

Stock Code: 6628.HK

# 2024 Annual Results Update

March 31, 2025



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## Transcenta Global Strategy and Integrated Capabilities





Actively seek partnership to maximize pipeline value





## Industry Leading

Antibody Generation and Bio-process Platforms



#### Lead

Discovery & Translational Research



#### Global

Clinical Strategy & Execution



## World-Class

CMC & CDMO Capability

## Pipeline Overview Diversified and Differentiated Pipeline



Drug candidate	Target	Modality	indications	Preclinical	IND	Phase 1	Phase 2	Pivotal Phase 3	Rights	Partne
	Claudin18.2	mAb	G/GEJC 1L	Combo with PD1/Chemo			Global	In-house		
Osemitamab (TST001)			G/GEJC 1L	Combo with Chemo						
			PDAC 1L	Combo with Chemo						
TST003	Gremlin1 (FIC)	mAb	Solid tumors	Mono					Global	In-hous
TST006	Claudin 18.2/PDL1	BsAb	Solid tumors	Mono					Global	In-hous
TST010	Undisclosed	mAb	Solid tumors	Mono					Global	In-hous
TST105	FGFR2b Bi-Specific	ADC	Solid tumors	Mono					Global	In-hous
TST012	FGFR2b	ADC	Solid tumors	Mono					Global	In-hous
TST013	LIV-1	ADC	Solid tumors	Mono					Global	In-hous
MSB2311	PD-L1	mAb	Solid tumors	Mono/Combo with VE	:GRi				Global	In-hous
MSB0254	VEGFR2	mAb	Solid tumors	Mono					Global	In-hous
TST005	PD-L1/TGF-β	BsP	Solid tumors	Mono					Global	In-hous
Blosozumab (TST002)	Sclerostin	mAb	Osteoporosis	Mono			US Ph II Completed	<b>&gt;</b>	Greater C	hina <i>Lill</i>
TST004	MASP2	mAb	IgAN, TMA	Mono					Global	<b>A</b> LEBUND <b></b> ◀
TST008	MSAP2/BAFF (FIC)	BsAb	SLE/LN/IgAN	Mono	•				Global	In-hous
TST801	BAFF/APRIL (FIC)	BsP	SLE/LN/IgAN	Mono					Global	In-hous
TST808	Undisclosed	mAb	IgAN	Mono					Global	In-hous

## **Key Highlights**

## **Key Pipeline Progress and Data Presentations**

Claudin 18.2 (BIC)
Osemitamab
(TST001)

Presented US and CN triple combination data at AACR, ASCO and ESMO 2024

• Announced collaboration with Agilent to develop companion diagnostic

Sclerostin (BIC)
Blosozumab
(TST002)

- Published SAD study result in the 2024 WCO-IOF-ESCEO Congress
- Published SAD study result at 2024 CSOBMR

Gremlin1 (FIC) (TST003)

- Completed dose escalation as monotherapy
- Presented a TiP poster at the AACR 2024

LIV-1 (BIC) (TST013)

- Site-specific conjugated ADC
- Presented a preclinical study poster at SABCS 2024

BAFF-APRIL (BIC) (TST801)

- Targeting memory B cells
- Initiated IND-enabling studies





### A Best-in-Class Anti-CLDN18.2 Antibody



Target Sales for Osemitamab (TST001)

## ~USD \$1B Sales in First-line G/GEJC Alone

## Multi-billion USD potential in G/GEJC PDAC and NSCLC

BIC Profile	<ul> <li>Improved antibody to benefit more patients with broader range of CLDN18.2 expression</li> <li>Promising clinical efficacy with on-target toxicities (N/V) mostly in the first 2 cycles</li> <li>Easily combinable with SOC in 1L</li> </ul>
Global Phase 3 Ready Asset	<ul> <li>Extensive China and US clinical datasets</li> <li>Dose optimization completed</li> <li>Approval from key regulatory authorities</li> <li>Global network with top KOLs</li> </ul>
Robust CMC	Industry leading continuous perfusion technology enables lower cost of good
Better CDx	High specificity for CLDN18.2 enables broader application beyond G/GEJ cancer



## Phase 1/2 Trial Overview - Study Design: Key G/GEJC Cohorts for First-line G/GEJC

	TranStar102	TranStar101 (U.S.)		
Study Design	All comers dose escalation     Ni	phort G: TST001 Q3W + CAPOX + ivolumab Il comers	<ul> <li>Cohort A: TST001 Q2W + FOLFOX +         Nivolumab     </li> <li>High, Medium, Low</li> </ul>	
Study Results	Updated data presented at ESMO	2 Patients enrolled across 2 dose levels pdated data presented at ASCO 2024	<ul> <li>18 Patients enrolled across 2 dose levels</li> <li>PK and safety data presented at AACR</li> <li>2024</li> </ul>	

Milestone in 2024

Presented the safety and PK data of TranStar 101 study Announced the collaboration with Agilent Technologies to develop a CLDN18.2 companion diagnostic June



Presented the efficacy and safety data of Cohort-G of osemitamab (TST001), plus Nivolumab and CAPOX

September



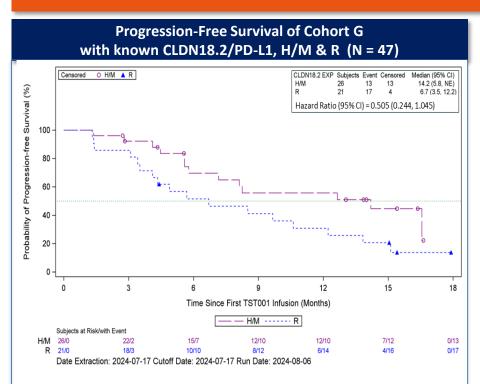
Presented updated PFS data from Cohort-G at ESMO 2024

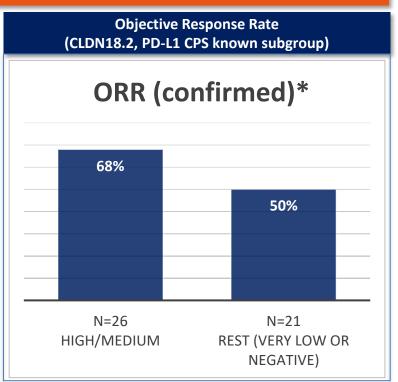
April



#### Demonstrated Encouraging Data from First-line Triple Combo Trial for G/GEJ Cancer

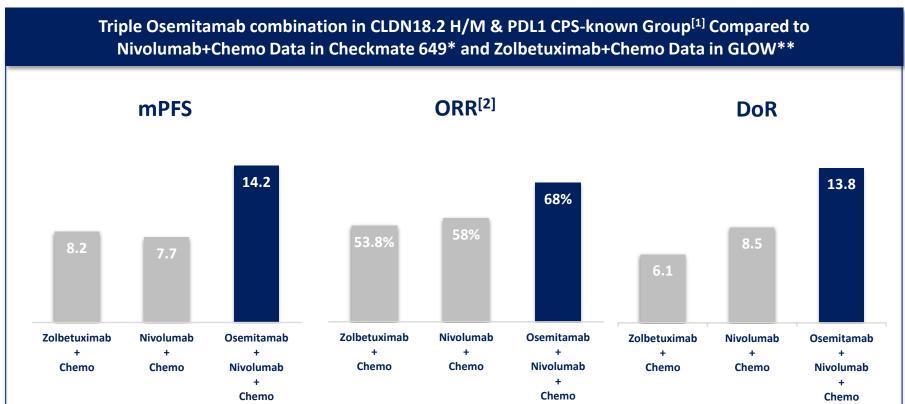
Efficacy results confirm predictive value of CLDN18.2 median PFS 14.2 months in H/M group





## **Comparative Efficacy to Benchmark – Cross Study Comparisons**





<sup>[1]</sup> The data for Osemitamab is up to 17 July, 2024. Date from Lin Shen. et al. ESMO 2024, 1419P. [2] Patients with measurable disease at baseline. \*Janijgian YY, et al. I Lancet. 2021 Jul 3;398(10294):27-40. \*\*Shah, M.A., et al. Nat Med 29, 2133–2141 (2023).

## **Development Plan and Multibillion Dollars Commercial Potential for Multiple Indications**



Combo with SOC (Checkpoint Inhibitor / Chemotherapy)

Potentially First Mover
Anti-CLDN18.2 mAb

**Peri-Operative GC** 

>100K addressable patients globally \* [1]



~70K

addressable patients globally \* [2]



## **First-line PDAC**

**First-line NSCLC** 

~75K

addressable patients globally \*[3]



~41K

addressable patients globally \* [4]



Source: [1] Decision Resources, ≥55% of all comers per proprietary IHC assay

- [2] Decision Resources, ~55% of all comers per proprietary IHC assay
- [3] Decision Resources, ~50% of all comers per proprietary IHC assay
- [4] Decision Resources, ~10% of all comers per proprietary IHC assay

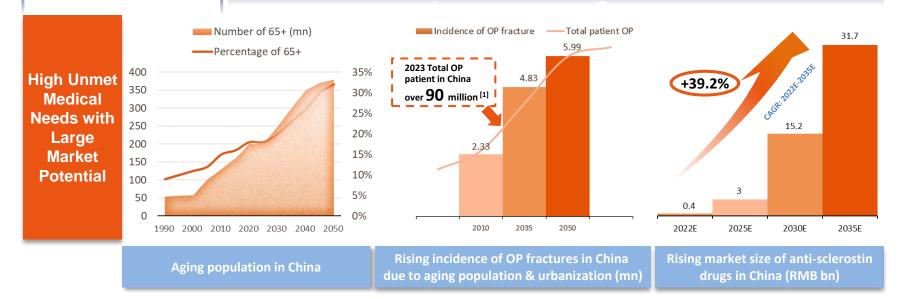
<sup>\*</sup> G7 (US, EU5, Japan) +China



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

Target Sales for Blosozumab in China

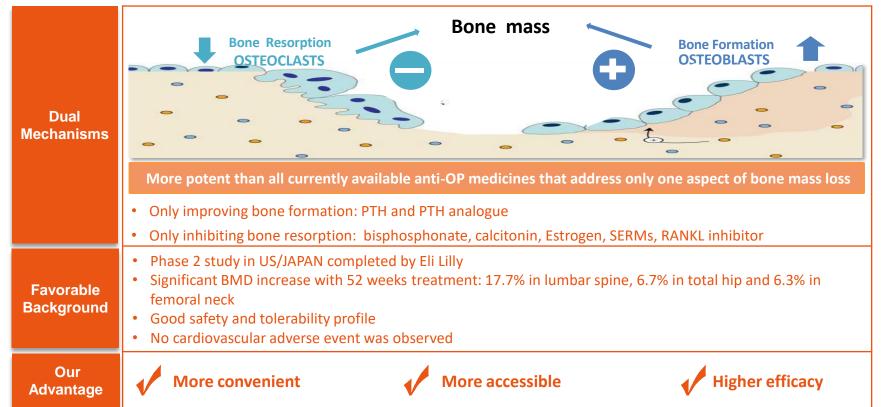
# >RMB 4B+ Sales in Osteoporosis with High Fracture Risk



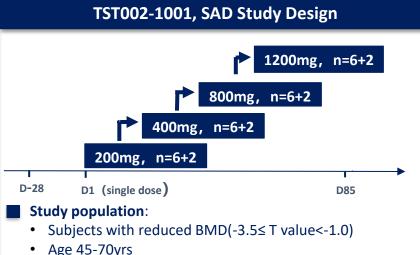
<sup>[1]</sup> Chinese Society of Osteoporosis and Bone Mineral Research. Guidelines for the diagnosis and treatment of primary osteoporosis (2022) \*calculated based on a study conducted in 2013 Projection of osteoporosis-related fractures and costs in China: 2010–2050, DOI 10.1007/s00198-015-3093-2



Unique dual mechanism and strong efficacy/safety data from early clinical trials poise Blosozumab to be the potential best medicine for Osteoporosis



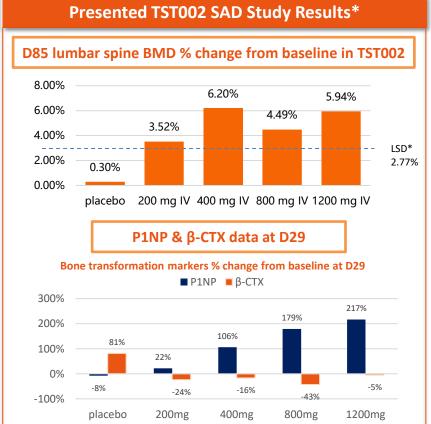




- Postmenopausal women or older men
- 32 subjects have been enrolled.

#### **Endpoint:**

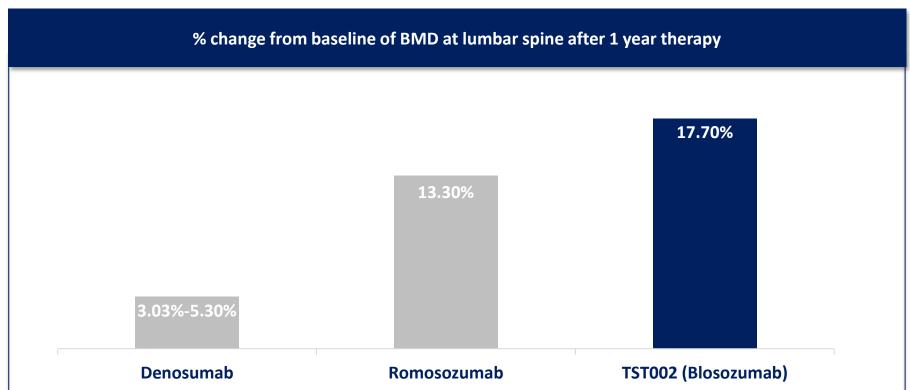
- Safety and tolerance
- PK
- PD: total sclerostin, bone turnover biomarkers, BMD
- **Immunogenicity**



<sup>\*</sup>Presented at 2024 WCO-IOFESCEO Congress



Potential better efficacy of TST002 (Blosozumab) than Romosozumab & Denosumab



## **Development Plan and Significant Commercial Potential for Multiple Indications**



Postmenopausal Osteoporosis in Women

~70 million patients in China[1]



~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>



<sup>\*</sup> Osteoporotic Vertebral Compression Fracture

Source: [1] 2022 Chinese Guidelines for the Diagnosis and Treatment of Primary Osteoporosis [2] 2021 Chinese Guidelines for the Diagnosis and Treatment of osteoporotic vertebral compression fractures



### A Novel Target with Potential for Multiple Solid Tumor Indications

Tumors enriched with stromal cells are less responsive to immunotherapy

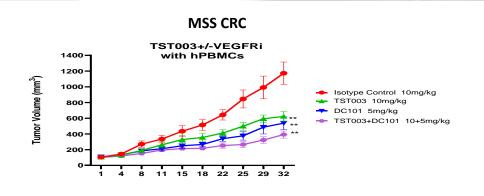
- TST003 is a humanized neutralizing antibody with high affinity to GREM1
- A global FIH study ongoing in the U.S. and China, dose escalation completed

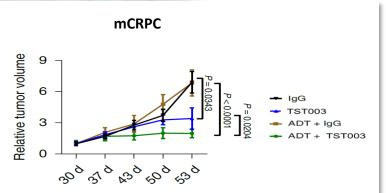
#### **Milestone**

TiP poster presented in the 2024 AACR conference in April

#### Gremlin-1

- Gremlin-1 abrogates BMP signaling in cancer cells and promotes their mesenchymal phenotype, stemness and invasion
- Gremlin-1 is highly upregulated in multiple solid tumor types and associated with poor prognosis
- Tumors with mesenchymal phenotypes are less responsive to checkpoint inhibitors







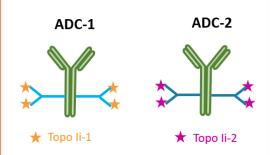
## A Next Generation ADC Candidate Targeting LIV-1, a Clinically Validated Tumor Antigen

- Reduced toxicities due to systemic exposure of payload toxin via site-specific conjugation
- Demonstrated promising tumor regression at low doses in in vivo pharmacology studies
- Initiated the process to enable Investigational New Drug applications

Milestone

Presented preclinical data at the 2024 SABCS in December

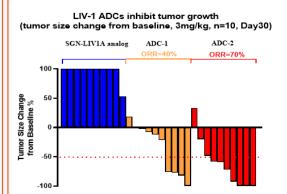
#### **Superior Tumor Regression**

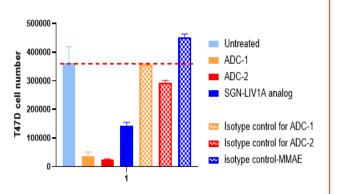


TST013's lead LIV-1 ADCs (ADC-1 and ADC-2) have demonstrated significant tumor regression activities in tumor models.

## ADC-1 and ADC-2 can elicit potent tumor regression at low dose

ADC-1 and ADC-2 have strong bystander effect





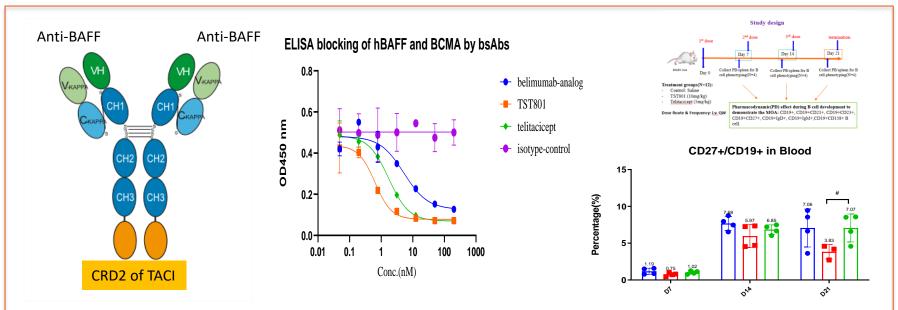
These data warrant further investigation of the lead LIV-1 targeting ADCs (ADC-1 and ADC-2) as potential next-generation therapeutic agent in LIV-1 positive breast cancer and other LIV-1 expressing solid tumors.

## **TST801**



## A First-in-class Bifunctional Antibody Fusion Protein of Anti-BAFF Antibody Fused with TACI Receptor

- BAFF and APRIL are ligands for the TACI receptor, regulating B cell activation and differentiation.
- They are validated targets for autoimmune diseases like SLE, LN, and IgAN.
- In vivo studies in human BAFF overexpressing transgenic mice demonstrated promising activity in reducing memory B cells, dsDNA, IgA, IgM, IgG, proteinuria, and kidney damage scores.
- IND-enabling studies for the lead molecule TST801 have been initiated.



## **Upcoming Milestones**





## Osemitamab (TST001) BIC

#### A Humanized ADCC Enhanced Second Generation Anti-CLDN18.2 mAb for Solid Tumors

- Advance global pivotal trial for First-line G/GEJ cancer
- · Submit pivotal trial applications with EMA and Japan
- Present data from ongoing trials
- Explore other CLDN18.2 expressing advanced solid tumors

## Blosozumab (TST002) BIC

#### A Humanized Sclerostin mAb for Osteoporosis

 Start the multiple ascending dose (MAD) Phase 2 in Greater China

## TST003 FIC

#### A First-in-Class Humanized Anti- Gremlin-1 Antibody

• Continue Phase 1 trial to obtain safety, pharmacokinetic and pharmacodynamic data

## TST013 BIC

## A Next Generation ADC Targeting LIV-1

Continue IND-enabling studies, progress to clinical trials

## TST801 BIC

#### A Next Generation BAFF/APRIL dual inhibitor

• Continue IND-enabling studies, progress to clinical trials

## CMC & CDMO





#### **Advanced Technology and Platform**

- Implemented intensified perfusion platform
- Achieved industry leading productivity of up to 8 g/L-day, >15-fold ↑ in output
- Expanded services: cell culture media, ADC, siRNA DP
- Acquired **lyophilization** capabilities, improved cycles for internal and CDMO use
- Developed new perfusion and fed-batch media for market launch
- Engaged potential partners for technology **out-licensing** opportunities

#### **High Quality Output**

End-to-end capabilities from lead to clinical supply with strong quality systems

#### **Experienced Team**

Led by seasoned MNC experts skilled in BLA submissions and manufacturing

#### **Excellent Execution**

• Achieved **100% success rate** in project execution

#### Preparation for launch facility for Osemitamab, supporting all clinical manufacturing, with fast track to clinic and market

- TST001 Phase 3 clinical supply is ready, successful FDA meeting to align comprability strategy in support of commercial supply.
- Completed TST001 high concentration top formulation selection for subQ administration.

## **Business Development**

#### Multinational Partners to Maximize Value





#### **Clinical Trial Collaboration**



Collaborating the clinical trial and completing the enrollment in TranStar102 and in the U.S. in TranStar101

#### **In-License**



• In-licensed Greater China rights (with ROFN for global) for all the bone disease franchise

## Merck



· Leveraging our expertise in continuous bioprocessing technology

**Technology-based Partnership** 

Partnering for the marketing and promotion of oligonucleotide (mini-NNA) APIs and formulation manufacturing services

#### Commercialization

## Tofflon

Collaborating for marketing and sales of HJB's ExcelPro CHO media

#### **Research Collaboration**











 Several research collaborations have been established with leading academic institutions worldwide. The research collaborations cover osemitamab (TST001), TST003 and TST005

#### **CDx Collaboration**



 Developing and commercializing TST001 of CDx for CLDN18.2 targeted therapy



03

**Financial & Outlook** 

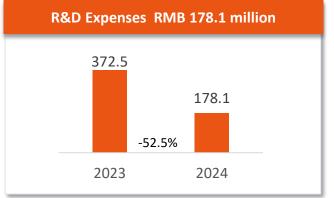


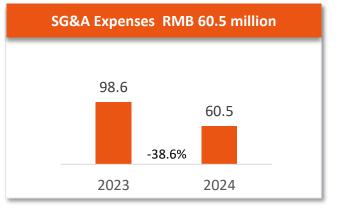
## **2024FY Financial Results (Non-IFRS)**











## **Outlook**

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





## **TRANSCENTA**

INNOVATE TO EXCEL

#### Research

- Expand pipeline with new modalities (ADC etc.,)
- **Deepen** translational research to expand indications
- Advance novel pipeline molecules into clinic

## Clinical Development

- Present updated data for osemitamab (TST001)
- Advance global Phase 3 trial for osemitamab (TST001)
- Initiate Phase 2 of blosozumab (TST002) in Greater China
- Complete the Phase 1 trial for TST003

## **CMC & CDMO**

- Develop and Grow CDMO business
- Enhance platform technology
- Prepare for commercial manufacturing
- Explore technology partnership

# Business Development & Finance

- Continue product and technology partnership
- Raise fund through multiple ways including newco formation
- Improve operational efficiency



**THANK YOU!** 

