创胜集团
TRANSCENTA Stock Code: 6628.HK

2023 Annual Results Update

March 28, 2024

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01

Key Highlights

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Key Highlights

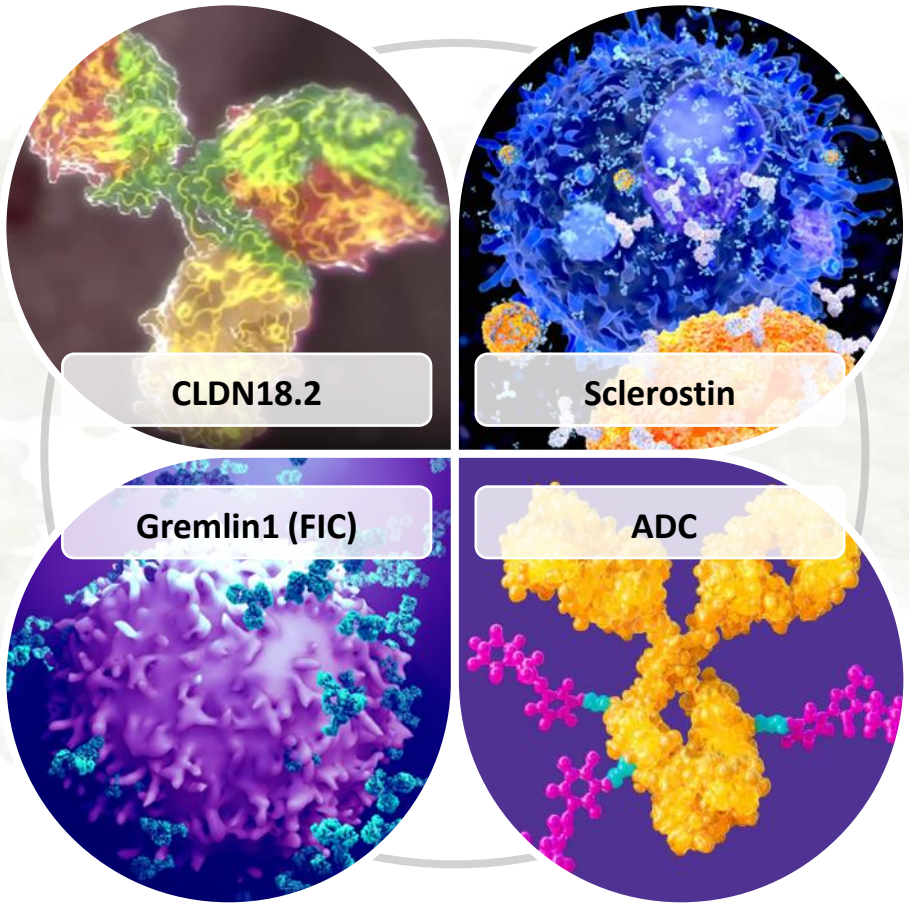
Significant Progress with Key Regulatory Interactions and Datasets Presentations

Osemitamab (TST001)

- Presented data at several major congresses
- Completed enrollment in key cohorts (supporting the Ph3 strategy)
- Received approvals for global Ph3 trial
- Received Orphan Drug Designation in US for PDAC
- Published the preclinical data of [^{177}Lu]Lu-TST001*
- Engaged and discussing with multiple parties on global partnership

TST003

- Completed the third dose cohort
- Presented preclinical data at AACR



Blosozumab (TST002)

- Completed Ph1 single dose escalation
- Observed significant BMD increases
- Obtained CDE approval for Ph2 trial

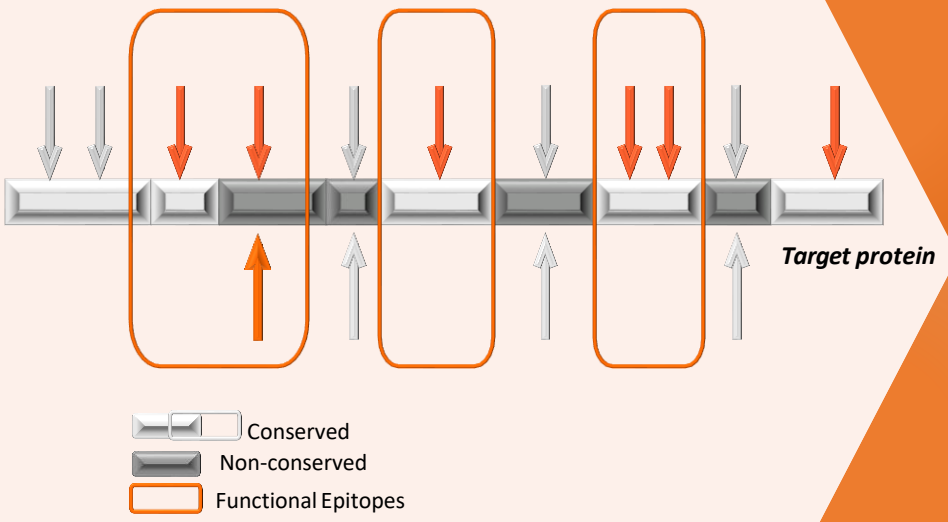
TST013

- IND enabling study to initiate

* Zeng, Z., Li, L., Tao, J. et al. [177Lu]Lu-labeled anti-claudin-18.2 antibody demonstrated radioimmunotherapy potential in gastric cancer mouse xenograft models. Eur J Nucl Med Mol Imaging (2023). https://doi.org/10.1007/s00259-023-06561-1

Proprietary IMTB Platform and Differentiated Antibodies

Our Proprietary Antibody Discovery Platform



mAb

- Osemitamab (TST001) (BIC) CLDN18.2
- TST003 (FIC) Gremlin1
- TST004 (BIC) MASP2

Bi-specific

- TST005 (BIC) PDL1-TGF-β
- TST006 PDL1-CLDN8.2
- TST008 (FIC) MASP2/BAFF
- TST801(FIC)

ADC

- TST012
- TST013

Pipeline Overview

Diversified and Differentiated Pipeline

Drug candidate	Target	Indications	IND	Phase 1	Phase 2	Phase3	Rights	Partner
Osemitamab (TST001)	Claudin 18.2	1L G/GEJC	Combo with Nivolumab/Chemo				Global	In-house
		1L PDAC	Combo with Chemo				Global	In-house
Blosozumab (TST002)	Sclerostin	Osteoporosis	Mono		US Ph II Completed		Greater China	Lilly
MSB0254	VEGFR2	Solid tumors	Mono				Global	In-house
TST003	Gremlin1 (FIC)	Solid tumors	Mono				Global	In-house
TST004	MASP2	IgAN, TMA	Mono				Global	ALEBUND
TST008	MASP2/BAFF Bi-Specific (FIC)	SLE/LN/IgAN	Mono				Global	In-house
TST801	Bi-specific (FIC)	SLE/LN/IgAN	Mono				Global	In-house
TST012	Undisclosed ADC	Solid tumors	Mono				Global	In-house
TST013	Undisclosed ADC	Solid tumors	Mono				Global	In-house

- Oncology
- Non-oncology

02

Business Update

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Osemitamab (TST001)

A Humanized ADCC-enhanced anti-Claudin 18.2 mAb for Solid Tumors

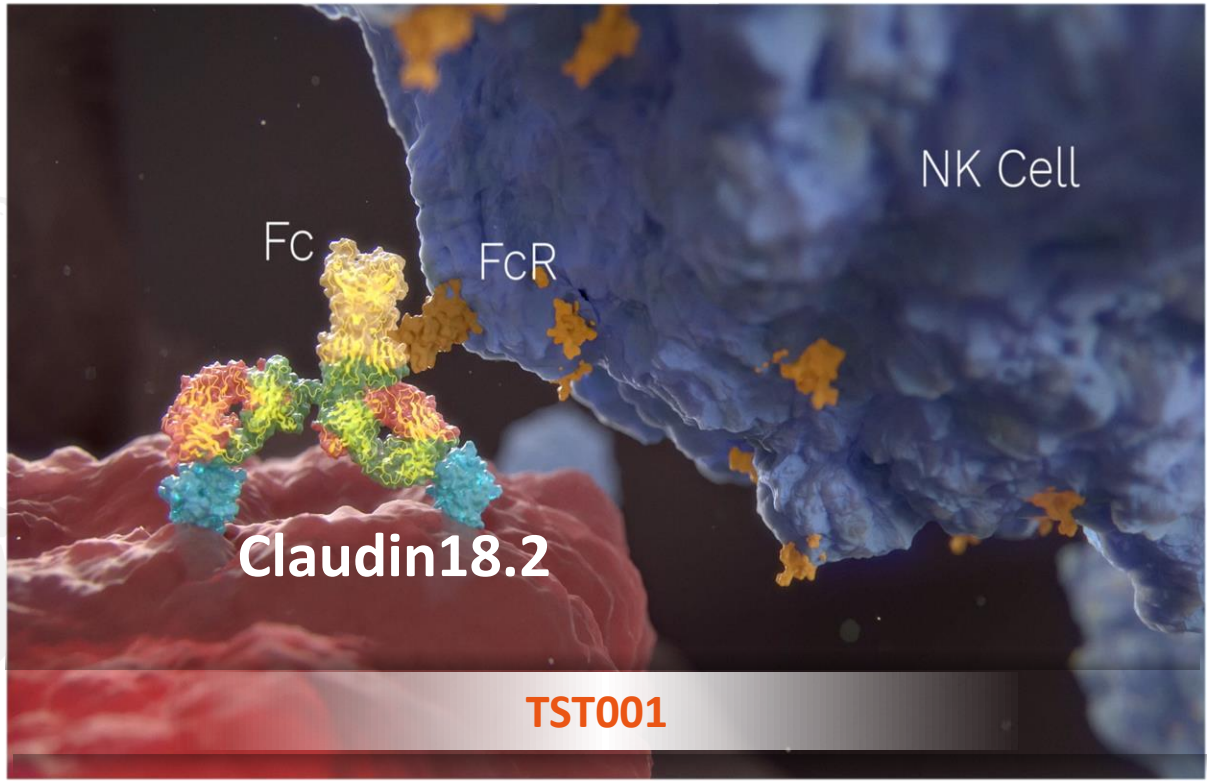
Osemitamab (TST001)

A BIC anti-CLDN18.2 mAb with the Potential of Leading a New Treatment Paradigm in G/GEJ Cancer

Target patient number 2023

>300K[1]

Worldwide[2]

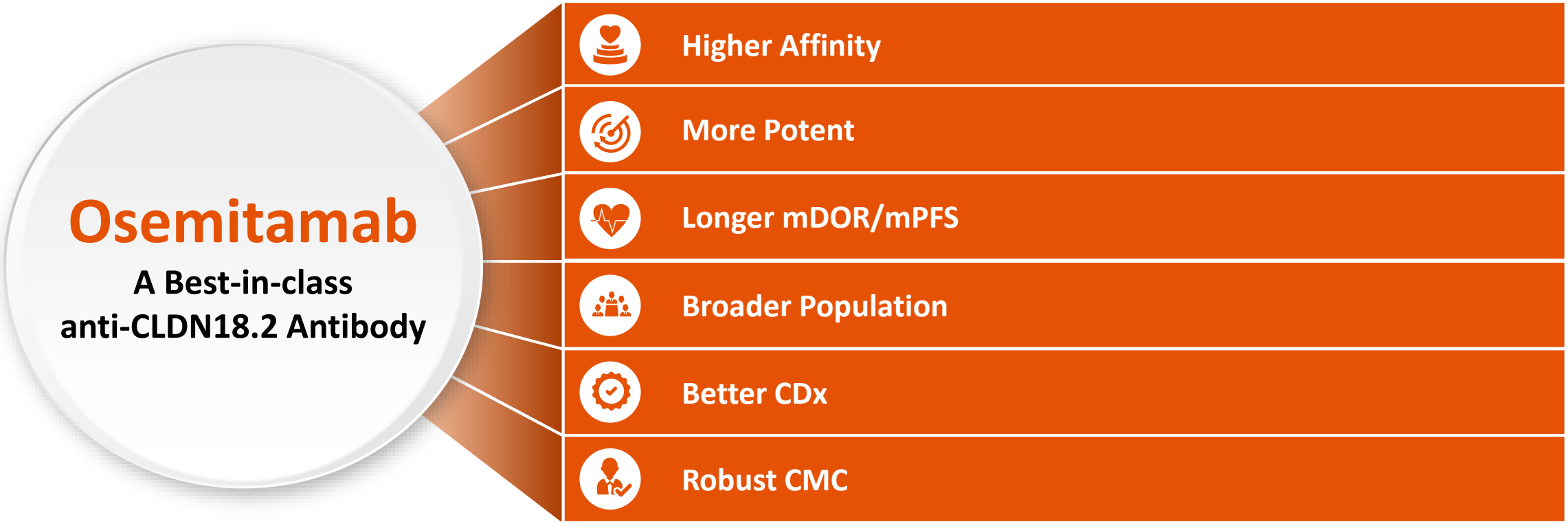


Cornerstone for the treatment of CLDN18.2 positive solid tumors

Note 1: 1L HER2-negative/CLDN18.2 positive mG/GEJC (>100K), CLDN18.2 positive peri-operative G/GEJC (~70K), 1L PDAC (~75K), NSCLC (>40K) and other tumor types (CRC, BTC, etc.)
2: Including US, EU5, Japan and China

Osemitamab (TST001)

Differentiation vs. Zolbetuximab



Note: G/GEJC = Gastric or gastroesophageal junction cancer
*just in 1L G/GEJC

Osemitamab (TST001)

Program Milestones in 2023

Q1

January

- FDA EOP1 meeting
- Ph1/2 design of TST001+Nivolumab+CAPOX /TST001+Nivolumab alone

March

- ODD for PDAC
- EU HA consultations for Ph3

Q2

April

- Enrollment completed in cohort C and G, supportive of Ph3 plans

June

- Updated data in combination with CAPOX
- PFS data per CLDN18.2 expression level from cohort C

Q3

July

- Clearance to proceed to Ph3 from CDE & MFDS

September

- FDA EOP2 consultation

October

- Updated efficacy data from cohort C

Q4

December

- Preclinical results of [^{177}Lu]Lu-TST001 published on EJNMMI

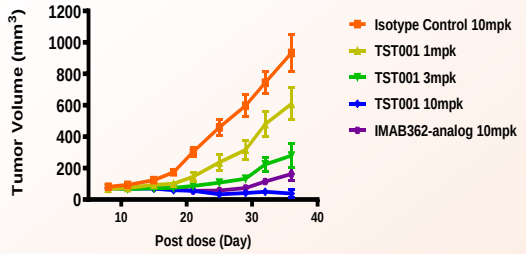
- TST001 based RDC
- In vivo tumor model data

Osemitamab (TST001)

The BIC Anti-CLDN18.2 mAb with a Differentiated Profile vs. Zolbetuximab

Better anti-tumor activities in CLDN18.2 positive gastric cancer tumor model

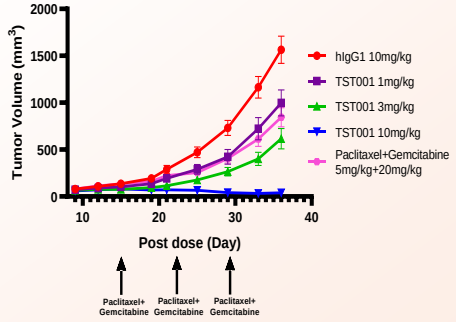
(MKN45-CLDN18.2 (40%))



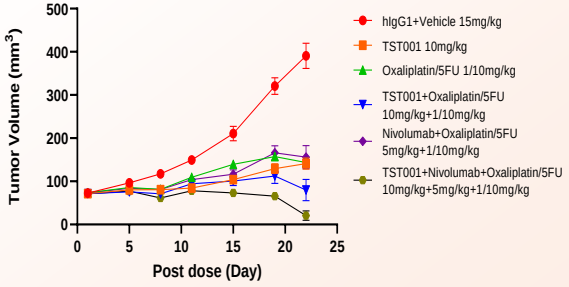
7/10 in Osemitamab Group vs. 0/10 in IMAB362 Group Achieved Tumor Clearance

Strong anti-tumor activities in CLDN18.2 positive pancreatic cancer tumor model

(BxPC3-CLDN18.2 (90%))

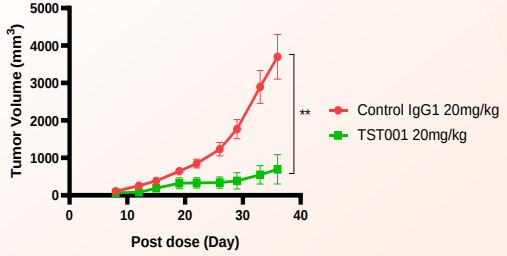


Synergistic anti-tumor activities seen with PD(L)1 mAb combination in PDL1-negative/CLDN18.2 positive PDX model



Strong anti-tumor activities in CLDN18.2 positive NSCLC tumor model

(DV90-CLDN18.2 (90%))

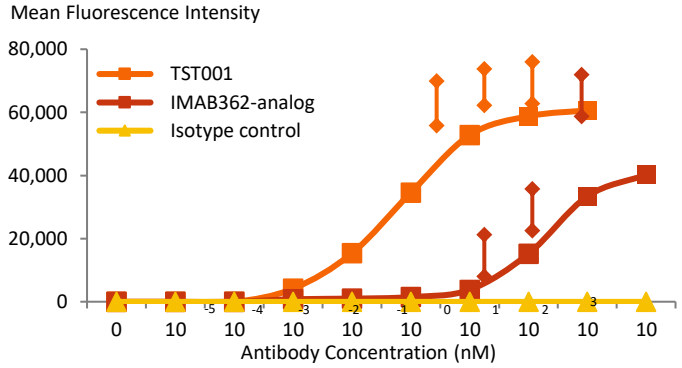


**: $p<0.01$

Significantly better than Zolbetuximab

Higher binding affinity

Enhanced ADCC*



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

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

Osemitamab (TST001)

TST001 Ph1/2 Trial Overview - Study Design: Key G/GEJC Cohorts

	Regimen		Setting	CLDN18.2 Level	# Subjects enrolled (as of Feb 2024)	Status
TranStar102 TST001-002 (NCT04495296)	Cohort C	TST001 Q3W + CAPOX	1L G/GEJC	≥ 10%, ≥1+	64	Updated data presented at ESMO 2023
	Cohort G	TST001 Q3W + CAPOX + Nivolumab	1L G/GEJC	All comers	82	Enrollment completed
TranStar101 TST001-001 (NCT04396821)	Cohort A	TST001 Q2W + FOLFOX + Nivolumab	1L G/GEJC	≥ 10%, ≥1+	18	Enrollment completed

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

Note: G/GEJC = Gastric or gastroesophageal junction cancer

Osemitamab (TST001)

Promising Efficacy Data of TST001 Chemotherapy Combo in 1L CLDN18.2 G/GEJC

	CLDN18.2	Applicable population	mPFS	cORR	mDOR	mOS
Osemitamab (TST001) +CAPOX* (N=49)	**≥10% & ≥1+** (by 14G11 LDT)	**55%**	**14.0m**	**54.8%**	**12.7m**	**NA**
Cross study comparison shows improved PFS and DOR in a broader patient population						
Zolbetuximab +CAPOX** (N=254)	**≥75% & ≥2+** (by 43-14A RxDx)	**38%**	**8.21m**	**53.8%**	**6.3m**	**14.37m**
CAPOX (N=249)	**≥75% & ≥2+** (by 43-14A RxDx)	**38%**	**6.8m**	**48.8%**	**6.2m**	**12.16m**

We have TranStar301 Ph3 Trial Consultations with:

- FDA
- CDE
- MFDS

*ASCO 2023 Poster 4046 including both high/med/low CLDN18.2 expressing patients, defined by IHC assay 14G11 LDT
** GLOW trial, Nature Medicine 2023, CLDN18.2 defined by Ventana 43-14A RxDx assay
Note: PFS: medium progression-free survival; cORR; confirmed objective response rate; DOR: duration of responses; OS: medium overall survival.

Osemitamab (TST001)

TST001 in Combination with Nivolumab plus Chemo could Lead the Treatment Paradigm in 1L G/GEJC

2021-2024

1L

- **Chemo**
- **PD1+chemo**

2025-2027

1L

- **Zolbetuximab + chemo**
- **PD1+chemo**

2028 and beyond

1L

- **TST001+ PD1 + chemo**
- Zolbetuximab + chemo
- PD1+chemo

A New Standard of Care Treatment
in 1L G/GEJC

Note: G/GEJC = Gastric or gastroesophageal junction cancer

Osemitamab (TST001)

Development Plan and Huge Potential for Multiple Indications

1L GC/GEJC

Combo with SOC
(Nivolumab / chemotherapy)

≥55% of all comers **

>100K addressable patients globally * [1]

Peri-Operative GC

Potentially first mover
anti-CLDN18.2 mAb

~55% of all comers **

~70K addressable patients globally * [1]

Other tumor types

1L PDAC

~50% of all comers **

~75K addressable patients globally * [2]

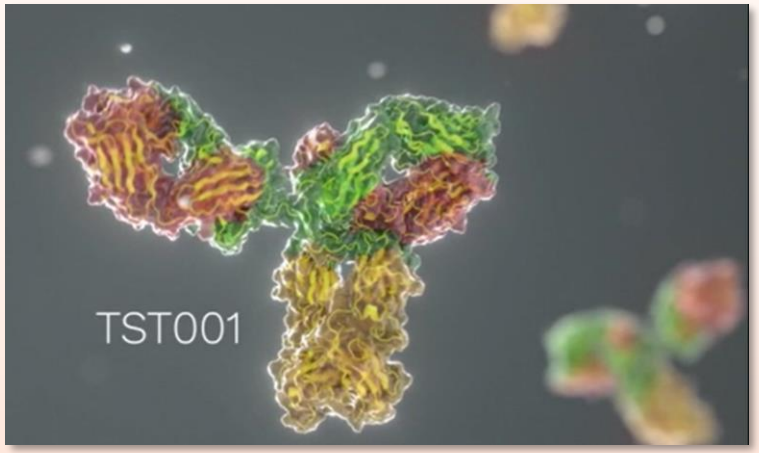
Lung Cancer

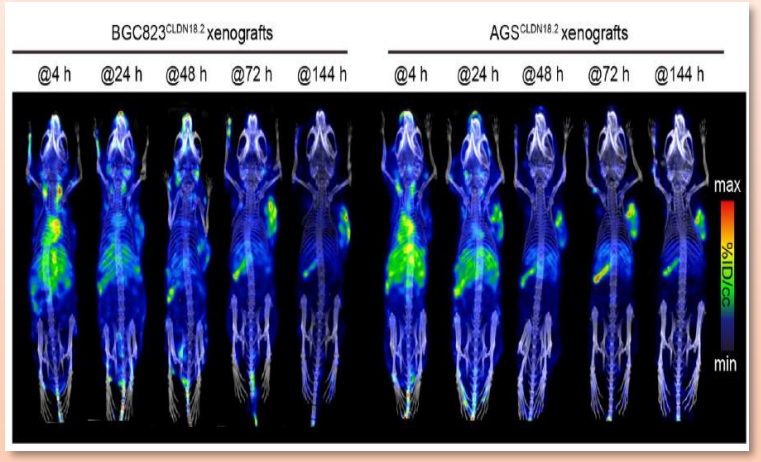
~41K addressable patients globally * [2]

* G7 (US, EU5, Japan) +China
** per proprietary IHC assay
Source: [1] Decision Resources
[2] Decision Resources and Globocan

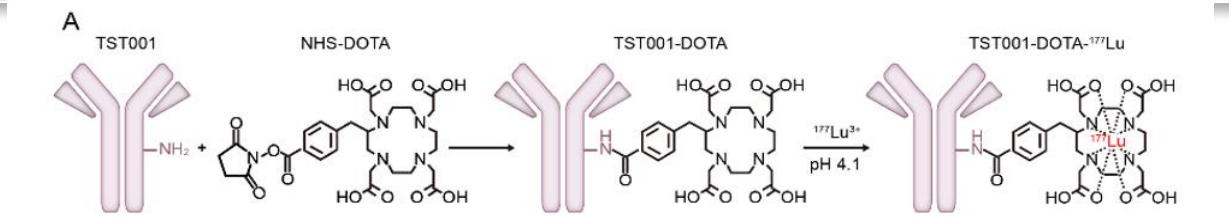
Osemitamab (TST001)

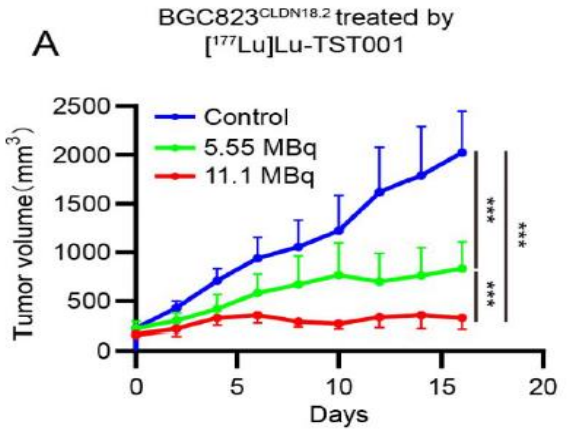
Promising Preclinical POC Study of ^{177}Lu-CLDN18.2 RDC, a Novel Approach for Targeting CLDN18.2 Positive Tumor

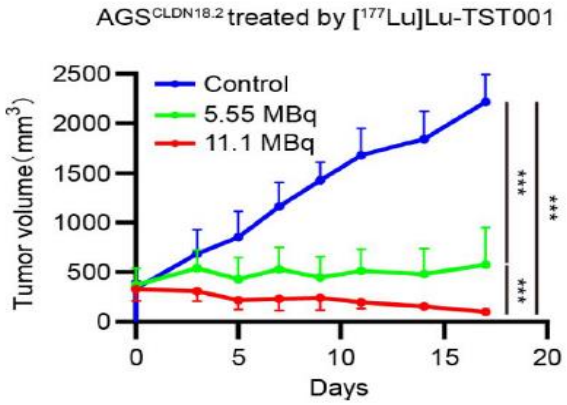


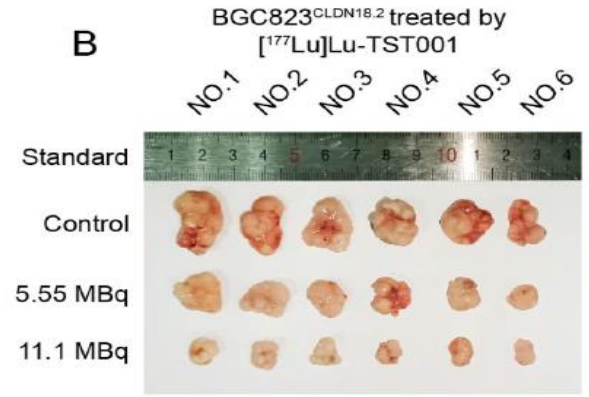


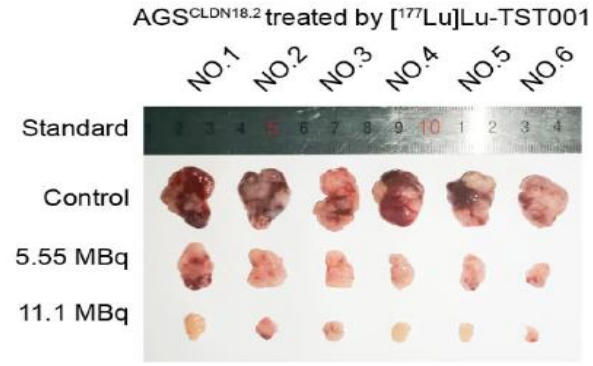
European Journal of Nuclear Medicine and Molecular Imaging
https://doi.org/10.1007/s00259-023-06561-1











Blosozumab (TST002)

A Humanized Sclerostin mAb for Osteoporosis

Blosozumab (TST002)

Anti-sclerostin mAbs are Poised to Address the Huge Unmet Needs of Osteoporosis in China

High Unmet Medical Needs with Large Market Potential

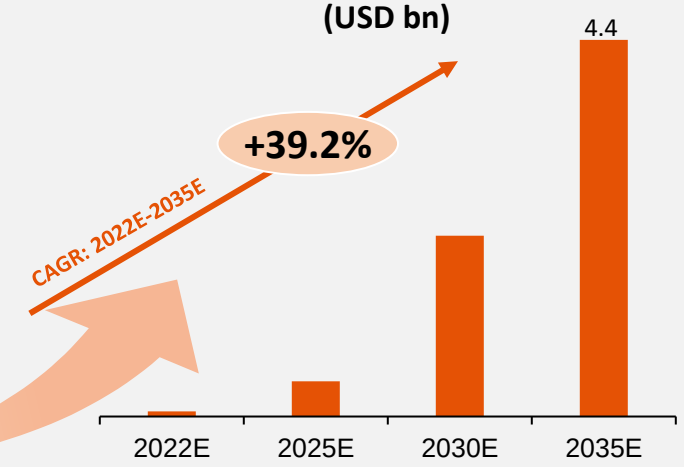
Total patient[1]
~90 million

Total case of fracture
~3.3 million*
per year

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

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

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



Key Drivers and Future trends

- ✓ Fast growth of prevalence in China due to aging population
- ✓ Increasing healthcare expenditure per capita
- ✓ Enhanced awareness of the impact of osteoporosis on quality of life
- ✓ No anti-sclerostin approved yet 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*

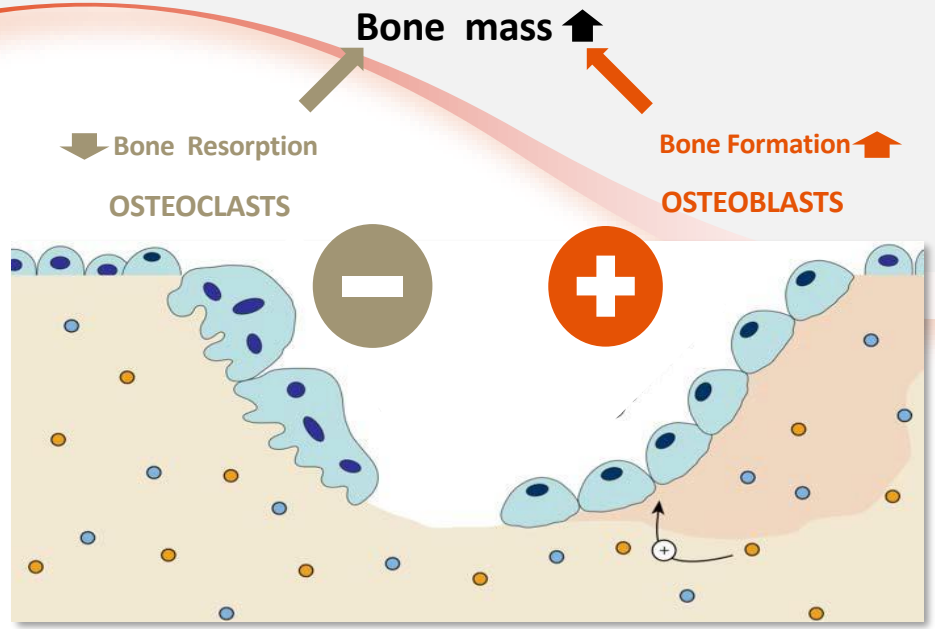
Blosozumab (TST002)

A Well Differentiated Anti-Sclerostin Antibody Targeting Sclerostin for Bone Disorders

Our Objectives

- More convenient
- Higher efficacy
- More accessible

Dual Mechanisms



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 tolerability profile
- No cardiovascular adverse event was observed

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

BMD: bone mineral density (BMD)

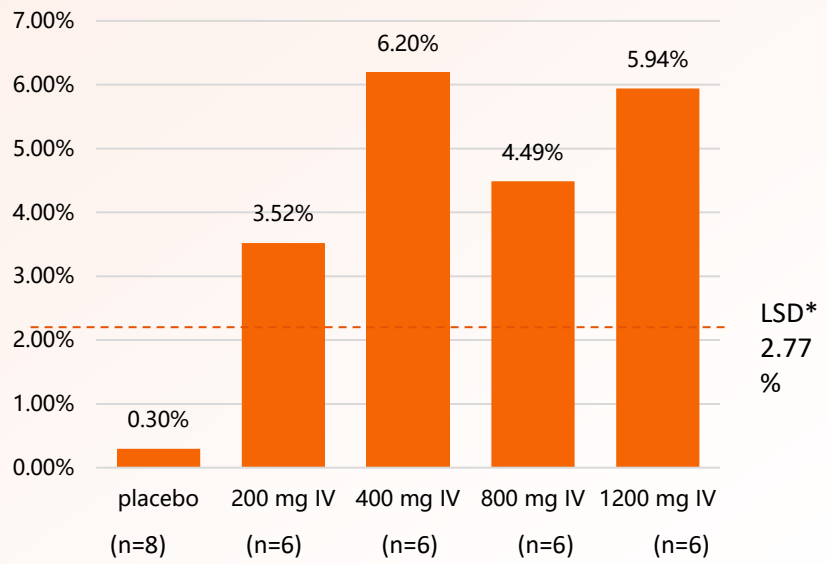
Blosozumab (TST002)

Encouraging Ph1 Efficacy Data Justifying Further Clinical Development

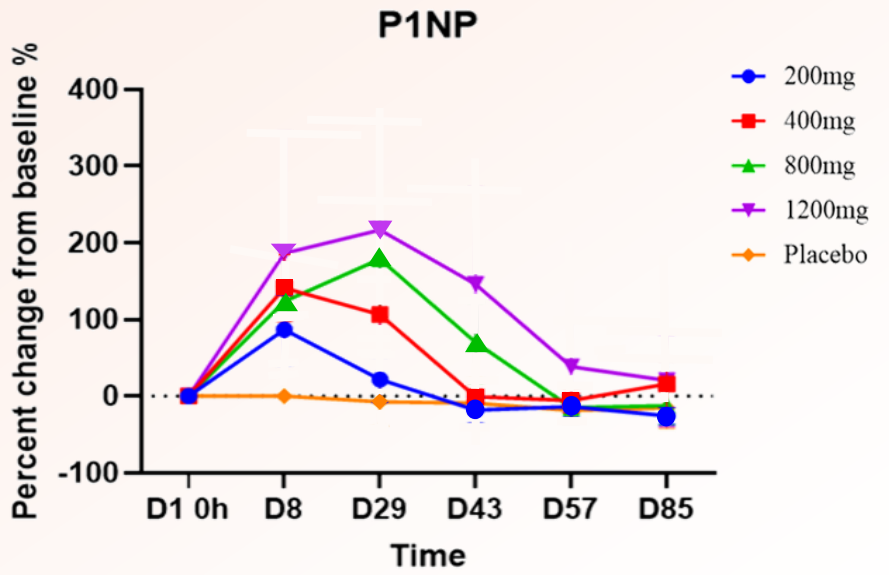
- **Finished the Ph1 study with the results to support further research**
- **Received CDE approval to initiate Ph2 trial**
- **Ph1 study abstract has been submitted to 2024 WCO-IOF-ESCEO Congress**

D85 lumbar spine BMD % change from baseline in TST002

Full study results to be presented in 2024



TST002 P1NP data



*LSD：least significant difference

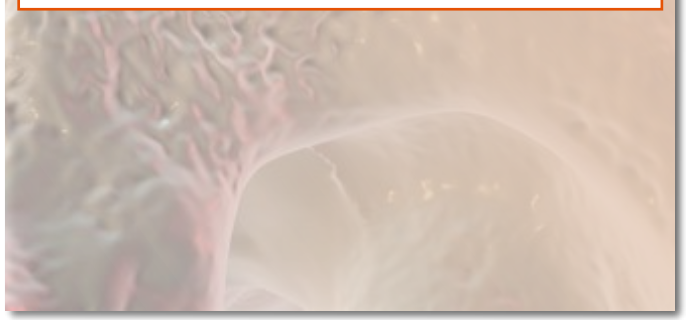
Blosozumab (TST002)

Huge Unmet Medical Needs and Broad Target Patient Populations for Anti-sclerostin Antibody

Postmenopausal Osteoporosis in Women

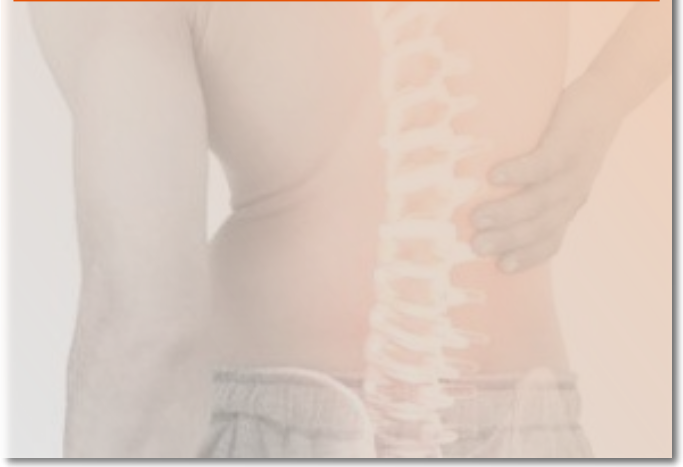
~70 million
patients in China[1]

~3 million
osteoporotic fractures in China



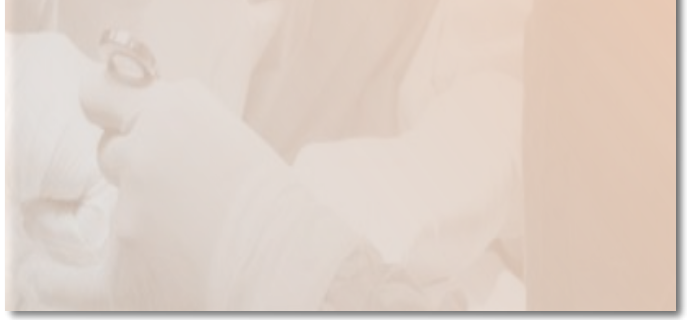
Osteoporosis in Men

20 million
patients in China[1]



Post OVCF* Surgery

1.5 million
new vertebral fracture case in 2020 in China[2]



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

*OVCF: Osteoporotic Vertebral Compression Fractures

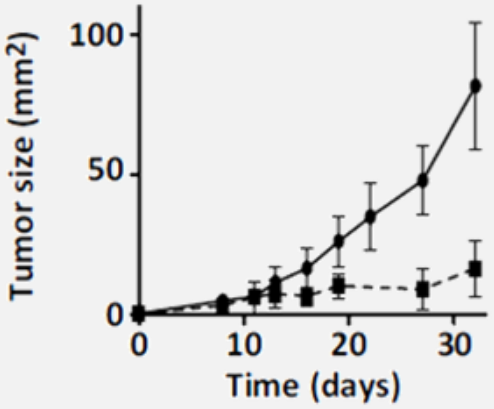
TST003 (Anti-Gremlin1)

A First-in-Class Humanized Anti-GREMLIN-1 Antibody

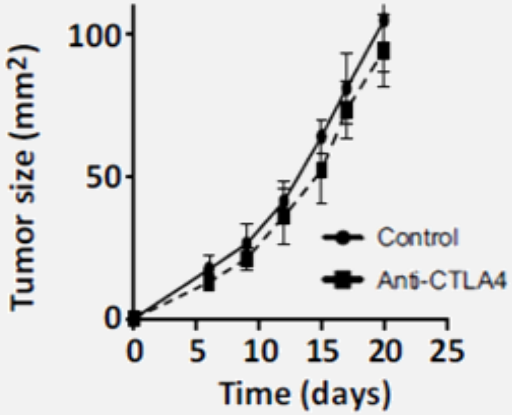
TST003
Target and Potential

Tumors enriched with stromal cells are less responsive to immunotherapy

A Epithelial tumors



B Mesenchymal tumors



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

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

Status

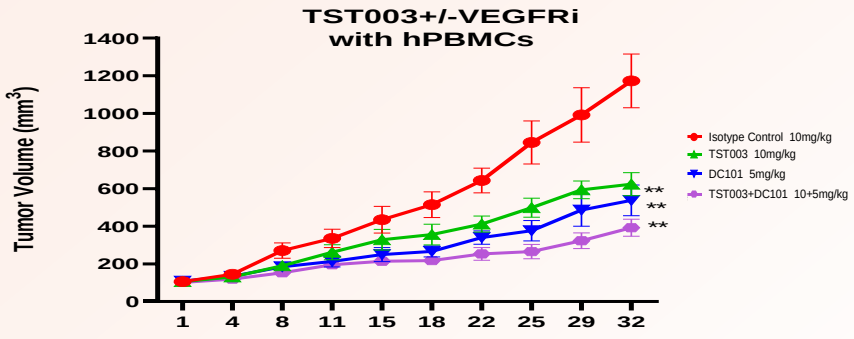
- ✓ **Obtained IND Clearance by FDA and CDE**
- ✓ **Presented preclinical data at AACR**
- ✓ **Initiated global FIH study**
- ✓ **Completed the 3rd dose cohort**

TST003

TST003 Displayed Potent Anti-tumor Activity in MSS CRC PDX Model and Mouse Model of mCRPC

- Displayed promising activity in MSS CRC either as single agent or in combination with angiogenic inhibitor
- Displayed potent single agent anti-tumor activity in mouse model of AR low or negative

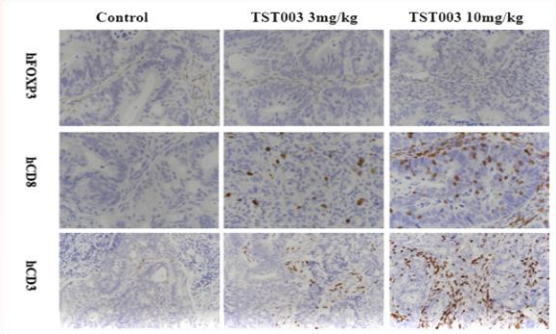
MSS CRC



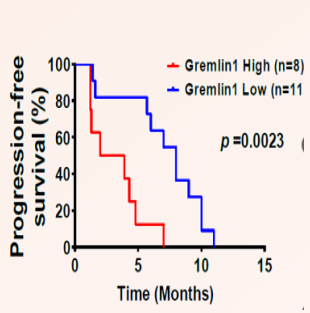
Post dose (Day)

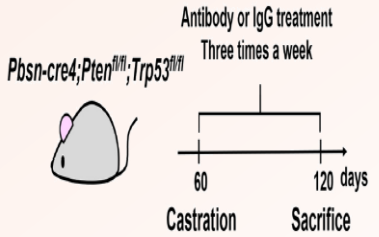
**: vs Isotype control, p<0.01; #: vs TST003, p<0.05.

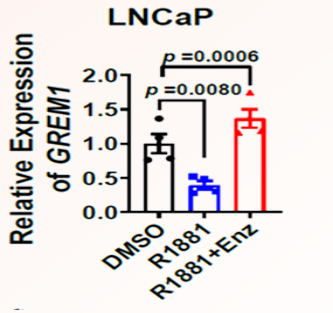
DC101 is a surrogate mAb for mouse VEGFR2

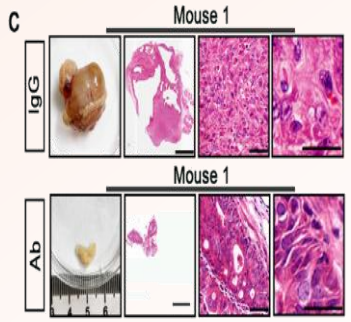


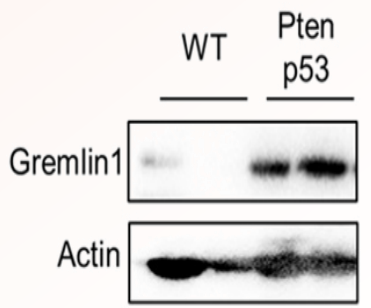
mCRPC

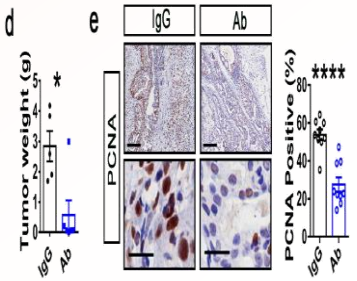












TST003

Major Indications with Unmet Medical Need and Substantial Market Size will be Explored

MSS CRC in combination with SOC

>~285K

addressable patient in 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 tumor types

Supported by preclinical data: e.g. NSCLC and SCLC

50% NSCLC and

30% SCLC express GREM1

We will explore the potential of TST003 as a single agent or combination therapy for multiple indications

* (G7+China)
Source: [1] Decision Resource reports and Globocan

Upcoming Milestones

1H 2024

Osemitamab (TST001)

- Advance global pivotal trial for 1L G/GEJ cancer
- Present data from ongoing Ph2 trials

Blosozumab (TST002)

- Present Ph1 SAD study data at a medical conference
- Initiate dose-ranging Ph2 study

TST003

- Complete the dose-escalation part of TST003 FIH trial and explore combinations with SOC in select tumor types

Emerging Pipeline of Oncology & Auto-Immune Drug Candidates

TST012

- **ADC product candidate** for gastric cancer, lung cancer etc.
- Lead antibody selected
- Potent anti-tumor activities in preclinical tumor model
- IND enabling study to start

TST013

- **ADC product candidate** for breast cancer and other solid tumors
- Lead antibody selected
- Differentiated profile observed relative to benchmark in preclinical study
- IND enabling study to initiate

TST008

- **First-in-class bispecific antibody** targeting MASP2 and receptors involved in regulating B cell activation and differentiation
- Target indications: SLE, LN & IgAN
- Lead molecule selected showed a potent inhibition on MASP2 dependent complement activation and sustainable reduction of B cells in vivo
- IND enabling study to initiate

TST801

- **First-in-class bifunctional antibody** targeting receptors involved in regulating B cell activation and differentiation
- Target indications include SLE, LN and IgAN
- Lead molecule selected and showed a potent and sustainable reduction of B cells in both in vitro and in vivo preclinical models
- Benchmark mAb approved in SLE and LN
- IND enabling study to initiate

Leader in Integrated Continuous Biomanufacturing platform (HiCB)

CMC & CDMO

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

Faster → **Quality** → **Significant cost saving** → **Leading perfusion technology**

Enhanced Pipeline Development

- Completed process characterization and developing a process control strategy of osemitamab (TST001)
- Increased productivity for blosozumab (TST002)
- Completed 58 GMP DS lots

Grew CDMO Services

- **Medium development based on** in-house medium expertise
- **Expanded drug product development to include siRNA**
- **Expanded to provide ADC CMC process development service**

Business Development

Clinical Trial Collaboration

Bristol Myers Squibb™

Osemitamab (TST001)

In-License

Lilly

Blosozumab (TST002)

Research Collaboration

Dana-Farber Cancer Institute

JOHNS HOPKINS UNIVERSITY

北京大学肿瘤医院 BEIJING CANCER HOSPITAL

上海交通大學 SHANGHAI JIAO TONG UNIVERSITY

上海市肺科医院 SHANGHAI PULMONARY HOSPITAL

Technology-based Partnership

MERCK

Synthesis Apextide

Joint Venture

ALEBUND

TST004

Commercialization

Tofflon

03

Financial & Outlook

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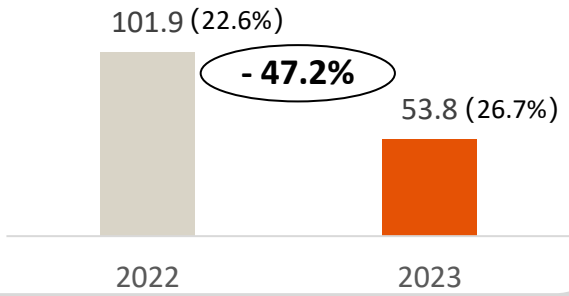
2023 Financial Results

Financial Profile

Key Income Statement Metrics (Non-IFRS)

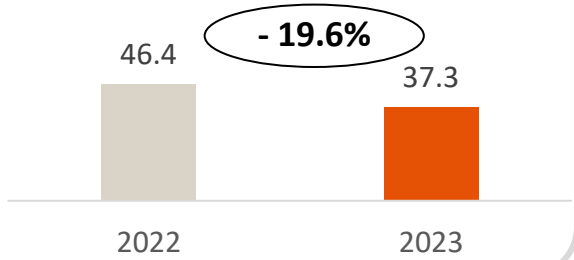
Revenue

RMB 53.8 million



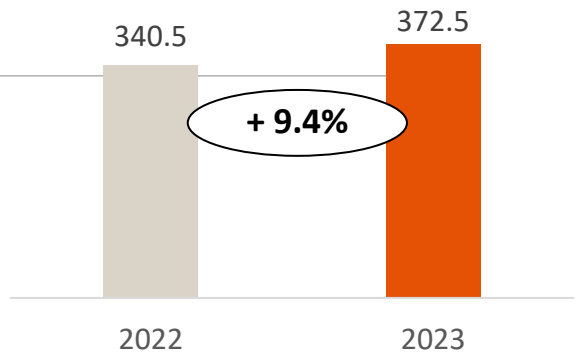
Other Income

RMB 37.3 million



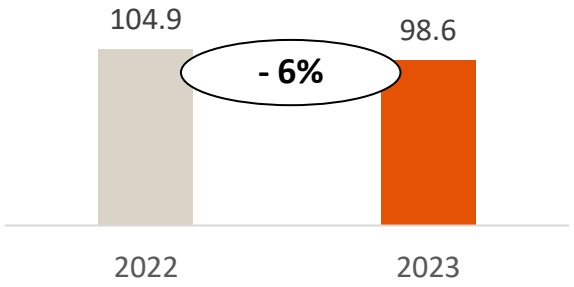
R&D expenses

RMB 372.5million



SG&A expenses

RMB 98.6 million



Bank deposits and cash as of December 31, 2023 is approximately RMB 596 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

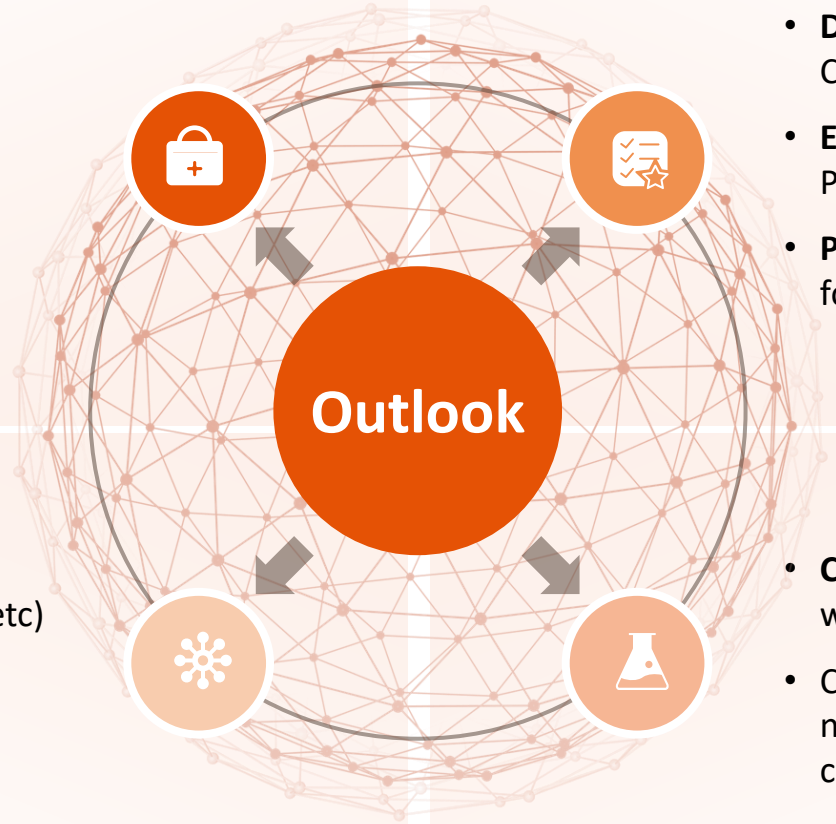
Integrated Platform, Cutting-edge Technology, Differentiated and Competitive Biologics

Clinical Development

- **Present**
  Ph2 data for Osemitamab (TST001)/Nivolumab/Chemo combo
- **Advance**
  global Ph3 trial for Osemitamab (TST001)
- **Present**
  Ph1 data for Blosozumab (TST002)
- **Complete**
  the TST003 FIH trial

Research

- **Expand**
  pipeline by designing new modalities (ADC etc)
- **Deepen**
  translational research to enable indication expansion



CMC & CDMO

- **Develop and grow**
  CDMO business
- **Enhance**
  Platform Technology and
- **Prepare**
  for commercial manufacturing

Business Development

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

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INNOVATE TO EXCEL

THANK YOU!

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