

## Simcere Pharmaceutical Group (2096 HK)

### Sanbexin on high growth path upon NRDL inclusion

- NRDL inclusion since Mar 2021 gives impetus to Sanbexin sales.** Sanbexin (edaravone and dexborneol injection) was approved by NMPA in Jul 2020. We see Simcere's strong execution on hospital channel expansion, which bodes well for Sanbexin's sales volume expansion in 2021. To date, sales channel of Sanbexin has covered c.1,000 hospitals (50% of which are Class III hospitals), which is expected to further increase to 1,800 hospitals by 2021, as per management. We forecast Sanbexin to be the largest growth driver with sales reaching RMB1.3bn/1.7bn/2.2bn in 2021E/22E/23E, contributing 20%/21%/23% of total revenue respectively. With global endorsement of clinical evidence of Sanbexin (Phase III results published in STROKE), the Company is looking for potential out-licensing opportunity, which could further provide upside on this drug. Furthermore, to complement sequential treatment need for acute ischemic patients, the Company is developing Y-2 (sublingual edaravone and dexborneol tablet) which is under Phase III trial in China and may file NDA in 1H23E.
- Blockbuster innovative drugs under development.** We expect approval of KN035 (subcutaneous PD-L1 mAb) in patients with MSI-H solid tumors in 4Q21E. Given that Simcere has obtained China's marketing and promotion rights of KN035 from Alphamab/3D Medicine, we forecast Simcere to record RMB275mn revenue (c.50-60% of retail sales) from KN035 in 2022E. Trilaciclib (CDK 4/6 small molecule inhibitor), which has been approved by US FDA for the treatment of chemotherapy-induced myelosuppression in ES-SCLC patients, is currently under Phase I/III clinical trial development in China. We expect trilaciclib to receive NMPA's approval by 2023E.
- Sizable BD team poised to bring in more in-licensing opportunities.** Simcere is armed with a global business development team of 20 personnel, of which 10/8/2 employees are based in China/the US/Europe, respectively. We believe the Company will continuously bring in quality assets, given 1) the global presence of its BD team with access to worldwide top-notch biotech firms and 2) deal sourcing focus on de-risked, late-stage innovative assets. As of end-2020, Simcere had RMB3.27bn cash on hand, indicating sufficient capital for the Company's potential in-licensing deals.
- Maintain BUY.** We maintain our financial forecasts unchanged and maintain TP of HK\$13.73 based on a 10-year DCF valuation (WACC: 10.4%, terminal growth rate 2.0%), implying 22.8x/17.5x FY21E/FY22E PE ratio.
- Risks:** Lower-than-expected sales from key products, slower-than-expected R&D progress of innovative drugs.

#### Earnings Summary

(YE 31 Dec)	FY19A	FY20A	FY21E	FY22E	FY23E
Revenue (RMB mn)	5,037	4,509	6,252	7,800	9,370
YoY growth (%)	12	(10)	39	25	20
Net income (RMB mn)	1,004	670	1,041	1,359	1,725
YoY growth (%)	37	(33)	55	31	27
EPS (RMB)	N/A	N/A	0.40	0.52	0.66
Consensus EPS (RMB)	N/A	0.28	0.40	0.53	0.61
PE	N/A	32.5	22.8	17.5	13.8
ROE (%)	67.8	12.4	18.0	21.5	24.5
Net gearing (%)	155	Net cash	Net cash	Net cash	Net cash

Source: Company data, Bloomberg, CMBIS estimates

**BUY (Maintain)**

Target Price	HK\$13.73
(Previous TP)	HK\$13.73)
Up/Downside	+25.24%
Current Price	HK\$10.96

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Mkt. Cap. (HK\$ mn)	28,591
Avg. 3mths t/o (HK\$ mn)	18.32
52W High/Low (HK\$)	11.68/7.65
Total Issued Shares (mn)	2,609

Source: Bloomberg

#### Shareholding Structure

Simcere Pharmaceutical Holding	45.85%
Artking Global	23.26%
Fortune Fountain Investment	4.64%
Premier Praise	4.41%
Excel Good Group	4.30%
King View Development International	2.25%
Excel Management	2.13%
Free float	13.16%

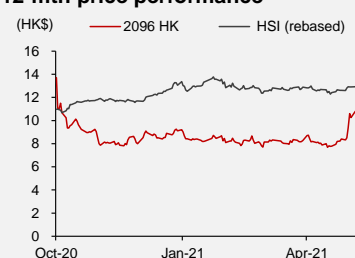
Source: HKEx, Bloomberg

#### Share performance

	Absolute	Relative
1-mth	32.3%	31.1%
3-mth	31.0%	31.9%
6-mth	32.2%	22.7%

Source: Bloomberg

#### 12-mth price performance



Source: Bloomberg

#### Auditor: KPMG

Web-site: [www.simcere.com](http://www.simcere.com)

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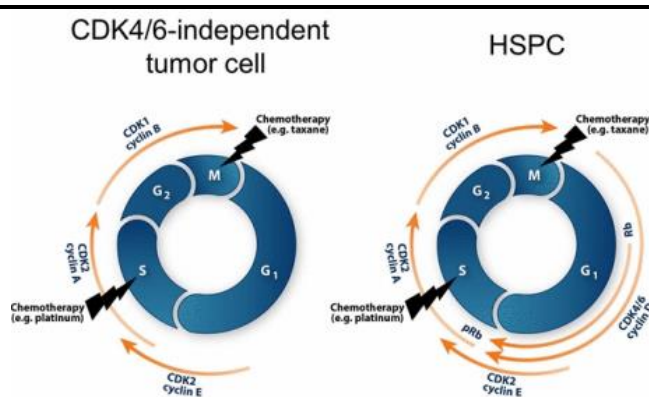
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## Trilaciclib is a first-in-class myeloprotective therapy

With Greater China development and commercialization rights acquired from G1 Therapeutics (GTHX US) in Aug 2020, Trilaciclib (brand name: COSELA) is a small molecule cyclin dependent kinases 4 and 6 (CDK 4/6) inhibitor, indicated for the treatment of chemotherapy-induced myelosuppression in adult patients with ES-SCLC, administered intravenously (IV) prior to receiving chemotherapy. Approved by the US FDA in Feb 2021, Trilaciclib is the first and only approved myeloprotective therapy.

**Figure 1: Trilaciclib's mechanism of action**



Source: G1 Therapeutics, CMBIS

**Mechanism of action.** CDK4/6 are typically required for cell proliferation. However, many cancers do not require CDK4/6 to grow and thus chemotherapy is typically used to treat these cancers, such as SCLC and triple negative breast cancer (TNBC). On the other hand, hematopoietic stem and progenitor cells (HSPCs), serving as reservoir from which all blood and immune system cells are formed, require CDK4/6 for cell proliferation and are thus prone to chemotherapy damage, leading to myelosuppression. By transiently inhibiting CDK4/6 in HSPCs, trilaciclib induces cell arrest of HSPC in G<sub>1</sub> phase of the cell cycle, preventing it from being killed by chemotherapy which usually acts on the S/G<sub>2</sub>/M phase of cell cycle.

Despite serious safety concerns, chemotherapy remains as the mainstay therapy for cancers, such as ES-SCLC. COSELA (trilaciclib) is the first and only therapy indicated to proactively help protect bone marrow from the damage of chemotherapy and is the first innovation in managing myelosuppression in decades.

**Clinical development progress in the US.** Trilaciclib is a “pipeline-in-a-molecule” with potential therapeutic opportunities across multiple tumour types. Beyond its approved indication as a myeloprotective therapy with common chemotherapy regimens in ES-SCLC, it is also being evaluated for induction of anti-tumor efficacy in a board portfolio of studies in the US, including registrational studies in **mCRC** and **TNBC**, and Phase II trials in **2L/3L NSCLC**, **1L bladder cancer** and **neoadjuvant breast cancer**. Data readouts of US Phase III trials for 1L mCRC and 1L/2L TNBC are expected in 1H23E/2H23E, respectively, according to G1 Therapeutics.

**Clinical development progress in China.** Simcere is conducting a Phase I/III trial to evaluate the efficacy and safety of trilaciclib in patients with **ES-SCLC**. We expect the trial to be completed by the end of 2022E and expect the drug to receive NMPA's approval by 2023E. Moreover, Simcere has already received IND approval from NMPA to evaluate trilaciclib for **CRC**, and filed IND to the NMPA for **TNBC**.

**Market opportunity in China.** According to Globocan data, we estimate a targeted population of 410,000 patients on chemotherapy being eligible for trilaciclib treatment, including 125,000 1L/2L SCLC patients, 268,000 1L/2L CRC patients, and 30,000 1L TNBC patients.

**Figure 1: Trilaciclib's targeted patient population in China**

	SCLC		CRC		TNBC
	1L	2L	1L	2L	1L
Line of treatment	1L	2L	1L	2L	1L
Cancer incidence per year ('000)	100	60	230	120	30
Proportion of patients on chemotherapy	95%	50%	80%	70%	55%
Targeted patient population ('000)	<b>95</b>	<b>30</b>	<b>184</b>	<b>84</b>	<b>17</b>
Average number of chemotherapy cycles	4-6 cycles	3-4 cycles	1-23 cycles	4-12 cycles	7-8 cycles

Source: Globocan, G1 Therapeutics, CMBIS estimates

## Valuation

Figure 2: Risk-adjusted DCF valuation (terminal growth rate: 2.0%)

DCF Valuation (in Rmb mn)	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	1,340	1,666	2,076	2,520	2,983	3,278	3,570	3,852	4,117	4,360
Tax rate	17.0%	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%
EBIT*(1-tax rate)	1,113	1,416	1,765	2,142	2,535	2,786	3,034	3,274	3,500	3,706
+ D&A	209	210	210	211	212	232	253	273	292	309
- Change in working capital	(119)	(166)	(168)	(226)	(236)	(259)	(282)	(305)	(326)	(345)
- Capex	(200)	(200)	(200)	(200)	(200)	(200)	(200)	(200)	(200)	(180)
<b>FCFF</b>	<b>1,002</b>	<b>1,260</b>	<b>1,607</b>	<b>1,927</b>	<b>2,311</b>	<b>2,559</b>	<b>2,805</b>	<b>3,042</b>	<b>3,266</b>	<b>3,491</b>
<b>Terminal value</b>										<b>42,513</b>

<b>Terminal growth rate</b>	2.0%
<b>WACC</b>	10.4%
Cost of Equity	13.0%
Cost of Debt	5.0%
Equity Beta	1.0
Risk Free Rate	3.0%
Market Risk Premium	10.0%
Target Debt to Asset ratio	30.0%
Effective Corporate Tax Rate	15.0%

Terminal value	15,842
Total PV	28,534
Net debt	(1,219)
Minority interest	34
Equity value (RMB mn)	29,720
<b>Equity value (HK\$ mn)</b>	<b>35,807</b>
No. of shares outstanding (mn)	2,609
<b>DCF per share (HK\$)</b>	<b>13.73</b>

Source: CMBIS estimates

Figure 3: Sensitivity analysis

		WACC				
		9.4%	9.9%	10.4%	10.9%	11.4%
Terminal growth rate	3.0%	17.36	15.98	14.80	13.77	12.87
	2.5%	16.54	15.30	14.23	13.29	12.45
	2.0%	15.83	14.71	13.73	12.86	12.09
	1.5%	15.21	14.18	13.28	12.48	11.76
	1.0%	14.66	13.72	12.88	12.13	11.46

Source: CMBIS estimates

Figure 4: CMBIS estimates vs consensus

RMB mn	CMBIS			Consensus			Diff (%)		
	FY21E	FY22E	FY23E	FY21E	FY22E	FY23E	FY21E	FY22E	FY23E
Revenue	6,252	7,800	9,370	6,347	7,869	8,956	-1%	-1%	5%
Gross Profit	5,127	6,396	7,683	5,207	6,481	7,371	-2%	-1%	4%
Operating Profit	1,254	1,598	2,030	1,295	1,627	1,643	-3%	-2%	24%
Net profit	1,041	1,359	1,725	1,043	1,365	1,442	0%	0%	20%
EPS (RMB cents)	40	52	66	40	53	61	1%	-1%	8%
Gross Margin	82.00%	82.00%	82.00%	82.03%	82.37%	82.30%	-0.03 ppt	-0.37 ppt	-0.30 ppt
Operating Margin	20.05%	20.49%	21.66%	20.40%	20.68%	18.35%	-0.35 ppt	-0.19 ppt	-3.31 ppt
Net Margin	16.64%	17.42%	18.41%	16.43%	17.35%	16.10%	0.21 ppt	0.07 ppt	2.31 ppt

Source: Company data, CMBIS estimates

Figure 5: Peers' valuation

Company	Ticker	Rating	Mkt cap LC mn	PER (x)		PBR (x)		EV/EBITDA (x)		ROE (%)	
				FY21E	FY22E	FY21E	FY22E	FY21E	FY22E	FY21E	FY22E
Simcere	2096 HK	BUY	28,591	22.8	17.5	4.1	3.8	14.5	11.8	18.0	21.5
Hansoh	3692 HK	N/A	197,510	48.4	39.9	8.2	6.9	17.8	15.8	16.5	17.6
Fosun Pharma	2196 HK	N/A	191,755	29.6	24.9	3.3	3.1	39.4	31.4	10.7	11.7
Sino Biopharm	1177 HK	N/A	164,850	26.8	26.7	5.9	5.1	N/A	N/A	22.5	20.7
CSPC	1093 HK	BUY	147,038	22.2	19.2	4.6	3.9	35.5	31.6	21.5	21.6
			<b>Average</b>	<b>30.0</b>	<b>25.6</b>	<b>5.2</b>	<b>4.6</b>	<b>24.5</b>	<b>20.6</b>	<b>17.9</b>	<b>18.6</b>

Source: Bloomberg, CMBIS estimates



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