CANCER

**970.000\***  
new patients diagnosed

**12.2 Bn USD\***  
estimated indication value





# Clinical/operational update

# Lytix partner Verrica Pharmaceutical's approval for Phase II study in the US for skin cancer diseases

- Verrica in-licensed LTX-315 for certain skin cancer types in August 2020
- Verrica intends to focus on the most common malignancy in humans<sup>1</sup>, as the lead indications
  - Estimated 5.4 million diagnoses of basal cell and cutaneous squamous cell carcinomas annually in the US alone
- Verrica received US FDA approval for the Phase II study in November 2021
  - The first patient is expected to be enrolled in Q1 2022



## Lytix partner Verrica Pharmaceutical's approval for Phase II study in the US for skin cancer diseases,

- Regulatory milestones based on development goals and sales milestones at >100 mill. USD
- Royalty rates from the low double-digits to the mid-teens based on net sales USD
- Together, basal cell and cutaneous squamous cell carcinomas represent a large market opportunity



# Kick-off for Phase II study in the US with our lead cancer drug candidate LTX-315 (ATLAS-IT-05)

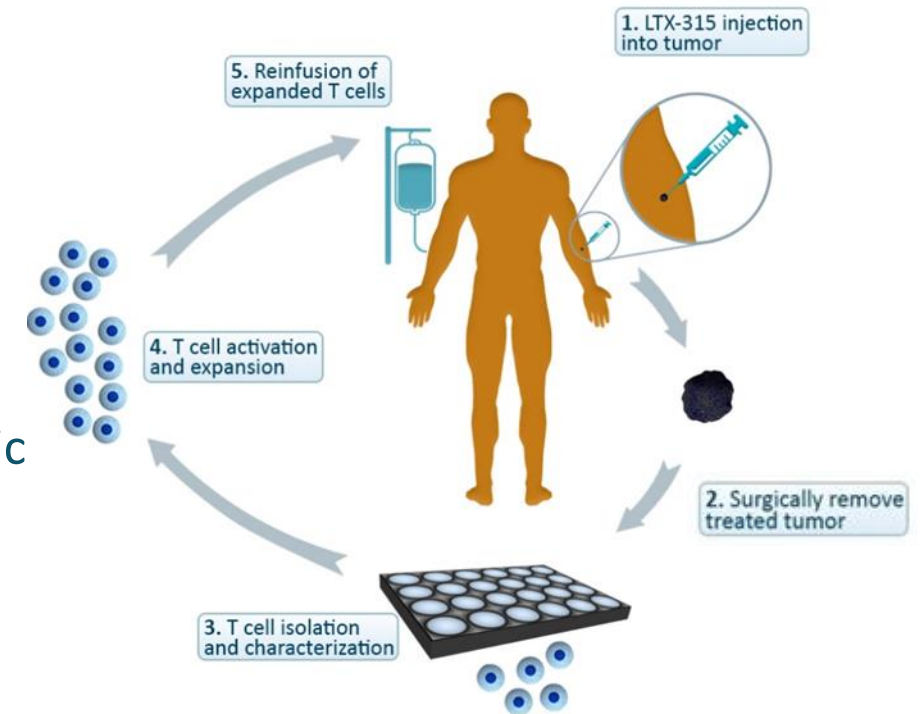
- ⊗ Building value in metastatic setting through clinical Phase II study in the US
- ⊗ A Phase II combination study evaluating LTX-315 and pembrolizumab in patients with solid tumors
- ⊗ First patient dosed at MD Anderson Cancer Center in December
  - Two sites have initiated recruitment, and enrollment is on track to be completed by the end of 2022
  - Additional sites in Europe and Australasia will initiate recruitment in 2022



# Fully enrolled Phase II study for patients with soft tissue sarcoma (ATLAS-IT-04)



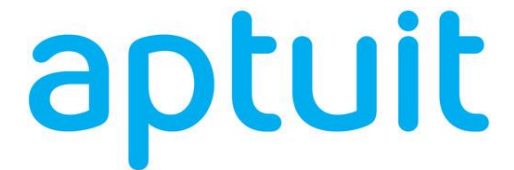
- A proof of principle study
  - evaluating LTX-315 in combination with adoptive T-cell therapy in advanced soft tissue sarcoma patients
- Treatment completed
- Data analysis ongoing
  - Clinical efficacy
  - LTX-315's ability to generate tumor specific T cells
- Results will be presented at an international cancer congress Q2/Q3





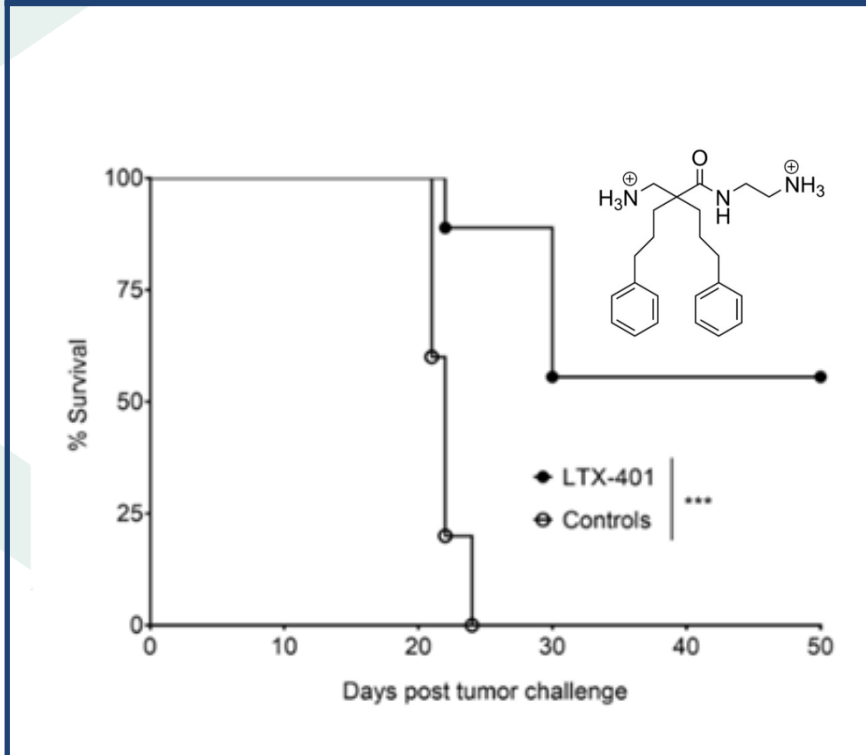
# LTX-401 – a next generation oncolytic molecule expanding the application of *in situ* vaccination

- A pre-clinical safety program evaluating LTX-401 is ongoing at Aptuit in Italy and is expected to complete 2022
- A second-generation oncolytic molecule with chemical properties suited for deep seated lesions, such as liver cancer
- Favorable safety data confirmed
  - LTX-401 is well tolerated in animals
  - Maximum tolerated dose established
- Phase I study planned in Europe
  - Preparations are ongoing

 aptuit

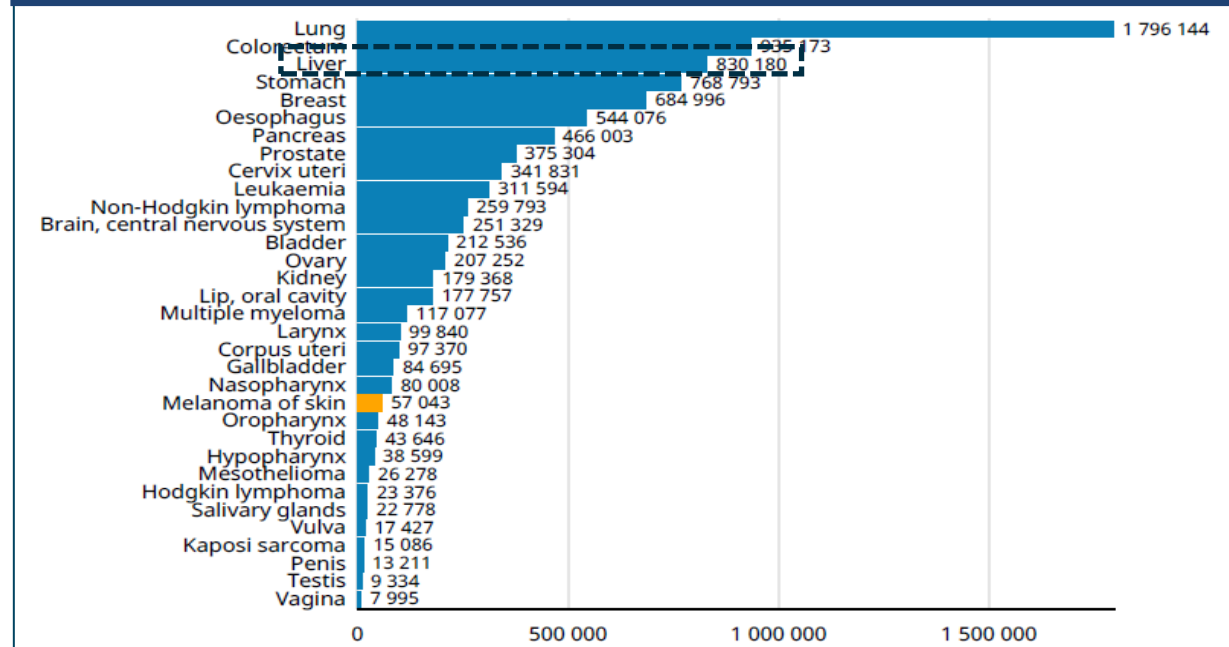
# LTX-401, a next generation oncolytic molecule targeting liver cancer

## LTX-401: Promising results in liver cancer animal models



LTX-401 treatment cured 50 % of animals with only 2 injections

## Number of deaths in 2020, all ages



Third most common cause of cancer related death globally, where hepatocellular carcinoma accounts for 80-90 % of the cases

Unmet need is high due to disease severity and low survival rates

# Summary and priorities for 2022

## Highlights of second half 2021

- Kick-off for Phase II study in the US with our lead cancer drug candidate LTX-315
- Fully enrolled Phase II study for patients with soft tissue sarcoma
- Lytix' partner Verrica's approval for Phase II study in the US for skin cancer diseases
- Key clinical data presented at the Society for Immunotherapy of Cancer
- Three additional patents granted in the EU and US

## Priorities for 2022

- Our Phase II combination trial, ATLAS-IT-05, is on track to complete enrollment by the end of 2022
- A second clinical phase II trial is expected to commence in Q1 2022, performed by our commercial partner Verrica Pharmaceuticals
- Data from the ATLAS-IT-04 trial is being prepared for presentation at an international cancer congress later this year
- We are mapping additional opportunities to expand our innovative pipeline of molecules



# Financials

# Key figures – profit and loss

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q4 2021	<i>Unaudited</i> Q4 2020	<i>Unaudited</i> H2 2021	<i>Unaudited</i> H2 2020	<i>Unaudited</i> FY 2021	FY 2020
Total operating income	719	1,951	2,626	5,433	25,827	6,678
Total operating expenses	(17,087)	(14,598)	(37,790)	(33,372)	(73,844)	(49,050)
Loss from operations	(16,368)	(12,646)	(35,164)	(27,940)	(48,017)	(42,372)
Loss for the period	(16,395)	(12,491)	(35,301)	(27,669)	(48,049)	(42,088)

- ⦿ Total operating expenses for the six ended 31 December 2021 were related to:
  - Increased R&D activities in connection to the ongoing ATLAS-IT-05 trial
  - Completing the ATLAS-IT-04 trial in Denmark
  - Progression of the preclinical development of LTX-401

# Key figures – balance sheet

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> 31.12.2021	31.12.2020
<b>Assets</b>		
Trade and other receivables	5,680	4,168
Cash and cash equivalents	197,282	28,450
<b>Total assets</b>	<b>202,962</b>	<b>32,617</b>
<b>Shareholder's equity and liabilities</b>		
Total equity	189,624	19,889
Total liabilities	13,338	12,728
<b>Total equity and liabilities</b>	<b>202,962</b>	<b>32,617</b>

- ⊗ Cash position at the end of the period was NOK 197.3 million compared to NOK 28.5 million as of December 31, 2020



# Company presentation



## FIRST IN CLASS

Unique therapeutic approach with universal mechanism of action

Promising efficacy signals in patients



## ENTERING PHASE II STUDIES IN U.S.

LTX-315 in Phase II development in US led by # 1 cancer hospital globally

Verrica's Phase II study to commence in Q1



## VALIDATED

Nobel Prize winner at the advisory board

Commercial deal within skin cancer

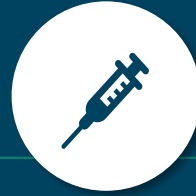
US biotech specialist investor on board





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FIRST IN CLASS



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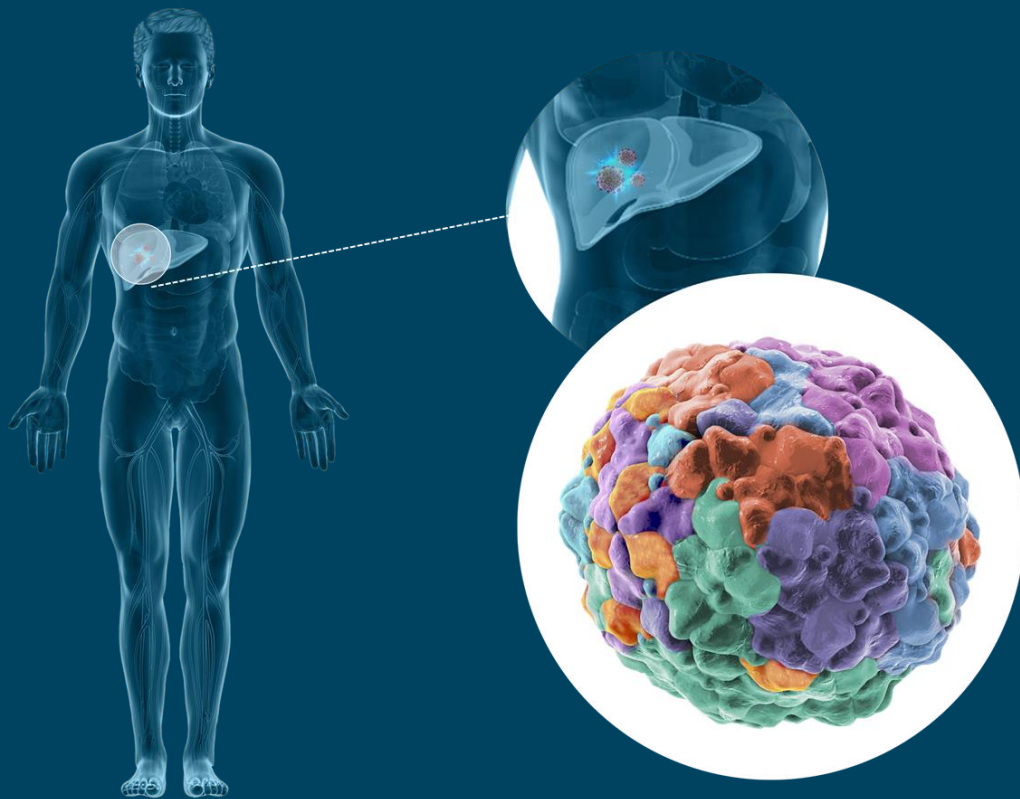
ENTERING PHASE II  
STUDIES IN U.S.



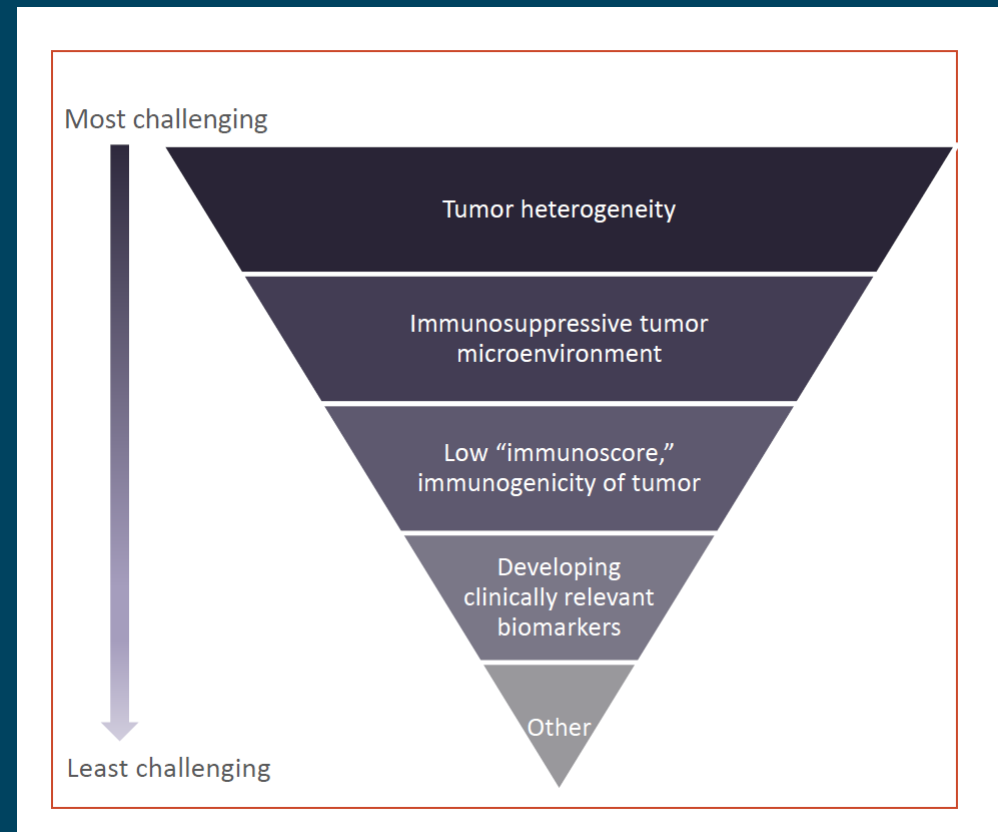
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VALIDATED

# Oncolytic molecules solve one of the major challenges in current cancer therapy



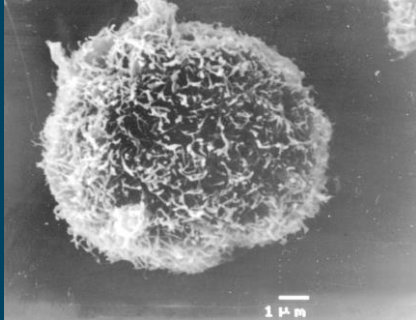
Tumors consist of many different cancer cells with different mutations



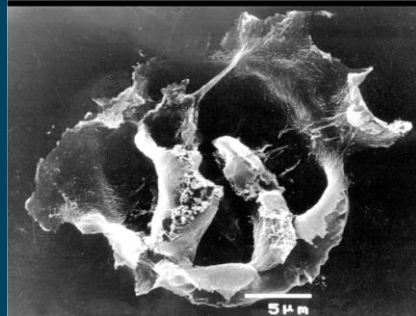
Source: GlobalData High-Prescriber Survey (December, 2020)

# Oncolytic molecules provides a new *in situ vaccination* principle

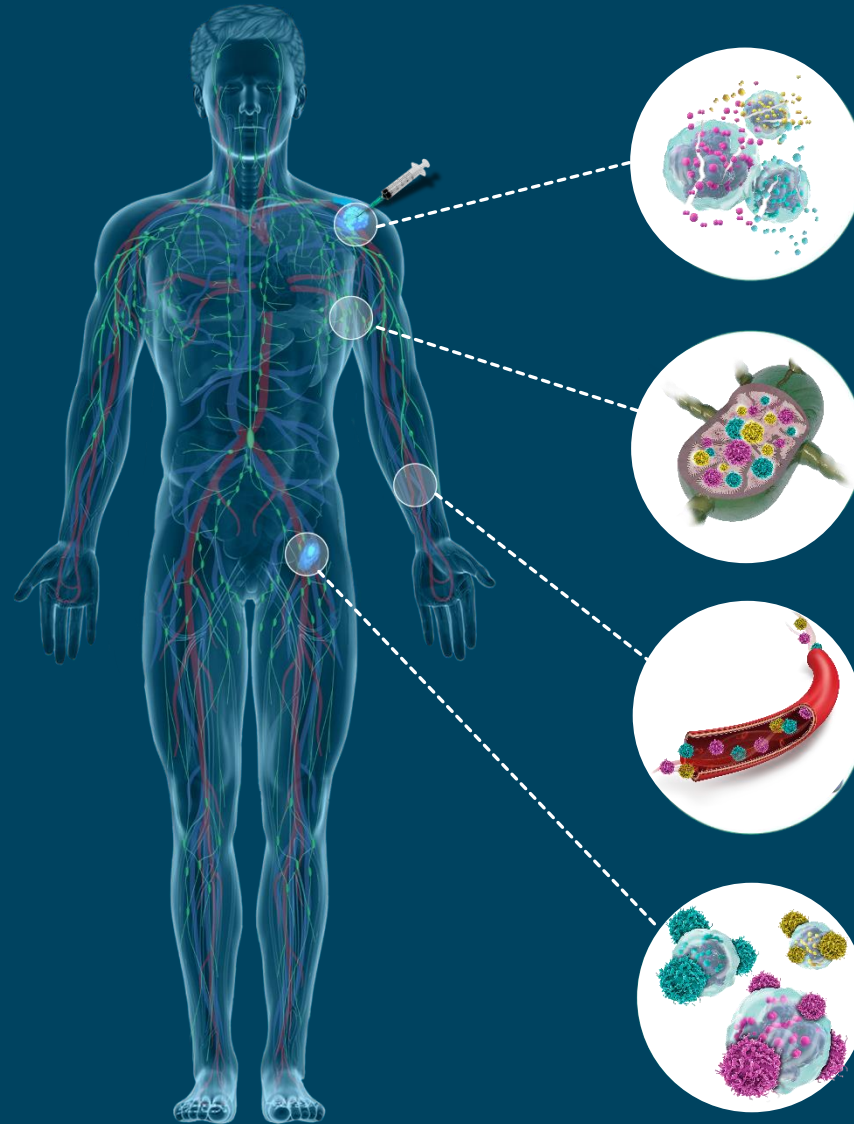
A cancer cell before treatment



A cancer cell after treatment



Immunogenic  
cell death



## TREATED TUMOR

Exposure of mutations (tumor antigens) from all dead cancer cells

## LYMPH NODE

Generating T cells that recognize the different mutations (tumor antigens)

## BLOOD VESSELS

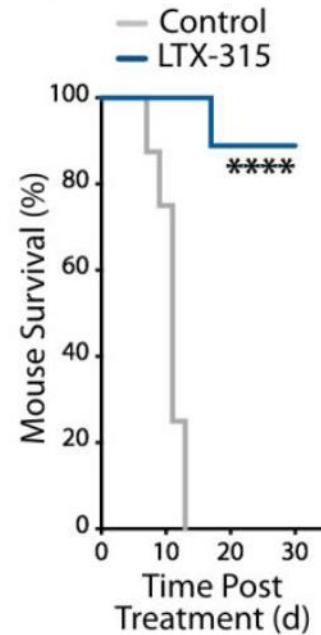
T cells enter the blood stream searching for cancer cells

## NON-TREATED TUMOR

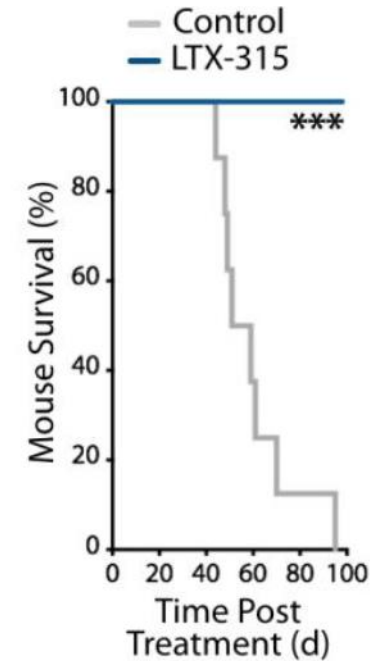
T cells infiltrate and eradicate distant cancer cells

# LTX-315 is effective in “hard to treat” cancer models

## B16F10 MELANOMA

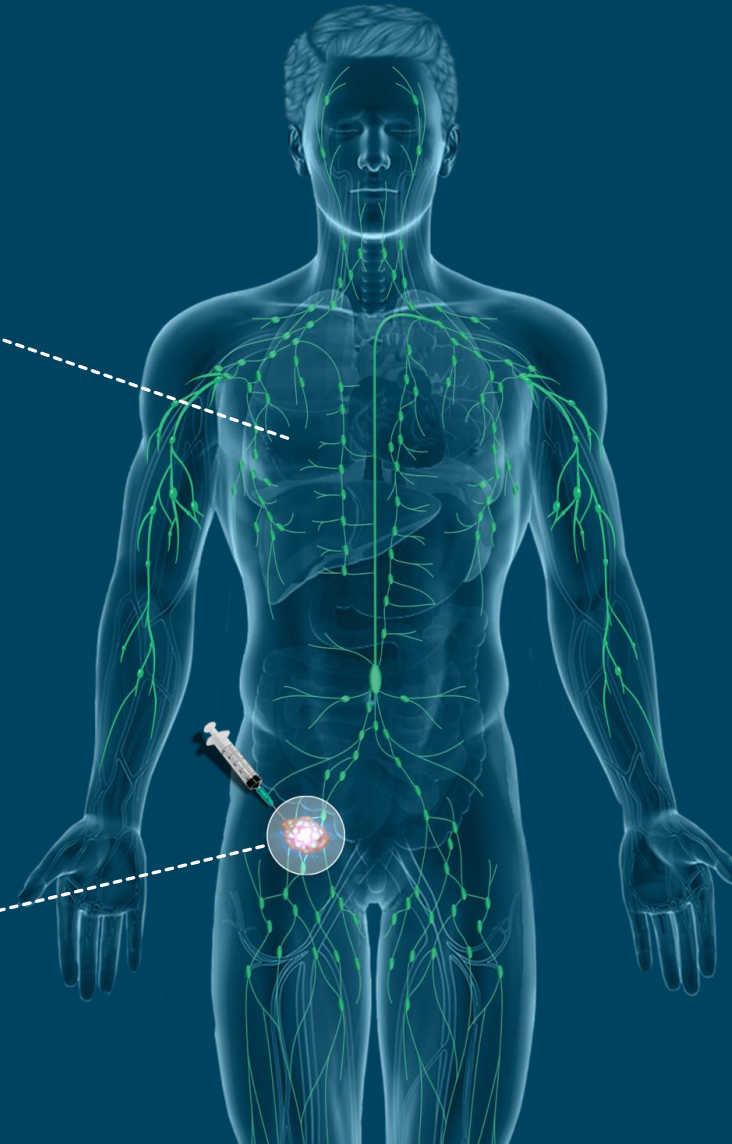
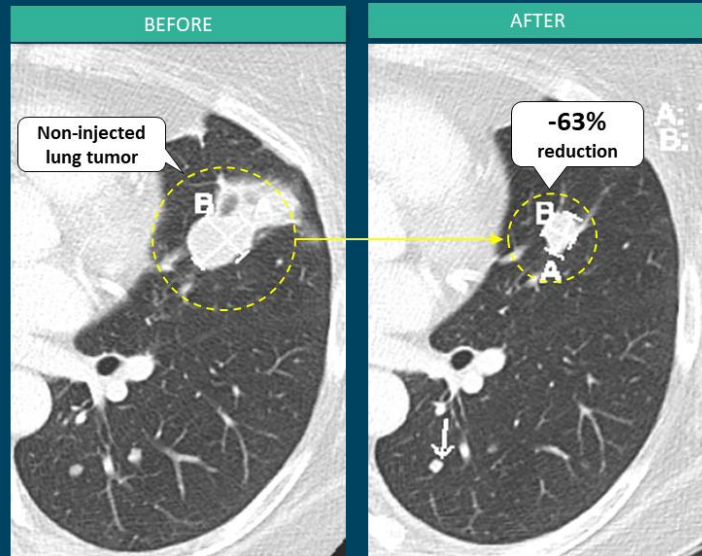


## BRAF MUTATED MELANOMA



No effect of chemotherapy or immune checkpoint inhibitors in the BRAF mutated melanoma model

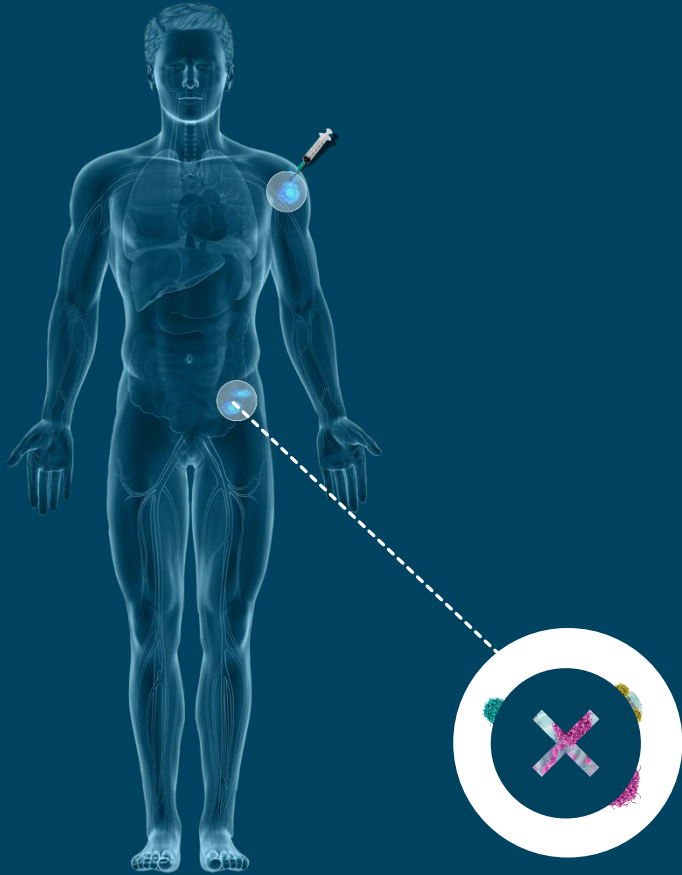
# Case study: Proof of Principle - Anti cancer effects in distant non-treated tumors confirmed in cancer patients



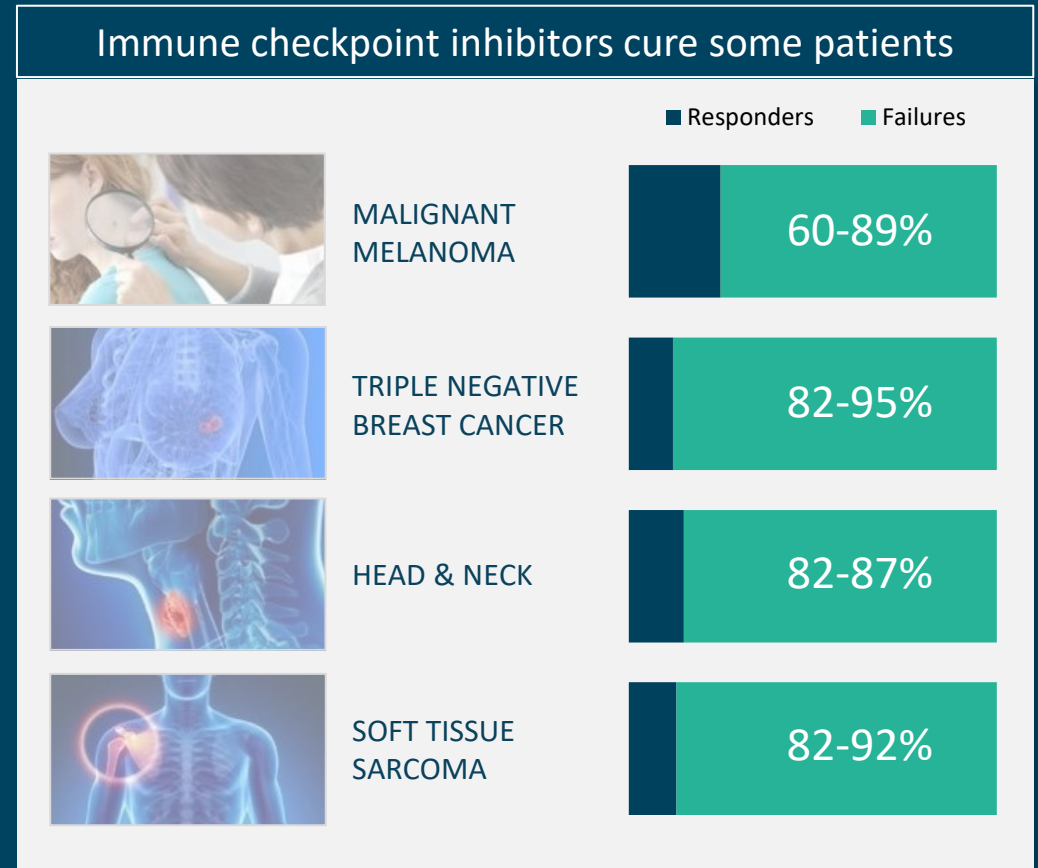
One tumor treated in the lower back



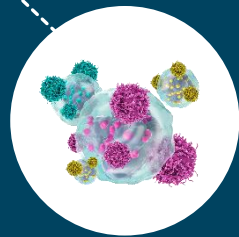
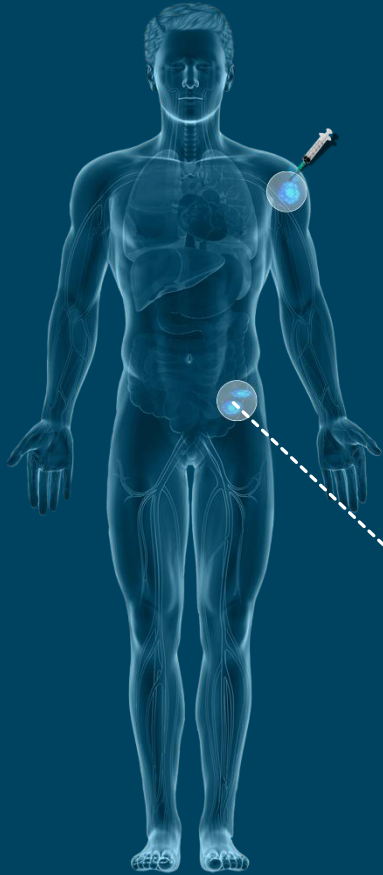
# Immune checkpoint inhibitors solve a different problem in cancer therapy



Some cancers can protect themselves by activating brakes in the immune system

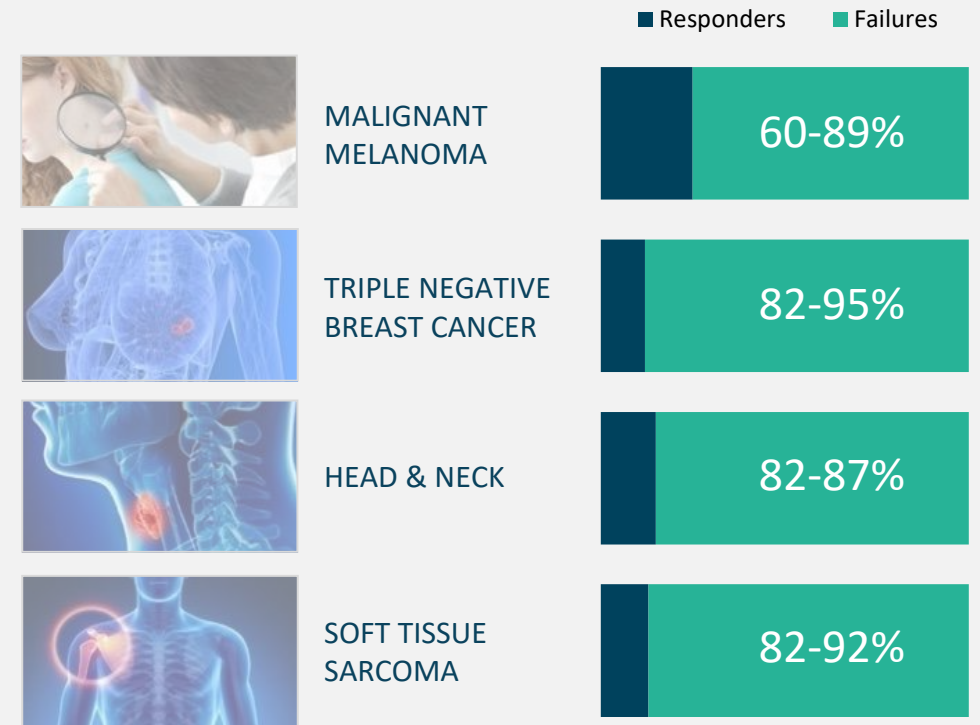


# Immune checkpoint inhibitors solve a different problem in cancer therapy

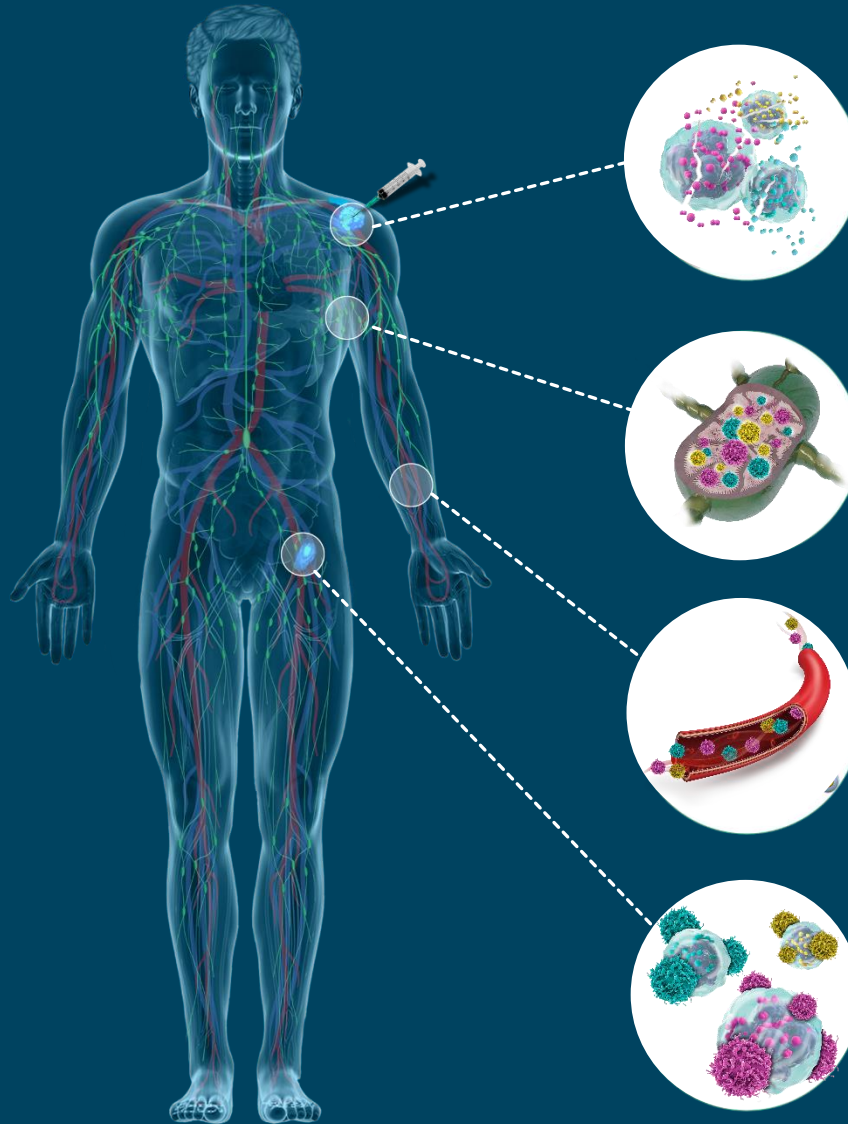


**Immune checkpoint inhibitors** can remove these brakes and keep the immune system ON

## Immune checkpoint inhibitors cure some patients



# Combination therapy with immune checkpoint inhibitors



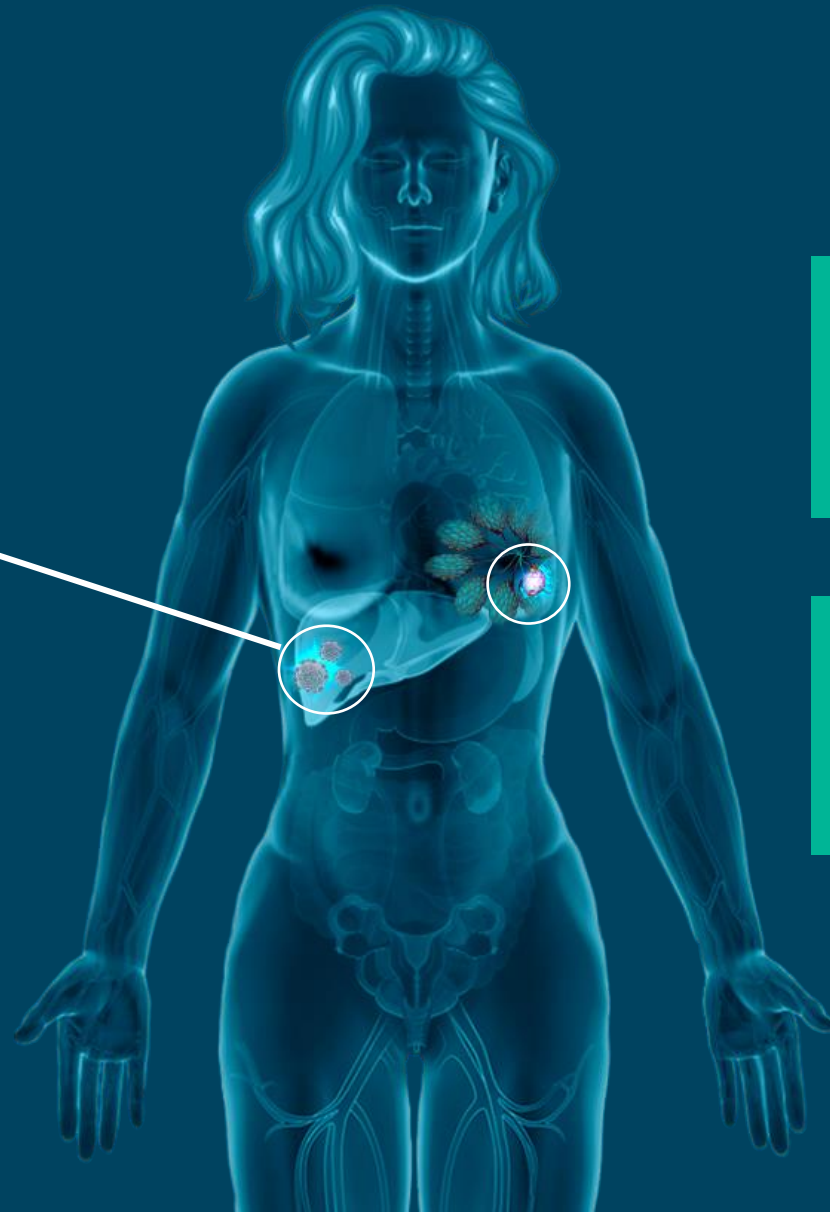
Oncolytic molecules  
generate T cells that recognize  
different cancer cells

+

Immune checkpoint inhibitors  
keeps the brakes off and make  
the T cells work more efficiently



# Case study: Proof of Principle - LTX-315 + checkpoint inhibitor showed effects not obtained with same checkpoint inhibitor alone in breast cancer patient



## The checkpoint inhibitor pembrolizumab alone

- No effect in liver metastasis
- 5 % overall response rate (ORR)

## LTX-315 + pembrolizumab

- Significant effects in liver metastasis
- 12,5% overall response rates



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FIRST IN CLASS



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ENTERING PHASE II  
STUDIES IN U.S.



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VALIDATED

# Clinical study with LTX-315 and the immune checkpoint inhibitor pembrolizumab is ongoing in US



- The study is led by MD Anderson Hospital
  - *Ranks as No. 1 globally in cancer care*



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FIRST IN CLASS



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ENTERING PHASE II  
STUDIES IN U.S.



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VALIDATED

# Science behind Lytix' technology documented by world leading cancer research institutions



National Cancer Institute  
at the National Institutes of Health



Institut de cancérologie  
**GUSTAVE ROUSSY**  
VILLEJUIF - [www.igr.fr](http://www.igr.fr)



 **STANFORD**  
SCHOOL OF MEDICINE



 **Oslo**  
University Hospital  
Norwegian Radium Hospital



 **Weill Cornell**  
Medicine



 **HARVARD**  
UNIVERSITY

Multiple collaborations leading to 50+ peer reviewed scientific publications, demonstrating the potential of oncolytic molecules

Nobel laureate Jim Allison, who discovered the first immune checkpoint inhibitor, is a member of our scientific advisory board

“The ability of an activated immune response to generate a **diverse** T-cell repertoire that adapts to **heterogeneous** and genetically unstable tumors (...) make it **absolutely essential** to expand our efforts to find rational **combinations** to unleash antitumor immune responses for the benefit of cancer patients.”



Jim Allison

- 2018 – Recipient of the Nobel price for the discovery of the first immune checkpoint inhibitor
- 2019 – Member of Lytix Advisory Board



## Lytix investor - the US healthcare specialist PBM Capital invest in game changing technologies



We **partner** with brilliant minds daring to advance science into **revolutionary** therapy.

## Our technology already commercially validated

- ⊗ US-based biotech focused on novel treatments for skin diseases
- ⊗ License of LTX-315 for the treatment of certain skin cancers
- ⊗ Regulatory milestones based on development goals and sales milestones at >100 mill. USD
- ⊗ Royalty rates from the low double-digits to the mid-teens based on net sales USD







# Summary

# Why we will succeed



## UNIQUE APPROACH

Lytix's molecules represent the missing piece

Ideal combination partners for checkpoint inhibitors



## SCIENCE

Science confirmed by top notch US and European cancer research institutions

Nobel Laureate advisory board member



## VALIDATION

Commercial deal within skin cancer

US health specialist fund as cornerstone investor



## EXECUTION

Management Board  
Advisory Board  
Competent investors  
Ongoing clinical study in US led by No 1 cancer hospital

# Q&A

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[ole.peter.nordby@lytixbiopharma.com](mailto:ole.peter.nordby@lytixbiopharma.com)