

Innovent Biologics (1801 HK)

Temporary setback paves the way for future success

FDA held a public ODAC meeting on 10 Feb discussing the BLA of sintilimab for treatment of 1L nsq-NSCLC. The independent advisory committee voted 14-1 to require additional clinical trial(s) of sintilimab to demonstrate its applicability to the US population and medical practice. The committee also raised concerns on using PFS instead of OS as the primary endpoint and the design of the comparator arm. There is an increasing number of oncology development programs based solely or predominantly on clinical data from China, with over 25 applications to FDA in drug development phases, planned to be submitted, or currently under review. Thus, the attitude of the FDA and ODAC towards the BLA for sintilimab implicates that “me too” drugs will be unlikely to obtain FDA approvals based solely on China data. Nevertheless, we believe innovative drugs addressing unmet clinical needs and providing high-quality MRCT data will have no problem receiving regulatory approvals in the US or other overseas regions. Innovent and many other Chinese biotech companies are conducting global trials for their highly innovative assets, such as IBI188 (CD47) of Innovent.

- Valuable experiences obtained regarding US registration process.** The Orient-11 trial was initially designed for marketing approval in China. Encouraged by FDA oncology chief Pazdur’s statement about bringing low-cost Chinese PD-1 drugs to the US in 2019, Innovent and Eli Lilly submitted the BLA for sintilimab based on Orient-11 study to the FDA in Mar 2021. Although the ODAC voting result was disappointing, Innovent, as a pioneer among Chinese biotech companies, has gained valuable experiences and established a strong registration team throughout the registration process, allowing the Company to efficiently develop innovative drugs in global markets in the future. It was also very impressive that FDA has identified no safety or efficacy issues about sintilimab, indicating the high-quality clinical practice of the Orient-11 study. This strengthened our confidence in Innovent’s execution capability in performing high-quality clinical studies in China.
- Rich innovative pipelines to deliver multiple catalysts in 2022E.** IBI188 (CD47) may start a pivotal study in MDS in 1H22E. IBI363 (PD-1/IL-2) and IBI395 (PD-1/IL-21/IL-2) may enter clinical stage in 2022E. We also expect PoC readouts for IBI110 (LAG3), IBI322 (CD47/PDL1), IBI351 (KRAS), IBI939 (TIGIT) and IBI323 (PD-L1/LAG3) in 2022E. Innovent aims to file BLAs to the NMPA for IBI376 (PI3Kδ), IBI326 (BCMA CART), IBI306 (PCSK9), IBI344 (ROS1/NTRK) and IBI310 (CTLA4) in 2022E.
- Maintain BUY.** We adjusted sales projections of sintilimab and three biosimilars and cut DCF-based TP from HK\$116.89 to HK\$75.45 (WACC: 9.9%, terminal growth rate: 4.0%). We remain positive on Innovent given its comprehensive pipeline portfolio, strong execution and attractive valuation.

Earnings Summary

(YE 31 Dec)	FY19A	FY20A	FY21E	FY22E	FY23E
Revenue (RMB mn)	1,048	3,844	3,746	5,427	6,309
YoY growth (%)	N/A	267%	(3%)	45%	16%
Net loss (RMB mn)	(1,720)	(998)	(2,199)	(1,334)	(867)
EPS (RMB)	(1.46)	(0.74)	(1.50)	(0.91)	(0.59)
Consensus EPS (RMB)	NA	NA	(1.12)	(0.72)	0.01
R&D expenses (RMB mn)	(1,295)	(1,851)	(2,200)	(2,400)	(2,600)
Capex (RMB mn)	(366)	(489)	(500)	(300)	(300)

Source: Company data, Bloomberg, CMBIS estimates

BUY (Maintain)

Target Price **HK\$75.45**
 (Previous TP) **HK\$116.89**
Up/Downside **+138.77%**
Current Price **HK\$31.60**

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Mkt. Cap. (HK\$ mn)	46,334
Avg. 3mths t/o (HK\$ mn)	474.81
52W High/Low (HK\$)	100.0/29.5
Total Issued Shares (mn)	1,466

Source: Bloomberg

Shareholding Structure

Yu De-Chao Michael	8.15%
Temasek Holdings	8.02%
FIL	9.54%
Capital	5.37%
Others	68.92%

Source: Bloomberg, HKEx

Share performance

	Absolute	Relative
1-mth	-31.5%	-32.8%
3-mth	-58.0%	-57.3%
6-mth	-55.7%	-52.8%

Source: Bloomberg

12-mth price performance



Source: Bloomberg

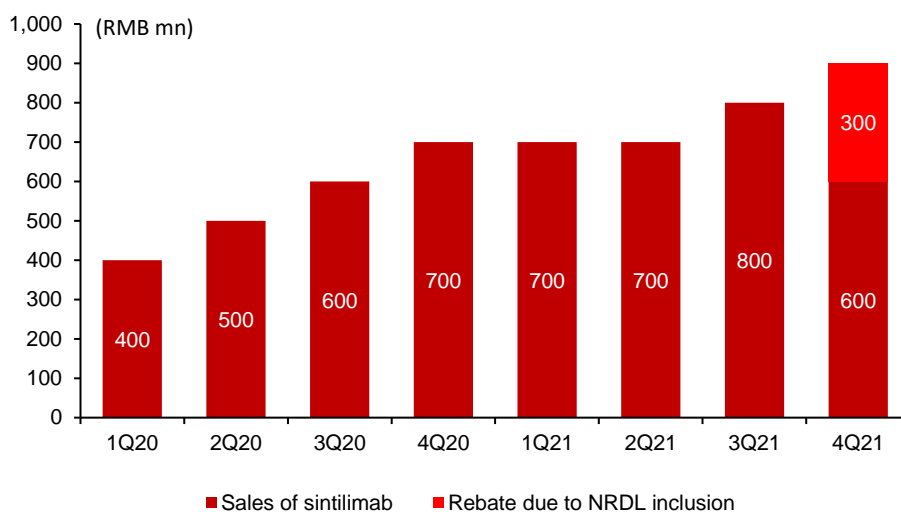
Auditor: Deloitte

Website: www.innoventbio.com

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Figure 1: Quarterly sales of sintilimab (1Q20-4Q21)



Source: Company data, CMBIS.

Note: In 4Q21, Innovent compensated distributors for sintilimab previously sold at the pre-NRDL price for around RMB 300mn.

Figure 2: Indications of sintilimab with positive results

Target Indication (Study Name)	N	Met Primary Endpoint	Regulatory Status in China
			(Approved)
 1L Non-squamous NSCLC (ORIENT-11) ^{1,2}	397	✓	✓
1L Squamous NSCLC (ORIENT-12) ³	357	✓	✓
2L Squamous NSCLC (ORIENT-3)	290	✓	
EGFR TKI failed NSCLC (ORIENT-31)	600	✓	Submitted
 r/r classic Hodgkin's Lymphoma (ORIENT-1) ^{4,5}	96	✓	✓
1L Esophageal Squamous Cell Carcinoma (ORIENT-15) ⁶	676	✓	Submitted
2L Esophageal Squamous Cell Carcinoma (ORIENT-2) ⁷	190	✓	
 1L Gastric Cancer (ORIENT-16) ⁸	650	✓	Submitted
1L Hepatocellular Carcinoma (ORIENT-32) ⁹	595	✓	✓

Source: Company data, CMBIS. Notes: 1. Yang Y, et al. *J Thorac Oncol.* 2020;15(10):1636-1646; 2. Yang Y, et al. *J Thorac Oncol.* 2021;16(12):2109-2120; 3. Zhou C, et al. *J Thorac Oncol.* 2021;16(9):1501-1511; 4. Shi Y, et al. *Lancet Haematol.* 2019;6(1):e12-e19; 5. Shi Y, et al. *J Clin Oncol.* 2018;36(15 suppl): Abstract 7536; 6. Shen L, et al. *Ann Oncol.* 2021;32(suppl 5):S1330. Abstract LBA52; 7. Xu J, et al. *J Clin Oncol.* 2020;38(15 suppl): Abstract 4511; 8. Xu J, et al. *Ann Oncol.* 2021;32(suppl 5):S1331. Abstract LBA53; 9. Ren Z, et al. *Lancet Oncol.* 2021;22(7):977-990.

Figure 3: Catalysts of Innovent

Product	Partner	Catalysts and timeline
Phase 3 / Pivotal 2		
Sintilimab (PD-1)	Eli Lilly	Approvals of additional indications currently under NMPA review: 1L ESCC (NDA in Sep 2021), 1L GC (NDA in Nov 2021), 2L EGFR-mutated nsq-NSCLC following EGFR-TKI treatment (NDA in Dec 2021)
IBI376 / Parsaclisib (PI3Kδ)	Incyte	To file NDA in China early 2022 for r/r FL
IBI326 (BCMA CAR-T)	IASO, Sana	To file NDA in China early 2022 for r/r Multiple Myeloma
IBI306 (PCSK9)		To file NDA in China in 2022 for nFH and HeFH To release data of its three phase 3 trials in 2022
IBI 310 (CTLA-4)		To file NDA in China for 2L cervical cancer (CC) To complete patient enrolment for 2L CC and release data in 2022
IBI 375 / Pemigatinib (FGFR)	Incyte	Approval for 2L cholangiocarcinoma currently under review in China (NDA in Jul 2021)
IBI 344 / Taletrectinib (ROS1/NTRK)	AnHeart	To complete enrolment for pivotal phase 2 study in ROS1+ NSCLC and file NDA in China in 2022
Phase 2 / Phase 1b		
IBI188 (CD47)		To initiate Phase 3 study for 1L MDS in 2Q22 To release updated MDS data in mid-2022
IBI110 (LAG3)		To release PoC data in 1H22
IBI362 (GLP1/GCGR)	Eli Lilly	To release phase 2 data in Type 2 diabetes in 1H22 To start phase 3 trial for Type 2 diabetes in China in 2H22
IBI302 (VEGF/Complement)		To release phase 2 data in nAMD by the end 2022 or early 2023
IBI112 (IL-23 p19)		To start phase 3 study in psoriasis in 2H22
Phase 1		
IBI322 (PD-L1/CD47)		To release PoC data in 1H22
IBI351 (KRAS G12C)	Genfleet	To release PoC data in 1H22
IBI939 (TIGIT)		To release PoC data in 1H22

Source: Company data, CMBIS

Figure 4: Risk-adjusted DCF valuation

DCF Valuation (in RMB mn)	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT	(2,273)	(1,432)	(954)	831	2,800	5,169	7,509	9,512	11,681	12,889	13,978	13,844	13,971	14,145	14,246
Tax rate	0%	0%	0%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
EBIT*(1-tax rate)	(2,273)	(1,432)	(954)	706	2,380	4,393	6,383	8,085	9,928	10,956	11,881	11,767	11,875	12,023	12,109
+ D&A	107	116	125	133	141	149	156	163	170	176	182	188	194	199	204
- Change in working capital	116	(201)	(68)	(185)	(446)	(261)	(465)	(361)	(341)	(164)	109	93	(0)	(11)	6
- Capex	(500)	(300)	(300)	(300)	(300)	(300)	(300)	(300)	(300)	(300)	(300)	(300)	(300)	(300)	(300)
FCFF	(2,549)	(1,816)	(1,197)	355	1,776	3,981	5,774	7,588	9,458	10,668	11,873	11,748	11,769	11,911	12,019
Terminal value															213,213
FCF + Terminal value	(2,549)	(1,816)	(1,197)	355	1,776	3,981	5,774	7,588	9,458	10,668	11,873	11,748	11,769	11,911	225,232
PV of enterprise (RMB mn)	83,290														
Net debt (RMB mn)	(8,531)														
Equity value (RMB mn)	91,822														
Equity value (HK\$ mn)	110,629														
No. of outstanding shares (mn)	1,466														
DCF per share (HK\$)	75.45														
Terminal growth rate	4.0%														
WACC	9.9%														
Cost of Equity	12.5%														
Cost of Debt	4.5%														
Equity Beta	0.9														
Risk Free Rate	3.0%														
Market Risk Premium	10.5%														
Target Debt to Asset ratio	30.0%														
Effective Corporate Tax Rate	15.0%														

Source: CMBIS estimates

Figure 5: Sensitivity analysis (HK\$)

		WACC				
		8.86%	9.36%	9.86%	10.36%	10.86%
Terminal growth rate	3.0%	84.15	75.88	68.87	62.87	57.68
	3.5%	88.94	79.66	71.90	65.32	59.69
	4.0%	94.71	84.15	75.45	68.17	62.00
	4.5%	101.80	89.56	79.66	71.50	64.67
	5.0%	110.72	96.21	84.73	75.45	67.79

Source: Company data, CMBIS estimates

Figure 6: CMBIS estimates revision

RMB mn	New			Old			Diff (%)		
	FY21E	FY22E	FY23E	FY21E	FY22E	FY23E	FY21E	FY22E	FY23E
Revenue	3,746	5,427	6,309	3,882	6,098	8,578	-4%	-11%	-26%
Gross Profit	3,184	4,613	5,331	3,300	5,183	7,248	-4%	-11%	-26%
Operating Profit	(1,585)	(707)	(332)	(1,543)	(523)	410	NA	NA	NA
Net profit	(2,199)	(1,334)	(867)	(2,177)	(1,225)	(307)	NA	NA	NA
EPS (RMB)	(1.50)	(0.91)	(0.59)	(1.49)	(0.84)	(0.21)	NA	NA	NA
Gross Margin	85.00%	85.00%	84.50%	85.00%	85.00%	84.50%	0.00pp	0.00pp	0.00pp

Source: Company data, Bloomberg, CMBIS estimates

Figure 7: CMBIS estimates vs consensus

RMB mn	CMBIS			Consensus			Diff (%)		
	FY21E	FY22E	FY23E	FY21E	FY22E	FY23E	FY21E	FY22E	FY23E
Revenue	3,746	5,427	6,309	4,131	6,025	8,397	-9%	-10%	-25%
Gross Profit	3,184	4,613	5,331	3,554	5,169	7,024	-10%	-11%	-24%
Operating Profit	(1,585)	(707)	(332)	(1,706)	(1,032)	(208)	NA	NA	NA
Net profit	(2,199)	(1,334)	(867)	(1,546)	(977)	42	NA	NA	NA
EPS (RMB)	(1.50)	(0.91)	(0.59)	(1.12)	(0.72)	0.01	NA	NA	NA
Gross Margin	85.00%	85.00%	84.50%	86.03%	85.80%	83.65%	-1.03ppt	-0.80ppt	+0.85ppt

Source: Company data, Bloomberg, CMBIS estimates

Financial Statements

Income statement						Cash flow summary					
YE 31 Dec (RMB mn)	FY19A	FY20A	FY21E	FY22E	FY23E	YE 31 Dec (RMB mn)	FY19A	FY20A	FY21E	FY22E	FY23E
Revenue	1,048	3,844	3,746	5,427	6,309	Profit before tax	(1,720)	(859)	(2,199)	(1,334)	(867)
Cost of sales	(125)	(388)	(562)	(814)	(978)	Depreciation and amortization	86	86	107	116	125
Gross profit	923	3,456	3,184	4,613	5,331	Changes in working capital	(141)	(334)	116	(201)	(68)
Administrative expenses	(255)	(437)	(650)	(597)	(631)	Tax paid	14	(140)	0	0	0
R&D expenses	(1,295)	(1,851)	(2,200)	(2,400)	(2,600)	Others	97	939	490	580	725
Selling and marketing expenses	(693)	(1,341)	(2,060)	(2,551)	(2,650)	Net cash from operating activities	(1,664)	(308)	(1,485)	(839)	(84)
Other income	144	247	226	228	218	Capex	(366)	(489)	(500)	(300)	(300)
Other gains and losses	15	(480)	(85)	0	0	Placement of term deposits with maturity dates over 3 mo	(4,264)	(7,126)	0	0	0
Operating profit	(1,161)	(406)	(1,585)	(707)	(332)	Other investing activities	2,061	2,431	126	128	118
Listing expenses	0	0	0	0	0	Net cash from investing activities	(2,569)	(5,185)	(374)	(172)	(182)
Finance costs	(59)	(68)	(51)	(30)	(31)	Net proceeds from shares	2,169	4,657	3,885	0	0
Royalties and other related	(500)	(384)	(562)	(597)	(505)	New borrowings raised	43	372	0	0	0
Pre-tax profit	(1,720)	(859)	(2,199)	(1,334)	(867)	Repayment of borrowings	(10)	(17)	(700)	0	0
Income tax	0	(140)	0	0	0	Other financing activities	(93)	(100)	(51)	(30)	(31)
Minority interests	0	0	0	0	0	Net cash from financing activities	2,109	4,912	3,134	(30)	(31)
Net profit (Net loss)	(1,720)	(998)	(2,199)	(1,334)	(867)	Net change in cash	(2,124)	(580)	1,275	(1,042)	(297)
						Fx Changes	25	(569)	0	0	0
						Cash at the beginning of the year	4,525	2,426	7,764	9,039	7,997
						Cash at the end of the year	2,426	1,276	9,039	7,997	7,700

Balance sheet						Key ratios					
YE 31 Dec (RMB mn)	FY19A	FY20A	FY21E	FY22E	FY23E	YE 31 Dec	FY19A	FY20A	FY21E	FY22E	FY23E
Non-current assets	1,775	2,368	2,761	2,944	3,119	Profit & loss ratios (%)					
PP&E	1,345	1,584	1,994	2,196	2,388	Gross margin	88	90	85	85	85
Right-of-use assets	92	327	309	292	274	EBITDA margin	N/A	N/A	N/A	N/A	N/A
Intangible assets	0	33	33	33	33	Net margin	N/A	N/A	N/A	N/A	N/A
Deposits for acquisition of PP&E	85	272	272	272	272	Effective tax rate (%)	N/A	N/A	N/A	N/A	N/A
Other non-current assets	254	152	152	152	152						
Current assets	5,455	9,467	10,690	9,932	9,756	Balance sheet ratios					
Inventories	359	706	616	669	670	Current ratio (x)	5	6	7	6	6
Trade receivables	248	475	513	743	864	Trade receivables turnover	86	34	50	50	50
Deposits, prepayments and other	152	165	165	165	165	Trade payables turnover days	186	96	120	120	120
Other financial assets	463	357	357	357	357	Total debt to asset ratio (%)	34	26	18	19	20
Cash and bank balances	4,233	7,764	9,039	7,997	7,700						
Current liabilities	1,044	1,486	1,550	1,633	1,687	Returns (%)					
Borrowings	17	255	255	255	255	ROE	(36)	(11)	(20)	(13)	(8)
Lease liabilities	16	16	16	16	16	ROA	(24)	(8)	(16)	(10)	(7)
Trade payables	84	121	185	268	321						
Other payables and accrued	885	974	974	974	974	Per share data					
Contract liabilities	42	120	120	120	120	EPS (RMB)	(1.46)	(0.74)	(1.50)	(0.91)	(0.59)
Non-current liabilities	1,431	1,569	870	871	872	DPS (RMB)	0.0	0.0	0.0	0.0	0.0
Contract liabilities	582	588	588	588	588	BVPS (RMB)	4.0	6.5	7.5	7.1	7.0
Borrowings	808	925	225	225	225						
Lease liabilities	25	10	11	12	13						
Government grants	17	46	46	46	46						
Total net assets	4,756	8,780	11,030	10,372	10,316						
Minority interest	0	0	0	0	0						
Shareholders' equity	4,756	8,780	11,030	10,372	10,316						

Source: Company data, CMBIS estimates

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