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# 2023 Interim Results Update

August 23, 2023



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1



**Results Highlights**

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2



**Business Update**

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3



**Financial & Outlook**

# 01 1H23 Results Highlights

The background features a warm orange and white color palette. A prominent white wavy line curves across the upper portion of the slide. Below this, a grid of semi-transparent orange arrows points in various directions. In the lower half, there are several faint, semi-transparent molecular models, including a purple one with five spheres and a yellow one with a more complex structure.

# 2023 Pipeline and Business Focus



## Focus

### Osemitamab (TST001)

#### Best-In-Class anti-CLDN18.2

- Conduct key Health Authority consultations and initiate global Ph3 trial

### Blosozumab (TST002)

#### Best-In-Class anti-Sclerostin

- Complete Ph1, initiate Ph2 trial after CDE consultation

### TST003

#### First-in-Class anti-GREM1

- Expedite Ph1 set-up in US and China and reach expected effective dose in the dose escalation study

**Optimize Continuous MFG Platform and Grow CDMO**

# Results Highlights



## Key Regulatory Approvals Received with Encouraging Data

### Osemitamab (TST001) Ph3



- Presented osemitamab-CAPOX combo data at ASCO 2023 & ESMO-GI 2023: improved PFS and DOR in a broader patient population with CLDN18.2 expression
- Completed enrollment of 82 patients in osemitamab-CAPOX-nivolumab cohorts of 1L G/GEJC patients
- Successful End of Ph1 meeting (FDA), as well as European and CDE consultation for Ph3
- Received safe to proceed for global Ph3 trial from China and South Korea
- Received FDA Orphan Drug Designation for PDAC

### Blosozumab (TST002) Ph2



- Completed Ph1 single dose escalation study with favorable safety profile
- Observed significant increases in BMD after single dose of TST002
- Received CDE approval to start Ph2 trial with longer dosing interval

### TST003 Ph1



- Received China IND clearance and a China site has been initiated
- Completed first dose cohort of global FIH study in the US
- Presented preclinical data package at the AACR Annual Meeting 2023

### CDMO Revenue

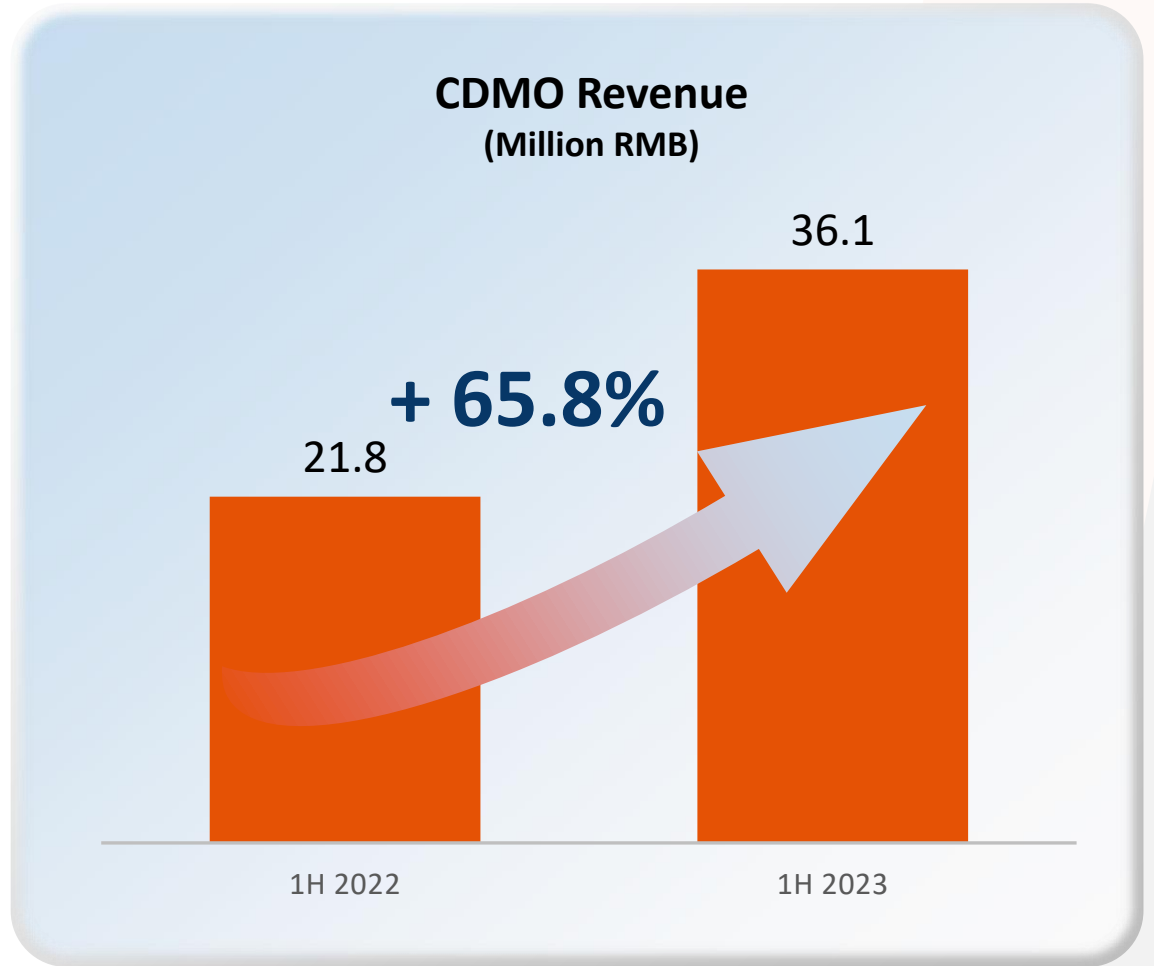
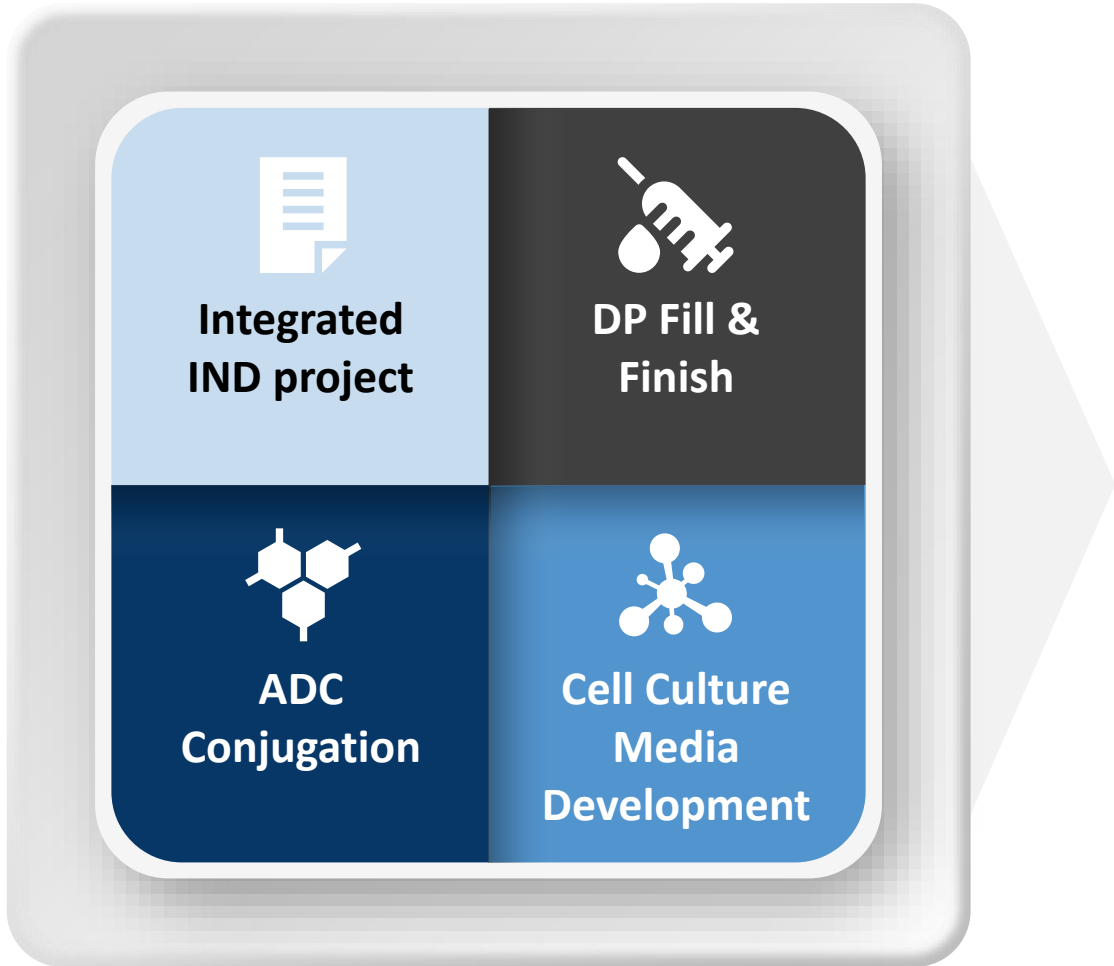


- 1H23 revenue increased **65%** from 21.8M RMB to 36.1M RMB
- Added more than 12 new clients
- Expanded services to include ADC conjugation and cell culture medium development

# CMC & CDMO



Broad Range of CDMO Service Capabilities with Cutting Edge Technology



**02**

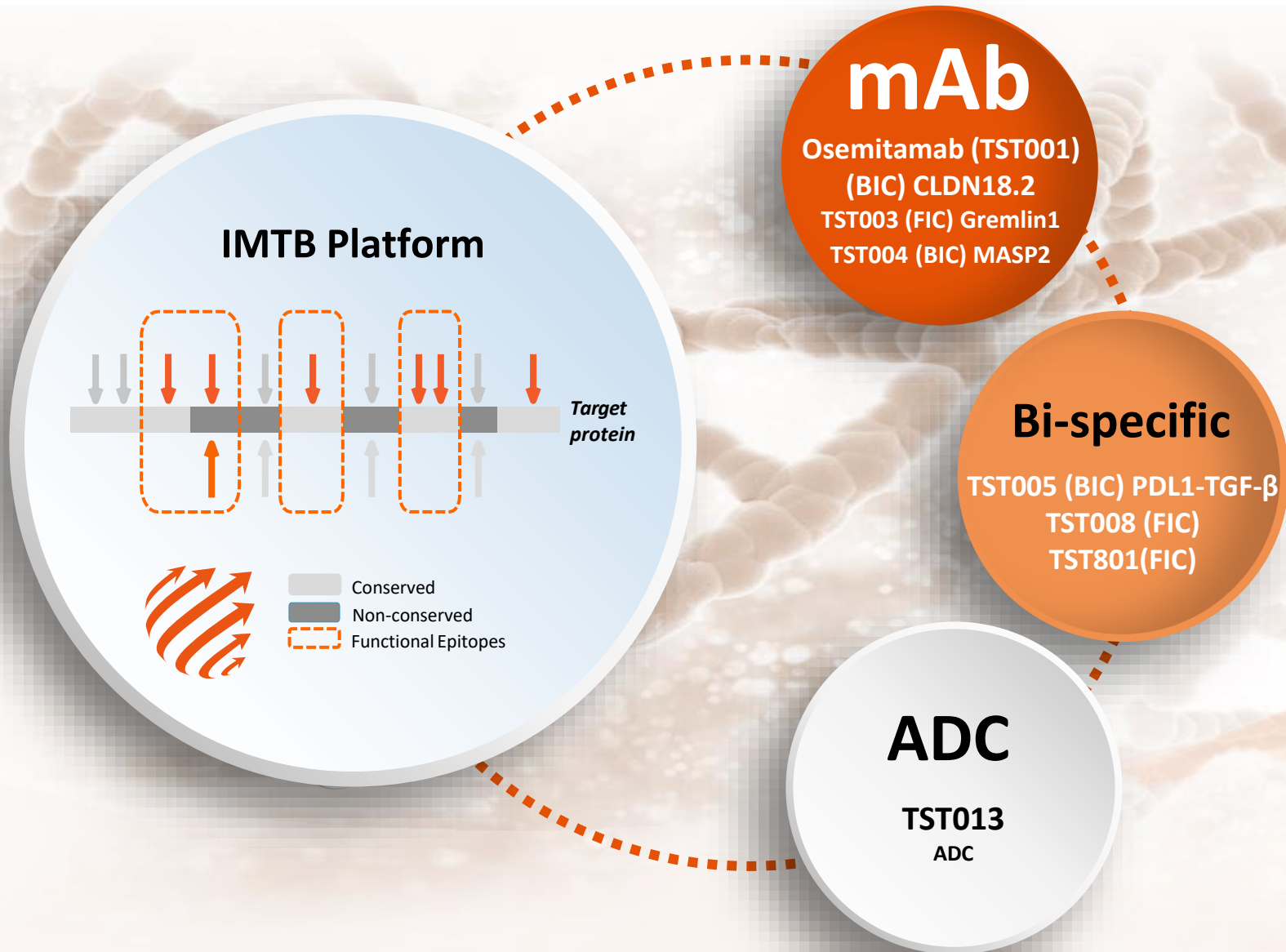
**Business Update**





# Proprietary IMTB Platform and Differentiated Antibodies

Our Proprietary Antibody Discovery Platform : IMTB Delivers Differentiated Lead Candidates

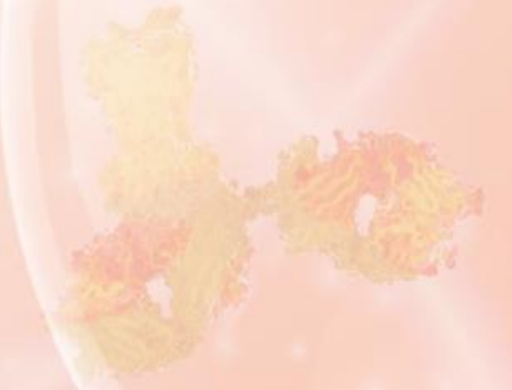


# Pipeline Highlights

## Diversified and Differentiated Pipeline

	Drug candidate	Target	Indications	Clinical trial region	Preclinical	IND	Phase 1a	Phase 1b/Phase 2a	Pivotal Phase 2b / Phase 3	Rights	Partner
Oncology	Osemitamab (TST001)	Claudin 18.2	G/GEJC	1L	Global	Combo with Nivolumab/Chemo				Global	In-house
				1L	China	Combo with Chemo					
			2/3L	Global	Combo with Nivolumab						
			PDAC	1L	Global	Combo with Chemo					
	MSB0254	VEGFR2	Solid tumors	China	Mono					Global	In-house
	TST005	PD-L1/TGF-β Bi-functional	Solid tumors (HPV+ and NSCLC, etc)	Global	Mono					Global	In-house
	TST003	Gremlin1 (FIC)	Solid tumors	Global	Mono					Global	In-house
	TST006	Bi-specific	Solid tumors	Global	Mono					Global	In-house
	TST010	Undisclosed ADCC enhanced mAb	Solid tumors	Global	Mono					Global	In-house
	TST012	Undisclosed mAb	Solid tumors	Global	Mono					Global	In-house
TST013	Undisclosed ADC	Solid tumors	Global	Mono					Global	In-house	
Non-oncology	MSB2311	PD-L1	TMB-H solid tumors	China	Mono					Global	In-house
			Solid tumors	China	Combo with VEGFRi						
	Blosozumab (TST002)	Sclerostin	Osteoporosis	China	Mono			US Ph II Completed	Greater China	Lilly	
	TST004	MASP2	IgAN, TMA	Global	Mono					Global	ALEBUND
	TST008	MASP2/BAFF Bi-specific (FIC)	SLE/LN/IgAN	Global	Mono					Global	In-house
	TST801	Bi-specific (FIC)	SLE/LN/IgAN	Global	Mono					Global	In-house

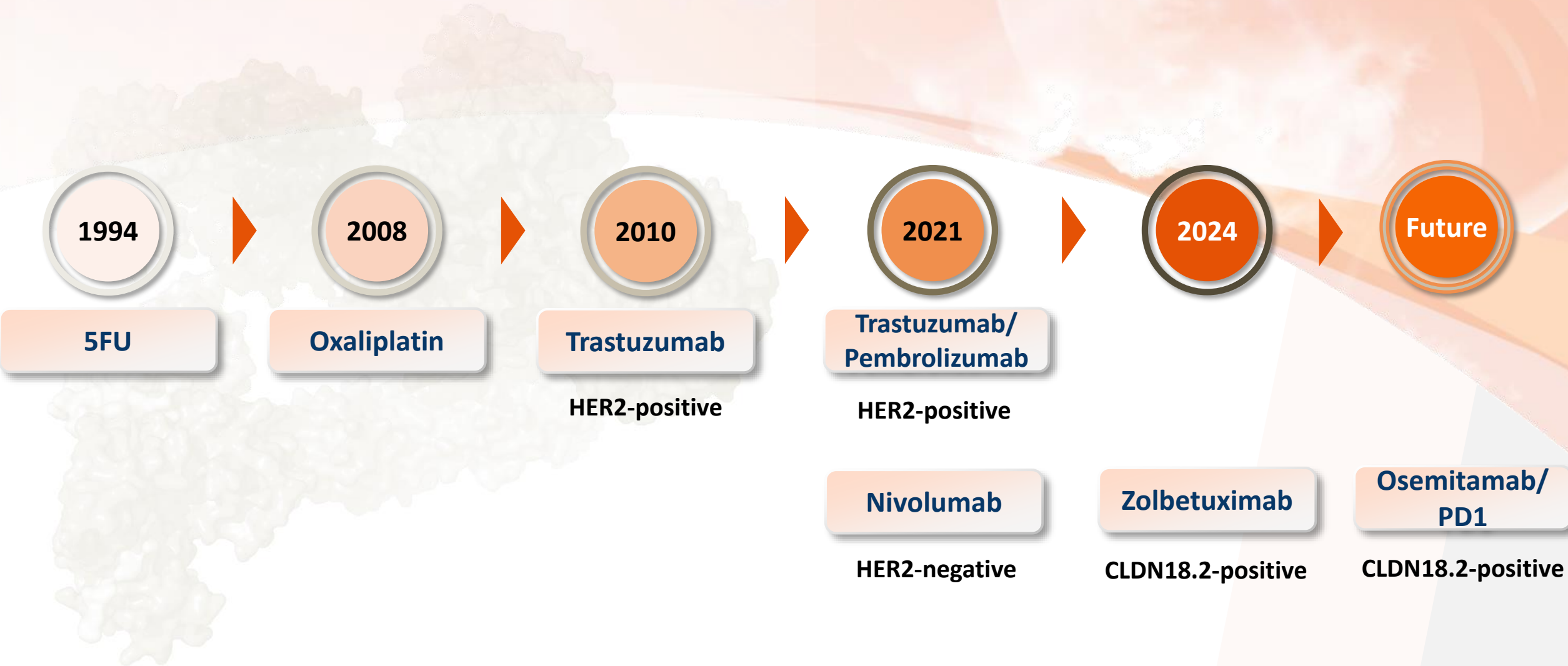
# Osemitamab (TST001)



# Osemitamab (TST001)



## Evolving Landscape for 1L Gastric Cancer



# Osemitamab (TST001)

Oncology



## The 2nd Leading Anti-CLDN18.2 mAb with a Differentiated Profile vs. Zolbetuximab

### BIC / FIC Potentials



**Humanized antibody**



**Higher binding affinity**

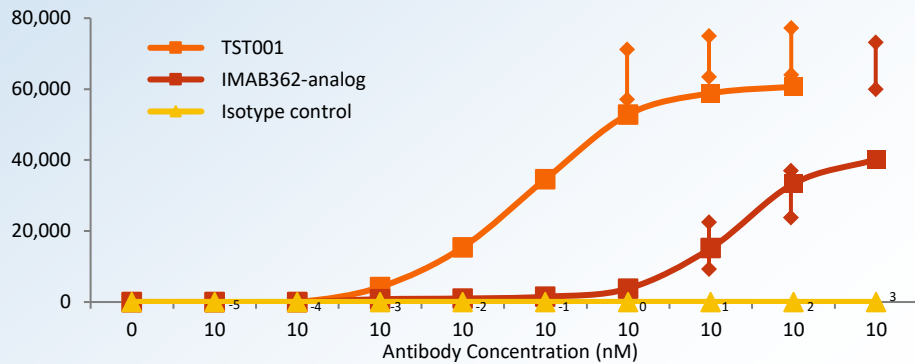


**Enhanced ADCC**

Reduced fucose in Fc and enhanced FcR binding with NK cell and ADCC activity (30-100 fold)

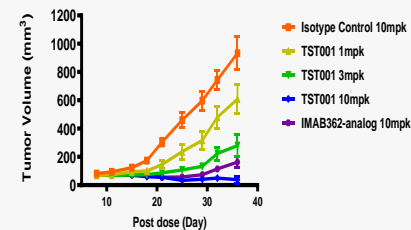
### Enhanced ADCC activity for CLDN18.2 low expressing gastric cancer cells

Mean Fluorescence Intensity



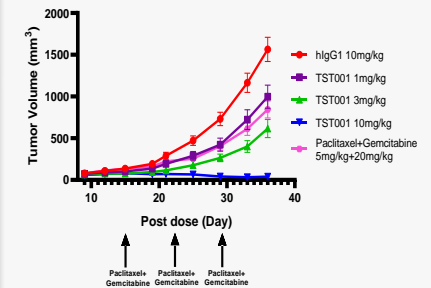
### Significantly better than Zolbetuximab

#### MKN45-CLDN18.2 (40%) Gastric Tumor Model

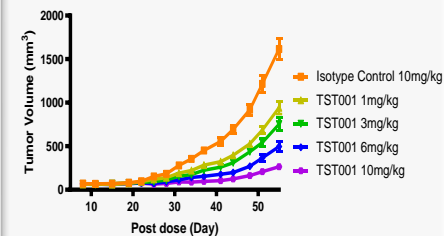


7/10 in Osemitamab Group vs. 0/10 in IMAB362 Group Achieved Tumor Clearance

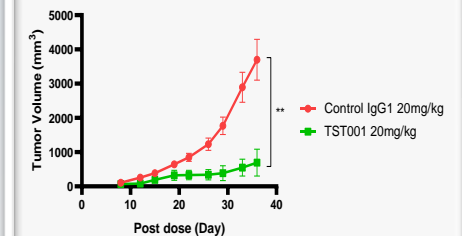
#### BxPC3-CLDN18.2 (90%) PDAC Tumor Model



#### H146 (CLDN18.2 90%) SCLC Tumor Model



#### DV90 (CLDN18.2 90%) NSCLC Tumor Model



\*\* : p<0.01

# Osemitamab (TST001) Development Status:



Solid data package supporting Ph3 plans in 1L G/GEJC

In the U.S. and China >300 patients dosed as of June 30, 2023 including >150 1L G/GEJC across a broad range of CLDN18.2 expression. Key cohorts below.



## TranStar102/TST001-1002 (CN) - NCT04495296

### Combination and setting

Cohort C: Q3W +CapOx in 1L G/GEJC

Cohort G: Q3W+CapOx+nivolumab in 1L G/GEJC

Cohort H: Q3W+ nivolumab in 3L+ G/GEJC

### CLDN18.2 expression (expansion)

≥10%, ≥1+

any

any

## TranStar101/TST001-1001 (US) - NCT04396821

### Combination and setting

Cohort A: Q2W+nivolumab+FOLFOX in 1L G/GEJC

Cohort B: Q3W+nivolumab in 2/3L+ G/GEJC

### CLDN18.2 expression (expansion)

≥10%, ≥1+

≥10%, ≥1+

# Osemitamab (TST001)



## Milestones in 2023



Jan

- ASCO GI 2023 combination with CAPOX
- EOP1 FDA



Mar

- Claudin 18.2-targeting Immuno-PET probe [89Zr]Zr-DFO-TST001
- Orphan drug designation for PDAC
- Positive EU HA consultations for Ph3



Apr

- Completed the enrollments of cohort-G (combination with Nivolumab and Capox in 1L G/GEJC)



Jun

- ASCO 2023
- ESMO GI 2023
- Updated supportive data including in low expressors



Jul

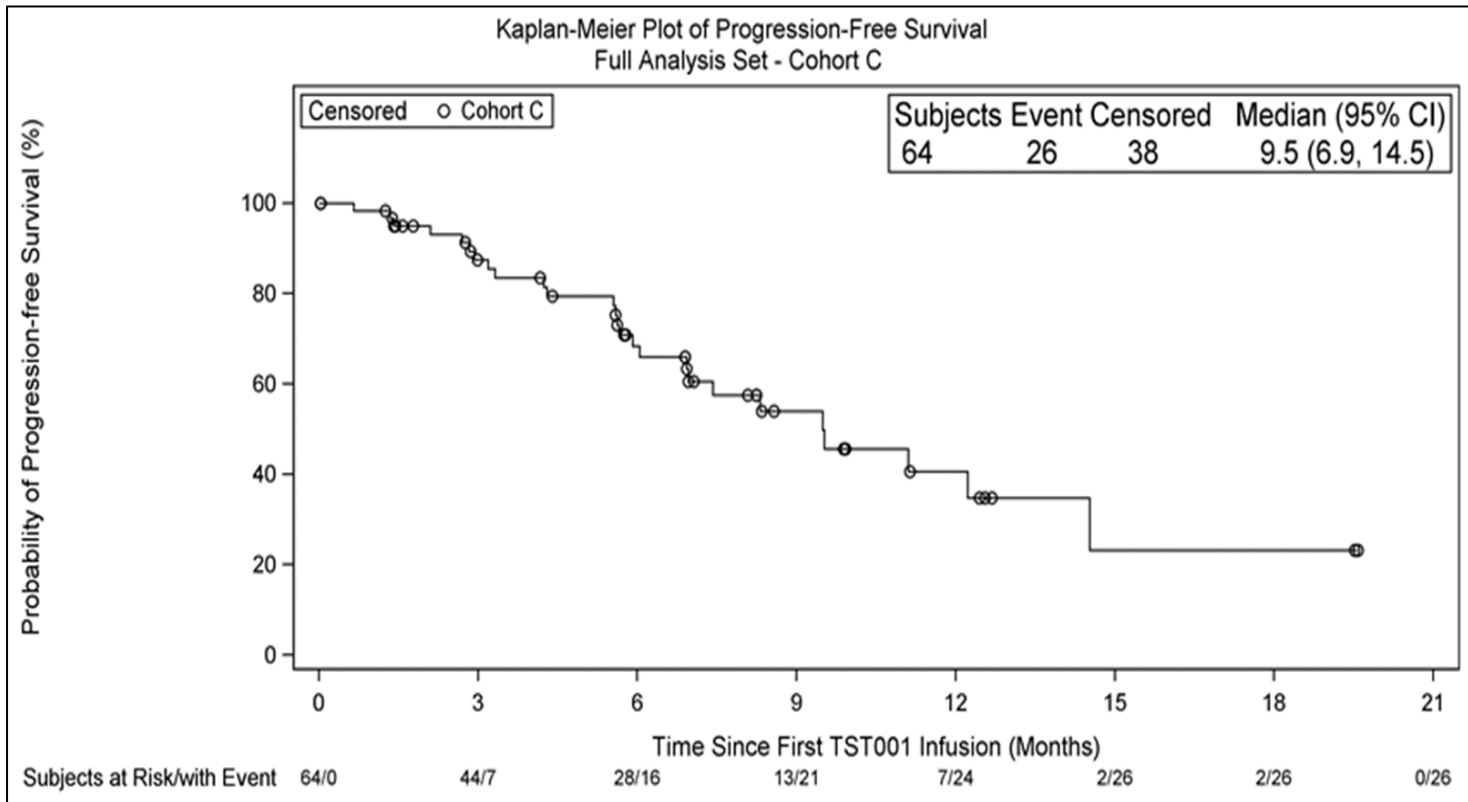
- Positive CDE consultation for Ph3 plans
- Received Safe to proceed for Ph3 study from CDE and South Korea MFDS
- In discussions with multiple regulatory agencies
- Ph3 operational implementation proceeding, including CDX ready

# Osemitamab (TST001)



Encouraging Efficacy Outcomes-Cohort C-1L G/GEJC in combination with CAPOX

Estimated mPFS of 9.5m in patients with CLDN18.2 expression  $\geq 10\%$  and  $\geq 1+^*$  - all doses of Osemitamab



\* ASCO 2023 Poster 4046 Cut-off date: 21 April 2023. Median follow up 195 days

\*\* ESMO GI PD-7

## Key Messages



**55%** screened patients enrolled based on their CLDN18.2 expression, with Transcenta proprietary IHC CDx assay

**9.9 m**

Estimated mDoR  
all doses

**9.5 m**

Estimated mPFS  
all doses

Consistent efficacy benefit observed across all levels of CLDN18.2  $\geq 10\%$  and  $\geq 1+^{**}$

TRAEs mostly grade **1-2**



2023 ASCO  
ANNUAL MEETING



WORLD CONGRESS ON  
Gastrointestinal  
Cancer  
ESMO



# Osemitamab (TST001)



## Osemitamab (TST001) -Clinical Differentiation

	Claudin 18.2 Cutoff	Prevalence (% of all G/GEJC cases)	mPFS	mDOR
<b>Osemitamab +CAPOX*</b> (n=64, all doses)	≥10%, ≥1+	55%	9.5m	9.9m
<b>Zolbetuximab +CAPOX**</b> (N=254)	≥75%, ≥2+	38%	8.21m	6.3m
<b>CAPOX**</b> (n=249)	≥75%, ≥2+	38%	6.8m	6.2m

**Cross study comparison shows improved PFS and DOR in a broader patient population**  
*Updated PFS and DOR at the recommended dose of 6mg/kg to be presented at ESMO 2023*



### Target patient number 2023

**Worldwide: >100K<sup>[1]</sup>**

HER2-negative CLDN18.2 positive\* 1L G/GEJC, 2023  
 55% all comers per proprietary IHC assay

Source: Decision Resources GC reports, 2022

\*Shen et al., ASCO 2023 abs 4046 Claudin 18.2 expressing patients, defined by IHC assay 14G11 with cutoff of April 21, 2023

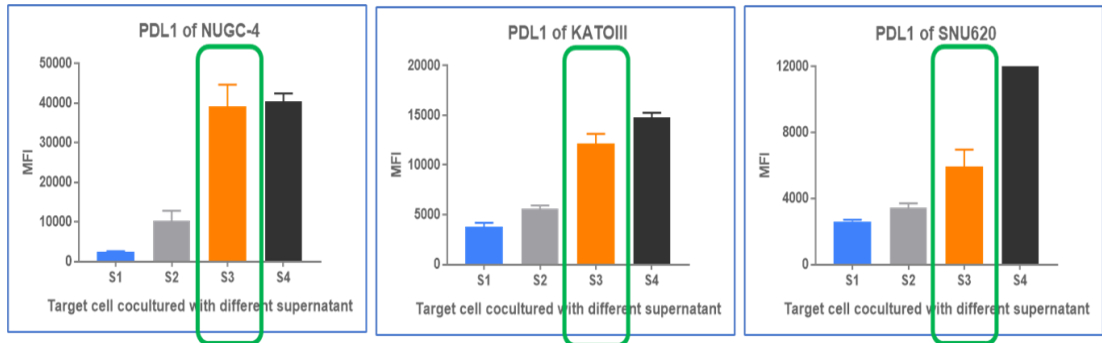
\*\* Xu. Et al. ASCO 2023, abs405736 GLOW trial, defined by Ventana 43-14A Rx/Dx assay.

# Osemitamab (TST001)



## Synergy Demonstrated between Targeted Therapy TST001 and Checkpoint Inhibitor Nivolumab

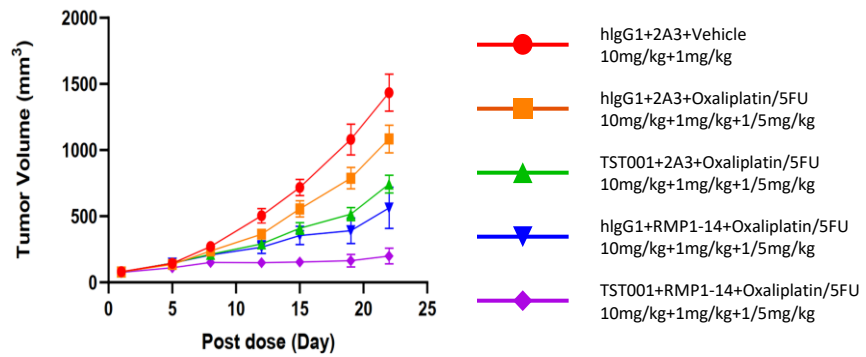
### TST001 Induces Upregulation of PDL1



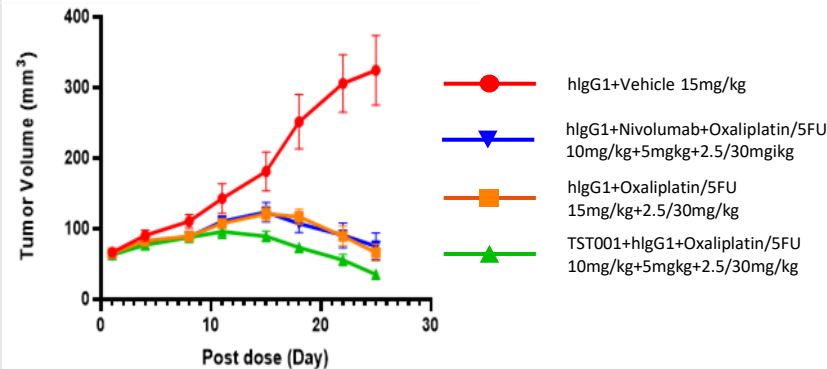
Supernatant of co-culture

- S1: Target cell alone
- S2: Target cell+PBMC+hIgG1
- S3: Target cell+PBMC+CLDN18.2 Ab
- S4: Target cell+IFN- $\gamma$

### CLDN18.2 (100%)/PDL1+ Syngeneic Model



### CLDN18.2 (>95%)/PDL1-Negative PDX Model



### Key Messages

“




**BIC potential: Enhanced ADCC modality and synergy with PDL1 supportive of development in a broader CLDN18.2+ population**

”

# Osemitamab (TST001)



Study Design - Cohort G and Cohort A -1L G/GEJC in combination with CAPOX plus PD-L1

Study Design 		Status	Key Messages
Cohort G	<p><b>TranStar102/NCT04495296</b> </p> <p><b>TST001 + Nivolumab + CAPOX – 1L G/GEJ cancer</b></p> <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid orange; padding: 5px; width: 45%;"> <p>TST001 6mg/kg + Nivolumab + CAPOX Q3W N=3-6</p> <p>TST001 3mg/kg + Nivolumab + CAPOX Q3W N=3-6</p> </div> <div style="border: 1px solid orange; padding: 5px; width: 45%;"> <p>TST001 6mg/kg + Nivolumab + CAPOX Q3W N= ~20-40</p> <p>TST001 3mg/kg + Nivolumab + CAPOX Q3W N= ~20-40</p> </div> </div> <p style="text-align: center;">Safety run-in      Expansion (CLDN18.2 expression)</p>	<p><b>Recruitment completed in April 2023:</b></p> <p><b>40 patients dosed with TST001 3 mg/kg,</b></p> <p><b>42 patients dosed with TST001 6 mg/kg</b></p>	
	Cohort A	<p><b>TranStar101/NCT04396821</b> </p> <p><b>TST001 + Nivolumab + FOLFOX6 – 1L G/GEJ cancer</b></p> <div style="display: flex; justify-content: space-around;"> <div style="border: 1px dashed gray; padding: 5px; width: 15%;"> <p>1:1</p> </div> <div style="border: 1px solid orange; padding: 5px; width: 85%;"> <p>Cohort A1: TST001 2mg/kg Q2W + Nivolumab + mFOLFOX6</p> <p>Cohort A2: TST001 4mg/kg Q2W + Nivolumab + mFOLFOX6</p> </div> </div> <p style="text-align: center;">Lead-in      Expansion (CLDN18.2 selected)</p> <p>Totally 15 subjects with CLDN18.2 expressing cancer for each dose</p>	<p><b>Recruitment ongoing</b></p>

*Key Messages*

“ No unexpected safety events; overall profile supportive of proceeding to Ph3 ”

# Osemitamab (TST001)

Ph3 global MRCT trial design & status



Locally Advanced or Metastatic  
Gastric or Gastroesophageal Junction  
(G/GEJ) Adenocarcinoma

1L treatment

CLDN18.2 positive

HER2 negative

Known PD-L1 CPS status

**TranStar301**

TST001 + CapOx or mFOLFOX6 + Nivolumab

Placebo + CapOx or mFOLFOX6 + Nivolumab

## Status

- Operationally on track, including CDx
- Received China CDE and SK MFDS Approval
- To consult FDA in September
- Plan to initiate dosing upon FDA clearance

# Osemitamab (TST001) Indication Potential



Development plan and huge potential for multiple indications enabled by Transcenta specific IHC CDx Assay.

## 1L GC/GEJC

**>100K**

addressable patients globally  
\* [1]

**≥55%**

of all comers \*\*

- Combo with SOC Nivolumab/ chemo
- Ph3 to start in 2023



## Peri-Operative GC

**~70K**

addressable patients globally  
\* [1]

**~55%**

of all comers \*\*

- Potentially first mover anti-CLDN18.2 mAb



## Other indications

### 1L PDAC

**~75K**

addressable patients globally  
\* [2]

**~50%**

of all comers \*\*



### Lung Cancer

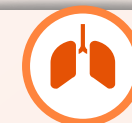
**~41K**

addressable patients globally  
\* [2]

**~11K**

addressable patients for Peri-operative NSCLC\*

**~10%** of all comers \*\*



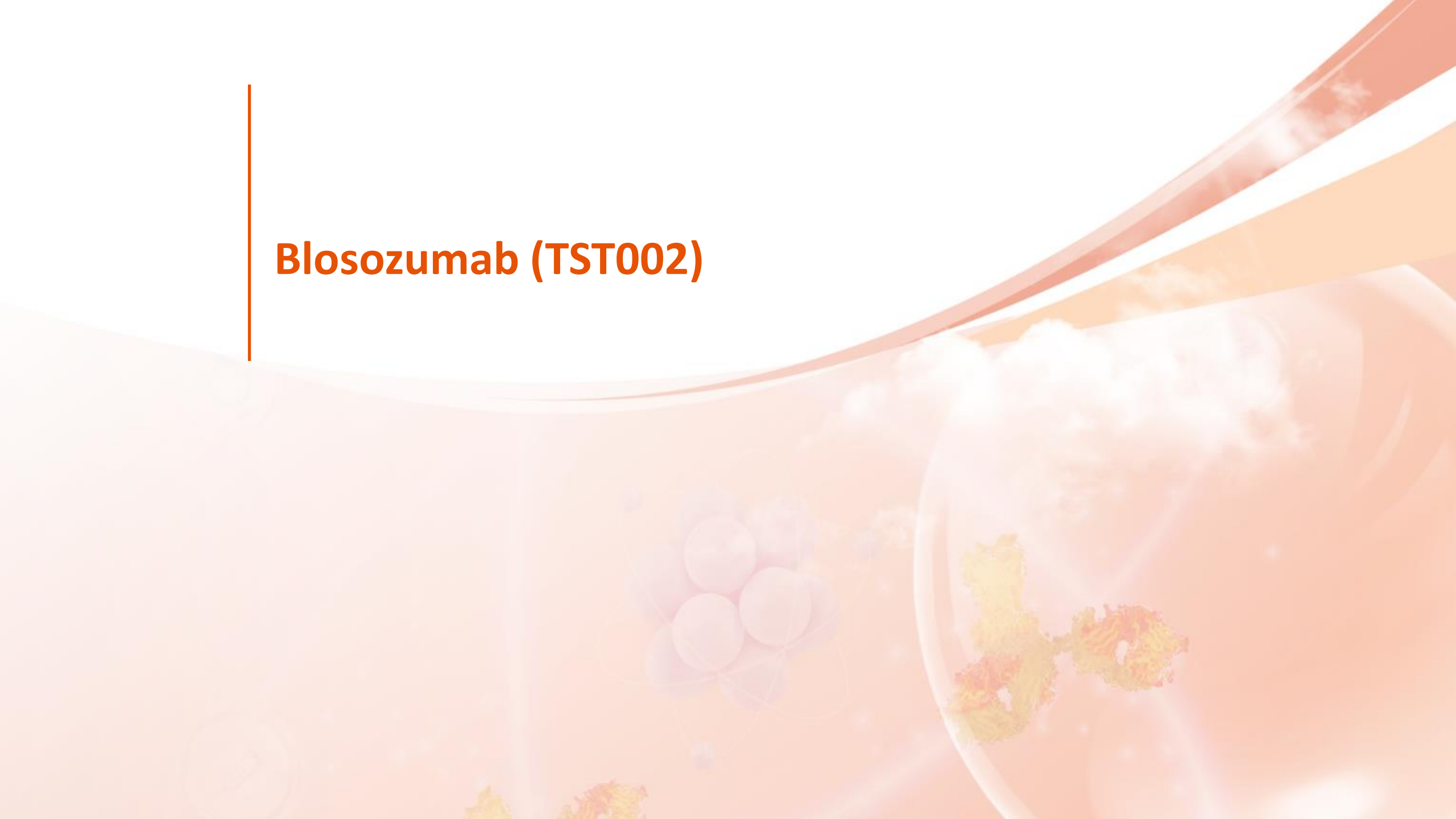
\* (G7+China)

\*\* per proprietary IHC assay

Source: [1] Decision Resources

[2] Decision Resources and Globocan

# Blosozumab (TST002)

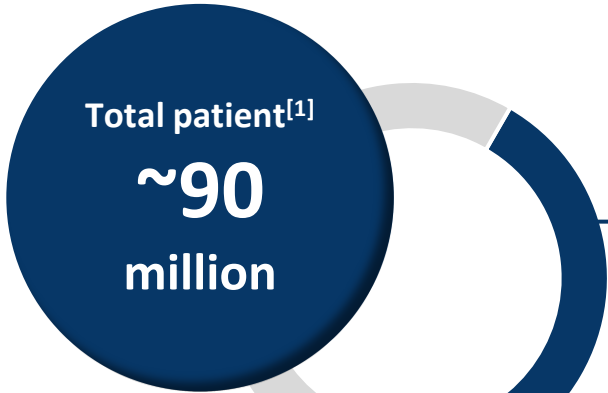


# Blosozumab (TST002)

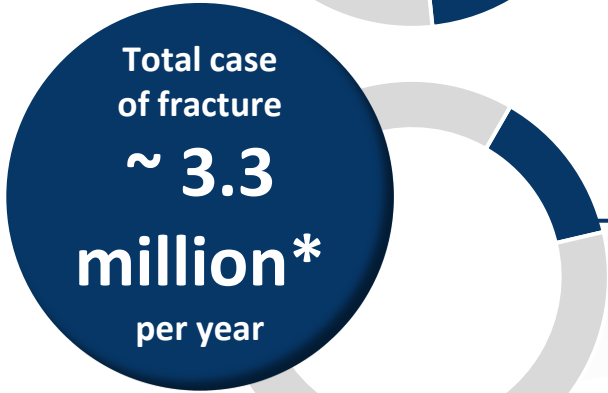


## Landscape

### High Unmet Medical Needs



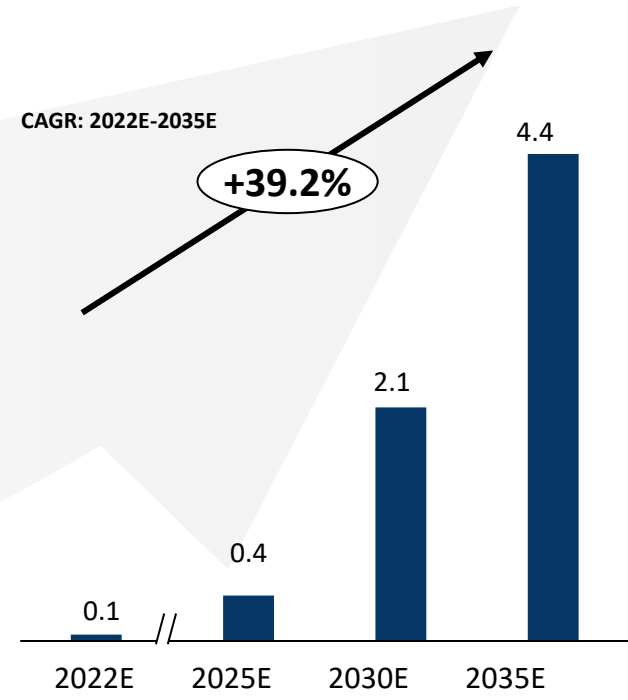
The lifetime risk of osteoporotic fracture in women is **~40%**



The lifetime risk of osteoporotic fracture in men is **~13%**

### Large Market Potential

Market size of China anti-sclerostin drugs (USD bn)



### Key Messages

“

#### Key Drivers and Future trends

- Fast growth of prevalence in China due to aging population
- Increasing healthcare expenditure per capita
- Enhancing awareness of the impact of osteoporosis on quality of life
- No antisclerostin approved in China

”

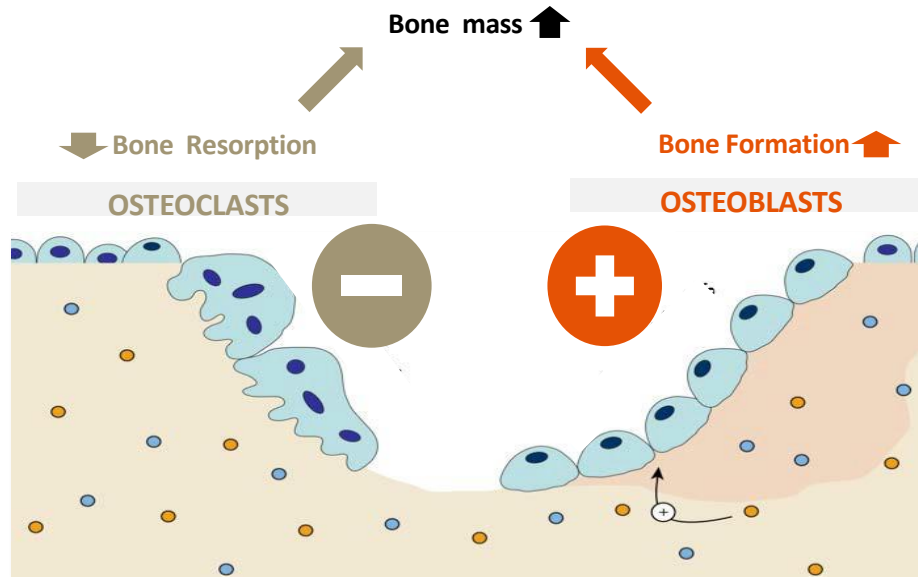
1. Chinese Society of Osteoporosis and Bone Mineral Research. Guidelines for the diagnosis and treatment of primary osteoporosis (2022)  
\*calculated based on a study conducted in 2013 *Projection of osteoporosis-related fractures and costs in China: 2010–2050, DOI 10.1007/s00198-015-3093-2*

# Blosozumab (TST002)



A Well Differentiated Monoclonal Antibody Targeting Sclerostin for Bone Diseases, Licensed from Eli Lilly

## Dual Mechanisms



*More potent than all currently available anti-OP medicines that address only one aspect of unmet needs*

- Only improving bone formation: PTH and PTH analogue
- Only inhibiting bone resorption: bisphosphonate, calcitonin, Estrogen, SERMs, RANKL inhibitor

## Favorable Background

- Ph2 study in US/JAPAN completed by Eli Lilly
- Outstanding BMD increase with 52 weeks treatment: 17.7% in lumbar spine, 6.7% in total hip and 6.3% in femoral neck
- Good safety and tolerance
- No cardiovascular adverse event was observed

## Our Objectives

### Efficacy

Replicate efficacy findings in Chinese population



### Dosage Forms

Offer more alternatives: less frequent (Q3M or Q2M) IV formulation



### Domestic Production

Low COGS



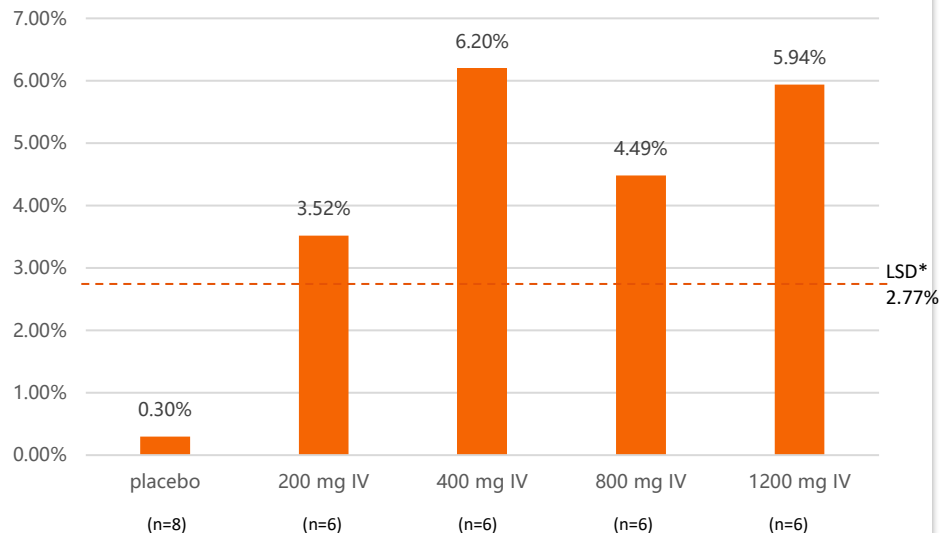


# Blosozumab (TST002)



Ph1 single ascending dose confirms significant efficacy and potential for longer dosing interval

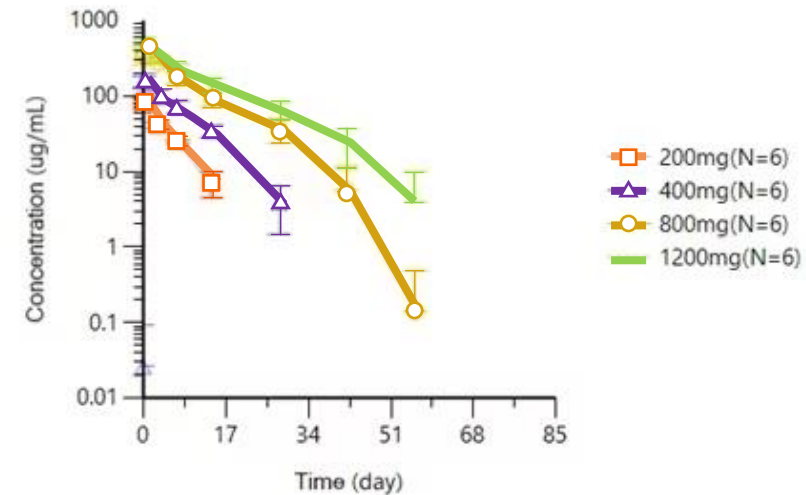
## D85 lumbar spine BMD % change from baseline in TST002



\*LSD: least significant difference

## Pharmacokinetic profile

Semi-logarithmic scale



## Key Messages

- Efficacy and clinical pharmacology data are consistent with Blosozumab data and support exploring longer dosing intervals in Ph2 (2-3 months)
- Received approval from CDE to initiate Ph2 trial

Full study readouts to be presented by End of 2023

# Blosozumab (TST002) Indication Potential



Huge unmet medical needs and broad target patient populations for anti-sclerostin antibody

No anti-sclerostin drug has been approved in China yet

## Postmenopausal Osteoporosis in Women

**~70 million**  
patients in China<sup>[1]</sup>

**~3 million**  
osteoporotic fractures in China



## Osteoporosis in Men

**20 million**  
patients in China<sup>[1]</sup>



## Post OVCF\* Surgery

**1.5 million**  
new vertebral fracture case in  
2020 in China<sup>[2]</sup>



\*OVCF: Osteoporotic Vertebral Compression Fractures

1. Chinese Society of Osteoporosis and Bone Mineral Research. Guidelines for the diagnosis and treatment of primary osteoporosis (2022)
2. 2021 Chinese Guidelines for the Diagnosis and Treatment of osteoporotic vertebral compression fractures

**TST003**





## First-In-Class anti-GREMLIN-1 mAb with Potentials in Multiple Tumor Types

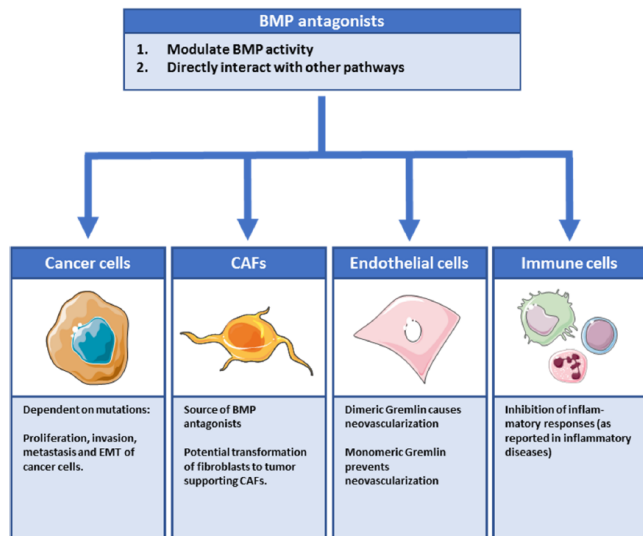
### Target and Potential

- Gremlin-1 is an antagonist of BMP signaling pathway
- Gremlin-1 may have multiple functions to promote tumor progression and metastasis
- Gremlin-1 is highly upregulated in multiple types of solid tumors
- Tumors with mesenchymal phenotypes is less responsive to checkpoint inhibitors
- TST003 is a humanized neutralizing antibody with high affinity to GREM1
- A global FIH study is ongoing in selected indications

### Key Messages

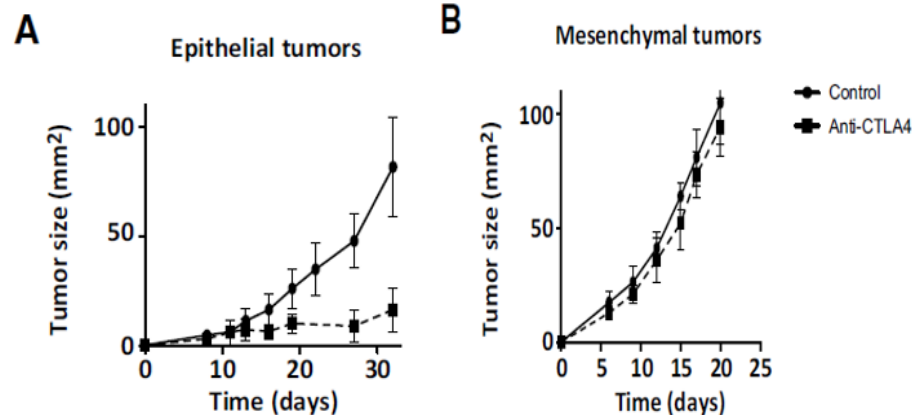


- IND Cleared by FDA and CDE
- IHC assay developed
- First dose level cohort completed
- Preclinical data presented at the AACR Annual Meeting 2023



Int. J. Mol. Sci. 2020, 21(11), 3888

### Epithelial-to-Mesenchymal Transition Contributes to Immunosuppression in Breast Carcinomas



Cancer Res. 2017 Aug 1;77(15):3982-3989.

# TST003 displayed potent anti-tumor activity in MSS CRC PDX model



## Grem1

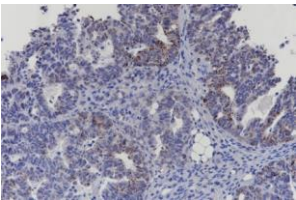
- Grem1 is highly upregulated in advanced MSS CRC

## TST003

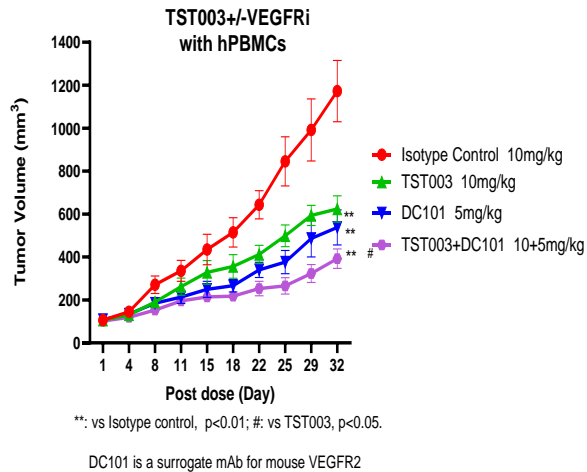
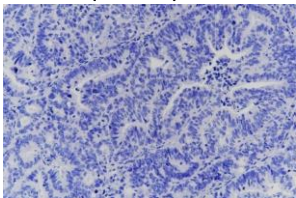
- TST003 enhanced BMP signaling and inhibited Wnt signaling (RNseq)
- TST003 facilitates infiltration of CD3/CD8 T cells into tumor (IHC)
- TST003 displayed promising activity in MSS CRC either as single agent or in combination with angiogenic inhibitor

## Displayed Single Agent and Combination Anti-tumor Activity in MSS CRC PDX Tumor Model

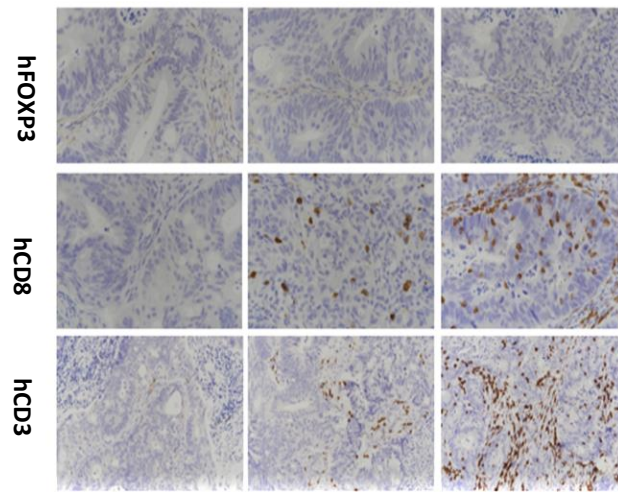
Gremlin (14E3)



PD-L1 (SP263)



Control TST003 3mg/kg TST003 10mg/kg



RNseq



LEF1 & WIF1  
 Genes inhibiting Wnt signaling and colon tumor cells growth

TST003



ID1 & ASCL2  
 Genes promoting colon stem cell growth and renewal

In house data

# TST003 displayed potent anti-tumor activity in mouse model of mCRPC



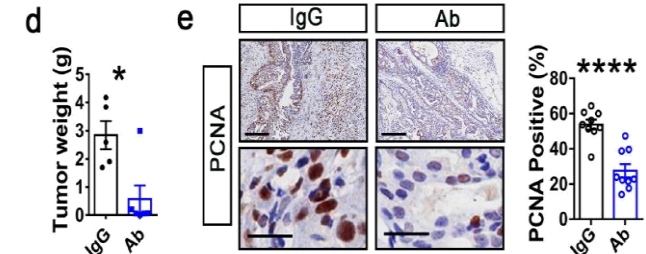
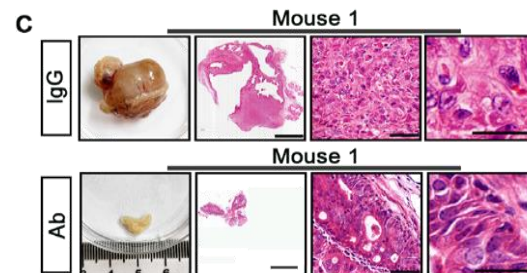
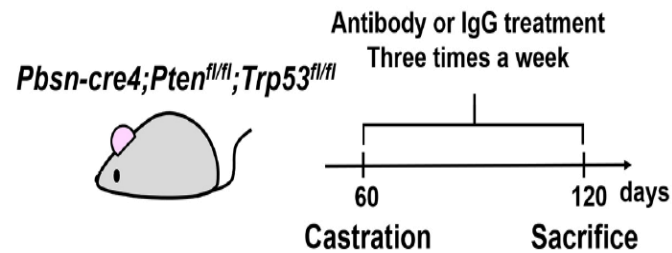
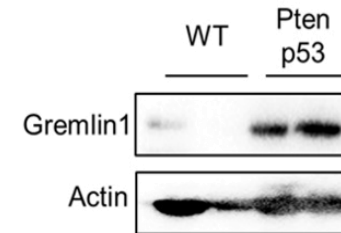
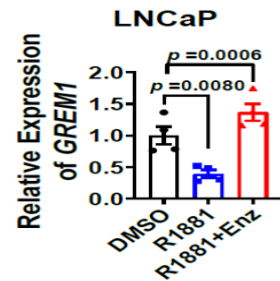
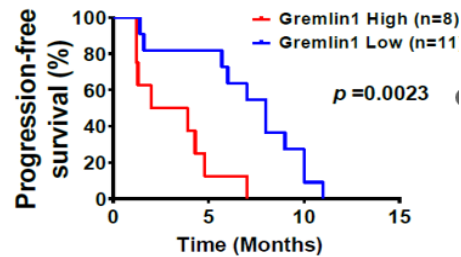
## Grem1

- Grem1 is highly upregulated in mCRPC

## TST003

- TST003 displayed potent single agent anti-tumor activity in mouse model of AR low or negative
- TST003 treatment can restore AR sensitivity and be synergistic with AR antagonist in PDX model

## Displayed Single Agent Activity in AR & Neuroendocrine Marker Double Negative CRPC Mouse Model



# TST003 Indication Potential



Development plan: major indications with unmet medical need and substantial market size will be explored

## MSS CRC in combination with SOC

**>~285K**

addressable patient in 1L and late lines of metastatic MSS CRC \*[1]

## CRPC in combination with AR inhibitors

**>~100K**

addressable patient in 1L and late lines of metastatic CRPC \*[1]

## Address unmet medical needs in other indications

Supported by preclinical data: eg NSCLC

**50%** NSCLC and

**30%** SCLC express grem1

CDP to refine TST003 potential in MSS CRC, CRPC and other indications such as NSCLC or SCLC, exploring optimal combinations and selection markers (GREM1)

\* (G7+China)

Source: [1] Decision Resource reports and Globocan

# Upcoming milestones



**Q3/23**

## **Osemitamab (TST001)**

- FDA EOP2 meeting
- First patient dosing of Ph3 TranStar-301

**Q4/23**

## **Osemitamab (TST001)**

- Presentation of updated PFS and preliminary OS data of osemitamab (TST001) /chemo combo Ph2

## **Blosozumab (TST002)**

- Ph2 initiation
- Present final data for Ph1

**1H/24**

## **Osemitamab (TST001)**

- Data readout for cohort-G (osemitamab/Nivo/Chemo combo Ph2 trial)

## **TST003**

- Completion of Ph1 dose-escalation study



# CMC & CDMO



Flawless Execution, Increased Efficiency, Global Quality Standard and Commercial Manufacturing Readiness

## Developed Specialized CDMO Services

Medium development

ADC CMC process development

Drug product development

### Enhanced Pipeline Development

- Completed process characterization of TST001
- Completed a DS resupply run for TST002

### Upgraded Platform Technology

- In-house cell line expression system
- Cell culture medium
- MCC and Combo systems

Integrated Continuous Biomanufacturing platform

Faster

Quality

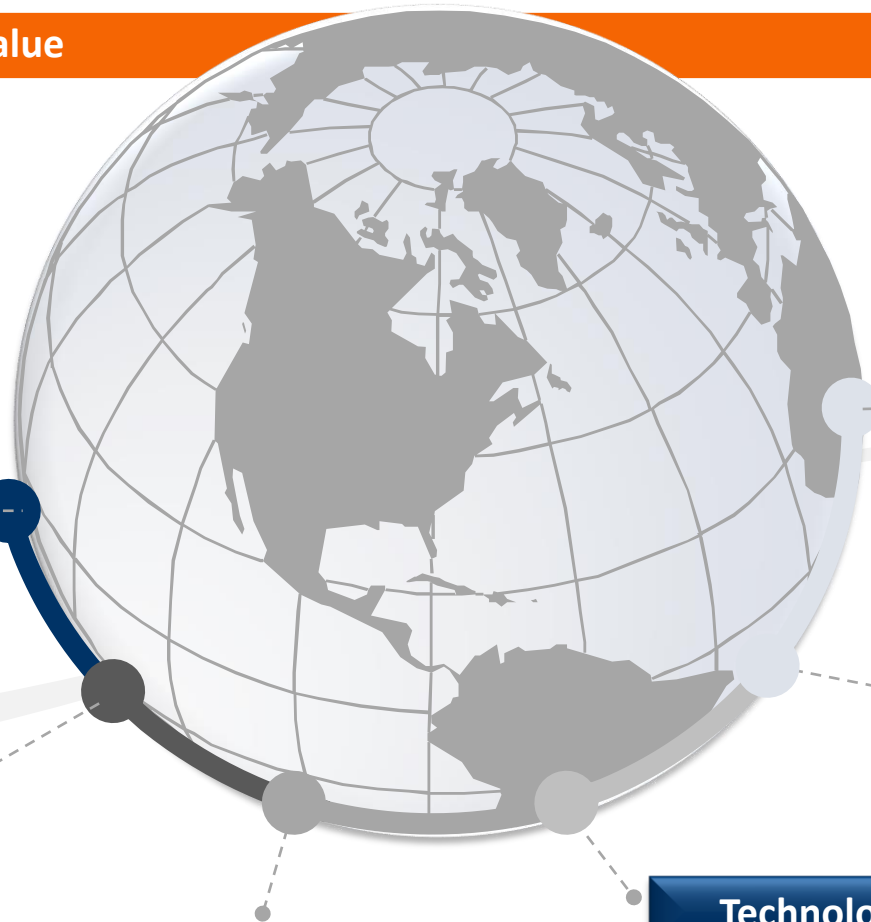
Significant cost saving

Leading perfusion technology

# Business Development



## Multinational Partners to Maximize Value



### Clinical Trial Collaboration

 Bristol Myers Squibb™  
TST001

### In-License

 Lilly TST002

### Research Collaboration

 Dana-Farber Cancer Institute  JOHNS HOPKINS UNIVERSITY  北京大学肿瘤医院 BEIJING CANCER HOSPITAL  上海交通大学 SHANGHAI JIAO TONG UNIVERSITY  上海市肿瘤医院 上海市肿瘤医院 上海交通大学附属上海市肿瘤医院 上海交通大学附属肿瘤医院

### Commercialization

Strategic cooperation agreement with “Tofflon” (Stock Code: SZ 300171) for the market development and sales of the medium.  


### Joint Venture

 ALEBUND TST004

### Technology-based Partnership



# 03 Financial & Outlook

The background features a warm, orange-toned abstract design. A prominent white, wavy line curves across the upper portion of the frame. Below this, there are faint, semi-transparent elements including a molecular model with purple and yellow spheres, and a globe-like structure. The overall aesthetic is clean and modern, typical of a corporate presentation.

# 1H2023 Financial Results

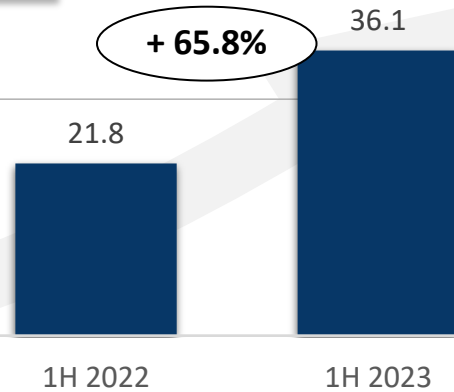


## Financial Profile

### Key Income Statement Metrics (Non-IFRS)

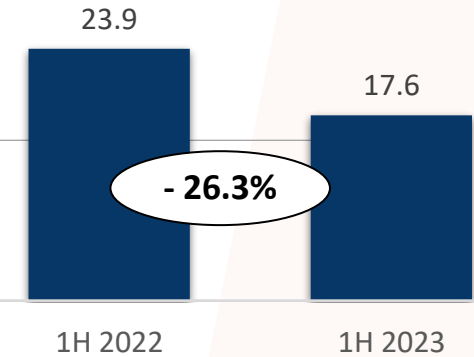
#### Revenue

RMB **36.1** million



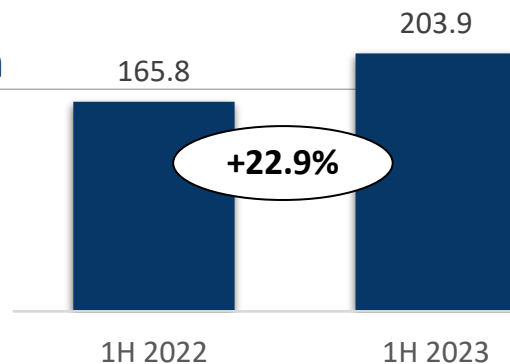
#### Other Income

RMB **17.6** million



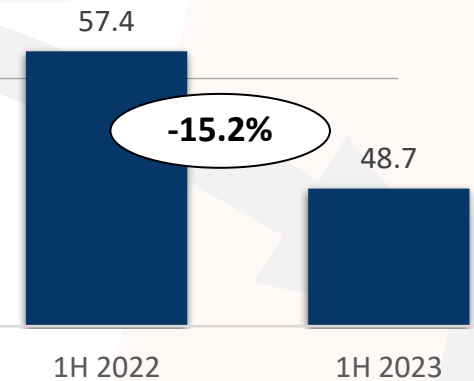
#### R&D expenses

RMB **203.9** million



#### Administrative expenses

RMB **48.7** million



Note: The difference between IFRS and the non-IFRS is mainly driven by the non-cash share-based compensation expenses booked during the reporting period.

# Outlook



Integrated Platform, Cutting-edge Technology, Differentiated and Competitive Biologics

## Clinical Development

- **Present** data for Osemitamab (TST001)
- **Initiate** global Ph3 trial for Osemitamab (TST001) in 2023
- **Initiate** Ph2 study for Blosozumab (TST002)
- **Complete** dose escalation study for TST003



## Research

- **Expand** pipeline by designing innovative agents of new modalities (ADC, bispecific etc)
- **Deepen** translation research to enable indication expansion



## CMC & CDMO

- **Develop and grow** CDMO business
- **Expand** service scope
- **Enhance** Platform Technology
- To fully **utilize capacities and generate** income



## Business Development

- **Continue discussions** with potential partners
- Continue to **identify, evaluate and build** new technology platforms through collaboration and partnership





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*INNOVATE TO EXCEL*

**THANK YOU!**