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Some of the statements we use in this presentation contain certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. You can identify some of these forward-looking statements by words or phrases, such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "target," "will," "would" or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events that we believe may affect our financial condition, results of operations, business strategy and financial needs.

These forward-looking statements include statements relating to the timing, progress and results of preclinical studies and clirical trials for our product candidates, including our product development plans and strategies; the timing, scope and likelihood of regulatory filings and approvals, including opportunities to use expedited regulatory pathways and final regulatory approval of our product candidates; the potential benefits and market opportunity for our product candidates; expectations regarding the size, scope and design of clinical trials; our plans and strategy with respect to our drug development efforts; our manufacturing, commercialization, and marketing plans and strategies; our plans to hire additional personnel and our ability to attract and retain such personnel; our estimates of the number of patients who suffer from the diseases we are targeting and potential growth in our target markets; our expectations regarding the approval and use of our product candidates; our competitive position and the development and impact of competing therapies that are or may become available; expectations and strategies for entering into potential collaborations and additional licensing agreements; our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights; the rate and degree of market acceptance and clinical utility of product candidates we may develop; our estimates regarding expenses, future revenue, capital requirements and needs for additional linancing; our future financial performance; the period over which we estimate our existing cash on hand will be sufficient to fund our future operating expenses and capital expenditure requirement

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This presentation also contains market data related to our business and industry, including projections that are based on a number of assumptions. If these assumptions turn out to be incorrect, our actual results may differ materially from the projections based on these assumptions. As a result, the market for our product candidates may not grow at the rates projected by these data, or at all.



# Investment Highlights Clinical Stage Biopharmaceutical Company Focused on the Treatment of Debilitating Diseases





- ✓ History of substantial shareholder value creation
- Multiple US and international approvals and commercial launches



#### **New Opportunity Identified**

- ✓ LX-101: Clinical-stage, payloadbearing, targeted therapy directed to IGF-1R with differentiated MOA
- ✓ Tremendous commercial potential in wide range of IGF-1R-driven oncology and autoimmune indications, including TED



## **Near-Term Value Creation Potential**

Focus on indications with opportunities for both near-term value creation and expedited approval pathways



## **Lirum Team: Track Record of Approvals & Launches**



Ivan Bergstein, MD
Chairman



Ken Hoberman
Director



Peter McDonald
Chief Executive Officer

- ✓ Veteran leadership team
- ✓ Proven track record of shareholder value creation
- ✓ Multiple drug approvals and commercial launches

\*Notably: ELZONRIS was approved on the basis of an innovative 3-stage, non-randomized, Phase 1/2 trial

And with a novel regulatory endpoint created by the company and its PIs







Commercial; oncology; US and EU









Commercial; oncology; US and EU







Commercial; neurodegenerative; US & EU







Commercial; renal; US



## **LX-101: Novel IGF-1R Targeted Therapy**

#### **Precision Targeting**

Targeted therapy, with novel payload-based approach, to IGF-1R

#### **Novel Mechanism of Action**

Differentiated mechanism with potential for efficacy and safety benefits over other IGF-1R-targeted agents

#### **Rational Payload**

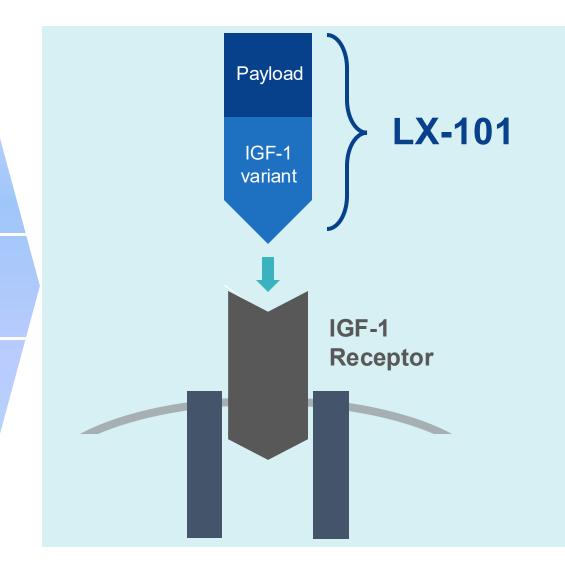
Delivers methotrexate (MTX), a drug used to treat a variety of cancers and autoimmune diseases, including TED

#### **Positive Clinical Experience**

Well-tolerated with single agent activity in Phase 1a trials

#### **Large Market Opportunity**

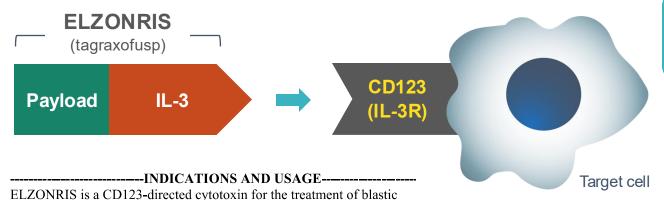
Wide range of oncologic & autoimmune indications, including TED





## LX-101: Leveraging the Successful ELZONRIS Development Strategy





- Breakthrough Therapy Designation
- ✓ US and EU approvals in BPDCN
- ✓ Commercial in US and EU

The NEW ENGLAND JOURNAL of MEDICINE

#### ORIGINAL ARTICLE

Tagraxofusp in Blastic Plasmacytoid Dendritic-Cell Neoplasm

N ENGL J MED 380;17 NEJM.ORG APRIL 25, 2019



#### Leverage our experience:

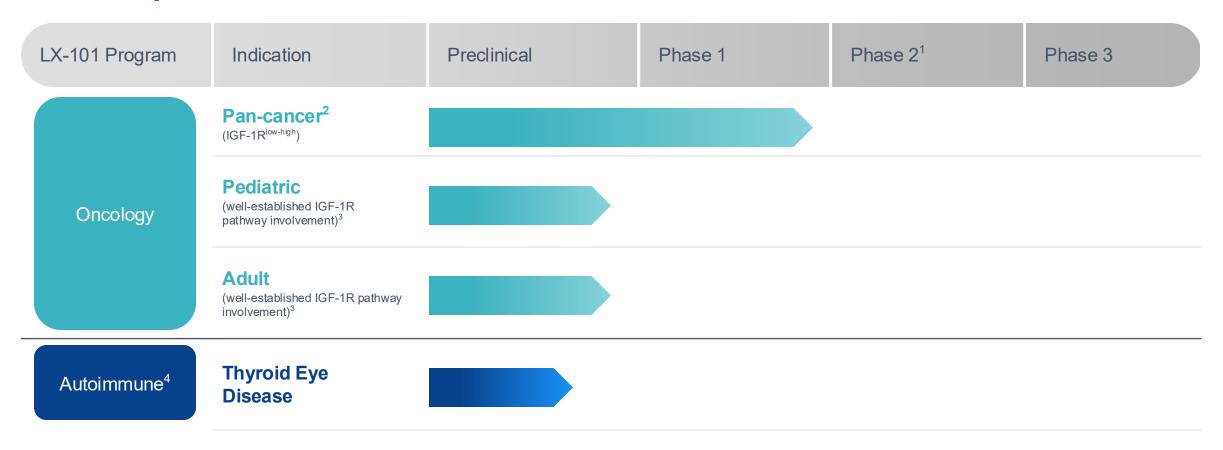
- Targeted approach for indications of unmet need that enable <u>innovative</u> and expedited development
- Unlock commercial potential in both oncology and autoimmune, including TED, quickly and efficiently



plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric

patients 2 years and older. (1)

## **Lirum Pipeline: Focused on IGF-1R Driven Indications**



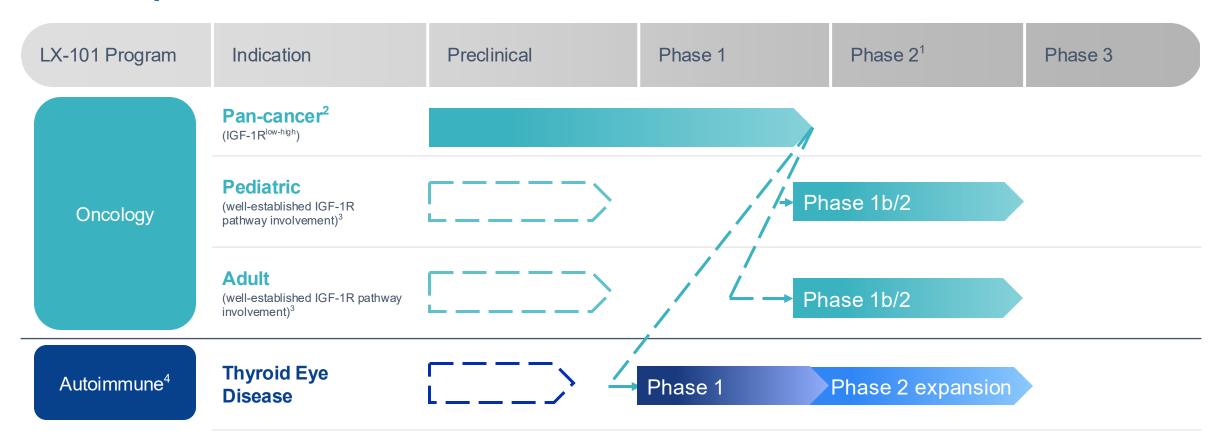
<sup>1</sup> Some indications by virtue of certain factors (e.g., unmet medical need, etc.) could lend themselves to the possibility of pivotal phase 2 studies or other expedited development pathways, although we cannot be assured that LX-101 or any future products will qualify.

<sup>&</sup>lt;sup>2</sup>This trial, conducted by the licensor with 765IGF-MTX, the former name of LX-101, enrolled patients with multiple cancer types including colorectal, endometrial, pancreatic, breast, basal cell carcinoma, Hodgkin's lymphoma, and others. IGF-1R expression was assessed on patient tumors via immunohistochemical staining and scored based on the proportion of cells that were positive (PS=proportion score; range 0%-100%) and Q score (range 0-7), which is the combination of PS and intensity score (IS).

<sup>3</sup> Cancers with "well-established IGF-1/IGF-1R pathway involvement" include those tumor types with genetic alterations relating to the pathway and/or elevated IGF-1R expression.

<sup>&</sup>lt;sup>4</sup>Reviewing opportunities in other autoimmune diseases including rheumatoid arthritis, Graves' disease, Cushing's syndrome, lupus, Crohn's disease, and others.

## **Lirum Pipeline: Focused on IGF-1R Driven Indications**



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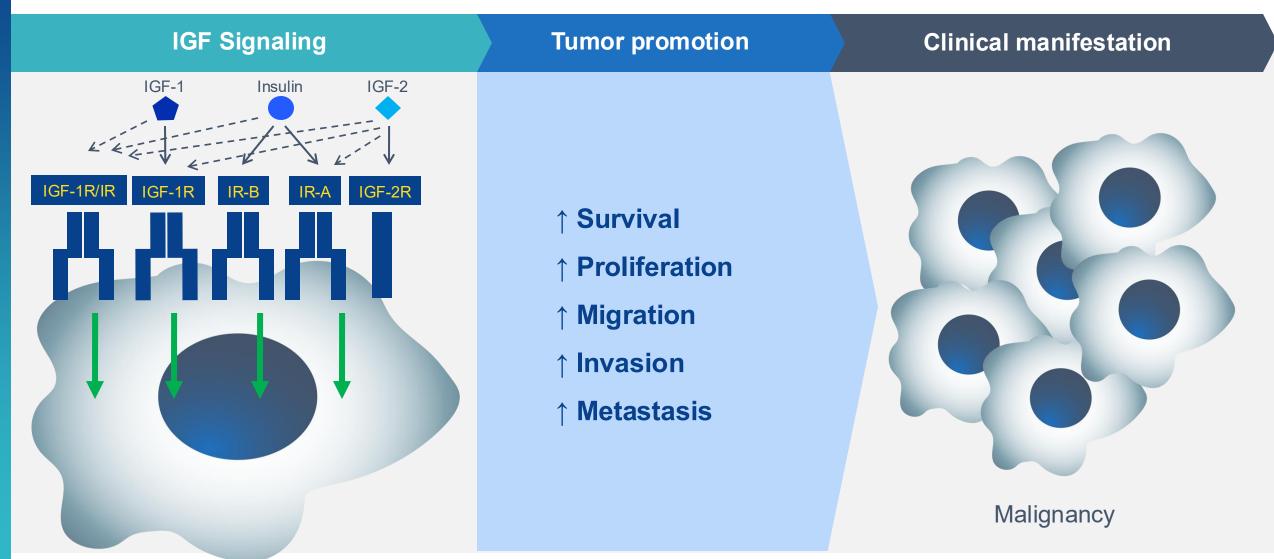
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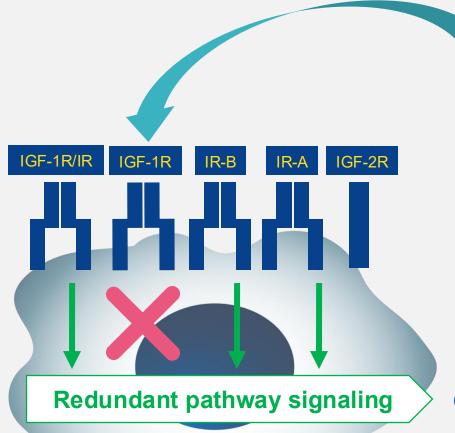


## IGF-1R Pathway: A Major, High-Profile Target in Oncology





## **IGF-1R Directed Therapy: Redundant Pathways Limited Past Efforts**



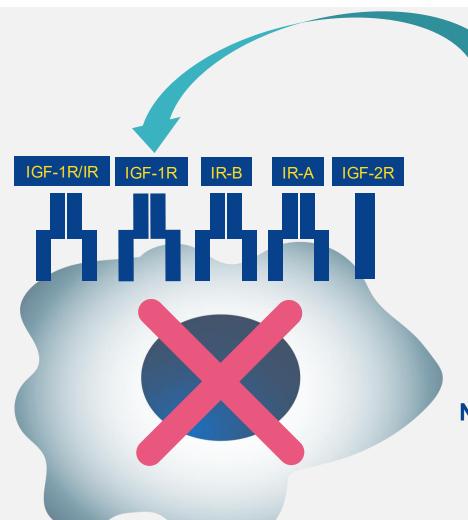
#### **Historical Approach**

- IGF-1/IGF-1R pathway is well-established in cancer, and past IGF-1R targeting approaches had evidence of clinical activity, but fell short of approval
- Cancer cells utilize escape mechanisms, including redundant pathways, enabling cells to work-around inhibition and continue to act as disease effectors
- Leaves room for improvement

Cell escape



## **IGF-1R Directed Therapy: Lirum's Rational Development Approach**



#### **Lirum Approach**

- LX-101 delivers payload directed to IGF-1R+ cells
- Cytotoxicity prevents redundant pathway escape mechanisms
- Development plan targets cancers with well-established ties to the IGF-1 / IGF-1R pathway
- > More definitive and focused approach

No escape



## LX-101: Positive Clinical Experience<sup>1</sup>



#### **Clinically tested**

- 19 patients with advanced, pre-treated cancers in Phase 1a trials<sup>2</sup>
- Some IGF-1R expression<sup>3</sup> (IGF-1R<sup>low-high</sup>)

#### **Favorable safety experience**



- Well-tolerated
  - Most common adverse events (AE): chills/rigors, hypoglycemia, nausea and vomiting
    - Including, grade 2: peripheral neuropathy (n=1); grade 3 (on an event basis): abdominal pain (n=6), back pain (n=1), bradycardia (n=1), hypoglycemia (n=1), hypotension (n=1), syncope (n=1), lymphopenia (n=1), anemia (n=1); grade 4: hypotension (n=1)
  - Low rate of treatment-related hyperglycemia (a known class side effect of IGF-1R inhibition that is potentially treatment-limiting)
- No DLT or MTD reached → Further dose escalation and schedule optimization



#### **Clinical activity**

- 1 PR (at highest dose tested)
- 1 bone marrow CR, 4 stable diseases (including 1 pathologic CR) (at lower doses)



#### **IGF-1R Expression**

- All enrolled and evaluated patients (n=17/19) had some degree of IGF-1R expression (IGF-1Rlow-high)2
  - 4/17 (24%) were "High IGF-1R Expressers" (IGF-1Rhigh)4; 3/4 evaluable for disease control
  - 2/3 (67%) achieved disease control, including 1/1 (100%) at highest dose tested

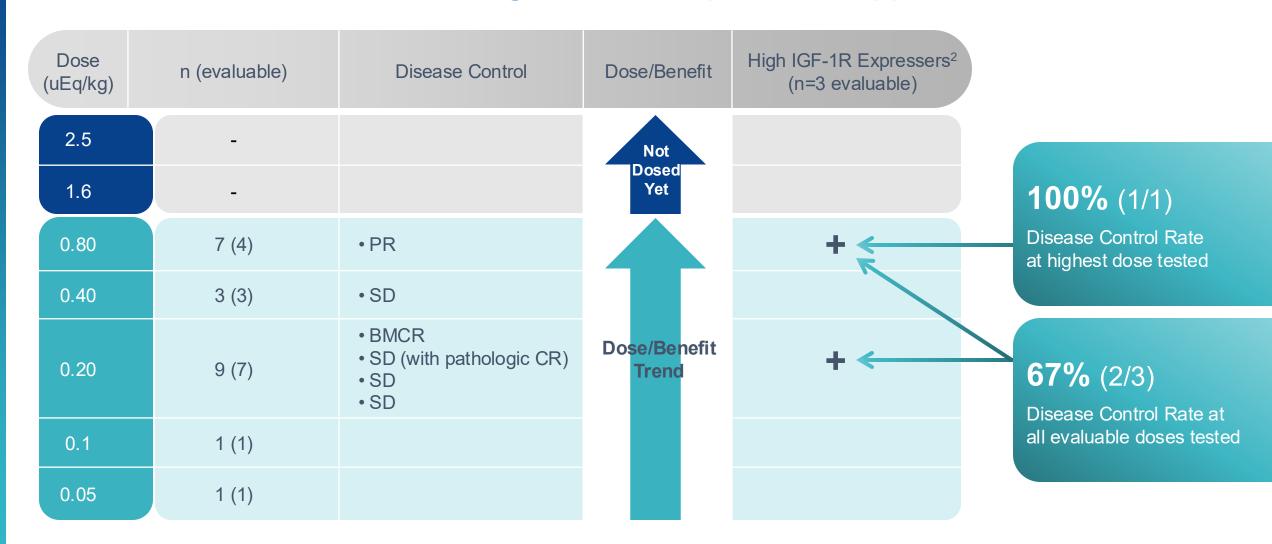


<sup>&</sup>lt;sup>1</sup> Source: Venepalli et al., Am J Clin Oncol, 2019; Alkhateeb et al., Anticancer Res, 2020; Investigator Brochure, April 25, 2017

<sup>&</sup>lt;sup>2</sup>This includes two patients who were dose escalated due to disease stability lasting greater than two cycles. Additionally, two patients were treated in a separate trial at the 0.20 uEq/kg dose.
<sup>3</sup>IGF-1R expression ≥ 10% IGF-1R by IHC or ≥ 0.1% by flow cytometry.

<sup>&</sup>lt;sup>4</sup>We considered "high IGF-1R expressers" (IGF-1R<sup>high</sup>) as patients whose tumors had both a very high Q score (>=6) and very high PS (>90%). DLT = dose limiting toxicity; MTD = maximum tolerated dose; PR = partial response; CR = complete response.

## LX-101: Dose/Benefit Trend; High IGF-1R Expressers Appear Sensitive<sup>1</sup>





¹ Source: Venepalli et al., Am J Clin Oncol, 2019; Alkhateeb et al., Anticancer Res, 2020; Investigator Brochure, April 25, 2017
²IGF-1R expression was assessed on patient tumors via immunohistochemical staining and scored as intensity score (IS, 0 = no stain, 1 = weak stain, 2 = intermediate stain, 3 = strong stain) and proportion score based on % of cells with IGF-1R positivity (PS, 0% - 9% = 0, 10% - 24% = 1, 25% - 49% = 2, 50% - 74% = 3, 75% - 100% = 4) combined to create a Q score (range 0-7). We considered "high IGF-1R expressers" (IGF-1R<sup>high</sup>) as patients whose tumors had a very high Q score (≥ 6) with IGF-1R expression ≥ 90%.

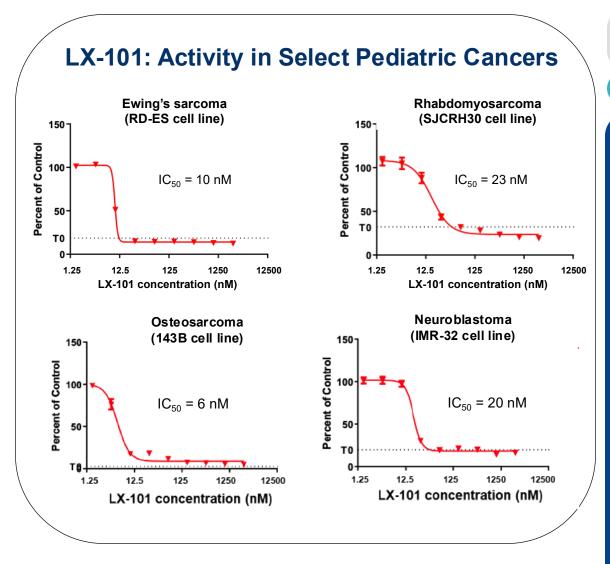
## LX-101: Indications with Strong Genetic and/or Epigenetic Links to IGF-1R

✓ Strong Scientific Rationale ✓ Potential for expedited regulatory pathways ✓ Compelling commercial opportunities

Cancer Type	Epigenetic and Genetic Alterations		US Incidence
Ewing's sarcoma DSRCT GIST Rhabdomyosarcoma Synovial Sarcoma Neuroblastoma Osteosarcoma Wilms Tumor Adrenocortical carcinoma	IGF-1R and poor outcomes IGF-1R and upregulation High IGF-1R in peds (WT) IGF-1R and short survival IGF-1R and more aggressive IGF-1R and poor outcome IGF-1R and poor prognosis IGF-1R and poor outcome IGF-2 overexpression	EWSR1-FLI1 EWSR1-WT1 NBF1-IGF1R PAX3/7-FKHR/FOXO1 SYT-SSX1/2  IGF-1R gene amplification	Group 1 ~4,500+ (range: ~125 to ~1,500)
Head & Neck Cancers: • HNSCC HPV(-) • Adenoid cystic carcinoma Bladder cancer, invasive Breast cancer, triple negative	IGF-1R and poor outcomes IGF-2 overexpression IGF-1R and higher mortality IGF-1R and short survival	MYB-NF1B	Group 2 >40,000 (range: ~5,500 to >25,000)
Patient subsets in lung, breast, colorectal, prostate, ovarian, gastric, esophageal, etc.	IGF-1R expression and over-explinked to poor outcomes	pression	<u>Group 3</u> Additional upside



## LX-101: Broad Activity in IGF-1 / IGF-1R Prominent Pediatric Tumor Types<sup>1</sup>

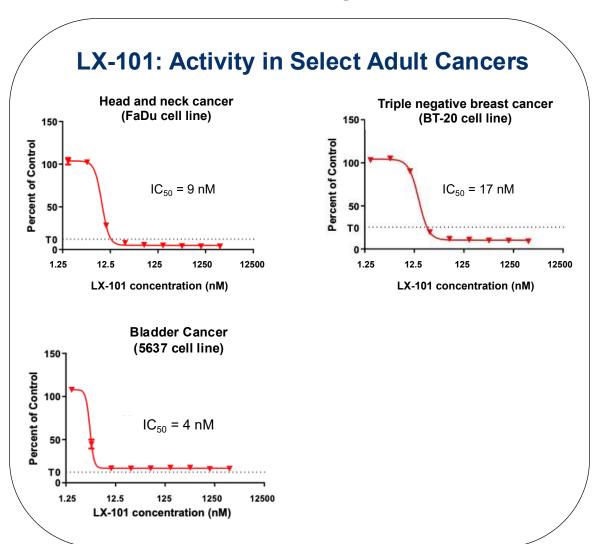


Population	Indication	Cell lines	Absolute IC <sub>50</sub> (nM IGF) <sup>2</sup>
Reference	Breast	MCF7	35
Pediatric	Ewing's sarcoma	RD-ES CADO-ES1 A673 SK-ES-1	10 14 14 29
	Adrenocortical carcinoma	SW-13 NCI-H295R	9 >2500
	Rhabdomyosarcoma	SJCRH30 (alveolar) TE 441.T (embryonal)	23 >2500
	Osteosarcoma	143B HOS U2OS Saos-2	6 7 32 >2500
	Synovial sarcoma	SW-982	>2500
	DSRCT	BOD JN; BER	100 >2500
	Neuroblastoma	SK-N-AS IMR-32 SH-SY5Y	16 20 30



<sup>1</sup>Source: Presentation ESMO TAT 2025

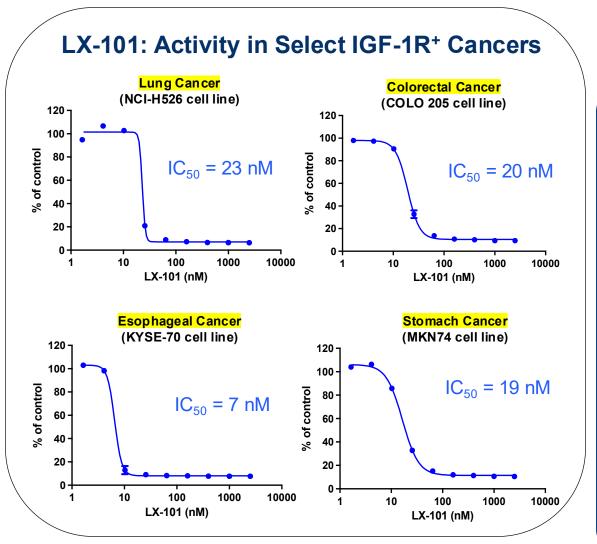
## LX-101: Broad Activity in IGF-1 / IGF-1R Prominent Adult Tumor Types<sup>1</sup>



Population	Indication	Cell lines	Absolute IC <sub>50</sub> (nM IGF)
Reference	Breast	MCF7	35
Adult	Head and neck cancer (HPV-)	FaDu (pharyngeal) SCC25 (tongue)	9 >2500
	Triple negative breast cancer	BT-20 HCC1143	17 >2500
	Bladder cancer	5637 T24	4 61



# LX-101: Activity Across Multiple Additional IGF-1R+ Cancer Types: Potential For Companion Diagnostic and/or Tumor Agnostic Strategy



Population	Indication	Cell lines	Absolute IC <sub>50</sub> (nM IGF)
Reference	Breast	MCF7	35
Adult	Lung	A549 NCI-H2122 NCI-H526	29 10 23
	Colorectal	COLO 205 HT-29	20 33
	Prostate	VCaP DU 145	>2,500 9
	Pancreas	Capan-2 PANC-1	>2,500 35
	Liver	Hep G2 HUH-7	9 18
	Esophagus	TE-1 KYSE-70	16 7
	Ovarian	OVCAR8 CAOV3	12 45
	Kidney	786-O Caki-1	5 69
	Stomach	MKN74 NUGC-4	19 30

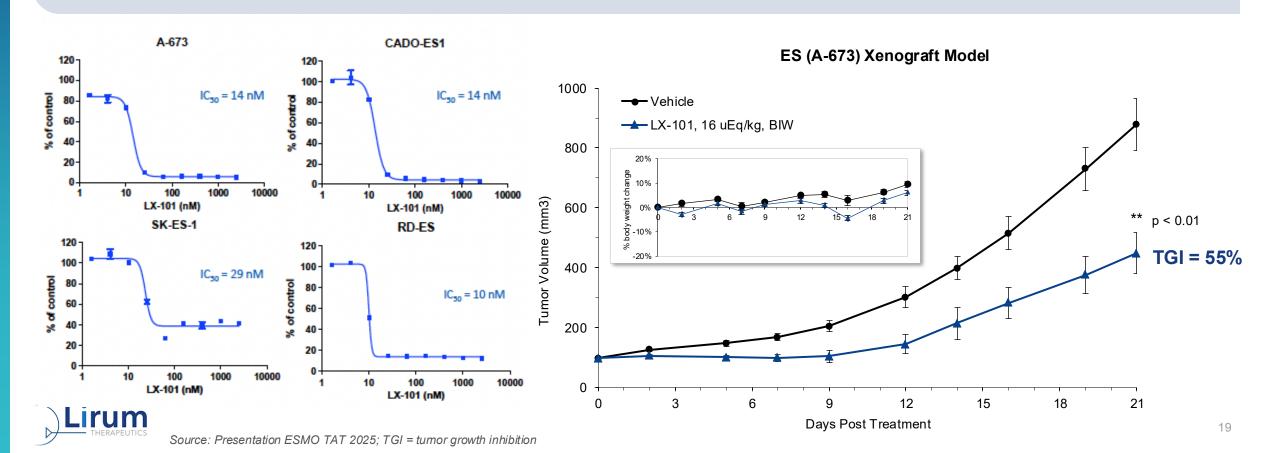


Source: Presentation ESMO TAT 2025

## LX-101: Potent Activity in Ewing's Sarcoma

#### LX-101 has potent activity against Ewing's Sarcoma in vitro and in vivo

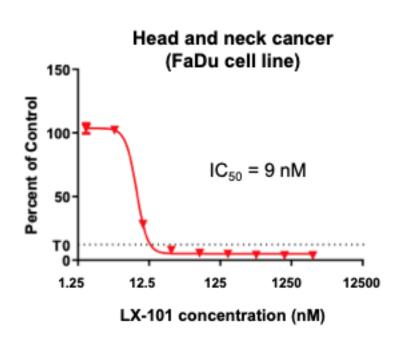
- Low nM IC50s against Ewing's sarcoma cell lines, including EWSR1-FL1 and EWSR1-ERG gene fusion-positive cell lines
- Significant in vivo anti-tumor efficacy observed in the A-673 Ewing's sarcoma xenograft model
- LX-101 administered IV at 16 uEq/kg (HED of 1.3 uEq/kg) twice a week for 3 weeks was well-tolerated

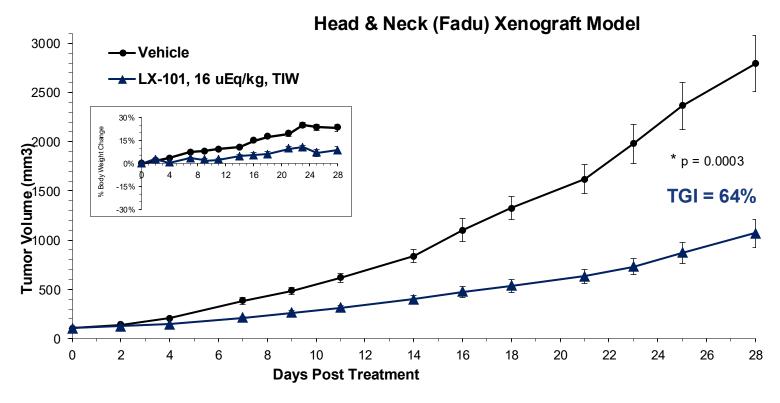


## **LX-101: Potent Activity in HPV-negative HNSCC**

#### LX-101 has potent activity against HNSCC in vitro and in vivo

- Low nM IC50s against HNSCC FaDu, an HPV-negative cell line
- Significant in vivo anti-tumor efficacy observed in the FaDu HNSCC xenograft model
- LX-101 administered IV at 16 uEq/kg (HED of 1.3 uEq/kg) three times a week for 4 weeks was well-tolerated







### **IGF-1R Prominent Pediatric Cancers**

#### Attractive Regulatory and Commercial Opportunity with Strong Scientific Rationale

## Areas of unmet medical need Poor outcomes / No approved drugs or effective standard of care in 1L and/or later lines

#### **Ewing's Sarcoma (~500 US incidence)**

• ~90% of cases arise from *EWS-FLI1* fusion which directly induces IGF-1R signaling and leads to ubiquitous overexpression of IGF-1R

#### GIST (~5,000 US incidence)

- 10-15% of patients lack mutations in KIT or PDGFRA genes and are wild-type (WT) tumors
- Wild type tumors especially pediatric cases present with large IGF-1R overexpression

#### **DSRCT** (~125 US incidence)

 Virtually 100% of cases characterized by EWSR1-WT1 fusion which directly interacts with and causes overexpression of IGF-1R

#### Rhabdomyosarcoma (RMS) (~400 US incidence)

- ~30% of cases are Alveolar RMS which carry poor prognosis and have a higher expression of IGF-1R
- ~60% of Alveolar RMS harbor the PAX3-FOXO1 fusion which directly induces overexpression of IGF-1R

#### Phase 1b (n=10-15)

Basket Trial (Pediatric/IGF-1R-based tumors)

Multiple near-term value creation opportunities over 12-18 months

#### **Multiple Phase 2 Expansion Options**

- ES (n=25-35)
- DSRCT (n=3-5)
- GIST (WT) (n=10-15 adults & peds)
- RMS (n=3-6)
- Additional types (n=5-20)

**Expedited Approval Opportunities** 

### **Head and Neck Cancers**

### Attractive Regulatory and Commercial Opportunity with Strong Scientific Rationale

#### **Head & Neck Cancers**

#### **H&N** squamous cell carcinoma (HNSCC)

- Large market (~66,000 US incidence)
- High unmet met need, especially in R/M setting

#### **Rationale and Development Strategy**

- > HPV(-) subset of HNSCC is our initial area of focus
  - ✓ Represents a naturally IGF-1R-enriched population
  - ✓ Poor prognosis subset & does worse with checkpoint inhibitors versus HPV(+)
  - ✓ Meaningful initial commercial opportunity (~6,000 US incidence) with potential for expedited regulatory path
  - ✓ Plan to broaden within H&N and beyond

#### **Adenoid Cystic Carcinoma (AdCC)**

- Niche market (~1,200 US incidence), high unmet need
- Upon relapse after surgery, outcomes are very poor and treatment options limited
- No approved therapies or standard of care; ORR <20%</li>

#### **Rationale and Development Strategy**

- √ 50-75% harbor the MYB-NFIB gene fusion which directly affects IGF-1R pathway
- √ ~50% of cases become R/M: 600 addressable US patients per year provide attractive regulatory opportunity for possible first (of many) approval(s)
- ✓ Opportunity for near-term value creation and expedited approval

#### Phase 1b (n=10-15)

- Cohort 1: HNSCC HPV(-)
- Cohort 2: AdCC

#### **Phase 2 Expansion**

- HNSCC HPV(-) (n=30-50)
- AdCC (n=8-12)

Expedited Approval Opportunities

Multiple near-term value creation opportunities over 12-18 months

## **LX-101: Highlights in Oncology**

#### **Summary/Key Points**

- ✓ Next generation IGF-1R-targeted therapy
- ✓ Leverage positive clinical experience and exciting new data in IGF-1R+ cancers
- ✓ Focused development strategy targets indications with attractive regulatory paths and commercial opportunities



### **Key Value-Creating Milestones in Oncology (12-18 month timeframe)**

Initiate Phase 1b/2 trials in IGF-1R prominent pediatric and adult H&N cancers



Generate value-creating clinical data <u>early</u> in the development process



Focus on <u>expedited</u> regulatory paths



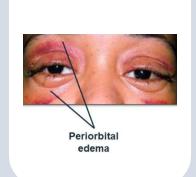


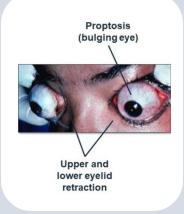


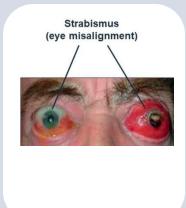
## Thyroid Eye Disease (TED): Overview

#### **The Condition**

- TED is an autoimmune disease characterized by progressive inflammation and damage to tissues around the eyes
- Acute/active (1-3 years) and chronic (>3 years) phases
- Symptoms range from mild to severe (including possible vision loss), and repeated exacerbations can occur







#### The Opportunity



#### **Incidence / Prevalence**

- Acute phase: ~20-25K/year U.S. incidence
- Chronic phase: >70K/year U.S. prevalence



#### **Large Market**

- Tepezza®, FDA approved naked mAb to IGF-1R
- ~\$2B in sales in '22 (3rd year on market)
- Over \$3.5B estimated global market



#### **Novel Approach**

 Numerous opportunities for a novel, differentiated approach to penetrate this expanding and segmented market

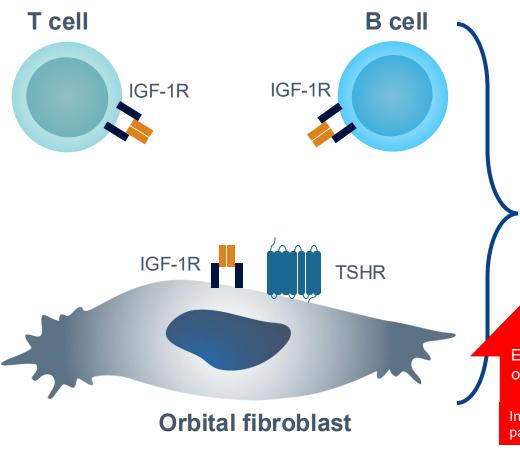


## **TED Pathogenesis**<sup>1</sup>

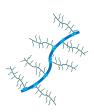
#### **Autoimmune process**

#### **Overproduction of molecular** and cellular factors

### Extraocular muscle enlargement and orbital expansion



Hyaluronan synthesis



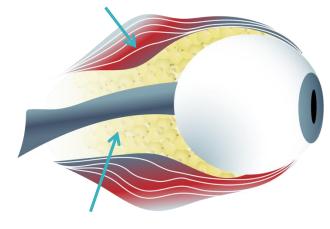
Differentiation (adipocytes, myofibroblasts)



Inflammatory cytokines IL-8 **Eotax** others

Inflammatory cytokines drive TED pathology and tissue remodeling

#### **Enlarged Muscle**



#### **Expanded Orbital** Tissue and Fat

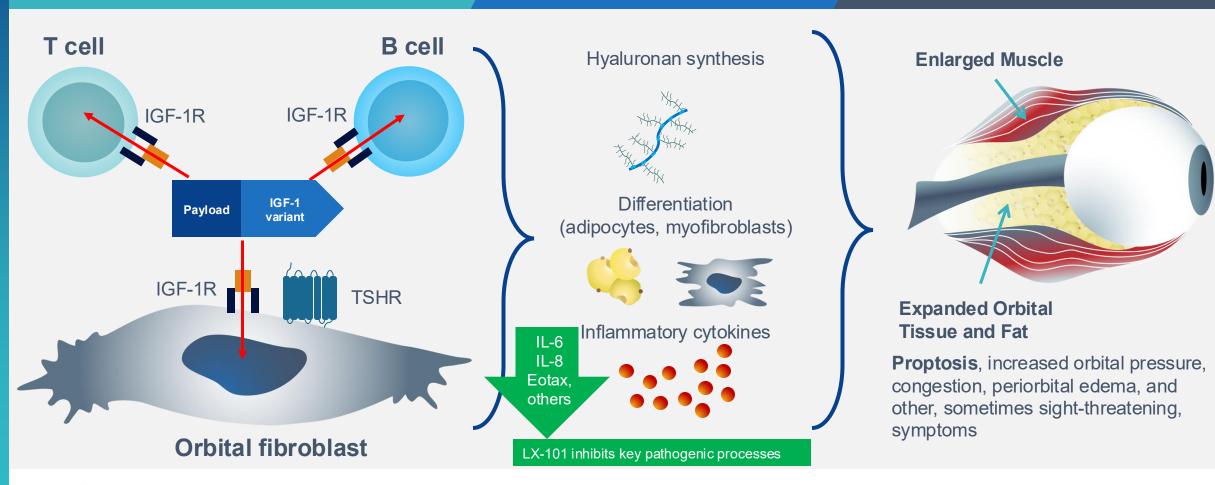
**Proptosis**, increased orbital pressure, congestion, periorbital edema, and other, sometimes sight-threatening, symptoms

## **TED Pathogenesis**<sup>1</sup>

#### **Autoimmune process**

## Overproduction of molecular and cellular factors

## Extraocular muscle enlargement and orbital expansion



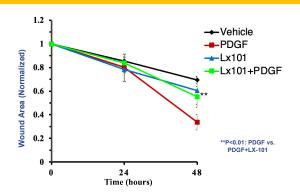


## LX-101: Potent Inhibition of Key Pathogenic Processes in TED

#### Findings demonstrate LX-101 can:

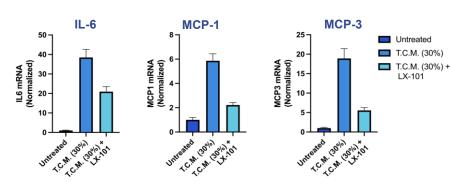
- Inhibit migration capacity of orbital fibroblasts, a marker of orbital tissue expansion and fibrosis,
- Decrease production of key inflammatory cytokines (IL-6, MCP-1, MCP-3),
- Reduce production of pro-fibrotic extracellular matrix (ECM) components (Periostin, LOX), and
- Modulate activity of TED T lymphocytes.

#### **Inhibits Migration of TED OFs**



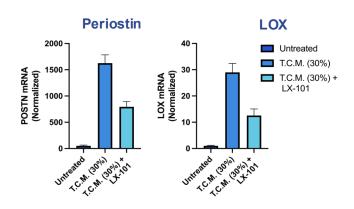
Inhibits OF migration capacity, a marker of orbital tissue expansion / fibrosis

#### **Decreases Production of Key Inflammatory Cytokines**



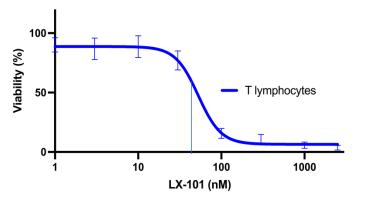
Decreases production of IL-6 and other key proinflammatory cytokines, by orbital fibroblasts

#### **Reduces Production Pro-Fibrotic ECM Components**



Mitigates production of pro-fibrotic extracellular matrix components by TED OFs

#### Modulates Activity of IGF-1R+ T Cells



Modulates IGF-1R+ T cell activity (IC50 ~52 nM)



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### **LX-101: Highlights in TED**

#### **Summary/Key Points**

- Novel approach to commercially validated target
- Supported by exciting new data
- Potential for highly competitive efficacy and safety profile
- Attractive market opportunity
  - >\$3.5B globally
  - Increasingly segmented patient populations with <u>multiple entry opportunities</u> for LX-101



### **Key Value-Creating Milestones for TED**

#### Phase 1 (n=20-30)

Patients not benefiting from available therapies and chronic patients

## Multiple near-term value creation opportunities over 12-18 months

#### **Phase 2 Expansion Arms**

- Refractory
- Tolerability issues
- Suboptimal durability
- Chronic disease
- Other

Focus on <u>expedited</u> regulatory paths

## **Key Take Aways**





## Lead by a veteran team with strong track record of success

- ✓ History of shareholder value creation
- Multiple approvals and commercial launches

## Innovative technology with differentiated MOA

- ✓ Positive clinical experience
- ✓ Differentiated profile compared to other IGF-1R targeted approaches
- ✓ Tremendous commercial opportunity in oncology and autoimmune diseases

#### **Next Steps**

- Advance LX-101 into IGF-1R-driven cancers and TED
- Continue to opportunistically expand pipeline



#### **Multiple Near Term Key Value-Creating Milestones**

Initiate clinical trials focused on cancer types and TED segments of high interest



Opportunity for nearterm value-creating data in oncology and TED



Focus on expedited regulatory pathways in oncology and TED





