Ascentage Pharma (6855 HK)

HQP-1351 NDA submitted in China

Ascentage just announced on 18 Jun that it has submitted an NDA to NMPA for HQP-1351 for treatment of r/r CP/AP-CML with T315I mutation, which is the first NDA of 3rd generation BCR-ABL inhibitor in China. We raise our TP to HK$61.1 and maintain BUY rating to reflect the Company's excellent execution regardless COVID-19 pandemic the year.

- **HQP-1351 submitted NDA in China.** After being granted ODD for CML by the US FDA one month ago, HQP-1351 submitted NDA to NMPA for r/r CP/AP-CML with T315Im. As the first 3rd generation BCR-ABL inhibitor in China, HQP-1351 showed comparable efficacy to and improved safety profile than ponatinib in phase I study. The submitted NDA is based on two pivotal phase II trials (NCT03883100 and NCT03883087), which have finished patient enrollment in Sep 2019. Such NDA submission is in line with our expectation, and we forecast HQP-1351 to launch in China in 2021E.

  In the US, In July 2019, HQP1351 obtained clearance from FDA to enter into Phase Ib clinical study. In May 2020, HQP1351 was granted ODD and Fast Track Designation by FDA.

- **APG-2575 exhibits large potential in NHL.** APG-2575 is initiating four phase Ib/II trials in the US and China, including a Phase Ib/II trial for r/r CLL/SLL (first patient enrolled in Mar 2020) in US, a Phase Ib/II trial for WM in US; a Phase Ib trial for r/r AML in China and a Phase Ib/II trial for r/r CLL/SLL in China. Previously, Phase I study of APG-2575 has shown a promising efficacy in enrolled patients, of which six out of eight CLL patients achieved hematological CR. In addition, no DLTs (dose limiting toxicities) and no TLS (tumor lysis syndrome) was observed with the MTD (maximum tolerable dose) not reached at 20-800mg dose levels so far.

- **Strong in-house R&D capability in apoptosis pathways and abundant combo potential.** Ascentage has a pipeline of eight clinical stage small molecule candidates, conducting 30+ phase I or II clinical trials in China, US and Australia. HQP1351 is expected to market in China 2021E. APG-2575 has entered into Phase Ib/II trials in both China and the US. Recent clinical data of Venetoclax (Bcl-2 inhibitor) + Ibrutinib (BTK inhibitor) for CLL implied promising outlook of this combination therapy. Worldwide, APG-2575 is the second Bcl-2 inhibitor entered into clinical stage.

- **Reiterate BUY with TP raised to HK$61.1**. We raised HQP-1351's PoS (probability of success) for risk-adjusted revenue to reflect the positive impact of its NDA submission. We raised our price target to HK$61.1 based on an 8-year DCF valuation (WACC: 10.98%, terminal growth 3.0%).

Earnings Summary

(YE 31 Dec)	FY18A	FY19A	FY20E	FY21E	FY22E
Revenue (RMB mn)	7	15	7	7	152
Net profit (RMB mn)	(345)	(1,481)	(729)	(794)	(822)
EPS (RMB)	N/A	(12.69)	(3.49)	(3.80)	(3.94)
Consensus EPS (RMB)	N/A	N/A	(3.54)	(3.59)	(3.93)
R&D expenses (RMB mn)	(250)	(464)	(600)	(600)	(600)
Capex (RMB mn)	(48)	(77)	(400)	(450)	(100)
Current ratio	9.4	4.5	0.5	0.1	0.1

Source: Company data, Bloomberg, CMBIS estimates

BUY (Maintain)

Target Price	HK$61.1
(Previous TP	HK$45.8)
Up/Downside	+30.2%
Current Price	HK$47.0

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Stock Data

Mkt. Cap. (HK$ mn)	9,808
Avg. 3mths t/o (HK$ mn)	12.14
52W High/Low (HK$)	53.6/19.8
Total Issued Shares (mn)	209

Source: Bloomberg

Shareholding Structure

Management	32.17%
Collected Mind (3SBio)	4.85%
Sino Biopharma	2.2%
Institution investors	26.28%
Free float	34.5%

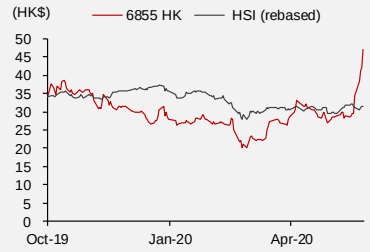
Source: SZSE

Share Performance

	Absolute	Relative
1-mth	48.0%	43.9%
3-mth	95.2%	85.4%
6-mth	34.3%	52.8%

Source: Bloomberg

12-mth Price Performance



Source: Bloomberg

Auditor: Ernst & Young

Related reports
HQP-1351 obtained ODD from US FDA – 6 May 2020

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https://euromoney.com/brokers

In ASH 2019, Ascentage Pharma updated the results of phase 1 study of HQP1351 in Chinese CML patients. From 26 Oct 2016 to 27 May 2019, 101 CML patients including 87 with chronic-phase CML (CP-CML) patients and 14 accelerated-phase CML (AP-CML) patients were enrolled in this study. Median duration of follow-up was 12.8 (range, 1.2-31.5) months.

As of 27 May 2019, of the evaluable patients with CP-CML, 95% of evaluable patients had a complete hematologic response (CHR), 69% had a major cytogenetic response (MCyR), 61% had a complete cytogenetic response (CCyR) and 37% had a major or complete molecular response (MMR). Of the evaluable CP-CML patients with T315I mutation, 97% had a CHR, 82% had a MCyR, and 52% had an MMR. For the evaluable patients with AP-CML, 85% had a CHR, 43% had a MCyR, 36% had a CCyR and 36% had an MMR. HQP1351 showed highly efficacy in the patients with T315I mutation.

Figure 1: Efficacy summary of HQP1351 Phase I trial in CML in China (as of 27 May 2019)

Variable	CP-CML patients			AP-CML patients		
	All patients	With T315I mutation	Without T315I mutation	All patients	With T315I mutation	Without T315I mutation
Hematological response						
No. of evaluable subjects -n	55	33	22	13	10	3
Complete hematological response -n(%)	52 (94.5%)	32 (97.0%)	20 (90.9%)	11 (84.6%)	8 (80.0%)	3 (100.0%)
Cytogenetic response						
No. of evaluable subjects -n	81	48	33	14	11	3
Major cytogenetic response -n(%)	56 (69.1%)	39 (81.3%)	17 (51.5%)	6 (42.9%)	6 (54.5%)	0
Complete cytogenetic response -n(%)	49 (60.5%)	37 (77.1%)	11 (33.3%)	5 (35.7%)	5 (45.5%)	0
Molecular response						
No. of evaluable subjects -n	86	51	35	14	11	3
Major/ Complete molecular response -n(%)	32 (37.2%)	27 (52.9%)	5 (14.3%)	5 (35.7%)	5 (45.5%)	0

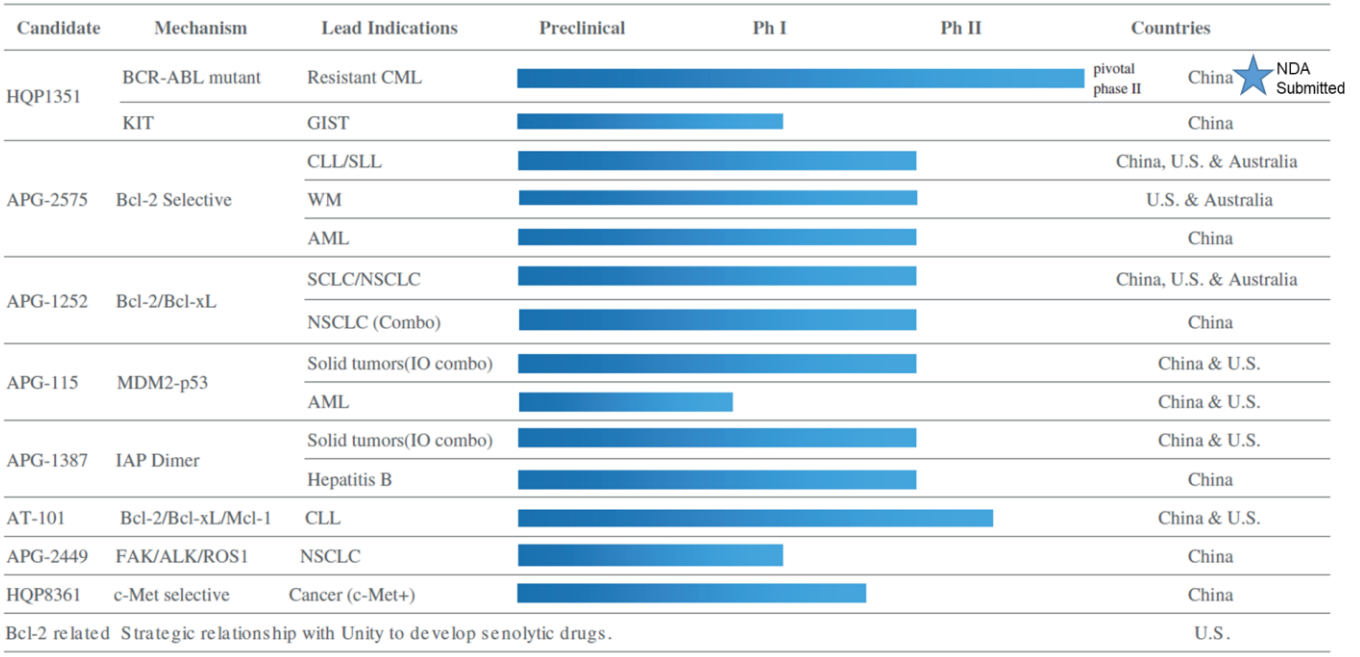
Source: ASH 2019, CMBIS

Figure 2: Comparison of efficacy between different therapies for CLL

CLL/SLL	Venetoclax + Ibrutinib	Venetoclax + Ibrutinib	Venetoclax + Obinutuzumab	Obinutuzumab + chlorambucil	Ibrutinib + Rituximab	Venetoclax	Ibrutinib	
Source	ASH 2019	NEJM	ASCO 2019	ASCO 2019	NEJM	NEJM	Blood Journal	
Trial registration No.	NCT02910583	NCT02756897	NCT02242942	NCT02242942	NCT02048813	NCT01328626	NCT01105247, NCT01109069	
Administration	Oral	Oral	Oral + Intravenous	Oral + Intravenous	Oral + Intravenous	Oral	Oral	
Trial phase	Phase II	Phase II	Phase III	Phase III	Phase III	Phase I	NA	
Line of treatment	1st line	1st line	1st line	1st line	1st line	2nd line	1st line	2nd line
Median follow-up (mo)	14.7 mos	14.8 mos	28.1 mos	28.1 mos	33.6 mos	17 mos	5-year	5-year
n	164	80	216	216	354	116	31	101
MRD-negativity in bone marrow	72%	69% (after 18 cycles of combo)	56.90%	17.10%	NA	5%	NA	NA
CR		74%	49.50%	23.10%	17.2%	20%	29%	10%
ORR		100%	84.70%	71.30%	95.8%	79%	87%	89%

Source: ASH, The New England Journal of Medicine (NEJM), ASCO, Blood Journal, CMBIS

Figure 3: Key pipeline of Ascentage



Source: Company data, CMBIS

Figure 4: CMBIS estimates vs consensus

(RMB mn)	CMBIS			Consensus			Diff (%)		
	FY20E	FY21E	FY22E	FY20E	FY21E	FY22E	FY20E	FY21E	FY22E
Revenue	7	7	152	11	41	229	-35%	-83%	-34%
Gross profit	7	7	106	11	39	189	-35%	-82%	-44%
Operating profit	(713)	(747)	(739)	(732)	(791)	(738)	N/A	N/A	N/A
Net profit	(729)	(794)	(822)	(774)	(863)	(822)	N/A	N/A	N/A
EPS (RMB)	(3.49)	(3.80)	(3.94)	(3.54)	(3.59)	(3.93)	N/A	N/A	N/A

Source: Company data, CMBIS estimates

Figure 5: Peers comparison

Ticker	Company	Rating	TP (HKD)	Current Px (HKD)	Mkt Cap (USD mn)	Px Change (%)			AVG Trading Turnover (HKD mn)			IPO	IPO Px
						30 d	60 d	90 d	30 d	60 d	90 d	Date	(HKD)
6855.HK	**Ascentage**	**BUY**	**61.1**	**46.95**	**1,266**	**61%**	**73%**	**124%**	**29**	**19**	**13**	**2019-10-28**	**34.20**
9969 HK	InnoCare	BUY	16.2	52.00	3,647	24%	33%	61%	7	5	4	2019-09-25	49.60
2696.HK	Henlius	BUY	57.2	14.24	2,369	-11%	12%	N/A	54	61	104	2020-03-23	8.95
6160.HK	Beigene	NR	N/A	106.00	13,823	8%	13%	18%	19	17	15	2018-08-08	108.00
1801.HK	Innovent	NR	N/A	48.95	8,482	12%	47%	65%	176	167	161	2018-10-31	13.98
1877.HK	Junshi	NR	N/A	53.90	5,454	23%	58%	79%	65	60	47	2018-12-24	19.38
6185.HK	CanSino	NR	N/A	184.00	5,286	-19%	46%	96%	537	398	370	2019-03-28	22.00
9926.HK	AkesoBio	NR	N/A	32.10	3,260	13%	N/A	N/A	180	N/A	N/A	2020-04-24	16.18
9966.HK	AlphaMab	NR	N/A	17.06	2,055	-23%	0%	22%	65	46	34	2019-12-12	10.20
2616.HK	CStone	NR	N/A	9.36	1,242	16%	15%	8%	20	17	13	2019-02-26	12.00
9939.HK	Kintor	NR	N/A	15.08	719	N/A	N/A	N/A	N/A	N/A	N/A	2020-05-22	20.15

Source: Bloomberg, CMBIS

Financial Summary

Income statement

YE 31 Dec (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Revenue	**7**	**15**	**7**	**7**	**152**
License fee income	0	11	0	0	0
Provision of R&D services	7	4	7	7	7
Cost of sales	0	(2)	0	0	(46)
Gross profit	**7**	**12**	**7**	**7**	**106**
Other income	61	49	19	19	19
Selling & distribution expenses	0	0	0	0	(76)
Milestone payment	0	0	0	(20)	(20)
Administrative expenses	(90)	(162)	(139)	(153)	(168)
R&D expenses	(250)	(464)	(600)	(600)	(600)
Operating profit	**(272)**	**(564)**	**(713)**	**(747)**	**(739)**
Other expenses	(38)	(914)	0	0	0
Finance costs, net	(37)	(4)	(16)	(48)	(84)
Pre-tax profit	**(347)**	**(1,482)**	**(729)**	**(794)**	**(822)**
Income tax	2	2	0	0	0
Minority interests	0	0	0	0	0
Net profit (Net loss)	**(345)**	**(1,481)**	**(729)**	**(794)**	**(822)**

Cash flow summary

YE 31 Dec (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Profit before tax	**(347)**	**(1,482)**	**(729)**	**(794)**	**(822)**
Depreciation & amortization, etc.	18	26	24	63	102
Change in working capital	27	15	(13)	0	(30)
Tax paid	0	0	0	0	0
Others	64	980	16	48	84
Net cash from operating	**(238)**	**(460)**	**(702)**	**(684)**	**(666)**
Capex	(48)	(77)	(400)	(450)	(100)
(Purchases of)/proceeds from retrieval of other financial assets, net	376	20	0	0	0
Other investing activities	(35)	(143)	0	0	0
Net cash from investing	**293**	**(201)**	**(400)**	**(450)**	**(100)**
Net proceeds from shares issued	911	432	0	0	0
Bank borrowing	35	50	600	1,000	800
Capital repurchase	(76)	0	0	0	0
Interests paid	(2)	(4)	(16)	(48)	(84)
Net cash from financing	**860**	**442**	**584**	**952**	**716**
FX changes	27	1	0	0	0
Net change in cash	**915**	**(219)**	**(517)**	**(182)**	**(50)**
Cash at the beginning of the year	15	957	882	365	183
Cash at the end of the year	**957**	**739**	**365**	**183**	**133**

Balance sheet

YE 31 Dec (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Non-current assets	**239**	**296**	**672**	**1,059**	**1,057**
PP&E	27	94	484	886	897
Righ-of-use assets	40	49	40	31	22
Other intangible assets	75	72	66	61	56
Goodwill	25	25	25	25	25
Equity investment measured at FVTPL	60	32	32	32	32
Other non-current assets	12	25	25	25	25
Current assets	**990**	**909**	**392**	**210**	**197**
Inventories	0	0	0	0	13
Trade receivables	0	0	0	0	25
Prepayments, other receivables	19	27	27	27	27
Other financial assets	14	0	0	0	0
Cash and bank balances	957	882	365	183	133
Current liabilities	**105**	**202**	**789**	**1,789**	**2,596**
Bank loans	38	92	692	1,692	2,492
Trade payables	5	13	0	0	8
Other payables and accruals	63	97	97	97	97
Contract liabilities	0	0	0	0	0
Non-current liabilities	**2,136**	**113**	**113**	**113**	**113**
Bank loans	4	9	9	9	9
Deferred tax liabilities	19	17	17	17	17
Convertible redeemable preferred shares	2,076	0	0	0	0
Other non-current liabilities	0	0	0	0	0
Others	37	86	86	86	86
Total net assets	**(1,012)**	**890**	**162**	**(633)**	**(1,455)**
Minority interest	**0**	**0**	**0**	**0**	**0**
Shareholders' equity	**(1,012)**	**890**	**162**	**(633)**	**(1,455)**

Key ratios

YE 31 Dec	FY18A	FY19A	FY20E	FY21E	FY22E
Sales mix (%)					
License fee income	1	73	0	0	0
Provision of R&D services	99	27	100	100	5
Total	100	100	100	100	5
Profit & loss ratios (%)					
Gross margin	100	86	100	100	70
EBITDA margin	N/A	N/A	N/A	N/A	N/A
Pre-tax margin	N/A	N/A	N/A	N/A	N/A
Net margin	N/A	N/A	N/A	N/A	N/A
Effective tax rate (%)	0	0	0	0	0
Balance sheet ratios					
Current ratio (x)	9	4	0	0	0
Trade receivables turnover	N/A	N/A	N/A	N/A	N/A
Trade payables turnover days	N/A	N/A	N/A	N/A	N/A
Net debt to total equity ratio (%)	N/A	N/A	N/A	N/A	N/A
Total debt to asset ratio (%)	182	26	85	150	216
Returns (%)					
ROE	N/A	N/A	N/A	N/A	1
ROA	N/A	N/A	N/A	N/A	(1)
Per share data					
EPS (RMB)	N/A	(12.69)	(3.49)	(3.80)	(3.94)
DPS (RMB)	0.00	0.00	0.00	0.00	0.00
BVPS (RMB)	N/A	Net	1.61	7.27	11.34

Source: Company data, CMBIS estimates

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