BeiGene (BGNE US)

Positive on the US BLA approval of tislelizumab despite the deferral

BUY (Maintain)

Target Price	**US$248.52**
(Previous TP	US$248.52)
Up/Downside	**40.3%**
Current Price	**US$177.15**

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- **FDA took deferred action on tislelizumab's BLA due to COVID-19 related travel restrictions**. On 14 Jul, BeiGene provided an update on the US BLA of tislelizumab in 2L ESCC, which was accepted by the FDA in Sep 2021 with an original PDUFA date of 12 Jul 2022. The FDA was unable to conduct required on-site inspections in China during the review period due to COVID-19 related travel restrictions. The FDA cited only travel restrictions and the inability to complete inspections as the reason for the deferral. The application remains under review, and the FDA did not provide a new anticipated action date given the uncertainties of travel restrictions.

- **Positive on BLA approval given the solid data from an MRCT trial**. The BLA was based on the results from RATIONALE302 study, a multi-regional Ph3 trial that enrolled 512 patients from 11 countries/regions, including 108 (or 21%) patients from Europe and North America. The trial demonstrated a 30% reduction in the risk of death (HR=0.70, P=0.0001), and extended median OS by 2.3 months compared to chemotherapy as a 2L treatment for ESCC patients. For cross-trial comparison, Keytruda showed a 22% reduction and Opdivo had a 23% reduction in the risk of death in similar patient population (*see Figure 1 for details*). Thus, we think tislelizumab's BLA is very likely to be approved upon the completion of on-site inspections. Additionally, for 1L treatment of ESCC patients, the Ph3 RATIONALE306 study demonstrated that tislelizumab plus chemo significantly extended the median OS by 6.6 months and reduced the risk of death by 34% compared to chemo only. For cross-trial comparison, Keytruda achieved 2.8 months OS extension and 28% risk reduction, while Opdivo realized 2.5 months OS extension and 26% risk reduction (*see Figure 2 for details*). The results from the MRCT trials support tislelizumab as a potential standard of care for ESCC patients, in our view.

- **Maintain BUY**. BeiGene's BTK inhibitor zanubrutinib has been approved in around 50 countries/regions, including the US, EU, and China. Backed by 11 pivotal trials conducted globally, tislelizumab (PD-1) is well-positioned for the global market. On the commercial side, we expect the Company to maintain strong sales momentum for tislelizumab in China and zanubrutinib across the globe in 2022 and beyond. We maintain our DCF-based target price unchanged at US$248.52 (WACC: 9.20%, terminal growth rate: 3.0%).

Earnings Summary

(YE Dec 31)	FY20A	FY21A	FY22E	FY23E	FY24E
Revenue (US$ mn)	308.9	1,176.3	1,397.9	2,206.4	3,339.8
Net profit (US$ mn)	(1,600.5)	(1,413.4)	(1,647.6)	(1,136.1)	(272.4)
EPS (Reported)(US$)	(19.1)	(15.2)	(16.0)	(11.0)	(2.6)
Consensus EPS (US$)	N/A	N/A	(11.0)	(10.0)	(5.2)
R&D expenses (US$)	(1,294.9)	(1,459.2)	(1,503.0)	(1,533.1)	(1,548.4)
CAPEX (US$ mn)	(117.5)	(262.9)	(320.0)	(100.0)	(100.0)

Source: Company data, Bloomberg, CMBIS estimates

Stock Data

Mkt Cap (US$ mn)	20,105
Avg 3 mths t/o (US$ mn)	44.49
52w High/Low (US$)	426.56/118.18
Total Issued Shares (mn)	103.0

Source: FactSet

Shareholding Structure

Amgen	18.45%
Baker Bros	11.42%
HHLR Advisor	11.02%
Capital	8.01%
Others	51.10%

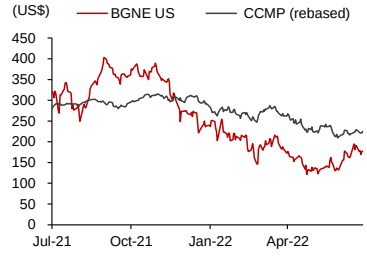
Source: Bloomberg

Share Performance

	Absolute	Relative
1-mth	32.4%	23.1%
3-mth	-2.9%	13.2%
6-mth	-25.8%	-3.5%

Source: FactSet

12-mth Price Performance



Source: FactSet

Auditor: Ernst & Young
Web-site: https://www.beigene.com

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Figure 1: Comparison of 2L ESCC registration trials

Drug	FDA status	Trial ID	Trial design	Trial regions	Primary endpoint	Patient number	OS in all ESCC pts (vs chemo)	OS in PD-L1+ ESCC pts (vs chemo)	OS in PD-L1+ pts (adenocarcinoma included)	Gr≥3 TRAE	Link
KEYTRUDA	Approved for PD-L1+ 2L ESCC pts in 2019.07	NCT02564263	Mono, open-label	Multi-region	OS in PD-L1+ pts, in all ESCC pts, and in all pts	628 (64% ESCC pts)	8.2 vs 7.1 mo; HR=0.78, P=0.0095	10.3 vs 6.7 mo; HR=0.64, 95% CI, 0.46-0.90	9.3 vs 6.7 mo; HR=0.69, P=0.0074	18.2% vs 40.9%	Link
Opdivo	Approved for 2L ESCC regardless of PD-L1 level in 2020.06	NCT02569242	Mono, open-label	Multi-region	OS in all ESCC pts	419 (all ESCC pts)	10.9 vs 8.4 mo; HR=0.77, P=0.019	HR=0.69, 95% CI, 0.46-1.04	-	18.2% vs 63.0%	Link
Tislelizumab	US BLA under review	NCT03430843	Mono, open-label	Multi-region (21% from Europe and North America)	OS in all ESCC pts	512 (all ESCC pts)	8.6 vs 6.3 mo; **HR=0.70**, P=0.0001	10.3 vs 6.8 mo; HR=0.54, P=0.0006	-	18.8% vs 55.8%	Link

Source: Pubmed, CMBIGM estimates. Notes: PD-L+ refers to the PD-L1 ≥10% patient group.

Figure 2: Comparison of 1L ESCC registration trials

Drug	Trial ID	Trial type	Trial region	Primary endpoint	Regimen	Patient number	OS in ITT pts (vs chemo)	OS in PD-L1+ pts (vs chemo)	PFS in ITT pts (vs chemo)	PFS in PD-L1+ pts (vs chemo)	Link
KEYTRUDA	NCT03189719	double-blind	Multi-region	OS in PD-L1+ ESCC pts; OS and PFS in ESCC pts	+chemo vs chemo only	373 vs 376	12.6 vs 9.8 mo; HR=0.72, P=0.0006	13.9 vs 8.8 mo; HR=0.57, P<0.0001 (PD-L1 ≥10%)	6.3 vs 5.8 mo; HR=0.65, P<0.0001	-	Link
Opdivo	NCT03143153	open label	Multi-region	OS and PFS in ITT pts	+chemo vs chemo only	321 vs 324	13.2 vs 10.7 mo; HR=0.74, P=0.002	15.4 vs 9.1 mo; HR=0.54, P<0.001 (PD-L1 ≥1%)	5.8 vs 5.6 mo; HR=0.81, P=0.04 (not significant)	6.9 vs 4.4 mo; HR=0.65, P=0.002 (PD-L1 ≥1%)	Link
					+Yervoy vs chemo only	325 vs 324	12.7 vs 10.7 mo; HR=0.78, P=0.01	13.7 vs 9.1 mo; HR=0.64, P=0.001 (PD-L1 ≥1%)	not tested	4.0 vs 4.4 mo; HR=1.02, P=0.09 (PD-L1 ≥1%)	
Tislelizumab	NCT03783442	double-blind	Multi-region	OS in ITT pts	+chemo vs chemo only	326 vs 323	17.2 vs 10.6 mo; **HR=0.66**, P<0.0001	16.6 vs 10.0 mo; HR=0.62, P=0.002 (PD-L1 ≥10%)	7.3 vs 5.6 mo; HR=0.62, P<0.0001	-	Link

Source: Pubmed, CMBIGM estimates. Notes: approval status in major markets: **KEYTRUDA**: (1) Approved for esophageal or GEJ carcinoma in the US in 2021.03; (2) Approved for PD-L1+ esophageal or GEJ carcinoma in the EU in 2021.06; (3) Approved for esophageal or GEJ carcinoma in China in 2021.09. **Opdivo**: (1) +chemo approved in China; (2) +chemo and +Yervoy both approved in the US in 2022.05 regardless of PD-L1 level; (3) +chemo and +Yervoy both approved in the EU in 2022.04 for PD-L1+ pts. **Tislelizumab**: met the primary endpoint in 2022.04, not yet approved.

Figure 3: Risk-adjusted DCF valuation

DCF Valuation (US$ mn)	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT	**(1,646)**	**(1,127)**	**(259)**	**(7)**	**771**	**1,477**	**2,087**	**2,686**	**3,042**	**3,194**	**3,341**	**3,464**	**3,511**	**3,606**
Tax rate	*0%*	*0%*	*0%*	*0%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*
EBIT*(1-tax rate)	(1,646)	(1,127)	(259)	(7)	656	1,255	1,774	2,283	2,586	2,715	2,840	2,944	2,985	3,065
+ D&A	67	70	72	74	76	78	79	81	82	84	85	86	87	88
- Change in working capital	275	(94)	(97)	(146)	(142)	(97)	(84)	(67)	(22)	14	19	25	38	31
- Capex	(320)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)
FCFF	**(1,623)**	**(1,251)**	**(384)**	**(179)**	**489**	**1,136**	**1,669**	**2,197**	**2,546**	**2,713**	**2,844**	**2,956**	**3,010**	**3,084**
Terminal value														**51,259**
FCF + Terminal value	**(1,623)**	**(1,251)**	**(384)**	**(179)**	**489**	**1,136**	**1,669**	**2,197**	**2,546**	**2,713**	**2,844**	**2,956**	**3,010**	**54,343**

PV of enterprise (US$ mn)	21,218
Net debt (US$ mn)	(4,370)
Equity value (US$ mn)	**25,588**
No. of ADS (mn)	103
DCF per ADS (US$)	**248.52**

Terminal growth rate	**3.0%**
WACC	**9.20%**
Cost of Equity	11.5%
Cost of Debt	4.5%
Equity Beta	0.9
Risk Free Rate	2.5%
Market Risk Premium	10.0%
Target Debt to Asset ratio	30.0%
Effective Corporate Tax Rate	15.0%

Source: CMBIGM estimates

Figure 4: Sensitivity analysis (US$)

			WACC		
Terminal growth rate	**8.20%**	**8.70%**	**9.20%**	**9.70%**	**10.20%**
4.0%	357.72	313.56	278.15	249.17	225.07
3.5%	330.44	292.81	262.03	236.44	214.86
3.0%	308.41	275.71	**248.52**	225.60	206.06
2.5%	290.25	261.36	237.02	216.28	198.41
2.0%	275.02	249.16	227.12	208.16	191.70

Source: CMBIGM estimates

Figure 5: CMBIGM estimate vs consensus

	CMBIGM			Consensus			Diff (%)		
US$ mn	**FY22E**	**FY23E**	**FY24E**	**FY22E**	**FY23E**	**FY24E**	**FY22E**	**FY23E**	**FY24E**
Revenue	1,398	2,206	3,340	1,446	2,115	2,983	-3%	4%	12%
Gross Profit	1,086	1,734	2,697	1,202	1,765	2,451	-10%	-2%	10%
Operating Profit	(1,656)	(1,137)	(269)	(1,503)	(1,189)	(844)	N/A	N/A	N/A
Net Profit	(1,648)	(1,136)	(272)	(1,403)	(1,080)	(644)	N/A	N/A	N/A
EPS (US$ per ADS)	(16.0)	(11.0)	(2.6)	(11.0)	(10.0)	(5.2)	N/A	N/A	N/A
Gross Margin	77.68%	78.57%	80.76%	83.12%	83.43%	82.17%	-5.44 ppt	-4.86 ppt	-1.41 ppt

Source: Company data, Bloomberg, CMBIGM estimates

Financial Summary

INCOME STATEMENT	2019A	2020A	2021A	2022E	2023E	2024E
YE 31 Dec (US$ mn)						
Revenue	**428**	**309**	**1,176**	**1,398**	**2,206**	**3,340**
Cost of goods sold	(71)	(71)	(165)	(312)	(473)	(643)
Gross profit	**(71)**	**238**	**1,011**	**1,086**	**1,734**	**2,697**
Operating expenses	**(1,317)**	**(1,896)**	**(2,450)**	**(2,742)**	**(2,871)**	**(2,966)**
SG&A expense	(388)	(600)	(990)	(1,238)	(1,337)	(1,417)
R&D expense	(927)	(1,295)	(1,459)	(1,503)	(1,533)	(1,548)
Others	(1)	(1)	(1)	(1)	(1)	(1)
Other income	16	39	0	8	1	(3)
Pre-tax profit	**(1,372)**	**(1,618)**	**(1,439)**	**(1,648)**	**(1,136)**	**(272)**
Income tax	(7)	18	25	0	0	0
Net profit	**(1,379)**	**(1,601)**	**(1,413)**	**(1,648)**	**(1,136)**	**(272)**
Minority interest	(2)	(4)	0	0	0	0
Adjusted net profit	**(1,377)**	**(1,597)**	**(1,413)**	**(1,648)**	**(1,136)**	**(272)**
BALANCE SHEET	**2019A**	**2020A**	**2021A**	**2022E**	**2023E**	**2024E**
YE 31 Dec (US$ mn)						
Current assets	**1,173**	**4,961**	**7,614**	**5,800**	**4,810**	**4,696**
Cash & equivalents	618	1,382	4,376	2,758	1,498	2,100
Account receivables	71	60	483	274	418	573
Inventories	29	89	243	256	382	511
Financial assets at FVTPL	365	3,269	2,242	2,242	2,242	1,242
Other current assets	91	160	271	270	270	270
Non-current assets	**440**	**640**	**1,032**	**1,278**	**1,308**	**1,336**
PP&E	242	358	588	840	871	899
Deferred income tax	38	66	110	110	110	110
Intangibles	6	5	47	47	47	47
Other non-current assets	153	211	287	280	280	280
Total assets	**1,612**	**5,601**	**8,646**	**7,078**	**6,118**	**6,032**
Current liabilities	**310**	**1,075**	**1,600**	**1,679**	**1,855**	**2,042**
Short-term borrowings	0	335	428	428	428	428
Account payables	122	232	262	342	518	704
Tax payable	13	20	21	21	21	21
Other current liabilities	174	488	888	888	888	888
Non-current liabilities	**166**	**656**	**803**	**803**	**803**	**803**
Long-term borrowings	83	184	202	202	202	202
Deferred income	0	0	220	220	220	220
Other non-current liabilities	83	473	381	381	381	381
Total liabilities	**477**	**1,732**	**2,403**	**2,482**	**2,659**	**2,845**
Share capital	2,926	7,415	11,191	11,191	11,191	11,191
Retained earnings	(1,956)	(3,553)	(4,966)	(6,614)	(7,750)	(8,022)
Other reserves	(8)	7	18	18	18	18
Total shareholders equity	**962**	**3,869**	**6,243**	**4,595**	**3,459**	**3,187**
Minority interest	16	0	0	0	0	0
Total equity and liabilities	**1,455**	**5,601**	**8,646**	**7,078**	**6,118**	**6,032**
CASH FLOW	**2019A**	**2020A**	**2021A**	**2022E**	**2023E**	**2024E**
YE 31 Dec (US$ mn)						
Operating						
Profit before taxation	**(1,372)**	**(1,618)**	**(1,439)**	**(1,648)**	**(1,136)**	**(272)**
Depreciation & amortization	19	32	46	67	70	72
Tax paid	(7)	18	25	0	0	0
Others	182	285	68	275	(94)	(97)
Net cash from operations	**(1,178)**	**(1,283)**	**(1,299)**	**(1,305)**	**(1,160)**	**(298)**

Investing						
Capital expenditure	(90)	(118)	(263)	(320)	(100)	(100)
Acquisition of subsidiaries/ investments	(1,169)	(5,690)	(2,191)	0	0	0
Net proceeds from disposal of short-term investments	1,882	2,751	3,147	0	0	1,000
Others	(69)	(112)	(52)	0	0	0
Net cash from investing	**554**	**(3,168)**	**641**	**(320)**	**(100)**	**900**
Financing						
Net borrowings	67	434	423	0	0	0
Proceeds from share issues	0	4,232	3,443	0	0	0
Others	18	537	(229)	0	0	0
Net cash from financing	**86**	**5,203**	**3,637**	**0**	**0**	**0**
Net change in cash						
Cash at the beginning of the year	741	621	1,390	4,383	2,758	1,498
Exchange difference	(10)	18	14	0	0	0
Cash at the end of the year	**193**	**1,390**	**4,383**	**2,758**	**1,498**	**2,100**
GROWTH	**2019A**	**2020A**	**2021A**	**2022E**	**2023E**	**2024E**
YE 31 Dec						
Revenue	na	(27.9%)	280.8%	18.8%	57.8%	51.4%
Gross profit	na	(434.6%)	324.6%	7.4%	59.7%	55.6%
Net profit	na	16.1%	(11.7%)	16.6%	(31.0%)	(76.0%)
Adj. net profit	na	16.0%	(11.5%)	16.6%	(31.0%)	(76.0%)
PROFITABILITY	**2019A**	**2020A**	**2021A**	**2022E**	**2023E**	**2024E**
YE 31 Dec						
Gross profit margin	(16.6%)	77.1%	86.0%	77.7%	78.6%	80.8%
Adj. net profit margin	(321.5%)	(517.0%)	(120.2%)	(117.9%)	(51.5%)	(8.2%)
GEARING/LIQUIDITY/ACTIVITIES	**2019A**	**2020A**	**2021A**	**2022E**	**2023E**	**2024E**
YE 31 Dec						
Net debt to equity (x)	(0.8)	(1.1)	(1.0)	(1.0)	(0.9)	(0.9)
Current ratio (x)	3.8	4.6	4.8	3.5	2.6	2.3
Receivable turnover days	47.7	77.6	84.3	80.0	80.0	80.0
Inventory turnover days	114.8	304.4	367.3	300.0	295.0	290.0
Payable turnover days	604.4	915.5	547.1	400.0	400.0	400.0
VALUATION	**2019A**	**2020A**	**2021A**	**2022E**	**2023E**	**2024E**
YE 31 Dec						
P/E	n/m	n/m	n/m	n/m	n/m	n/m
P/E (diluted)	n/m	n/m	n/m	n/m	n/m	n/m
P/B	112.0	58.3	64.1	51.6	68.5	74.4

Note: The calculation of net cash includes financial assets. Source: Company data, CMBIGM estimates

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