Transcenta(6628.HK)

Exciting news in TST001, which is a leading player in CLDN18.2 market

Investment Rating

BUY
Initial Coverage

Company Background	
Name	Transcenta
Sector	Bio-tech
Establishment Date	2010-08-20
Registered Capital	87,938 USD
Registered Address	Cayman Islands
Total Employees	363
Chairman	Zhao Yining

Shareholding Structure	
Shareholder Name	Share
Dr. Xueming Qian	13.09%
LAV Fund	15.84%
China Structural Reform Fund Corporation Limited	8.85%

Key Data	
Close Price(HKD)	3.55
5 days change(%)	1.14
10 days change(%)	2.6
5 days moving average (HKD)	3.56
10 days moving average (HKD)	3.51
10 days avg vol(k)	53.5

Report Date：2022-09-29

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Core perspective

Transcenta ranked the second leading company to develop an anti-Claudin 18.2 antibody therapeutic candidate globally. The management teams are from world-renowned pharmaceutical companies, with an average of more than 20 years of experience in the biopharmaceutical industry. The management team has a track record in leading discovery, preclinical research, clinical development and operations, process development and manufacturing, regulatory affairs and business development, and multinational company cooperation.

Growth logic

The top-down and integrated R&D has led to efficiency in drug candidate discovery, translational research, technological advancement, and commercialization. The company has made substantial achievements and subsequently led to developing 10 drug candidates(with 9 gained global rights). The company achieved operational efficiency in CDMO by lowering operational cost and is expected to achieve sustainable growth.

In the form of a poster at the 2022 European Society for Medical Oncololy(ESMO) on 13th Sept , the company announced interim safety and efficacy data of dose expansion cohort from the phase I/II study of TST001, its anti-Claudin18.2 monoclonal antibody, in combination with Capecitabine and Oxaliplatin (CAPOX) as a first line treatment of locally advanced or metastatic gastric or gastroesophageal junction (G/GEJ) cancer.It demonstrated good tolerability and encouraging anti-tumor activity, the company said Phase III clinical trials are currently in the planning stage. TST001 has a proven track record in gastric and pancreatic cancer treatment with substantial market potential.

The diagnosis rate and treatment awareness of osteoporosis in China is still very low. With the increase in medical expenditure and the aging population, it is expected that doctors and the elderly will pay greater attention to osteoporosis. TST002 was officially accepted by the State Food and Drug Administration on July 6, 2021. In April this year, the first patient with osteoporosis was successfully dosed in China. The company is developing Blosozumab as an intravenous drug every 2 to 3 months, which may lead to better efficacy and better patient compliance.

Valuation

Based on the clinical stage of TST001 and TST002, the DCF method is used to value the company: WACC=6.43%, sustainable growth rate=3.0%, and the company's valuation is HK$6.076 billion, corresponding to the target price of 13.64.

Key Risk：Delays in clinical/regulatory milestones, price competition

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1 Global leader in CLDN18.2 and building international team

1.1 Background

Registered in the British Virgin Islands in 2010, Transcenta was established in October 2018 after the merger with Mabspace and Just Biotherapeutics Asia. Transcenta emerged into an integrative clinical-stage biotech company focused on discovering, R&D, and manufacturing biotech. The globalization strategy has enabled the company to improve operational efficiency and run a pipeline of ten drug candidates covering oncology, orthopedics, and kidney disease.

As one of the global market leaders in CLDN18.2 targets, the company is the second to develop an anti-Claudin18.2 antibody therapeutic candidate globally. On 13th Sept 2022, the company announced its humanized targeting 18.2 monoclonal antibody TST001 (Osemitamab) with enhanced ADCC activity in combination with CAPOX for advanced and metastatic stage gastric cancer and gastroesophageal junction (G/GEJ) cancer at The Society of Internal Medicine (ESMO) Annual Meeting. Phase III clinical trials are currently being considered.

Figure 1： Company's pipeline

Source： Company's website, VCL prepared

1.2 International team with superior management and research experience

The management team is from world-renowned pharmaceutical companies, with an average of more than 20 years of experience in the biopharmaceutical industry. The team has gained a track record in leading discovery, preclinical research, clinical development and operations, process development and manufacturing, regulatory affairs and business development, and multinational cooperations.

Dr. Qian Xueming is an experienced commercial antibody researcher with over two decades of experience in the field. He has been involved in many aspects of antibody development, from discovery to development, and has played a vital role in many successful projects. He is the former senior vice president of Beijing Sheng Nuoji Pharmaceutical Technology and the chief scientist of Amgen Inc. and led several project teams to discover new antibody drugs for treating autoimmune and metabolic diseases, such as those affecting bones and kidneys. He is the primary inventor of several antibody patents. He graduated from Fudan University's Department of Biophysics, a Master's in Neurology and Physiology from Columbia University, and his Doctorate in Neurology and Pharmacology from Albany Medical Center.

Dr. Caroline Germa (Executive Vice President, Global Drug Development and Chief Medical Officer), Dr. Caroline Germa is a distinguished medical oncologist and drug development leader with more than 20 years of experience in early-stage clinical trials through late-stage clinical trials. In addition, she led the late-stage clinical development of several critical oncology assets, especially the global registration strategy and approval of Ribociclib (CDK4/6 inhibitor - Kisqali) and Neratinib. She has served AstraZeneca, Bristol-Myers Squibb, Novartis, Pfizer, Eli Lilly and Sanofi-Aventis. She received a medical doctorate and Medical Oncologist degrees from the Universities of Paris and Lille, France, and a Master's degree in Breast Diseases and Immunology.

Dr. Christopher Hwang (Executive Vice President, Chief Technology Officer) Dr. Christopher Hwang has nearly 30 years of experience in process development and scale-up, technology transfer, production, and regulatory support. He has participated in 7 commercialization projects and 6 mid/late stages development projects in recombinant proteins, monoclonal antibodies, and gene therapy. Dr. Christopher Hwang's core expertise includes continuous flow production technology platforms, and he has served Genzyme and Sanofi. He

obtained Ph.D. in Biochemical Engineering from the Massachusetts Institute of Technology.

Dr. Feng Ye (Executive Vice President of Technical Operations, Chief Operating Officer) Dr. Feng Ye has extensive experience in production, quality control, and corporate operations. He has 20 years of experience in the biopharmaceutical industry and has served for Schering-Plough, GlaxoSmithKline, and Amgen. He held responsibility for leading the production and quality control of biological drugs, including many internationally renowned pharmaceutical companies. He is a Member of the American Association of Pharmacists (AAPS), American Statistical Association (ASA), International Society for Pharmaceutical Engineering (ISPE), and Ph.D. in Biostatistics, the University of North Carolina at Chapel Hill.

Dr. Xiaoming Yang (Executive Vice President, Global Process and Product Development) Dr. Xiaoming Yang has over 30 years of experience in product and process development and scale-up, technology transfer, new equipment startup, GMP manufacturing, and IND/BLA filings in the biopharmaceutical industry. He was previously the Senior Project Engineer and Head of Commercial Manufacturing for Merck, Bioprocess Division Manager for Allergan, and Process and Product Development Scientific Director for Amgen. Dr. Yang received Ph.D. in Biochemical Engineering from Rutgers University.

2 Strength in top-down integrative strategy

2.1 R&D Capability

The company has an integrated biopharmaceutical platform that supports drug candidates from drug discovery, translational research, and process development to commercialization. Key achievements include the discovery and development of nine global rights drug candidates. The company has developed a unique antibody discovery platform, the Immune Tolerance Breaking(IMTB) technology platform, capable of generating both non-conserved and conserved protein and discovering hidden epitopes. This platform has facilitated the acquisition of lead antibody candidates with broader epitope diversity, differentiated biological properties (specificity, affinity, and P.K. exposure), and desirable CMC properties, allowing for the selection of candidates with enhanced druggability and intellectual property protection molecular. Consequently, the company has generated the pipeline of TST001 (targeting the anti-Claudin 18.2 conserved epitope) and TST005, TST003, and TST010.

The translational research platform facilitates tumor response models to experimental drugs, strengthens the understanding of PK/PD status, provides clinical design and clinical studies guidelines, and evaluates combination therapy options using drugs targeting different signaling pathways. This platform has enabled the screening of antibodies for target detection and immunohistochemical methods for clinical trials. In addition, this platform has improved the company's efficiency in recruiting patients through increased precision in selecting patients and maximizing the success rate in clinical trials.

The Chemistry, Manufacturing, and Controls(CMC) in drug development include drug candidate molecules for drugability verification, cell line development, cell culture/purification process development, analytical method development, formulation development, GMP production, etc. The CMC development plays an essential role in the life cycle of candidate drugs from early development to post-marketing. Additionally, pharmaceutical companies with high-efficiency CMC development capabilities often have an edge in IND filings and clinical outcomes. The high CMC capability embedded in the company has led to a competitive advantage in all technical aspects of biological drug development.

Endowed with experienced management teams who have renowned pharmaceutical companies, the company has an edge in maximizing operational efficiency and obtaining regulatory approval in the United States. Additionally, the global strategy has enabled the company to conduct clinical trials effectively in the United States and China.

2.2 Competitive advantages in production

Based in Hangzhou Medical Port, the company's GMP production is an IP-designed modular concept production plant, T-BLOC. The T-BLOC has high flexibility and scalability and can reduce the reconfiguration cost, production safety, and process stability.

The company also has made substantial progress in technological improvements. The company has developed an integrated continuous flow bioprocess (ICB) manufacturing platform that combines a proprietary, high-productivity, ongoing upstream perfusion process (jointly developed with Merck Group). The ICB production process has succeeded in lowering the cost of goods sold while maximizing production and minimizing operational risk. The company has achieved a high industry standard: daily volumetric productivity of >6g/L and

multiple cell lines yields 10 times higher than traditional fed-batch processes.

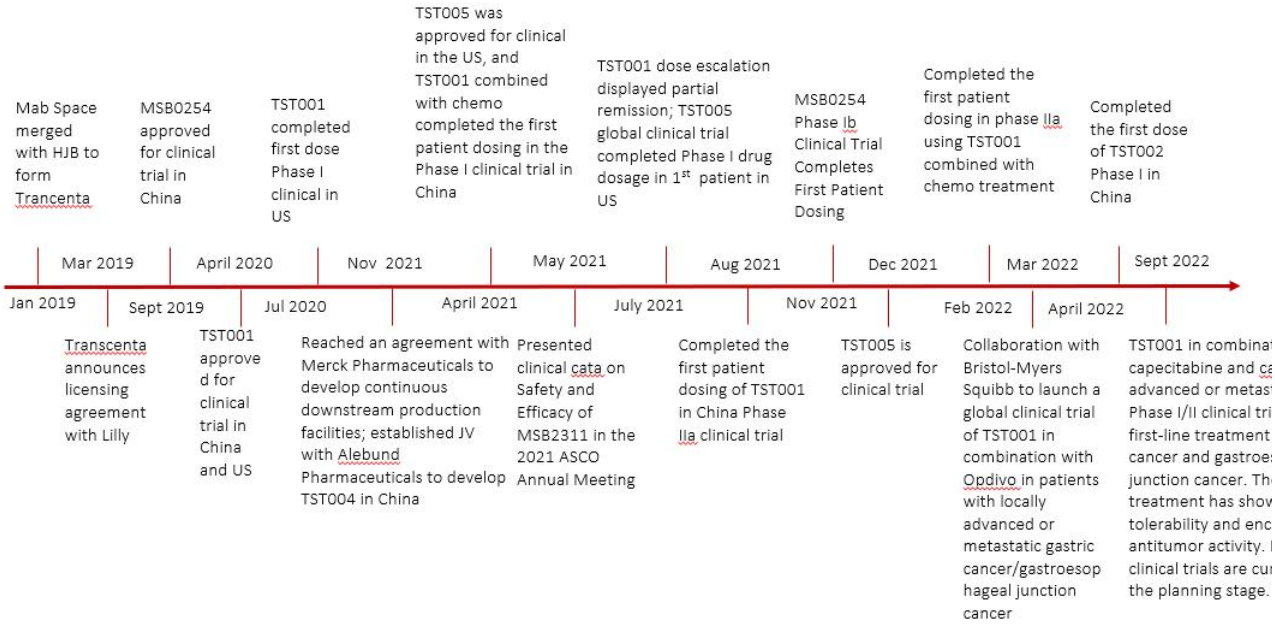
In April 2022, the subsidiary HJB successfully passed the E.U. Quality Authorized Person (QP) audit. The company has achieved a high standard in Quality Management systems (QMS) to ensure compliance with GMP requirements, which is essential for clinical research in the E.U. In the same period, HJB obtained the approval of the China Food and Drug Administration and the FDA, respectively, and changed the TST001 process from the flow-feeding process to the enhanced perfusion process, which increased capacity by eight times.

3 Milestone and Shareholder:

Milestone

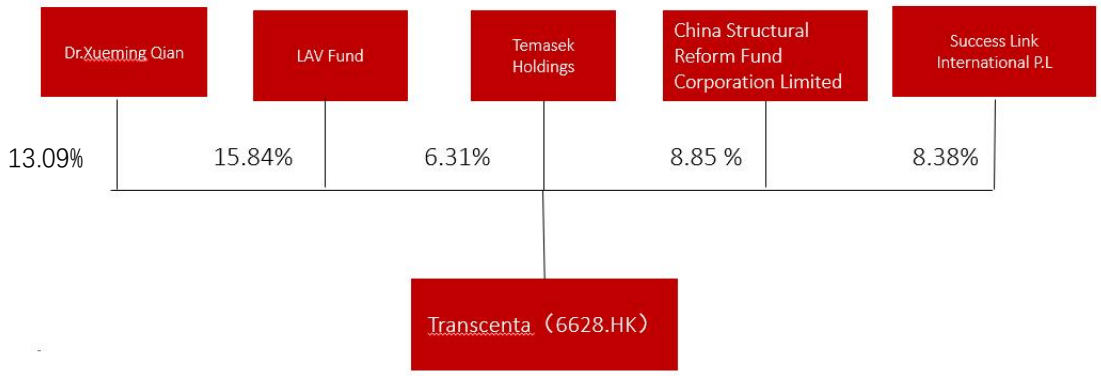
The company has received well-known institutional investors from participating in cornerstone investments, including LAV Fund, Temasek, China State-owned Enterprise Structural Adjustment Fund, Qatar Investment Authority, Hillhouse Capital, and Sequoia Capital.

Figure 2： Milestone



Source： Company Annoucement, VCL prepared

Figure 3： Shareholder Structure



Source：Company Annoucement, HKEX news, VCL prepared

4 CDMO Business segment

4.1 CDMO performance

The company has yet to achieve commercial sale from its pipeline but achieve revenue from CDMO services and R&D services. The 2022 interim results achieved revenue totaled at RMB 21.8 million. CDMO and government subsidies (1H22: 13.9 million) will be the primary income source before the company's pipeline products are commercialization. In the first half of the year, the company added more than 15 new customers and expanded its business in analytical testing, formulation research, particle investigation, and drug filling. The company plans to offer exploratory, experimental services to customers seeking continuous process development to attract contract transactions on the ICB platform. The company's CDMO business continues to reduce costs, increase efficiency, and provide the company's customers with more powerful cell line options at lower prices. We expect the company's CDMO business to continue to achieve solid growth throughout the year.

4.11 View on CDMO market

The pharmaceutical industry has experienced significant growth in the global environment and China, which recorded 41% and 58% growth in June. In June, there were 602 new clinical trials of new drugs globally, representing 10% month-on-month and 31% year-on-year growth,

focusing on the second and third phases of clinical trials. Class 1 new drug IND applications have achieved 32% year-on-year growth in China. And the Phase I, II, and III clinical trials have also increased by 41%/104%/26%, respectively. The company's production base has multiples 200-2000L raw liquid production lines and a fully automatic preparation filling production line with isolators and has reserved space for line expansion. The annual production capacity is expected to exceed one ton in the future. As of 1Q22, the existing GMP production has been operating for four years and has completed over 50 internal and external batches. In the first quarter of 2022, the GMP production base has been working for four years and has undertaken more than 50 batches of GMP batches of internal and external projects, with a success rate of 100%. Foreseeing the growth in global pharmaceutical R&D spending and the company's expansion, we expect the CDMO business to have a CAGR of approximately 36% from 2022 to 2024, and the revenue in 2022/2023/2024 is expected to grow to 7,033/9,706/126.18 million, respectively

5 Core Products

5.1 TST001

5.11 Intro to TST001

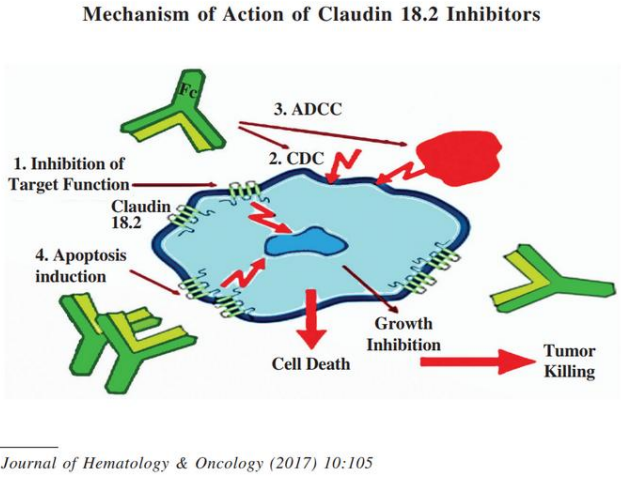
TST001 is the second anti-Claudin18.2 antibody therapeutic candidate developed globally. It is a potential best-in-class humanized antibody with best-in-class potential and ranked first in China via its Immune Tolerance Breaking (IMTB) technology platform. Claudin 18.2 is a tight junction protein whose expression is restricted to differentiated epithelial cells in the stomach in normal tissues. However, further analysis has shown that Claudin18.2 is also found in pancreatic, lung, and other solid tumors. TST001 portrayed features of higher affinity with CLDN18.2, enhanced antibody-dependent cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC) activities and displayed stronger PDX in animal experiments. The U.S. Food and Drug Administration (FDA) has granted orphan drug designation to TST001 for the treatment of gastric cancer and gastroesophageal junction cancer.

5.12 Mechanism

Located in the outer membrane of cells, Claudin 18.2 and has an exposed extracellular loop for mAb binding. Although Claudin 18.2's biological characteristics is an attractive target for therapy molecule, it

has a highly conserved protein sequence across species and has substantial difficulty generating antibodies with high binding capacity. TST001 can enhance affinity for tumor cells and improve the efficiency when interacting with N.K. cells, killing tumor cells expressing Claudin18.2 through ADCC and CDC mechanisms. Using an optimized glycoengineering process, TST001 reduces the fucose level in the antibody's Fc region, thereby increasing the affinity for FcRs, especially FcR III expressed by natural killer cells. Enhanced binding to Claudin 18.2 on tumors and increased binding to FcR on natural killer cells leads to increased efficiency of interaction between tumor cells and natural killer cells.

Figure 4： Mechanism of Claudin 18.2



Source：IPO Prospectus, VCL prepared

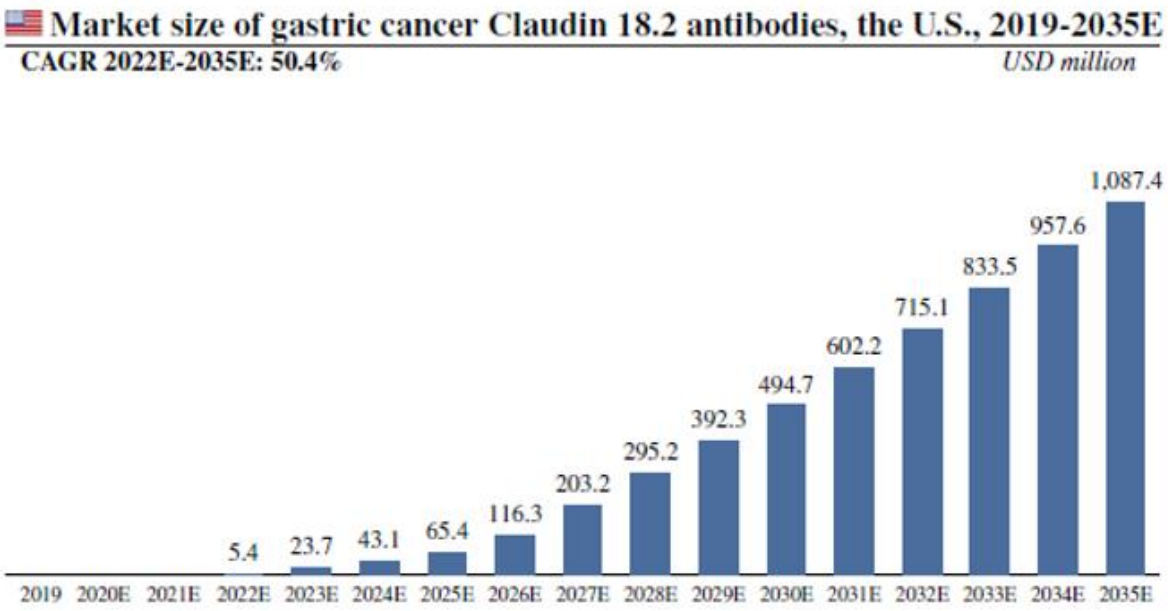
5.13 Market

Gastric Cancer Patients

Gastric cancer is one of the most common digestive system cancers worldwide and the third leading cause of cancer death worldwide. The overall 5-year survival rate of patients with metastatic gastric and gastroesophageal junction cancer is less than 20%. Smoking and obesity are believed to be the leading causes of gastric cancer. Gastric cancer is mainly caused by damage to the gastric mucosal barrier, which increases the expression of oncogenes and the probability of gene mutation in stem cells. Carcinogens differentiate new primary cells into poorly differentiated or abnormal cells that gradually encroach on the space of normal gastric cells, eventually leading to organ failure and death. Globally, the incidence of gastric cancer reached 1,057.5 thousand in 2019. According to the company's prospectus, it is estimated that by 2035, the market size of gastric

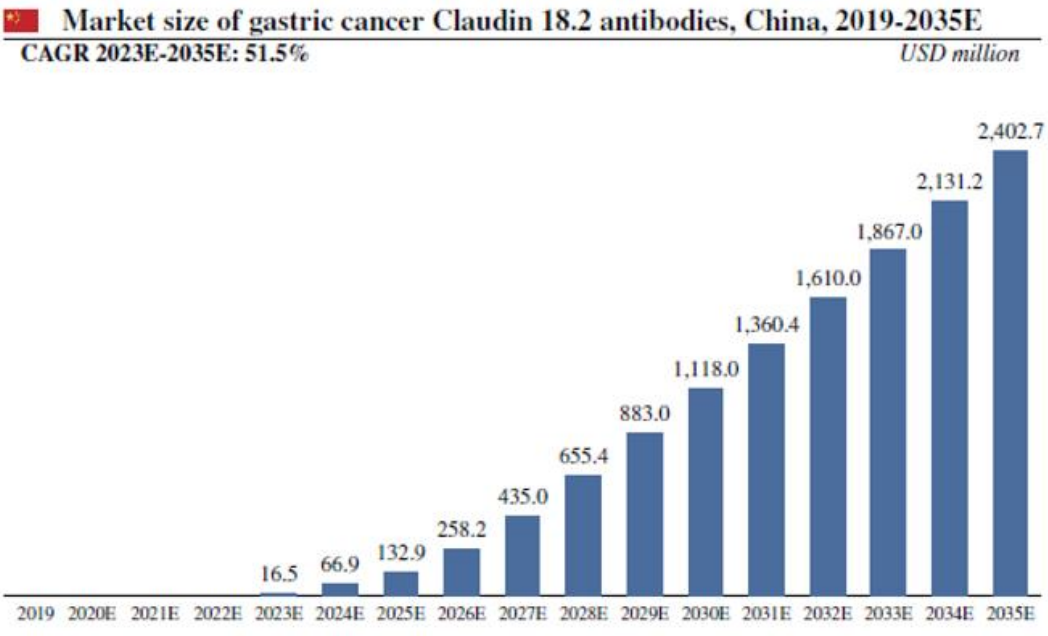
cancer Claudin 18.2 inhibitors in the United States and China will reach US$ 1,087.4 million and US$ 2,402.7 million, respectively. The CAGR in both countries from 2023 to 2035 is reaching 51%. The incidence of gastric cancer in China reached 5,00.3 thousand in 2019 and is expected to reach 5,99.8 thousand by 2030. The demand for gastric cancer treatment remained high

Figure 5： The U.S. gastric cancer Claudin 18.2



Source：IPO Prospectus, VCL prepared

Figure 6： China gastric cancer Claudin 18.2



Source: IPO Prospectus, VCL prepared

About 80% of gastric cancer patients in China are in the advanced or metastasis stage at the time of diagnosis, and relatively few (<20%) patients with advanced metastatic gastric cancer are HER2 positive. Currently, gastric cancer targeted therapy (such as Herceptin) can be used to treat HER2-positive patients; HER2-negative patients (especially first-line gastric cancer patients) have limited approved treatment options other than chemotherapy. For previously treated gastric cancer, a variety of drugs have been approved by the FDA, including Cyramza (which targets VEGFR2 as monotherapy or in combination with chemotherapy and PD-1 biologics for second-line treatment), launched in 2014. gastric cancer), Kreda and Opdivo (for treating third-line gastric cancer, approved in 2017 and established in 2020). In China, only lapatinib and PD-1 are approved for treating third-line gastric cancer patients. However, Claudin 18.2 is considered a new therapeutic target for gastric cancer, and its expression rate is as high as more than 90%. The combination therapy of anti-Claudin 18.2 inhibitor and P.D.-(L)1 inhibitor may become a potential therapy for gastric cancer patients. For patients with high expression rates (>75%), 80% of U.S. and 50% of Chinese patients will use the anit Claudin 18.2 antibody.

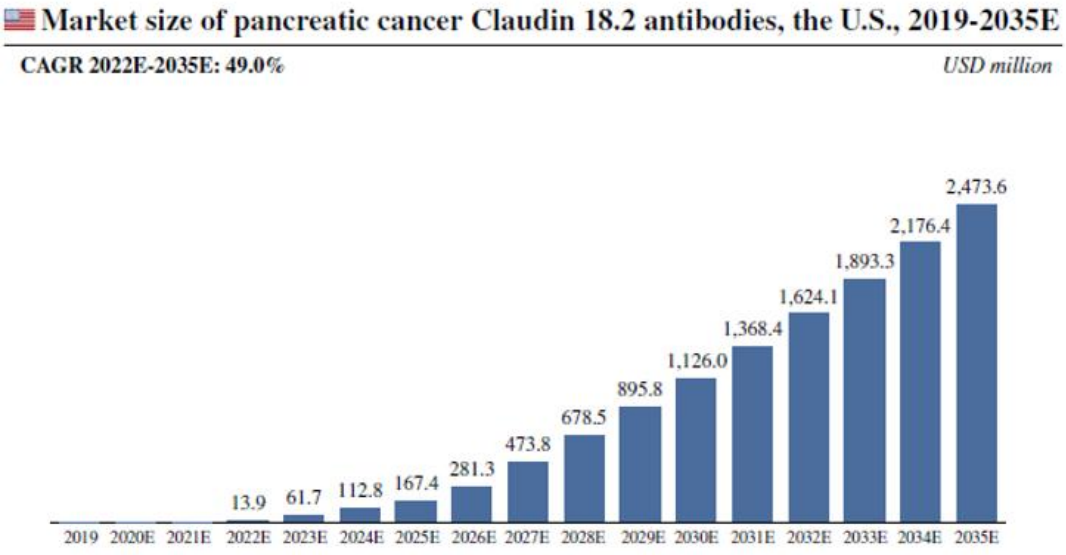
Claudin 18.2 is a gastric-specific membrane protein identified as a potential target for gastric cancer therapy. Astellas' zolbetuximab (anti -Claudin 18.2 antibody) Phase 2 clinical results show that its combined chemotherapy can significantly prolong progression-free and overall survival in patients with advanced gastric cancer overexpressing Claudin 18.2. An ongoing global phase 3 trial tests whether its combination with chemotherapy in first-line gastric cancer patients with Claudin 18.2 expression (>75% tumor cells with 2++ intensity) can prolong progression-free survival compared to standard chemotherapy alone. The test will potentially be a new treatment option for first-line gastric cancer patients with Claudin 18.2 expression (>75% tumor cells with 2++ intensity).

Pancreas Cancer Patients

Pancreatic cancer is another digestive system cancer and can invade other tissues. While the disease is commonly found in the United States and China, most patients develop symptoms in advanced and metastatic stages due to difficulty in early detection. Chemotherapy remained the preferred option for metastatic pancreatic cancer. According to the NCCN guidelines, the ORR approximates 25% for first-line therapy and O.S. of 6 to 11 months. Erlotinib is an EGFR-targeted drug for the third-line treatment of patients with

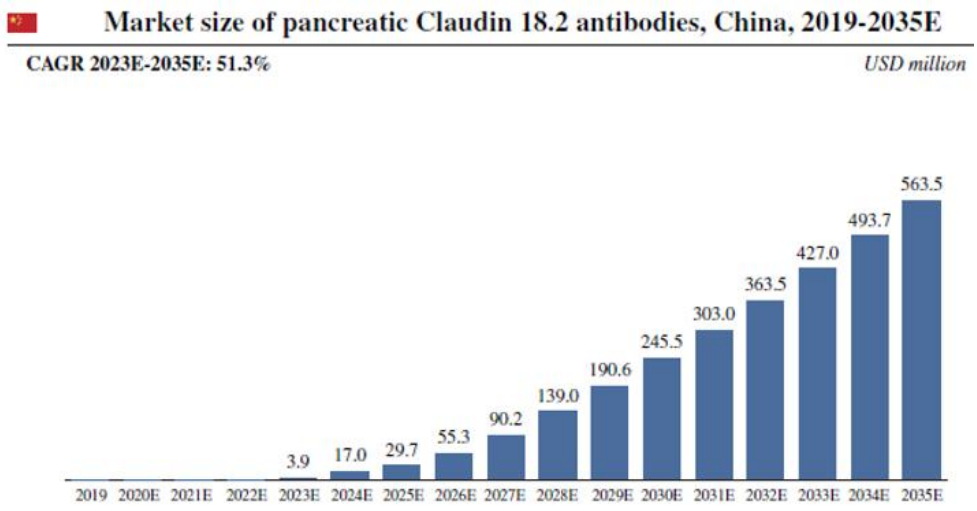
advanced pancreatic cancer. The drug can be used with the chemotherapy drug gemcitabine, but the overall effect is not significant. Globally, the incidence of pancreatic cancer reached 480.5 thousand in 2019. According to the prospectus data, it is estimated that by 2035, the market size of the pancreatic cancer Claudin 18.2 inhibitor in the United States and China will reach US$ 2,473.6 million and US$ 563.5 million, respectively. The compound growth rates of the two countries from 2023 to 2025 are 49% and 51.3%, respectively. The incidence of pancreatic cancer in China reached 1,08.4 thousand in 2019 and is expected to increase to 149.4 thousand by 2030.

Figure 7： The U.S. pancreatic cancer Claudin 18.2



Source： IPO Prospectus, VCL prepared

Figure 8： China’s pancreatic cancer Claudin 18



Source： IPO Prospectus, VCL prepared

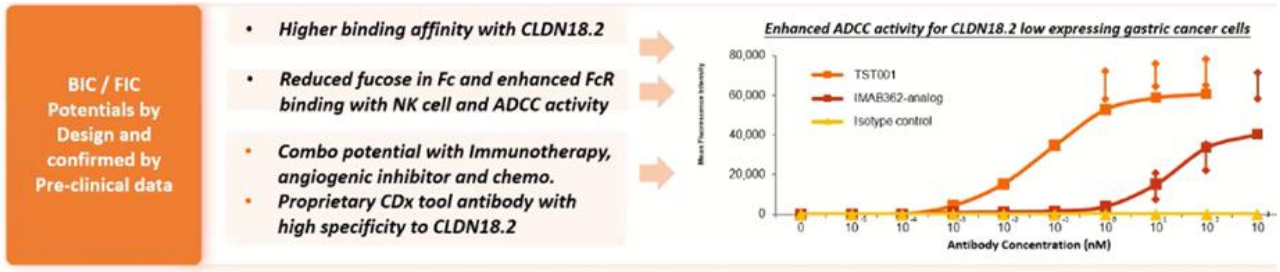
About 76% of pancreatic cancer patients in China are in the advanced or metastatic stage, and only 15% of patients are suitable for radical resection. There are no biologics for pancreatic cancer worldwide, and immunotherapies, such as P.D.-(L)1 inhibitor, are ineffective in treating pancreatic cancer. Since the expression rate of Claudin 18.2 in pancreatic cancer patients is about 40%, Claudin 18.2-targeted drugs may have a potential treatment for pancreatic cancer. When Claudin 18.2 antibody is combined with standard chemotherapy, TST001 will serve as the first-line treatment for pancreatic cancer and three other potential drug candidates. Among the three drug candidates, Astellas' zolbetuximab in combination with chemotherapy for first-line pancreatic cancer is the most promising therapy in Phase II in addition to TST001.

The competitive advantage of Claudin 18.2 inhibitors is mainly reflected in the high expression rate and the safety of combined chemotherapy/monotherapy, with an expression rate of 96% in gastric cancer and over 40% in pancreatic cancer. For patients with advanced metastatic gastric cancer, the expression rate of HER2 is less than 20%, while the medium-high expression rate of Claudin 18.2 is about 50%. Only 14% of Claudin 18.2-positive patients in the FAST study co-expressed HER2, indicating that Claudin 18.2 may be regarded as a non-overlapping target for gastric cancer treatment, and Claudin 18.2 has the potential to become the first-choice drug for gastric and pancreatic cancer. In addition, for pancreatic cancer, bile duct cancer, and other cancers that lack targeted therapy drugs, the high expression rate of Claudin 18.2 is a condition that is conducive to its first-line treatment. Compared with chemotherapy alone, Zolbetuximab (Claudin 18.2 antibody) prolonged mean PFS from 4.8 months to 7.9 months and median O.S. from 8.4 months to 13.2 months. For patients with high and moderate Claudin 18.2 expression in more than 70% of tumor cells, the median O.S. of patients treated with EOX combined with Zolbetuximab was nearly twice that of EOX alone (16.7 months vs. nine months), and no significant increment in Grade 3 adverse reactions.

5.14 Development in the clinical trial

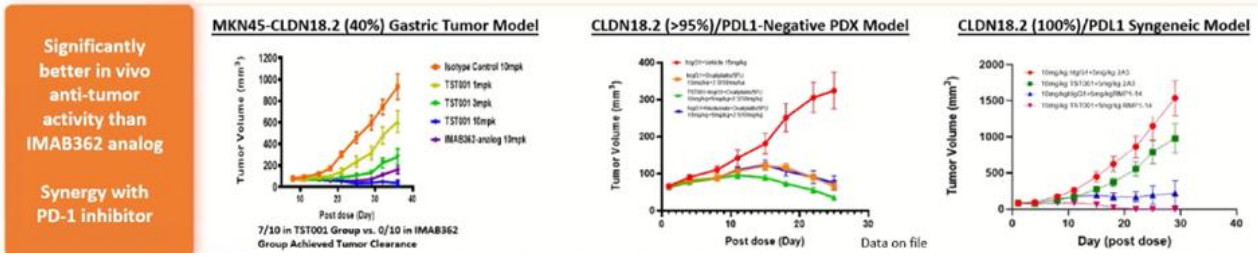
Preclinical data show that TST001 has reasonable specificity, antitumor activity, and BIC/FIC potential. Data shows more than a 10-fold improvement in affinity and a 30-100-fold increase in ADCC activity, with TST001 data outperforming chemotherapy and PD-1.

Figure 9： TST001's encouraging result in the pre-clinical trial data



Source： Company Presentation, VCL prepared

Figure 10： TST001 performs better than IMAB362, and generates synergy with the PD-1 inhibitor



Source： Company Presentation, VCL prepared

Suzhou On 22nd March 2022, the company announced that it has entered into a global clinical research cooperation agreement with U.S.-based Bristol Myers Squibb to carry out the anti-Claudin18.2 humanized monoclonal antibody. An international clinical trial of the PD-1 inhibitor Opdivo® (nivolumab) in patients with unresectable advanced or metastatic gastric and gastroesophageal junction cancer.

The collaboration includes two open, multi-center Phase I/II global clinical studies conducted in China and the United States. The aim is to evaluate the safety, tolerability, and antitumor efficacy of TST001 combined with Opdivo® in patients with unresectable advanced or metastatic gastric cancer and gastroesophageal junction cancer that expressed Claudin18.2 regardless of prior treatment.

At the European Society of Medical Oncology (ESMO) annual meeting on 13th September 2022, the company announced its humanized anti-Claudin18.2 monoclonal antibody TST001 with enhanced ADCC activity combined with capecitabine and oxaliplatin (CAPOX) in the form of a poster. The poster presented the initial result for this first-line treatment for advanced or metastatic gastric and gastroesophageal junction cancer. It included interim safety and

efficacy data from a dose-expansion cohort study in the Phase I/II clinical trial.

A total of 51 patients were enrolled and treated, including 36 patients who received TST001 (Osemitab) in combination with CAPOX at a dose of 6 mg/kg Q3W during the expansion phase (median follow-up of 65 days). Among the 15 patients with measurable disease and at least one post-treatment tumor assessment measured via RECIST 1.1 criteria: 11 (73.3%) achieved partial response, 4 (26.7%) had a stable response, and the control rate achieved 100%. Among them, 6 of 8 patients with moderate/high Claudin18.2 expression and 5 of 5 patients with unknown expression of Claudin18.2 achieved partial responses, 73.3% achieved partial response, and 100% disease control rate. All 51 enrolled patients underwent safety and tolerability assessments.

Summary: The data show that TST001 alone and in combination with chemotherapy is well tolerated, with relatively flat P.K. values. More importantly, its tolerance level is similar to chemotherapy, and the effect is reflected in both Chinese and American patients. Clinical data showed that the drug produced mild side effects, and the adverse events that occurred during treatment were mainly graded 1-2, and only seven patients (or 17.%) had more severe grade 3 adverse events. The data show that TST001 (Osemitamab) combined with CAPOX for the first-line treatment of Claudin18.2 has demonstrated good tolerability and encouraging antitumor activity. Given the tolerability and significant efficacy, the company's Phase 3 clinical trials are being considered.

5.15 Financial Forecast

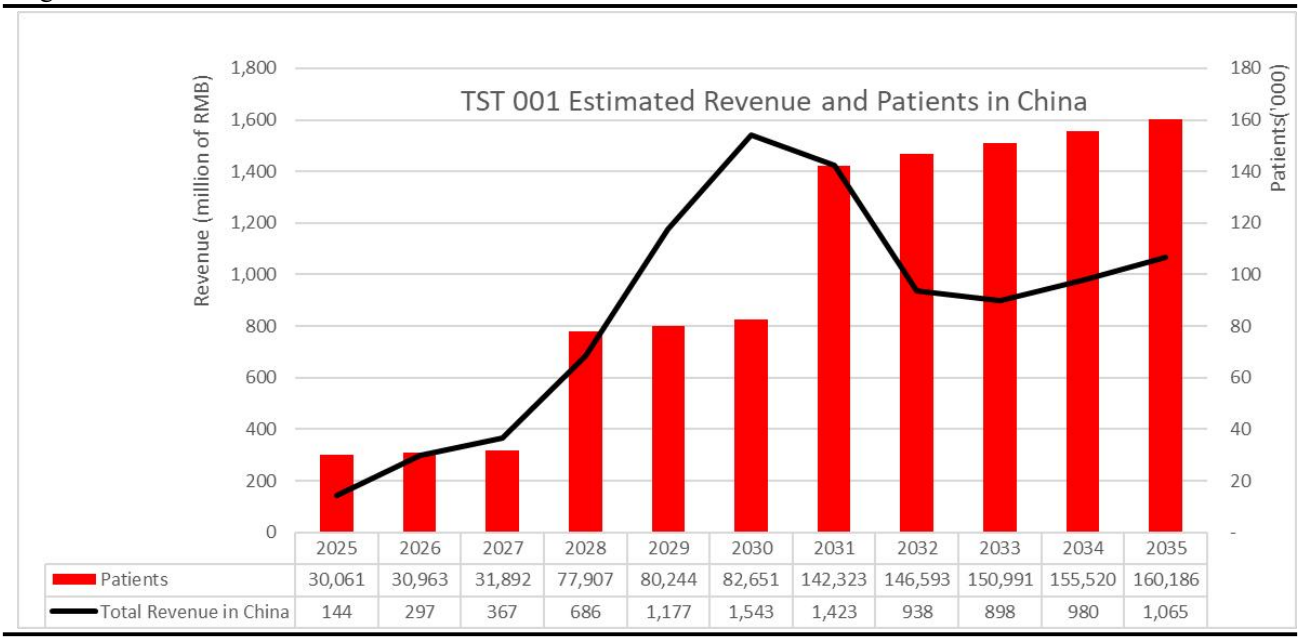
TST001 is expected to launch in China and the United States. In China, sales is generated through external marketing and distribution partnerships with internal sales teams and CSOs. Overseas sales are conducted through a partnership with international partners to achieve global development and commercialization of the drug.

Figure 11： TST001 revenue forecast in China

								Exclusive Period End						
Gastric Cancer- China ('mil)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Ability to Pay(ATP)														
Patients for ATP at 160K RMB	22,755	23,438	24,141	24,865	25,611	26,379	27,171	27,986	28,825	29,690	30,581	31,498	32,443	33,416
Patients for ATP at 80K RMB	53,968	55,587	57,254	58,972	60,741	62,563	64,440	66,373	68,365	70,415	72,528	74,704	76,945	79,253
Patients for ATP at 40K RMB	90,224	92,931	95,719	98,590	101,548	104,594	107,732	110,964	114,293	117,722	121,254	124,891	128,638	132,497
Market														
Market ATP at 160K RMB	3,641	3,750	3,863	3,978	4,098	4,221	4,347	4,478	4,612	4,750	4,893	5,040	5,191	5,347
Market for ATP at 80K RMB	4,317	4,447	4,580	4,718	4,859	5,005	5,155	5,310	5,469	5,633	5,802	5,976	6,156	6,340
Patients for ATP at 40K RMB	3,609	3,717	3,829	3,944	4,062	4,184	4,309	4,439	4,572	4,709	4,850	4,996	5,146	5,300
Competitor				2	2	2	3	3	3	3	4	4	4	4
First mover advantage				1.2	1.2	1.2	1.1	1.1	1	1	0.8	0.7	0.7	0.7
Market share				50.00%	50.00%	50.00%	33.33%	33.33%	33.33%	33.33%	25.00%	25.00%	25.00%	25.00%
Market penetration				5.00%	10.00%	12.00%	30.00%	50.00%	70.00%	75.00%	80.00%	85.00%	90.00%	95.00%
Revenue for ATP at 160k RMB				119	246	304								
Revenue for ATP at 80k RMB							567	973	1,276					
Revenue for ATP at 40k RMB										1,177	776	743	810	881
								Exclusive Period End						
Pancreatic Cancer- China ('mil)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Ability to Pay(ATP)														
Patients for ATP at 160K RMB	4,755	4,898	5,045	5,196	5,352	5,513	5,678	5,848	6,024	6,205	6,391	6,582	6,780	6,983
Patients for ATP at 80K RMB	11,278	11,616	11,965	12,324	12,693	13,074	13,466	13,870	14,287	14,715	15,157	15,611	16,080	16,562
Patients for ATP at 40K RMB	18,855	19,420	20,003	20,603	21,221	21,858	22,514	23,189	23,885	24,601	25,339	26,099	26,882	27,689
Market ATP at 160K RMB														
Market for ATP at 80K RMB	761	784	807	831	856	882	908	936	964	993	1,023	1,053	1,085	1,117
Patients for ATP at 40K RMB	902	929	957	986	1,015	1,046	1,077	1,110	1,143	1,177	1,213	1,249	1,286	1,325
Competitor	754	777	800	824	849	874	901	928	955	984	1,014	1,044	1,075	1,108
First mover advantage				2	2	2	3	3	3	3	4	4	4	4
Market share				1.2	1.2	1.2	1.1	1.1	1	1	0.8	0.7	0.7	0.7
Market penetration				50.00%	50.00%	50.00%	33.33%	33.33%	33.33%	33.33%	25.00%	25.00%	25.00%	25.00%
Revenue for ATP at 160k RMB				5.00%	10.00%	12.00%	30.00%	50.00%	70.00%	75.00%	80.00%	85.00%	90.00%	95.00%
Revenue for ATP at 80k RMB				25	51	64								
Revenue for ATP at 40k RMB							119	203	267					
										246	162	155	169	184
Total Revenue in China				**144**	**297**	**367**	**686**	**1,177**	**1,543**	**1,423**	**938**	**898**	**980**	**1,065**

Source： Public information, VCL prepared

Figure 12： TST001 revenue trend in China



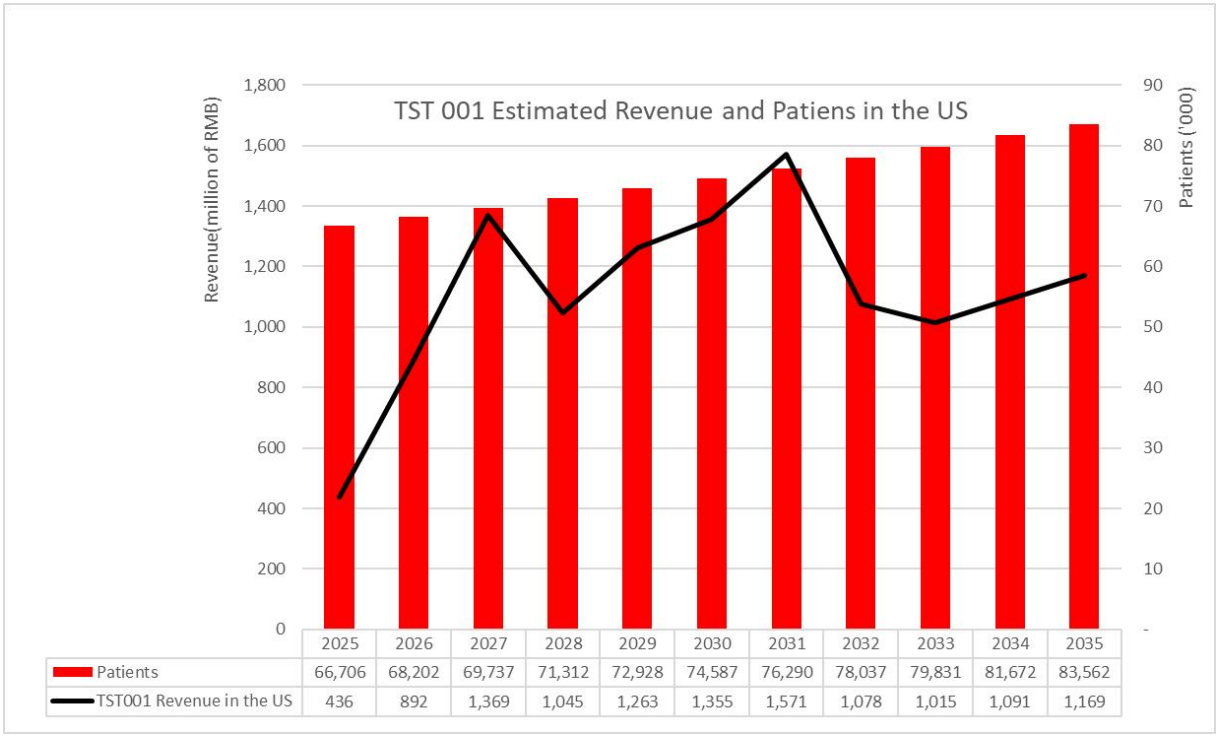
Source: Public information, VCL prepared

Figure 13： TST001 revenue forecast in the US

In RMB								Exclusive Period End						
Gastric Cancer-China ('mil)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Patients (Claudin 18.2)	26,380	26,683	26,990	27,300	27,613	27,931	28,251	28,576	28,904	29,236	29,572	29,912	30,256	30,603
Market Size	17,675	17,878	18,083	18,291	18,501	18,713	18,928	19,146	19,366	19,588	19,813	20,041	20,271	20,504
Competitors				2	2	2	3	3	3	3	4	4	4	4
Coverage				0.904	0.904	0.904	0.904	0.904	0.904	0.904	0.904	0.904	0.904	0.904
First mover advantaghe				1.2	1.2	1.2	1.1	1.1	1	1	0.8	0.7	0.7	0.7
Market share				50.00%	50.00%	50.00%	33.33%	33.33%	33.33%	33.33%	25.00%	25.00%	25.00%	25.00%
Market penetration				6.00%	12.00%	18.00%	22.00%	26.00%	30.00%	34.00%	38.00%	40.00%	42.00%	44.00%
TST001 revenue in the US				595	1,204	1,827	1,380	1,650	1,751	2,007	1,361	1,268	1,347	1,427
								Exclusive Period End						
Pancreatic Cancer-China ('mil)	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Patients (Claudin 18.2)	36,063	37,144	38,259	39,407	40,589	41,806	43,061	44,352	45,683	47,053	48,465	49,919	51,417	52,959
Market Size	24,162	24,887	25,633	26,402	27,194	28,010	28,851	29,716	30,608	31,526	32,472	33,446	34,449	35,483
Competitors				2	2	2	3	3	3	3	4	4	4	4
Coverage				0.904	0.904	0.904	0.904	0.904	0.904	0.904	0.904	0.904	0.904	0.904
First mover advantaghe				1.2	1.2	1.2	1.1	1.1	1	1	0.8	0.7	0.7	0.7
Market share				50.00%	50.00%	50.00%	33.33%	33.33%	33.33%	33.33%	25.00%	25.00%	25.00%	25.00%
Market penetration				6.00%	12.00%	18.00%	22.00%	26.00%	30.00%	34.00%	38.00%	40.00%	42.00%	44.00%
TST001 Revenue in the US				859	1,770	2,735	2,104	2,561	2,767	3,230	2,231	2,116	2,289	2,470
TST001 revenue in the US				**436**	**892**	**1,369**	**1,045**	**1,263**	**1,355**	**1,571**	**1,078**	**1,015**	**1,091**	**1,169**

Source： Public Information, VCL prepared

Figure 14： TST001 revenue trend in the US



Source： Public Information, VCL prepared

5.2 TST002 (Blosozumab)

5.21 Intro to TST002

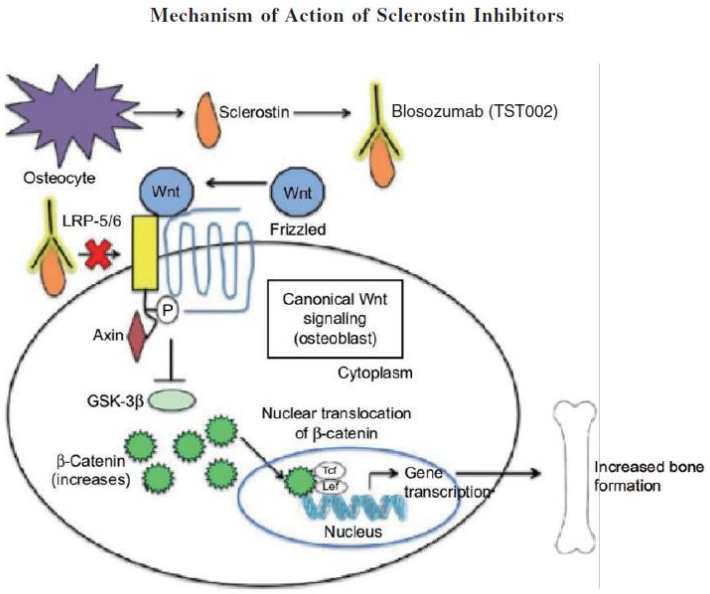
In 2019, the company obtained authorization from Eli Lilly to introduce the rights to develop and commercialize TST002 (Blosozumab) in Greater China. TST002 is a humanized anti-sclerostin monoclonal antibody candidate for severe osteoporosis. The dual absorption action promotes bone formation and inhibits bone loss, resulting in a rapid increase in bone density and bone strength. Blocking sclerostin activity is a practical approach to increase bone mineral density (BMD) and reduce fracture risk in people treated with anti-sclerostin antibodies or genetic deletions. Only Amgen's Romosozumab has been approved in the U.S., the European Medicines Agency (EMA), and Japan. However, there is no approved anti-sclerostin antibody therapy in China.

5.22 Mechanism

The balance between bone resorption and bone deposition is determined by the activity of two major cell types: osteoclasts and osteoblasts. Therefore, the bone remodeling cycle needs to start from two aspects: inhibiting osteoclasts or promoting osteoblasts. The loss of gonadotropins has reduced the conversion of bone marrow stromal cells to adipocytes and the differentiation of osteogenic precursor cells. Increased osteoclast activity leads to bone cell death while enhancing bone resorption.

Sclerostin is a glycoprotein encoded by the SOST gene and produced in bone cells. Sclerostin is an inhibitor of the WNT/β-catenin signaling pathway and stimulates osteoblast differentiation and bone formation. By inhibiting the activity of sclerostin, a sclerostin monoclonal antibody can promote bone formation, reduce bone resorption, and increase bone density and bone strength, thereby reversing the symptoms of osteoporosis. Osteoporosis is more prevalent in elderly women due to postmenopausal estrogen deficiency. The increase in osteoclast resorption activity is due to diminished inhibitory effects due to estrogen decrement. Subsequently, the amount of bone resorption exceeds that of bone deposited, resulting in a net loss of bone. In 2019, Amgen's anti-sclerostin monoclonal antibody was approved in the United States, Japan, and the European Union for the treatment of osteoporosis in postmenopausal women with heightened fracture risk.

Figure 15： The mechanism of Sclerostin

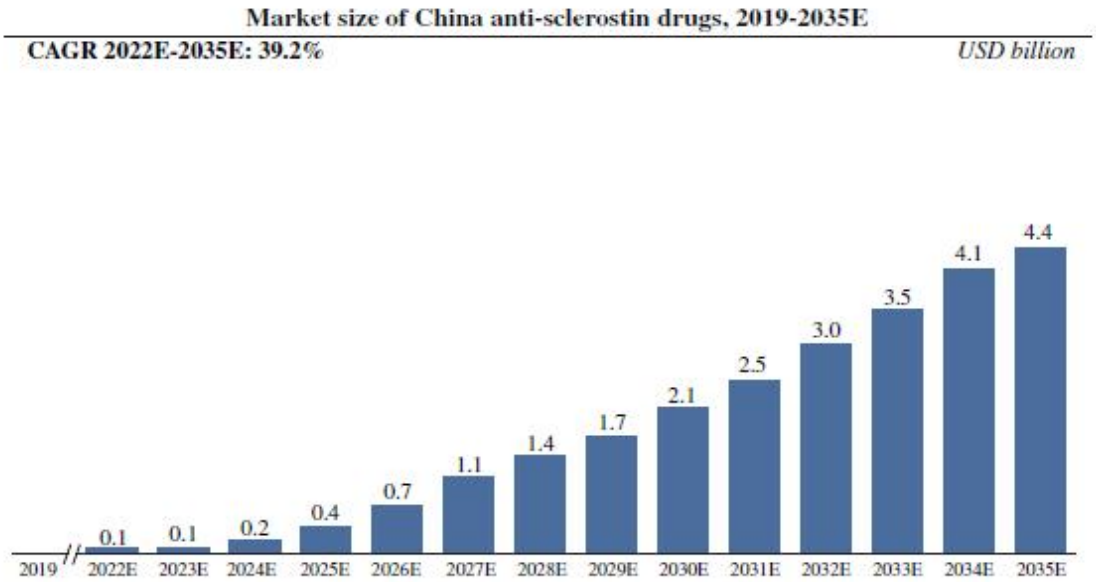


Source： IPO Prospectus, VCL prepared

5.23 Market

According to IPO prospectus, the prevalence of osteoporosis for age over 50 years old is estimated to be 19.2%, and the prevalence rate of people over 65 years old is estimated to be 32.0%. Due to aging population, Chinese osteoporosis patients in the past five years has higher growth rate than the global average. In 2010, there were approximately 2.5 million cases of osteoporotic fractures in China, with associated medical costs of US$9.45 billion. It is expected that there will be approximately 4.4 million osteoporotic fractures in China in 2030 and approximately 6 million in 2050, and the related medical expenses will reach US$17.8 billion and US$25.4 billion. Osteoporotic hip fracture has led adverse events including higher mortality rate ranging between 15% and 33%. CIC expects the market size of sclerostin inhibitors in China to further grow to US$4.4 billion in 2035, with a CAGR of 39.2% from 2022 to 2035.

Figure 16： Market Size of China anti-sclerostin drug



Source：IPO Prospectus, VCL prepared

Amgen's (Romosozumab) is the only anti-sclerostin antibody drug approved by the U.S. FDA. The product was launched in 2019, with sales of US$539 million at the end of the following year. Currently, there is no approved anti-sclerostin antibody drug in China. TST002 (Blosozumab) has dual anabolic and anti-resorptive effects, stimulates bone formation and inhibits bone resorption, resulting in a rapid action in enhancing bone density and bone strength. In a randomized, double-blind, placebo-controlled, multi-center Phase 2 clinical trial of Blosozumab in postmenopausal women with low BMD by Eli Lilly, Blosozumab treatment resulted in greater spinal, femoral neck and total hip BMD than placebo indicating statistically significant dose-dependent. In the highest dose group, spine BMD increased by 17.7% and total hip BMD increased by 6.2% in 12 months compared with baseline result. The sclerostin biologics market has benefited from the aging population in China, with the number of people over 50 years old increasing from 390 million in 2014 to 460 million in 2019, which attributed to the largest age group. In addition, the diagnosis rate and treatment awareness of osteoporosis in China are still very low. With the increase in medical expenditure and aging population, specific biological therapy will receive greater acceptance, which leading to long term growth.

5.24 Clinical Trial

Eli Lilly's Phase 2 Blosozumab study in postmenopausal women with low bone density showed significant changes in efficacy after 12 weeks of treatment. After 52 weeks of treatment, Blosozumab 180 mg Q4W, Blosozumab 180 mg Q2W and Blosozumab 270 mg were assigned to Women in Q2W had a mean increase from baseline of 8.4%, 14.9%, and 17.7% at the primary study. In the highest dose group, TST002 treatment increased spine BMD by 17.7% and total hip BMD by 6.2% within 12 months compare with the baseline. In terms of safety, minor injection site reactions were reported more frequently in the blosozumab group than in the placebo group, and adverse event rates were similar across treatment and 3-month follow-up for all treatment groups. Mild reactions at the injection site, including itching, swelling, erythema, bruising, and pain, were not related to the production of anti-drug antibodies. Blosozumab had a significant anabolic effect on bone at 1 year and was well tolerated.

TST002 submitted an IND application in China in June 2021, and was officially accepted by the State Food and Drug Administration on 6th July 2021. In April 2022, the first patient with osteoporosis was successfully dosed in China, and Blosozumab to be administered intravenously every 2 to 3 months. This approach has allowed less frequent dosing and more suitable for elderly patients, leading to greater efficacy and compliancy.

Given Blosozumab's proof-of-concept in the Phase 2 study, the company plans to initiate a Phase 3 study after the conclusion of the Phase 1 dose-expansion study. After seeking NMPA approval, the company will use 12-month bone density as a surrogate endpoint to expedite conditional approval in the initiation of the Phase 3 study. Also, the study would continue to follow up on fracture information and submit 3-year fracture data (as a post-approval commitment). After discussion and agreement with the State Food and Drug Administration, the company plans to enroll about 1,500 patients in the Phase 3 registrational study, and use the 12-month bone density data of the first 300-400 patients enrolled in the NDA application. In addition, the company would also submit 36-month fracture data for full FDA approval.

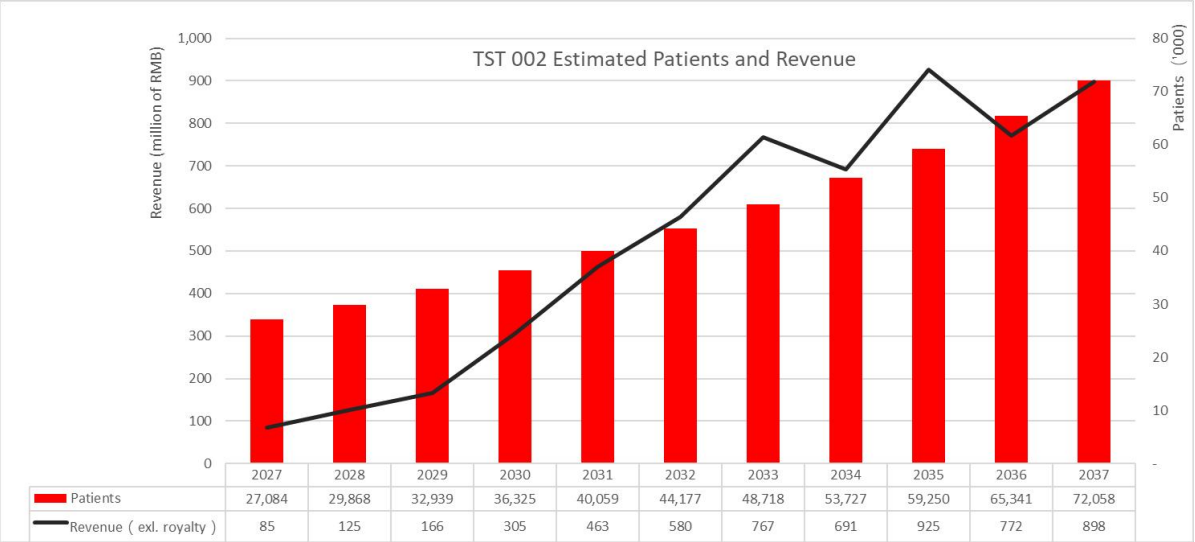
5.25 Revenue Forecast

Figure 17： TST002 revenue forecast in China

Osteoporosis in China (mil	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037
Patients	113	118	122	127	132	137	143	148	154	160	166	173	179	186	194	201
Market size	38,744	42,727	47,119	51,963	57,305	63,196	69,692	76,857	84,758	93,471	103,080	113,676	125,362	138,249	152,461	168,134
competitor						2	3	3	3	3	4	4	4	4	4	4
first mover advantage						1.2	1.2	1.2	1.2	1.1	1	1	0.7	0.7	0.5	0.5
market share						0.5	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
market penetration						5.00%	10.00%	12.00%	20.00%	30.00%	50.00%	60.00%	70.00%	85.00%	90.00%	95.00%
TST 002 Revenue						95	139	184	339	514	644	853	768	1,028	858	998
Revenue（exl. royalty）						**85**	**125**	**166**	**305**	**463**	**580**	**767**	**691**	**925**	**772**	**898**
TST 002 market	16,605	18,312	20,194	22,270	24,559	27,084	29,868	32,939	36,325	40,059	44,177	48,718	53,727	59,250	65,341	72,058

Source： Public Information, VCL prepared

Figure 18： TST002 revenue trend in China



Source： Public Information, VCL prepared

6 Other pipelines

On 14th September, the company announced that its first-in-class, Gremlin1-targeting and high-affinity humanized monoclonal antibody TST003. The TST003 has gained approval from the U.S. Food and Drug Administration (FDA) for clinical trials. The company prospectus explained that TST003 is planned for IND application in 1H2022.TST003 is a potential drug for various solid tumors with high-affinity humanized monoclonal antibody targeting regulatory proteins highly expressed in stromal cells of various human cancers (especially

esophageal: carcinoma, pancreatic, gastric, colon, lung, breast and prostate cancers).

On 28th June, the company announced that its humanized monoclonal antibody (TST004) targeting mannan-binding lectin-associated serine protease 2 (MASP2) at the 2022 International Society of Nephrology Complement-Associated Nephropathy in Bergamo, Italy. TST004 is expected to treat immunoglobulin A nephropathy (IgAN), a high incidence of chronic kidney disease for which currently lacking alternative treatments. Preclinical data show that TST004 selectively binds to MASP2 in a high-affinity manner.

In addition, TST004 showed stronger in vitro activity in blocking MASP2-dependent activation of the lectin complement pathway than alternate investigational drug.

Moreover, TST004 showed longer-lasting on-target inhibition than the same-target investigational drug in cynomolgus monkey PK/PD studies.

Consequently, TST004 demonstrated excellent tolerability and safety in non-human primates in single and multiple dose toxicity studies following subcutaneous injection.

7 Valuation

Based on public information, population structure, disease incidence, target occupancy rate, cost changes of comparable treatment plans, and sales models at home and abroad, clinical stage of TST001 and TST002, the DCF method is adopted to estimate company's analysis. Valuation: WACC=6.42%, sustainable growth rate=3.0%, the company's valuation is HK$6.076 billion, corresponding to a stock price of 13.64.

Figure 19： DCF for Transcenta

('000) RMB	2,022	2,023	2,024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
EBIT	(483,485)	(507,536)	(531,290)	(342,407,714)	(108,066,262)	86,511,292	104,645,673	361,373,140	616,055,592	742,238,860	504,486,271	508,062,170	430,613,033	382,385,292
Tax	-	-	-	(47,937,080)	(15,129,277)	12,111,581	14,650,394	50,592,240	86,247,783	103,913,440	70,628,078	71,128,704	60,285,825	53,533,941
EBIT*(1-T)	(483,485)	(507,536)	(531,290)	(294,470,634)	(92,936,985)	74,399,711	89,995,279	310,780,901	529,807,809	638,325,420	433,858,193	436,933,466	370,327,208	328,851,351
D&A	44,543	46,045	47,552	45,295	46,171	46,946	46,092	46,350	46,401	46,209	46,362	46,393	46,301	46,336
Working Capital	(239,393)	(359,711)	(236,449)	(34,004,322)	23,197,696	(14,546,567)	25,011,134	11,126,180	50,479,380	23,744,507	26,704,121	24,102,096	18,959,207	19,279,322
Capex	(43,693)	(34,954)	(27,963)	(10,244,268)	7,002,280	(4,406,941)	7,546,312	3,294,883	15,186,785	7,080,381	8,054,207	7,187,658	5,730,733	5,740,825
Free Cash Flow(FC)	(155,856)	(66,826)	(219,325)	(250,176,748)	(123,090,791)	93,400,165	57,483,925	296,406,189	464,188,045	607,546,742	399,146,226	405,690,106	345,683,569	303,877,539
Terminal Value														9,135,725,296
Discount Rate	1.00	0.94	0.88	0.83	0.78	0.73	0.69	0.65	0.61	0.57	0.54	0.50	0.47	0.45
PV	(155,856)	(62,791)	(193,639)	(207,540,663)	(95,947,553)	68,408,186	39,560,241	191,668,995	282,039,954	346,855,404	214,117,854	204,487,778	163,720,764	135,230,829

Source： Public Information, VCL prepared

Figure 20： DCF Valuation

DCF	
Perpetual growth	3.00%
Terminal Value	4,065,557,832
Present Value	1,342,189,502
Equity Value	5,407,747,335
Equity Value(HKD)	6,076,120,601
HKDCNY： CUR0.89	
Total Shares	445,331,917
Per Share Value	13.64
Assumptions	
beta	0.7744
WACC	6.43%

Source： Company Information, VCL prepared

Figure 21： Transcenta's Income Statement and cash flow statement

	2019A	2020A	2021A	2022E	2023E	2024E
Revenue	44,140.0	80,980.0	50,242.0	70,338.8	97,067.5	126,187.8
yoy	0.0%	83.5%	-38.0%	40.0%	38.0%	30.0%
Operating Revenue	-37,226.0	-62,778.0	-40,874.0	-57,510.0	-78,384.0	-99,077.4
Gross Profit	6,914.0	18,202.0	9,368.0	13,364.4	19,413.5	26,499.4
Gross Margin	15.7%	22.5%	18.6%	19.0%	20.0%	21.0%
Other Income	7,554.0	11,944.0	32,906.0	35,000.0	35,000.0	40,000.0
Selling Expense	-1,302.0	-2,759.0	573.0	-2,110.2	-2,912.0	-3,785.6
Administrative Expense	-121,616.0	-155,190.0	-157,376.0	-149,507.2	-142,031.8	-134,930.2
Reseach and Development	-214,563.0	-200,312.0	-344,370.0	-378,807.0	-416,687.7	-458,356.5
Loss before tax	-426,520.0	-323,010.0	-1,715,543.0	-497,227.0	-522,385.1	-545,739.9
Tax	-10,834.0	110.0	105.0	0.0	0.0	0.0
Loss	-437,354.0	-322,900.0	-1,715,543.0	-497,227.0	-522,385.1	-545,739.9
Loss attributable to owners	-437,354.0	-322,900.0	-1,715,543.0	-497,227.0	-522,385.1	-545,739.9
Adjusted loss	672.5	-322,825.2	-1,715,543.0	-497,227.0	-522,384.1	-545,737.9
Adjusted loss ratio	1.5%	-398.6%	-3414.6%	-706.9%	-538.2%	-432.5%
EPS HKD	0.00	-0.86	-4.58	-1.33	-1.39	-1.46
Cash flow statement ('000)						
Net cash used in operating activities	**-234,960.0**	**-174,398.0**	**-384,494.0**	**-442,091.7**	**-484,757.4**	**-553,343.3**
Capex	-154,735.0	-63,329.0	-54,616.0	-43,692.8	-34,954.2	-27,963.4
Other Investments	3,442.0	5,632.0	4,818.0	3,892.9	2,370.8	1,175.9
Net cash used in investing activities	**-232,280.0**	**-57,738.0**	**-69,769.0**	**-39,799.9**	**-32,583.4**	**-26,787.5**
Interest paid	0.0	0.0	0.0	0.0	0.0	0.0
Change in borrowings	129,048.0	-11,004.0	113,851.0	-44,218.3	-184,066.6	-75,660.7
Net cash used in financing activities	**540,805.0**	**620,172.0**	**879,712.0**	**261,902.9**	**152,666.7**	**294,745.9**
Net cash(incl. exchange rate changes)	73,565.0	388,036.0	425,449.0	-219,988.7	-364,674.1	-285,384.9
Cash at the end of the year	**458,100.0**	**813,592.0**	**1,222,026.0**	**987,397.0**	**601,324.8**	**298,257.1**

	FY 2019	FY 2020	FY 2021	FY 2022E	FY 2023E	FY 2024E
Bank balances and cash	458,100	813,592	1,222,026	987,397	601,325	298,257
Trade and other receivables	18,721	31,635	43,380	65,070	97,605	146,408
Inventories	6,315	7,901	20,792	41,584	83,168	166,336
Other current assets	4,809	38,329	109,404	109,404	109,404	109,404
Current assets	**487,945**	**891,457**	**1,395,602**	**1,203,455**	**891,502**	**720,405**
Property, plant and equipment	409,656	449,176	435,103	456,759	469,482	482,206
Right-of-use assets	16,834	24,057	38,057	60,891	97,426	155,881
Goodwill	471,901	471,901	471,901	471,901	471,901	471,901
Other non-current assets	179,379	254,333	204,292	200,850	202,112	201,944
Non-current assets	**1,077,770**	**1,199,467**	**1,149,353**	**1,190,401**	**1,240,922**	**1,311,932**
Total assets	**1,565,715**	**2,090,924**	**2,544,955**	**2,393,856**	**2,132,423**	**2,032,337**
Contract liabilities	16,576	7,029	35,967	53,951	60,425	80,365
Trade and other payables	49,562	88,690	101,964	112,160	123,376	135,714
Bank borrowings	79,820	91,312	273,339	300,673	330,740	363,814
other current liability	4,021	7,507	14,540	6,272	6,272	6,272
Current liabilities	**149,979**	**194,538**	**425,810**	**473,056**	**520,813**	**586,165**
Bank borrowings	169,903	145,938	77,390	135,433	270,865	474,014
Other non current liabilities	1,881,993	2,566,694	76,186	76,382	76,899	76,489
Non-current liabilities	**2,051,896**	**2,712,632**	**153,576**	**211,815**	**347,764**	**550,503**
Total liabilities	**2,201,875**	**2,907,170**	**579,386**	**684,871**	**868,577**	**1,136,668**
Total equity	(636,160)	(816,245)	1,965,569	1,708,985	1,263,846	895,669
Total liabilities and total equity	1,565,715	2,090,925	2,544,955	2,393,856	2,132,423	2,032,337

Source： VCL prepared

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