

BeiGene (BGNE US)

Superior PFS vs ibrutinib in r/r CLL further supports the best-in-class potential of zanubrutinib

- Superiority in PFS of zanubrutinib vs ibrutinib in r/r CLL.** BeiGene announced superiority in PFS of BRUKINSA (zanubrutinib) vs ibrutinib in the final PFS analysis of the global Ph3 ALPINE trial in patients with r/r CLL, as assessed by both an independent review committee (IRC) and investigator ([link](#)). In this head-to-head trial, a total of 652 r/r CLL/SLL patients were enrolled across Europe (60%), the US (17%), China (14%), New Zealand and Australia (9%). The detailed data will be disclosed at an upcoming medical conference. Zanubrutinib has previously demonstrated PFS benefit at the interim analysis of ALPINE trial. With median 15.3 months of follow-up, the 1-year PFS rate was 94.9% in the zanubrutinib arm vs 84.0% in the ibrutinib arm (descriptive p=0.0007, descriptive HR=0.40; [link](#)).
- Superiority in the primary ORR endpoint and advantages in cardiac safety as previously reported.** In the ALPINE trial, zanubrutinib achieved superiority in the primary endpoints of both IRC and investigator assessed ORRs versus ibrutinib. ORR by investigator at the interim analysis was 78.3% vs 62.5%, p=0.0006; and ORR by IRC at final ORR analysis was 80.4% vs 72.9%, p=0.0264 (CMBIGM report [link](#)). Zanubrutinib also demonstrated advantages in the overall cardiac toxicity profile compared to ibrutinib. In the interim analysis with median 15.3 months of follow-up, the atrial fibrillation/flutter rate was significantly lower with zanubrutinib vs ibrutinib (2.5% vs 10.1%, p=0.0014). Similarly, in the final ORR analysis (median 24.2 months of follow-up), the rate of atrial fibrillation/flutter was 4.6% vs 12.0% in the two groups, indicating zanubrutinib's superior safety profile.
- Best-in-class potential in the global BTKi market.** Zanubrutinib is the only second-generation BTKi demonstrating superior PFS benefits and safety advantages vs ibrutinib in head-to-head trials. Acalabrutinib achieved better cardiac safety than ibrutinib, but was just equally effective than ibrutinib in r/r CLL patients, as shown in a head-to-head Ph3 trial (mPFS 38.4 in both arms, HR=1.00; rate of atrial fibrillation/flutter 9.4% v 16.0%, p=0.023; [link](#)). Additionally, in a head-to-head Ph3 trial in WM patients, zanubrutinib also demonstrated numerically better efficacy than ibrutinib (CR+VGPR rate 36% vs 22%; [link](#)).
- To gain meaningful share in the global BTKi market backed by NCCN guideline recommendations.** Based on the Ph3 ALPINE trial in r/r CLL/SLL and the Ph3 SEQUOIA trial in 1L CLL/SLL, BeiGene is seeking the US FDA approval of zanubrutinib in CLL/SLL, with the FDA target action date of 20 Jan 2023. Even before the FDA decision, the NCCN guideline has endorsed zanubrutinib as a preferred treatment for both newly diagnosed and r/r CLL/SLL patients. NCCN guideline recently upgraded the recommendation of zanubrutinib for CLL/SLL from category 2A to category 1, which will drive a significant market share gain for zanubrutinib in the global BTKi market, in our view. Sales of zanubrutinib increased 203% YoY or 23% QoQ to US\$128.7mn in 2Q22, largely driven by the strong sales in the US. We are optimistic about zanubrutinib's approval for CLL/SLL in the US, and forecast zanubrutinib to realize US\$4.2bn risk-adjusted global peak sales.
- Maintain BUY.** We revised our DCF-based TP from US\$252.55 to US\$253.13 (WACC: 9.20%, terminal growth rate: 3.0%).

Earnings Summary

(YE 31 Dec)	FY20A	FY21A	FY22E	FY23E	FY24E
Revenue (US\$ mn)	309	1,176	1,416	2,379	3,300
Net profit (US\$ mn)	(1,601)	(1,413)	(1,757)	(1,017)	(404)
EPS (Reported) (US\$)	(19.13)	(15.23)	(16.94)	(9.81)	(3.89)
R&D expenses (US\$)	(1,295)	(1,459)	(1,503)	(1,533)	(1,548)
CAPEX (US\$ mn)	(118)	(263)	(320)	(100)	(100)

Source: Company data, Bloomberg, CMBIGM estimates

BUY (Maintain)

Target Price	US\$253.13
(Previous TP)	US\$252.55
Up/Downside	66.7%
Current Price	US\$151.89

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Stock Data

Mkt Cap (US\$ mn)	17,287
Avg 3 mths t/o (US\$ mn)	37.03
52w High/Low (US\$)	392.30/118.18
Total Issued Shares (mn)	104

Source: FactSet

Shareholding Structure

Amgen	18.3%
Baker Bros	11.3%

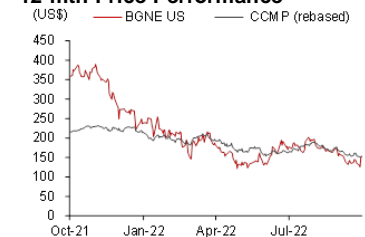
Source: Bloomberg

Share Performance

	Absolute	Relative
1-mth	-6.7%	1.9%
3-mth	-10.5%	-5.5%
6-mth	-19.1%	3.7%

Source: FactSet

12-mth Price Performance



Source: FactSet

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

Related report:

- Strong sales continued in 2Q22 ([link](#)) – 8 Aug 2022
- Positive on the US BLA approval of tislelizumab despite the deferral ([link](#)) – 18 Jul 2022
- Harvest season for a global leading biopharma company ([link](#)) – 17 Jun 2022

Figure 1: Risk-adjusted DCF valuation

DCF Valuation (US\$ mn)	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT	(1,755)	(1,007)	(390)	202	804	1,512	2,150	2,771	3,212	3,451	3,563	3,640	3,635	3,684
Tax rate	0%	0%	0%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
EBIT*(1-tax rate)	(1,755)	(1,007)	(390)	172	683	1,285	1,827	2,356	2,730	2,933	3,029	3,094	3,090	3,131
+ D&A	67	70	72	74	76	78	79	81	82	84	85	86	87	88
- Change in working capital	265	(109)	(119)	(157)	(104)	(103)	(88)	(71)	(35)	1	25	33	47	38
- Capex	(320)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)
FCFF	(1,743)	(1,147)	(538)	(11)	555	1,160	1,719	2,265	2,677	2,918	3,039	3,113	3,123	3,157
Terminal value														52,475
PV of enterprise (US\$ mn)	21,999													
Net debt (US\$ mn)	(4,250)													
Equity value (US\$ mn)	26,250													
No. of ADS (mn)	104													
DCF per ADS (US\$)	253.13													
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 2: Sensitivity analysis (US\$)

Terminal growth rate	WACC				
	8.20%	8.70%	9.20%	9.70%	10.20%
4.0%	364.36	319.35	283.25	253.69	229.08
3.5%	336.63	298.27	266.87	240.74	218.70
3.0%	314.24	280.88	253.13	229.73	209.77
2.5%	295.78	266.30	241.45	220.25	201.99
2.0%	280.30	253.90	231.39	212.00	195.16

Source: CMBIGM estimates

Figure 3: CMBIGM estimates revision

US\$ mn	New			Old			Diff (%)		
	FY21E	FY22E	FY23E	FY21E	FY22E	FY23E	FY21E	FY22E	FY23E
Revenue	1,416	2,379	3,300	1,430	2,190	3,410	-1%	9%	-3%
Gross Profit	1,087	1,863	2,576	1,110	1,722	2,750	-2%	8%	-6%
Operating Profit	(1,655)	(1,007)	(390)	(1,632)	(1,149)	(216)	NA	NA	NA
Net profit	(1,757)	(1,017)	(404)	(1,623)	(1,148)	(219)	NA	NA	NA
EPS (US\$ per ADS)	(16.94)	(9.81)	(3.89)	(15.79)	(11.10)	(2.12)	NA	NA	NA
Gross Margin	76.77%	78.33%	78.06%	77.62%	78.60%	80.64%	-0.86 ppt	-0.27 ppt	-2.58 ppt

Source: Company data, CMBIGM estimates

Figure 4: CMBIGM estimate vs consensus

US\$ mn	CMBIGM			Consensus			Diff (%)		
	FY22E	FY23E	FY24E	FY22E	FY23E	FY24E	FY22E	FY23E	FY24E
Revenue	1,416	2,379	3,300	1,396	2,096	2,836	1%	13%	16%
Gross Profit	1,087	1,863	2,576	1,129	1,723	2,293	-4%	8%	12%
Operating Profit	(1,655)	(1,007)	(390)	(1,687)	(1,342)	(923)	N/A	N/A	N/A
Net Profit	(1,757)	(1,017)	(404)	(1,674)	(1,266)	(899)	N/A	N/A	N/A
EPS (US\$ per ADS)	(16.94)	(9.81)	(3.89)	(12.7)	(9.4)	(6.0)	N/A	N/A	N/A
Gross Margin	76.77%	78.33%	78.06%	80.88%	82.20%	80.87%	-4.11 ppt	-3.87 ppt	-2.80 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	1,416	2,379	3,300
Cost of goods sold	(71)	(71)	(165)	(329)	(515)	(724)
Gross profit	(71)	238	1,011	1,087	1,863	2,576
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	(102)	(9)	(14)
Pre-tax profit	(1,372)	(1,618)	(1,439)	(1,757)	(1,017)	(404)
Income tax	(7)	18	25	0	0	0
Minority interest	(2)	(4)	0	0	0	0
Net profit	(1,379)	(1,601)	(1,413)	(1,757)	(1,017)	(404)
Adjusted net profit	(1,377)	(1,597)	(1,413)	(1,757)	(1,017)	(404)
BALANCE SHEET	2019A	2020A	2021A	2022E	2023E	2024E
YE 31 Dec (US\$ mn)						
Current assets	1,173	4,961	7,614	5,709	4,866	4,663
Cash & equivalents	618	1,382	4,376	2,638	1,482	1,931
Account receivables	71	60	483	288	456	645
Inventories	29	89	243	270	417	575
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	6,987	6,175	5,999
Current liabilities	310	1,075	1,600	1,698	1,902	2,130
Short-term borrowings	0	335	428	428	428	428
Account payables	122	232	262	360	565	793
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	2,501	2,705	2,934
Share capital	2,926	7,415	11,191	11,191	11,191	11,191
Retained earnings	(1,956)	(3,553)	(4,966)	(6,723)	(7,740)	(8,144)
Other reserves	(8)	7	18	18	18	18
Total shareholders equity	962	3,869	6,243	4,486	3,469	3,065
Minority interest	16	0	0	0	0	0
Total equity and liabilities	1,455	5,601	8,646	6,987	6,174	5,999

CASH FLOW	2019A	2020A	2021A	2022E	2023E	2024E
YE 31 Dec (US\$ mn)						
Operating						
Profit before taxation	(1,372)	(1,618)	(1,439)	(1,757)	(1,017)	(404)
Depreciation & amortization	19	32	46	67	70	72
Tax paid	(7)	18	25	0	0	0
Others	182	285	68	265	(109)	(119)
Net cash from operations	(1,178)	(1,283)	(1,299)	(1,425)	(1,056)	(451)
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	2,638	1,482
Exchange difference	(10)	18	14	0	0	0
Cash at the end of the year	193	1,390	4,383	2,638	1,482	1,931
GROWTH	2019A	2020A	2021A	2022E	2023E	2024E
YE 31 Dec						
Revenue	na	(27.9%)	280.8%	20.3%	68.0%	38.7%
Gross profit	na	na	324.6%	7.4%	71.5%	38.3%
PROFITABILITY	2019A	2020A	2021A	2022E	2023E	2024E
YE 31 Dec						
Gross profit margin	(16.6%)	77.1%	86.0%	76.8%	78.3%	78.1%
Adj. net profit margin	(321.5%)	(517.0%)	(120.2%)	(124.1%)	(42.7%)	(12.2%)
Return on equity (ROE)	na	(66.3%)	(28.0%)	(32.8%)	(25.6%)	(12.4%)
GEARING/LIQUIDITY/ACTIVITIES	2019A	2020A	2021A	2022E	2023E	2024E
YE 31 Dec						
Net debt to equity (x)	(0.8)	(1.1)	(1.0)	(0.9)	(0.9)	(0.8)
Current ratio (x)	3.8	4.6	4.8	3.4	2.6	2.2
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/B	112.0	58.3	64.1	37.7	48.8	55.2

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

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