

InnoCare Pharma (9969 HK)

Orelabrutinib to initiate trial in multiple sclerosis in US

- Encouraging progress of Orelabrutinib (ICP-022).** Orelabrutinib received approval from FDA to initiate a Phase II clinical trial treating Relapsing-Remitting multiple sclerosis patients (RRMS). This randomized, double-blind, placebo-controlled and multi-center phase II trial will be conducted in the US and several European countries, and is planned to enroll 160 patients. Recall that InnoCare has submitted NDAs to the NMPA of orelabrutinib for treatment of r/r-CLL/SLL and r/r-MCL in Nov 2019 and Mar 2020, respectively. We expect orelabrutinib to receive approvals from NMPA in 4Q20E, which will make it the third BTK inhibitor approved in China.
- Large potential in multiple sclerosis (MS) market.** MS is an autoimmune, inflammatory disease of the central nervous system that is mediated by autoreactive B and T cells, and there is large unmet medical need for MS patients. According to the MS International Federation (MSIF), more than 2.8mn people around the world are affected by MS with around 500k in the US and around 1mn in EU. According to Frost & Sullivan (F&S), global market of MS drugs reached \$23.0bn in 2018, and it is expected to reach \$30.8bn by 2023E, representing a CAGR of 6.0%, where the US market accounted for about 70% of the global market and China accounted for about 2% of the global market.
- Orelabrutinib is potentially a best-in-class BTK inhibitor for MS.** Although several classes of drugs are available for MS patients, substantial unmet medical needs remain for drugs with improvements in efficacy, safety and convenient dosing. Although three BTK inhibitors have been marketed in worldwide, none of them were approved for MS. Two BTK inhibitor candidates (Merck Serono's evobrutinib and Sanofi/Principia's SAR442168) have delivered good Phase II data in MS and has moved into Phase III trials. With a superior safety and potent efficacy profile, as well as good level of Brain Blood Barrier (BBB) penetration capability, we think Orelabrutinib has the potential to become a best-in-class BTK inhibitor for MS.
- Maintain BUY.** Considering that Orelabrutinib's trial in MS is still at early stage, we did not change our financial forecasts at the moment. We remain positive on orelabrutinib's potential efficacy in MS. We maintain our DCF-based TP unchanged at HK\$16.21 (WACC: 10.0%, terminal growth rate: 5.0%).

Earnings Summary

(YE 31 Dec) (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Revenue	2	1	2	106	274
Attributable net profit (loss)	(550)	(2,141)	(549)	(341)	(168)
R&D expense	(150)	(213)	(400)	(400)	(219)
ROA (%)	(25)	(82)	(12)	(11)	(6)
EPS (RMB)	N/A	N/A	(0.43)	(0.26)	(0.13)
Consensus EPS (RMB)	N/A	N/A	(0.55)	(0.55)	(0.30)
Net gearing (%)	Net cash	Net cash	Net cash	Net cash	Net cash
Current ratio (x)	29	37	249	109	75

Source: Company data, Bloomberg, CMBIS estimates

BUY (Maintain)

Target Price	HK\$16.21
(Previous TP)	HK\$16.21)
Up/Downside	+48.96%
Current Price	HK\$10.88

China Healthcare Sector

Sam Hu, PhD

(852) 3900 0882
samhu@cmbi.com.hk

Jill Wu, CFA

(852) 3900 0842
jillwu@cmbi.com.hk

Mkt. Cap. (HK\$ mn)	14,026
Avg. 3mths t/o (HK\$ mn)	19.88
52W High/Low (HK\$)	16.80/9.31
Total Issued Shares (mn)	1,289

Source: Bloomberg

Shareholding Structure

Management	36.39%
Pre-IPO and Cornerstone investors	43.95%
Free float	19.67%

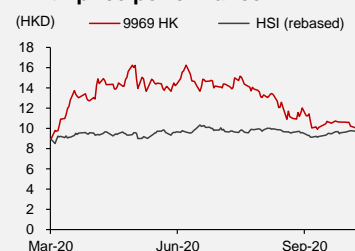
Source: Bloomberg

Share performance

	Absolute	Relative
1-mth	7.7%	1.3%
3-mth	-26.2%	-27.6%
6-mth	-24.0%	-24.9%

Source: Bloomberg

12-mth price performance



Source: Bloomberg

Auditor: Ernst & Young

Web-site: www.innocarepharma.com

Related report:

Well prepared for the first product commercialization – 18 Sep 2020
 Biopharmaceutical company developing global innovative therapies in oncology and autoimmune areas – 12 May 2020

Figure 1: Adverse events comparison of Orelabrutinib and three marketed BTK inhibitors

Index	Orelabrutinib	Zanubrutinib	Acalabrutinib	Ibrutinib
	N=200	N=671	N=612	N=1,124
Major bleeding	0.5%	2.7%	2.0%	3.0%
Atrial fibrillation (Grade 3 or Grade 4)	0.0%	0.6%	1.0%	4.0%
Hypertension (Grade 3 or Grade 4)	2.5%	3.1%	2.5%	5.0%
Infection (>=Grade 3)	16.0%	21.3%	18.0%	24.0%
Secondary malignancy	0.5%	7.9%	10.6%	10.0%
Diarrhea	7.0%	18.2%	38.4%	39.0%

Source: Company data, CMBIS; Note: Data showed above are not from head-to-head comparative studies but extracted from some pooled analyses. Orelabrutinib as of the data cut-off date of 30 Sep 2019 for ICP-CL-00102 trial, 9 Aug 2019 for ICP-CL-00103 trial and 31 Aug 2019 for ICP-CL-00104, ICP-CL-00105 and ICP-CL-00106 trial.

Figure 2: Earnings revision

RMB mn	New			Old			Diff (%)		
	FY20E	FY21E	FY22E	FY20E	FY21E	FY22E	FY20E	FY21E	FY22E
Revenue	2	106	274	2	106	274	0%	0%	0%
Gross Profit	2	87	230	2	87	230	0%	0%	0%
Operating Profit	(407)	(341)	(168)	(407)	(341)	(168)	0%	0%	0%
Net profit	(549)	(341)	(168)	(549)	(341)	(168)	0%	0%	0%
EPS (RMB)	(0.43)	(0.26)	(0.13)	(0.43)	(0.26)	(0.13)	0%	0%	0%
Gross Margin	80.00%	82.00%	84.00%	80.00%	82.00%	84.00%	0.00 ppt	0.00 ppt	0.00 ppt

Source: Company, CMBIS estimates

Figure 3: CMBIS estimates vs consensus

RMB mn	CMBIS			Consensus			Diff (%)		
	FY20E	FY21E	FY22E	FY20E	FY21E	FY22E	FY20E	FY21E	FY22E
Revenue	2	106	274	13	170	513	-84%	-37%	-47%
Gross Profit	2	87	230	11	133	429	-85%	-34%	-46%
Operating Profit	(407)	(341)	(168)	(497)	(480)	(340)	N/A	N/A	N/A
Net profit	(549)	(341)	(168)	(540)	(511)	(269)	N/A	N/A	N/A
EPS (RMB)	(0.43)	(0.26)	(0.13)	(0.55)	(0.55)	(0.30)	N/A	N/A	N/A
Gross Margin	80.00%	82.00%	84.00%	84.95%	78.35%	83.78%	-4.95 ppt	+3.65 ppt	+0.23 ppt

Source: Company, CMBIS estimates

Financial Statements

Income statement						Cash flow summary					
YE 31 Dec (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E	YE 31 Dec (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Revenue	2	1	2	106	274	Profit before tax	(554)	(2,150)	(549)	(341)	(168)
Orelabrutinib - risk adjusted	0	0	0	106	274	Depreciation and amortization	5	9	4	4	4
ICP-192 - risk adjusted	0	0	0	0	0	Change in working capital	47	21	(13)	(12)	(20)
ICP-105 - risk adjusted	0	0	0	0	0	Others	484	2,040	110	(32)	(10)
R&D services	2	2	2	0	0	Net income tax paid	0	0	0	0	0
Cost of sales	0	0	(0)	(19)	(44)	Net operating cash flow	(18)	(80)	(448)	(381)	(194)
Gross profit	2	1	2	87	230	Interest received	0	0	78	78	56
Other income	31	104	182	182	90	Purchases of PP&E	(4)	(45)	(250)	(100)	(50)
Selling & distribution expenses	(1)	(3)	(50)	(100)	(137)	Purchases of other intangible assets	(16)	(0)	0	0	0
R&D expenses	(150)	(213)	(400)	(400)	(219)	Net purchases of financial assets	(160)	85	0	0	0
Administrative expenses	(18)	(64)	(90)	(60)	(82)	Others	(708)	8	4	4	4
Other expenses	(28)	(160)	(50)	(50)	(50)	Net investing cash flow	(888)	47	(168)	(18)	10
Operating profit (loss)	(163)	(334)	(407)	(341)	(168)	Net proceeds from shares issued	1,165	422	2,255	0	0
Fair value changes of convertible redeemable preferred shares	(388)	(1,814)	(142)	0	0	Bank borrowing, net	873	(50)	0	(1,200)	0
Finance costs	(3)	(2)	0	0	0	Acquisition of non-controlling interests	0	0	0	0	0
Pre-tax profit (loss)	(554)	(2,150)	(549)	(341)	(168)	Others	63	(9)	0	0	0
Income tax	0	0	0	0	0	Net financing cash flow	2,101	363	2,255	(1,200)	0
Minority interests	4	9	0	0	0	FX changes	13	18	0	0	0
Attributable net profit (loss)	(550)	(2,141)	(549)	(341)	(168)	Net change in cash	1,196	331	1,639	(1,598)	(184)
						Cash at the beginning	37	1,245	2,292	3,931	2,332
						Cash at the end	1,245	1,594	3,931	2,332	2,148

Balance sheet						Key ratios					
YE 31 Dec (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E	YE 31 Dec	FY18A	FY19A	FY20E	FY21E	FY22E
Non-current assets	138	207	453	549	595	Sales mix (%)					
PP&E	5	48	297	396	444	Orelabrutinib - risk adjusted	0	0	0	100	100
Goodwill	3	3	3	3	3	ICP-192 - risk adjusted	0	0	0	0	0
Other intangible assets	37	37	37	36	36	ICP-105 - risk adjusted	0	0	0	0	0
Right-of-use assets	13	86	84	82	80	R&D services	100	100	100	0	0
Investment in JVs	1	1	1	1	1	Total	100	100	100	100	100
Other non-current assets	78	31	31	31	31						
Current assets	2,064	2,409	4,011	2,431	2,275	Profit & loss ratios (%)					
Inventories	0	0	0	4	8	Gross margin	100	100	80	82	84
Trade receivables	0	0	0	12	30	EBITDA margin	NA	NA	NA	NA	NA
Prepayments, other receivables & other assets	18	37	0	3	7	Pre-tax margin	NA	NA	NA	NA	NA
Cash and cash equivalents	1,877	2,292	3,931	2,332	2,148	Net margin	NA	NA	NA	NA	NA
Others	169	80	80	80	80	Effective tax rate	0	0	0	0	0
Current liabilities	72	66	16	22	30	Balance sheet ratios					
Trade payables	2	8	0	5	12	Current ratio (x)	29	37	249	109	75
Loans and borrowings	50	0	0	0	0	Trade receivables turnover days	NA	NA	40	40	40
Other payables and accruals	5	42	0	1	2	Trade payables turnover days	NA	NA	100	100	100
Lease liabilities	5	6	6	6	6	Net debt to total equity ratio (%)	Net cash	Net cash	Net cash	Net cash	Net cash
Loans from a related party	9	9	9	9	9						
Others	0	1	1	1	1	Returns (%)					
Non-current liabilities	2,967	5,498	5,690	4,540	4,590	ROE	NA	NA	NA	NA	NA
Convertible redeemable preferred shares	1,935	4,214	4,356	4,356	4,356	ROA	(25)	(82)	(12)	(11)	(6)
Convertible loan	957	1,117	1,167	17	67						
Loans and borrowings	0	0	0	0	0						
Others	75	167	167	167	167						
Total net assets	(838)	(2,948)	(1,242)	(1,582)	(1,750)						
Minority interest	66	57	57	57	57						
Shareholders' equity	(904)	(3,005)	(1,299)	(1,639)	(1,807)						

Source: Company data, CMBIS estimates

Disclosures & Disclaimers

Analyst Certification

The research analyst who is primary responsible for the content of this research report, in whole or in part, certifies that with respect to the securities or issuer that the analyst covered in this report: (1) all of the views expressed accurately reflect his or her personal views about the subject securities or issuer; and (2) no part of his or her compensation was, is, or will be, directly or indirectly, related to the specific views expressed by that analyst in this report.

Besides, the analyst confirms that neither the analyst nor his/her associates (as defined in the code of conduct issued by The Hong Kong Securities and Futures Commission) (1) have dealt in or traded in the stock(s) covered in this research report within 30 calendar days prior to the date of issue of this report; (2) will deal in or trade in the stock(s) covered in this research report 3 business days after the date of issue of this report; (3) serve as an officer of any of the Hong Kong listed companies covered in this report; and (4) have any financial interests in the Hong Kong listed companies covered in this report.

CMBIS or its affiliate(s) have investment banking relationship with the issuers covered in this report in preceding 12 months.

CMBIS Ratings

BUY : Stock with potential return of over 15% over next 12 months
HOLD : Stock with potential return of +15% to -10% over next 12 months
SELL : Stock with potential loss of over 10% over next 12 months
NOT RATED : Stock is not rated by CMBIS

OUTPERFORM : Industry expected to outperform the relevant broad market benchmark over next 12 months
MARKET-PERFORM : Industry expected to perform in-line with the relevant broad market benchmark over next 12 months
UNDERPERFORM : Industry expected to underperform the relevant broad market benchmark over next 12 months

CMB International Securities Limited

Address: 45/F, Champion Tower, 3 Garden Road, Hong Kong, Tel: (852) 3900 0888 Fax: (852) 3900 0800

CMB International Securities Limited ("CMBIS") is a wholly owned subsidiary of CMB International Capital Corporation Limited (a wholly owned subsidiary of China Merchants Bank)

Important Disclosures

There are risks involved in transacting in any securities. The information contained in this report may not be suitable for the purposes of all investors. CMBIS does not provide individually tailored investment advice. This report has been prepared without regard to the individual investment objectives, financial position or special requirements. Past performance has no indication of future performance, and actual events may differ materially from that which is contained in the report. The value of, and returns from, any investments are uncertain and are not guaranteed and may fluctuate as a result of their dependence on the performance of underlying assets or other variable market factors. CMBIS recommends that investors should independently evaluate particular investments and strategies, and encourages investors to consult with a professional financial advisor in order to make their own investment decisions.

This report or any information contained herein, have been prepared by the CMBIS, solely for the purpose of supplying information to the clients of CMBIS or its affiliate(s) to whom it is distributed. This report is not and should not be construed as an offer or solicitation to buy or sell any security or any interest in securities or enter into any transaction. Neither CMBIS nor any of its affiliates, shareholders, agents, consultants, directors, officers or employees shall be liable for any loss, damage or expense whatsoever, whether direct or consequential, incurred in relying on the information contained in this report. Anyone making use of the information contained in this report does so entirely at their own risk.

The information and contents contained in this report are based on the analyses and interpretations of information believed to be publicly available and reliable. CMBIS has exerted every effort in its capacity to ensure, but not to guarantee, their accuracy, completeness, timeliness or correctness. CMBIS provides the information, advices and forecasts on an "AS IS" basis. The information and contents are subject to change without notice. CMBIS may issue other publications having information and/ or conclusions different from this report. These publications reflect different assumption, point-of-view and analytical methods when compiling. CMBIS may make investment decisions or take proprietary positions that are inconsistent with the recommendations or views in this report.

CMBIS may have a position, make markets or act as principal or engage in transactions in securities of companies referred to in this report for itself and/or on behalf of its clients from time to time. Investors should assume that CMBIS does or seeks to have investment banking or other business relationships with the companies in this report. As a result, recipients should be aware that CMBIS may have a conflict of interest that could affect the objectivity of this report and CMBIS will not assume any responsibility in respect thereof. This report is for the use of intended recipients only and this publication, may not be reproduced, reprinted, sold, redistributed or published in whole or in part for any purpose without prior written consent of CMBIS.

Additional information on recommended securities is available upon request.

For recipients of this document in the United Kingdom

This report has been provided only to persons (I) falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended from time to time) ("The Order") or (II) are persons falling within Article 49(2) (a) to (d) ("High Net Worth Companies, Unincorporated Associations, etc.") of the Order, and may not be provided to any other person without the prior written consent of CMBIS.

For recipients of this document in the United States

CMBIS is not a registered broker-dealer in the United States. As a result, CMBIS is not subject to U.S. rules regarding the preparation of research reports and the independence of research analysts. The research analyst who is primary responsible for the content of this research report is not registered or qualified as a research analyst with the Financial Industry Regulatory Authority ("FINRA"). The analyst is not subject to applicable restrictions under FINRA Rules intended to ensure that the analyst is not affected by potential conflicts of interest that could bear upon the reliability of the research report. This report is intended for distribution in the United States solely to "major US institutional investors", as defined in Rule 15a-6 under the US, Securities Exchange Act of 1934, as amended, and may not be furnished to any other person in the United States. Each major US institutional investor that receives a copy of this report by its acceptance hereof represents and agrees that it shall not distribute or provide this report to any other person. Any U.S. recipient of this report wishing to effect any transaction to buy or sell securities based on the information provided in this report should do so only through a U.S.-registered broker-dealer.

For recipients of this document in Singapore

This report is distributed in Singapore by CMBI (Singapore) Pte. Limited (CMBISG) (Company Regn. No. 201731928D), an Exempt Financial Adviser as defined in the Financial Advisers Act (Cap. 110) of Singapore and regulated by the Monetary Authority of Singapore. CMBISG may distribute reports produced by its respective foreign entities, affiliates or other foreign research houses pursuant to an arrangement under Regulation 32C of the Financial Advisers Regulations. Where the report is distributed in Singapore to a person who is not an Accredited Investor, Expert Investor or an Institutional Investor, as defined in the Securities and Futures Act (Cap. 289) of Singapore, CMBISG accepts legal responsibility for the contents of the report to such persons only to the extent required by law. Singapore recipients should contact CMBISG at +65 6350 4400 for matters arising from, or in connection with the report.