

TRANSCENTA HOLDING LIMITED

2021 Interim Results Presentation

December, 2021



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Transcenta at a Glance

Global

Global rights - drug candidates

Global approach - clinical development and pathway

Global standard

- CMC and manufacturing

Global network

9 out of 10 innovative drugs developed internally

Innovative

Pipeline

Claudin 18.2 2nd gen. PD-L1 TST003 Sclerostin PD-L1 / TGF-β MASP2 Targeting high unmet medical need Integrated Platform

Advanced research and discovery

Global standard clinical development

Next gen, low-cost CMC and manufacturing

Fully integrated **BLA and** registration capability Experienced Management

Top tier scientists

Long track record in biopharma / biotech

Held senior leadership positions at MNCs such as Amgen, Novartis, Roche, MSD, AstraZeneca

Academic excellence







02 Oncology Pipeline Program Highlights



Non-Oncology Pipeline Program Highlights



Future Growth Strategy





01/ Company Overview

Transcenta is an Integrated Biopharma with Global Footprint

Employing cutting edge technologies to develop innovative and affordable biologics for patients around the world







We boast a seasoned and global management team with solid knowledge and experience across lead discovery, pre-clinical research, clinical development and operations, process development and manufacturing, regulatory affairs and business development.



Xueming Qian, PhD AMGEN Founder and CEO

>20-year industry antibody discovery & development experience SVP & R&D Head at Shenogen Pharma Team Leader and Principal Scientist at Amgen





>20-year biologics quality and manufacturing management experience in US and China





>20-year industry clinical research experience Member of ASCO, ASH and ESMO



Daniel Weng EVP. CFO



>20-year finance management experience in reputable biotech & pharmaceutical listed companies



Ambrx Yi Gu. PhD SVP, Head of Research AstraZeneca

>20-year experience in the biopharma industry and NME development



Christopher Hwang, PhD EVP, CTO SANOFI GENZYME 🎝

Nearly 30-year process development, tech transfer & manufacturing

pwc

Albert Zhu

SVP. Finance



Jerry Yang, PhD **EVP, Global Process & Product Development**



>30-year biopharma experience in P&PD, scale up/technology transfer, GMP manufacturing



Jane Xia





>20-year industrial experience in business analysis and brand strategy in oncology and bone health



18-year accounting and M&A experience in US and China at PwC

IMTB: Our Proprietary Antibody Discovery Platform

Our proprietary antibody discovery platform IMTB enables us to generate antibodies to both non-conserved and conserved proteins, which are difficult to generate in rodents, and to discover hidden epitopes that are challenging to discover using conventional platforms.



World-class CMC Team, Bioprocessing Platform and Infrastructure

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We have built an experienced CMC team, a highly productive platform and efficient infrastructure to accelerate drug development and future commercialization while significantly lower cost of goods* and enhance product control.

CMC Team and Capability



Over 200 team members led by industry veterans from MNC with late-stage and commercial manufacturing experience



Strong track record with > 98% success rate in CMC project delivery since inception**



*> 40% COGs savings projected when compared to conventional batch processes
 **16 CMC projects and 48 manufacturing lots since Q2'2018

***Novel clone selection methodology, proprietary cell culture media and extensive perfusion know-how

Bioprocessing Platform

Demonstrated Industry leading productivity***, > 10-fold output increases for multiple cell lines



Biomanufacturing Infrastructure



Highly flexible modular design, global standard, low up-front cost, expand capacity as needed



Hangzhou *T-BLOC* facility with annual output of > one metric ton, leveraging *ICB*







Our Comprehensive Product Pipeline

	Drug candidate	Target	Indications	Clinical trial region	Preclinical	IND	Phase 1a	Phase 1b/ phase 2a	Pivotal Phase 2b / Phase3	Rights	Partner
			Late-line gastric cancer	China	Monotherapy						
			Other Solid tumors	Global	Monotherapy						
	TST001	Claudin18.2	First-line gastric cancer	Global	Combo with chemo					Global	In-house
			Second-line gastric cancer	Global	Combo with chemo						
			Solid tumors	Global	Monotherapy						
Oncology	MSB2311		TMB-H solid tumors	China	Monotherapy						
		PD-L1	Other solid tumors	China	China Monotherapy				Global	In-house	
			Solid tumors	China Combo with VEGFRi	Combo with VEGFRi						
	TST005	PD-L1/TGF-β Bi-functional	Solid tumors (HPV+ and NSCLC, etc.)	Global	Monotherapy			_		Global	In-house
	MSB0254	VEGFR2	Solid tumors	China	Monotherapy					Global	In-house
	TST003	BMP Antagonist (FIC)	Solid tumors	Global	Monotherapy					Global	In-house
	TST006	Claudin 18.2/PD-L1 Bi-specific (FIC)	Solid tumors	Global	Monotherapy					Global	In-house
	TST010	Undisclosed	Solid tumors	Global	Monotherapy					Global	In-house
λâc	TST002	Sclerostin	Osteoporosis	China	Monotherapy		US	Ph2 Completed	/	Greater China	Lilly
Non-oncolo	TST004	MASP2	IgA nephropathy TMA	Global	Monotherapy					Global	ALEBUND
	TST008	MASP2-based Tri-functional (FIC)	SLE	Global	Monotherapy					Global	In-house





Transcenta Pipeline Highlights

Oncology **Existing CPI non-responding and resistant tumors**



TST001 (BIC) mAb to Claudin18.2

Pivotal trial in 2H22 1L GC/GEJ Other tumors Ph1b study in 2022 Combo w/ PD1 and Chemo (1st line)



TST005 (BIC) PDL1-TGF-β

Ph1 in US PD1 refractory TGF-β enriched tumors NSCLC, Cervical, PADC, BTC



TST003 (FIC) (Novel Target)

Ph1 in 2H22 PD1 refractory CRC, NSCLC, GC, ESCC, PC, BC



TST002	TST004
Sclerostin	MASP2
Enter Clinical Study Ph 1	<u>Ph1 in 2H22</u>
in 2022	lgAN
	TMA
Osteoporosis	others
Osteogenesis Imperfecta	
Osteoporosis in CKD	

Non-Oncology

Technology Platforms: Perfusion-based Processing, Bispecific, ADC, etc.



O2/ Oncology: Target existing CPI non-responding and resistant tumors

TST001

A Second Generation Claudin18.2 Antibody with FIC / BIC Potential



CLDN18.2 is a Clinically and Commercially Validated Target for 1L Gastric Cancer

- Astellas' Zolbetuximab (IMAB362) validated Claudin 18.2 for mAbs and demonstrated positive data in first line GC patients
- Astellas paid \$1.4 billion (460M USD upfront payment and 937m USD milestone payment) for phase 2 stage IMAB362

		Zolbetuximab (>75% Claudin 18.2 Expression) ¹	Zolbetuximab (>70% Claudin 18.2 Expression) ²	Zolbetuximab (>40% Claudin 18.2 Expression) ²	Nivolumab (PD-L1 CPS ≥5) ³	Trastuzumab ⁴	Bemaritu-zumab⁵
	Target		Claudin18.2		PD-1	HER2	FGFR2b
	Chemo	+ mFLOFOX6	+E	OX	+ mFLOFOX6 Or XELOX	+ cisplatin and 5-FU or capecitabine	+ mFLOFOX6
Phase	e / Pt. Number	Ph2 (21 pts)	Ph2 (730 screene N =	ed; 252 included) : 77	Ph3 (1,581 pts) N=789	Ph3 (810 included) N=294	Ph2 POC (155 included) N=77
	Expression%	~20%	~24%	~52%	60%	~16%	30%
iemo	mOS (vs. Control)	NR	16.5 mos (+7.6 mo)	13.0 mos (+4.7 mo)	14.4 mos (+3.3 mo)	13.8 mos (+2.7 mo)	NR
Ab + Ch	mPFS (vs. Control)	13.7 mos (+7 mo)	9.0 mos (+3.3 mo)	7.5 mos (+2.2 mo)	7.7 mos (+1.6 mo)	6.7 mos (+1.2 mo)	9.5 mos (+2.1 mo)
Ê	ORR	63.2%	49%	39%	50%	47%	53%
0	mOS	~11.5 mos	~8.3	mos	~11.1 mos	7.9-11 mos	~12.9 mos
hem Ione	mPFS	~6.7 mos	~5.5 mos		~5.4 mos	~5.5 mos	~6.7 mos
^ש כ	ORR	40%	25	5%	38%	35%	40%

Notes:

1. Klempner et al, ASCO 2021; e16063. 2. Sahin et al, Annals of Oncology; Vol 32 609-619. 3. Janjigian et al, Lancet. June 2021. 4. Bang et al, Lancet 2010; 376: 687-97. 5. Wainberg et al, ASCO GI 2021; LBA160.



TST001: Leading the Market with Potentially BIC / FIC Profiles and Promising Anti-tumor Activities

TST001 is the second leading Claudin 18.2 targeting mAb being developed globally following Zolbetuximab, but shows a differentiated and potentially BIC/FIC profile. Recent TST001 dose escalation study early result has 1 PR achieved in late line GC patient at 6mg/kg, ~1/3 of the dosage of Zolbetuximab.



MKN45-Claudin 18.2 (40%) Gastric Tumor Model with PBMC Co-innoculation

Data on file



TST001 has Demonstrated Anti-Tumor Activity and Response in Dose Escalation Study

TST001			IMAB362 (Zolbetuximab)			
	Phase 1	Phase 1	Phase 2a	Phase 2		
Mono / Combo	• Mono	• Mono	• Mono	Combo with chemo		
Pre-treatment	 Heavily pretreated: Failed multiple lines of chemo, PD-1 immunotherapy and anti-VEGF inhibitor 	 No prior PD-1 or VEGFi treatments received 	 No prior PD-1 or VEGFi treatments received Received ≥ 1 prior line of chemotherapy 	 No prior PD-1 or VEGFi treatments received Excludes patients received previous chemo 		
Expression %	• NA	Positive CLDN18.2 expression confirmed by immunohistochemistry	 Moderate or strong (2+/3+) CLDN18.2 membrane staining intensity in ≥ 50% of tumor cells 	 Moderate or strong (2+/3+) CLDN18.2 membrane staining intensity in ≥ 40% of tumor cells 		
Dosage	• 0.3-20mg/kg	• 33-1,000mg/m ² (0.99-30mg/kg)	 300 and 600mg/m² (9 and 18mg/kg) 	 EOX alone / with Zolbetuximab at 600/800mg/m^{2*} (18/24mg/kg) and 1,000mg/m²(30mg/kg) 		
Response	 6mg/kg Q3W: 1 PR out of 3 pts 37% tumor shrinkage at 6 wk Confirmed at 12th week Significant decrease in tumor biomarkers 	 18mg/kg: Only one SD Less significant tumor marker (CA125, CA19-9, CEA) decrease compared to TST001 Rest cases: all PD No PR 	 9mg/kg: All PD 18mg/kg: 4 PR (10%, n=40) as BOR; 2 PR (8%, n=26) at week 11/12 	 18/24mg/kg*: 8 (10.4%) and 22 (28.6%) CR and PR, respectively <i>* Loading dose, 800mg/m² then</i> 600mg/m² 		





Perfusion Bioprocessing Enabled Transcenta to Achieve Competitive Manufacture COGS



♦ Batch O Continuous





- ✓ **Humanized** vs. chimeric antibody
- ✓ Higher affinity (20 pm vs. sub nM)
- ✓ **Stronger ADCC activity** (30-100 fold)
- ✓ More active at lower dose (6 mg/kg vs. 18 mg/kg)
- ✓ More active also in patients with mid-high CLDN18.2 expressing tumors
- Better IHC antibody and detection assay
- ✓ More affordable (perfusion based production)
- ✓ **Higher** potential for indication expansion and **larger** targeted population





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TST001: Higher Commercial Potential for Broader Indications beyond Gastric Cancer

	The second s			Earge market potentian
Claudin 18.2 (negative)		Pancreatic cancer and other Claudin18.2+ tumors	~70% of GC & ~50% PC	 More indications in early lines to be explored including BTC/Pancreatic/Esophageal cancers
Claudin 18.2+		Claudin18.2+ GC (All IHC <u>></u> 1+)	•	Unmet needs:
(weaк)		~70% of G	~70% of GC	Limited treatment options
		(All IHC >2+ and		Primary resistance
Claudin 18.2++		>40% tumor cells)		 Fairly short PFS and OS
(medium)	And the second		~50% of GC •	Claudin 18.2 advantage vs. SOC:
		Claudin18.2+GC		 Target specificity
Claudin		tumor cells)		Restricted expression
18.2+++			~20% of GC	Combo potential
(strong)				 Great potential in prolonging PFS in advanced GC



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A PD-L1/TGF-β Trap Molecule The Next Generation Cancer Immunotherapy





TST005: A Differentiated PD-L1/TGF-β Trap Molecule --Targeting TGF-β pathway activated solid tumors





TST003

A First in Class Humanized Antibody Candidate for PD1 Resistant Tumors





TST003: First-in-class mAb with Anti-tumor Activities in I/O Refractory Tumor Models; IND Filing is Planned for 2022





Green: Stromal fibroblast

Dongre, A., et al Cancer Discovery 2020 DOI: 10.1158/2159-8290.CD-20-0603

MOA	 Novel BMP antagonist Highly expressed in stromal cells in tumor microenvironment Targeting PD1 resistant tumors including NSCLC, CRC, ESCC, GC, PC
Molecule	 A high affinity humanized antibody targeting a protein that is highly expressed by stromal fibroblasts. Demonstrated significant anti-tumor activities both in vitro and in vivo in preclinical studies as mono or in combo with CPI and/or other antitumor agents.





Milestone US / CN IND in 2H 2022



/ Non-Oncology: Expand into large untapped opportunities in bone and kidney diseases



Humanized Anti-Sclerostin Antibody for Severe Osteoporosis





Osteoporosis is an Increasing Burden on Health and Society

Osteoporosis Has High Unmet Medical Needs Total patient Total case of fracture million > 150 million per year The risk of osteoporotic The risk of osteoporotic fracture in women (40%) is fracture (13%) in men is higher than that of breast higher than prostate cancer cancer, endometrial cancer and ovarian cancer combined

Guidelines for diagnosis and treatment of primary osteoporosis (2017)



Key Drivers and Future Trends



Increasing healthcare expenditure per capita

Continuous development new drugs

Mild Moderate Severe Osteoporosis Anti-sclerostin • Evenity: first anti-**RANKL** inhibitor sclerostin mAb First anti-RANKL mAb approved in • approved in Japan, US in 2010 and China in Jun 2020 Calcium + US and EU in 2019. Vitamin D • Anti-RANKL mAb can only inhibit and already bone absorption included in Fosamax etc (Biphosphonates) treatment guideline in the US

China Anti-Sclerostin Market Size Towards 2035







TST002: A Well Differentiated Anti-Sclerostin mAb for Severe Osteoporosis

TST002 is a monoclonal antibody that binds to sclerostin, a negative regulator of osteoblast activity and new bone formation, in licensed from Eli Lilly for development and commercialization in Greater China in 2019 after Eli Lilly completed phase 2 studies of Blosozumab in the United States and Japan.

Dual Mechanism of Bone Resorption and	d Formation	TST002: Favorab	ble Product Characteristics Throughout Value Chain		
<u>Dual effect target</u> Resorption	Formation		Blosozumab / TST002 (Phase 2 conducted by Eli Lilly)		
 Bisphosphonate Calcitonin Estrogen SERMs RANKL inhibitor OSTEOCLASTS 	PTH PTH analogue OSTEOBLASTS	EFFICACY	 Statistically significant dose-dependent increases in spine, femoral neck, and total hip BMD as compared with placebo In the highest dose group, BMD increased by 17.7% at the spine, and 6.2% at the total hip from baseline within 12 months. 		
		SAFETY	So far no observed cardiovascular risk		
			 Once 2-3 months IV dosing Improved patient compliance 		
			 Lower COGS and better affordability for China patients 		



TST004

An Anti-MASP2 Antibody with Favorable Lectin Pathway Inhibitory Activity and PK/PD Profile





TST004: Potential Solution for IgAN, A Highly Prevalent Chronic Kidney Disease with Very Limited Treatment Options

TST004 is a humanized mAb targeting mannan-binding lectin serine protease 2 (MASP2) and designed to prevent the lectin pathway complement-mediated inflammation. We plan to develop TST004 for IgAN, a highly prevalent chronic kidney disease with very limited treatment options. It also has potential in a number of other indications, such as thrombotic microangiopathy (TMA). TST004 is currently at IND-enabling stage

No approved biolo OMS721, the most adv subm	ogics for the treatment of IgAN is available globally vanced drug, is currently in Phase 3 clinical trial and has itted a rolling BLA for TMA to the FDA		Superior pre-clinical data		
Current treatment	ACEI and ARB ¹ combined with corticosteroids / other immunosuppressive therapies:		TST004		
options	 Modest efficacy Toxicity is too high Long-term use can cause additional risk to the patients 	Dosing	SubQ formulationPotentially less frequent dosing		
Biologics under development	 The other MASP-2 mAb OMS721 (by Omeros) showed significant activity in prolonging the life of TMA patients, and also active in reducing proteinuria in select patients Telitacicept (Blys/APRIL) is under Ph2 development in China 	Binding affinity	 Higher binding affinity Specifically bound to MASP-2 in the Lectin pathway, and no binding to MASP-1, MASP-3 and C1s/C1r Only blocked complement activation initialized from the MBL pathway, but not the other two complement pathways 		
Note: 1. Angiotensin conve	rting enzyme inhibitors (ACEI) and angiotensin receptor blockers (ARB)				
<u>Chir</u>	a IgAN Market Size Towards 2035 2.6	PK/PD	 Long lasting inhibition effect: 3 weeks in cynomolgus model 		
(US\$bn) O	0.2 0.5	Dev. plan	 Co-develop with Alebund in China 2H2022 IND in China and US 		

2019

2028E

2030E



2035E



TST004: Has Potential to be Used in Other Complement Mediated Diseases





C3 Glomerulopathy (C3G) IgA nephropathy (IgAN) Lupus nephritis Membranous nephropathy (MN) Atypical Haemolytic Uraemic Syndrome (aHUS)



Age-Related Macular Degeneration (AMD) Recessive Stargardt Disease (STGD1) Uveitis



Paroxysmal Nocturnal Haemoglobinuria (PNH) Autoimmune Haemolytic Anaemias (AIHA) Thrombotic Microangiopathy (TMA)



Virus infection trigged complements over activation induced multi organ injury

Notable diseases

Nature Reviews Immunology 2009 Mol Immunol. 2018 Oct;102:89-119.

Pathological activation of complement system



04/ Future Growth Strategy





Enhance our pipeline through in-house discovery and business development efforts



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IMTB Technology Platform Strong R&D and resources

Enhance ICB and expand manufacturing facilities to support our expanding pipeline





Deliver innovative, differentiated and affordable medicines to patients around the world



Maximize the global value of our drug candidates



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Continue strengthening our commercialization capabilities

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05/ Financial Statements



		Six months ended June 30
	2021	2020
		(RMB in thousands, Unaudited)
Revenue	26,685	28,309
Cost of sales	(22,165)	(17,170)
Gross profit	4,520	11,139
Other income	11,209	5,492
Other gains and losses, net	(762,548)	(3,232)
Impairment losses under expected credit loss model	(2,940)	-
Selling expenses	(2,275)	(710)
Research and development expenses	(166,901)	(77,148)
Administrative expenses	(39,940)	(42,808)
Share of loss of a joint venture	(94)	-
Finance costs	(6,618)	(7,113)
Listing expenses	(29,453)	-
Loss before tax	(994,950)	(114,380)
Income tax credit	55	55
Loss for the period	(994,895)	(114,325)
Other comprehensive (expense) income for the period	611	(816)
Loss for the period attributable to:		
 Owners of the Company 	(994,284)	(112,084)
 Non-controlling interests 	-	(2,241)
Total comprehensive expenses for the period attributable to:		
 Owners of the Company 	(994,284)	(112,900)
 – Non-controlling interests 	-	(2,241)





Balance Sheet and Statement of Cash Flows

	As of June 30	As of December 31
	2021	2020
	(RM	IB in thousands, Unaudited)
Total current assets	1,030,439	891,457
Total non-current assets	1,211,733	1,199,467
Total assets	2,242,172	2,090,924
Total current liabilities	328,813	194,537
Total non-current liabilities	3,717,597	2,712,632
Total liabilities	4,046,410	2,907,169
Share capital	73	66
Treasury shares	(7)	-
Reserves	(1,804,304)	(816,311)
Total deficits	(1,804,238)	(816,245)

Six months ended June 30	
2021	2020
	(RMB in thousands, Unaudited)
(172,180)	(88,795)
(18,536)	(24,136)
342,018	169,926
151,302	56,995
813,592	458,100
(7,286)	5,156
957,608	520,251
	Six n 2021 (172,180) (172,180) (18,536) 342,018 151,302 813,592 (7,286) 957,608





INNOVATE TO EXCEL

Employing cutting edge technologies to discover, develop and deliver differentiated and affordable innovative medicines to patients around the world.

运用最前沿的技术,开发具有分化特色和可支付 得起的创新生物药,惠及全球病患。

