

InnoCare Pharma (9969 HK)

Orelabrutinib showed impressive efficacy in r/r-CLL/SLL

- Impressive data update of orelabrutinib.** At the first national lymphocyte disease academic conference of Chinese Medical Association (中华医学会第一次全国淋巴瘤疾病学术大会) held on 16-18 Apr 2021, InnoCare released orelabrutinib's updated clinical data in a phase I/II (part II) study (NCT03493217) with 80 r/r-CLL/SLL patients treated with orelabrutinib 150mg QD achieving 21.3% CR and 93.9% ORR, while the previous update at ASH2020 indicated 10% CR and 91.3% ORR. Furthermore, the median follow-up time was 25.6 months, and the PR rate was 61.3% (PR with lymphocytosis was 11.3%). Median time to response was 1.87 months, while neither PFS nor DOR was achieved. Orelabrutinib also showed good safety profile with low incidence of AEs, good tolerance and no atrial fibrillation. Other AEs due to BTKi off-target effect such as \geq G3 bleeding, hypertension and diarrhea were much lower. We believe the impressive efficacy and superior safety profile make orelabrutinib the potential best-in-class BTK inhibitor.
- Entering into commercial stage with Orelabrutinib's first NDA approval in China.** In Dec 2020, Orelabrutinib (宜诺凯®) obtained NMPA's approval for treating r/r-CLL/SLL and r/r-MCL, which made Orelabrutinib the second-to-market domestic BTK inhibitor in China. CLL/SLL and MCL are the two major sub-types of NHL, accounting for approximately 8% of total NHL cases in China. Besides CLL/SLL and MCL, Orelabrutinib is also assessed for treatment of other types of NHLs in China, including WM (plan to file NDA in 1H22), MZL (pivotal trial to complete enrollment in 2H21), 1L CLL/SLL (Ph III ongoing), CNSL (Ph II ongoing), etc. In addition to oncology, InnoCare is exploring the use of orelabrutinib for various autoimmune diseases. Orelabrutinib is being assessed in a Ph IIa trial for SLE and a global Ph II trial for MS in the US, Europe and China.
- Establishing strong commercial team.** Given the approval by the NMPA, InnoCare started commercial sales of orelabrutinib in Jan 2021. InnoCare currently has a commercial team of over 150 members, covering more than 500 core hospitals in China. InnoCare plans to expand the commercialization team to 200 members covering over 900 hospitals by the end of 2021.
- Highly differentiated pipelines driven by strong inhouse R&D capabilities.** Besides orelabrutinib, InnoCare has three clinical stage assets incl. potential best-in-class pan-FGFR inhibitor ICP-192, potential first-in-class FGFR4 inhibitor ICP-105 and 2nd-generation pan-TRK inhibitor ICP-723. For ICP-192, early efficacy data of the Phase I/II clinical trials were promising. Of the 12 patients with FGF/FGFR gene aberrations who had completed at least one tumor assessment, the ORR was 33.3% including 1 cholangiocarcinoma patient (8.3%) achieving CR and 3 patients (25%) with PR.
- Maintain BUY.** Given the promising clinical data, we revised up forecasts for orelabrutinib and upgraded our TP from HK\$21.71 to HK\$24.59 (WACC: 9.1%, terminal growth rate: 5.0%).

Earnings Summary

| (YE 31 Dec) (RMB mn) | FY19A | FY20A | FY21E | FY22E | FY23E |
|--------------------------------|----------|----------|----------|----------|----------|
| Revenue | 1 | 1 | 116 | 305 | 668 |
| Attributable net profit (loss) | (2,141) | (464) | (309) | (150) | 42 |
| R&D expense | (213) | (403) | (400) | (275) | (334) |
| ROA (%) | (82) | (10) | (5) | (2) | 1 |
| EPS (RMB) | N/A | (0.48) | (0.21) | (0.10) | 0.03 |
| Consensus EPS (RMB) | N/A | N/A | (0.35) | (0.25) | 0.29 |
| Net gearing (%) | Net cash | Net cash | Net cash | Net cash | Net cash |
| Current ratio (x) | 37 | 39 | 293 | 191 | 119 |

Source: Company data, Bloomberg, CMBIS estimates

BUY (Maintain)

| | |
|---------------|------------|
| Target Price | HK\$24.59 |
| (Previous TP) | HK\$21.71) |
| Up/Downside | +17.09% |
| Current Price | HK\$21.00 |

China Healthcare Sector

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| | |
|--------------------------|------------|
| Mkt. Cap. (HK\$ mn) | 31,493 |
| Avg. 3mths t/o (HK\$ mn) | 106.77 |
| 52W High/Low (HK\$) | 23.80/9.63 |
| Total Issued Shares (mn) | 1,500 |

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 | 4.2% | 5.7% |
| 3-mth | 55.5% | 55.0% |
| 6-mth | 95.4% | 64.5% |

Source: Bloomberg

12-mth price performance



Source: Bloomberg

Auditor: Ernst & Young

Web-site: www.innocarepharma.com

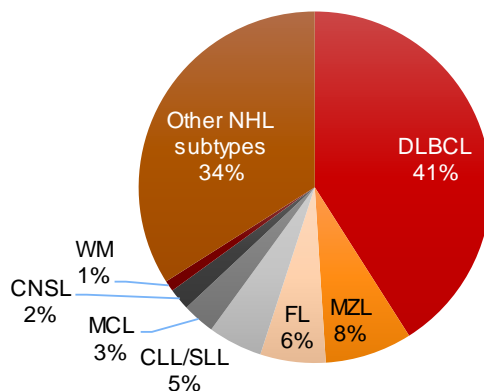
Related report:

- Entering into commercial stage – 29 Mar 2021
- Orelabrutinib received approvals for treating r/r-CLL/SLL and r/r-MCL in China – 29 Dec 2020
- Orelabrutinib to initiate trial in multiple sclerosis in US - 4 Nov 2020

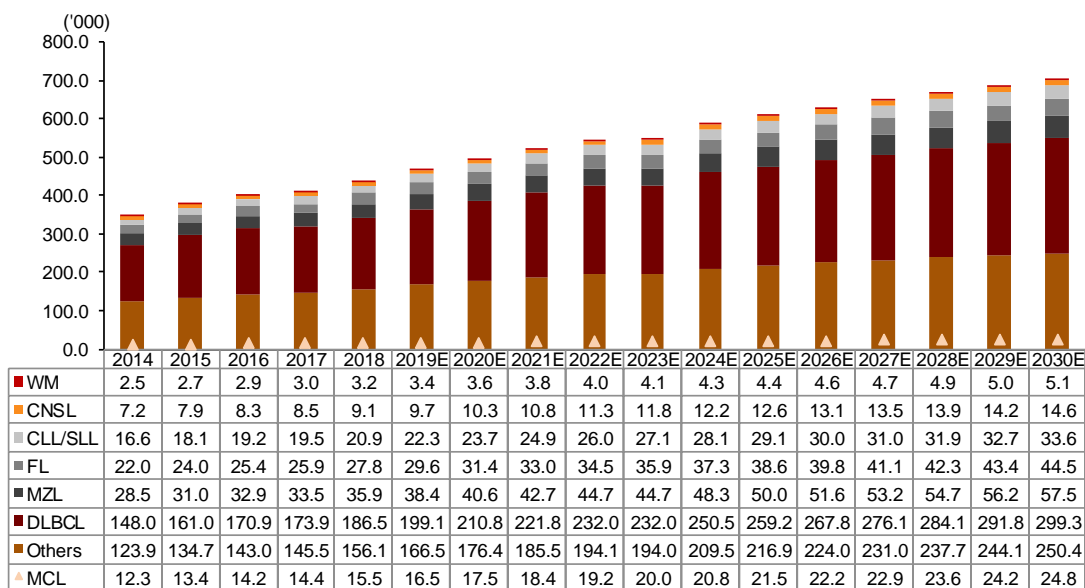
Figure 1: Comparison of NMPA-approved BTK inhibitors' clinical trial data on CLL/SLL

| | Orelabrutinib | | Ibrutinib | Zanubrutinib |
|---------------------|---------------------------|----------------------------|--------------------------------------|---------------------------|
| Source | 2020 ASH | 2021 中华医学会-全国 淋巴瘤疾病学术大会 | 2019 ASCO | 2019 ICML |
| Trial ID | ICP-CL-00103/ NCT03493217 | | RESONATE (PCYC-1112)/ NCT01578707 | BGB-3111-205/ NCT03206918 |
| Indication | r/r CLL/SLL | | r/r CLL/SLL | r/r CLL/SLL |
| N (patients on BTK) | 80 | | 195 | 91 |
| Phase | I/II | | III | II |
| Line of treatment | ≥2L | | ≥2L | ≥2L |
| Regimen | 150mg QD | | 420mg QD | 160mg BID |
| Median follow-up | 14.3m | 25.6m | 65.3m | 15.1m |
| ORR | 91.3% | 93.9% | 88.0% | 84.6% |
| CR | 10.0% | 21.3% | 11.0% | 3.3% |
| PR | 63.8% | 61.3% | 77.0% | 81.3% |
| PFS | NR | NR | 44.1m | NR |
| OS | - | - | 67.7m | - |

Source: Company data, ASH, ASCO, EHA, ICML, 中华医学会第一次全国淋巴瘤疾病学术大会, CMBIS

Figure 2: Prevalence of NHL Subtypes in China (2018)

Source: F&S, CMBIS

Figure 3: Prevalence of NHL Subtypes in China (2014-2030E)

Source: F&S, CMBIS

Figure 4: 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 (Data showed above are not from head-to-head comparative studies but extracted from some pooled analyses)

Figure 5: Valuation on risk-adjusted DCF valuation

| DCF Valuation (in Rmb mn) | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E | 2027E | 2028E | 2029E | 2030E |
|--------------------------------------|---------------|--------------|--------------|-----------|------------|--------------|--------------|--------------|--------------|---------------|
| EBIT | (409) | (271) | (68) | 245 | 804 | 1,423 | 1,811 | 2,072 | 2,312 | 2,571 |
| Tax rate | 0% | 0% | 15% | 15% | 15% | 15% | 15% | 15% | 15% | 15% |
| EBIT*(1-tax rate) | (409) | (271) | (58) | 208 | 684 | 1,210 | 1,540 | 1,761 | 1,965 | 2,185 |
| + D&A | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| - Change in working capital | 19 | (22) | (42) | (68) | (93) | (120) | (71) | (52) | (45) | (47) |
| - Capex | (100) | (60) | (60) | (60) | (60) | (60) | (60) | (60) | (60) | (60) |
| FCFF | (486) | (348) | (156) | 84 | 535 | 1,034 | 1,413 | 1,653 | 1,865 | 2,082 |
| Terminal value | | | | | | | | | | 53,120 |
| FCF + Terminal value | (486) | (348) | (156) | 84 | 535 | 1,034 | 1,413 | 1,653 | 1,865 | 55,202 |
| Present value of enterprise (RMB mn) | 25,673 | | | | | | | | | |
| Net Debt | (4,989) | | | | | | | | | |
| Minorities | 56 | | | | | | | | | |
| Equity value (RMB mn) | 30,606 | | | | | | | | | |
| Corporate value (HK\$ mn) | 36,875 | | | | | | | | | |
| # of shares outstanding | 1,499,673,235 | | | | | | | | | |
| TP per share (HK\$) | 24.59 | | | | | | | | | |
| Terminal growth rate | 5.0% | | | | | | | | | |
| WACC | 9.1% | | | | | | | | | |
| Cost of Equity | 11.2% | | | | | | | | | |
| Cost of Debt | 5.0% | | | | | | | | | |
| Equity Beta | 0.8 | | | | | | | | | |
| Risk Free Rate | 3.0% | | | | | | | | | |
| Market Risk Premium | 10.0% | | | | | | | | | |
| Target Debt to Asset ratio | 30.0% | | | | | | | | | |
| Effective Corporate Tax Rate | 15.0% | | | | | | | | | |

Source: CMBIS estimates

Figure 6: Earnings revision

| RMB mn | New | | | Old | | | Diff (%) | | |
|------------------|--------|--------|--------|--------|--------|--------|-----------|-----------|-----------|
| | FY21E | FY22E | FY23E | FY21E | FY22E | FY23E | FY21E | FY22E | FY23E |
| Revenue | 116 | 305 | 668 | 116 | 298 | 594 | 0% | 2% | 13% |
| Gross Profit | 93 | 250 | 555 | 93 | 244 | 493 | 0% | 2% | 13% |
| Operating Profit | (308) | (149) | 51 | (308) | (143) | 61 | N/A | N/A | -18% |
| Net profit | (309) | (150) | 42 | (309) | (144) | 51 | N/A | N/A | -18% |
| EPS (RMB) | (0.21) | (0.10) | 0.03 | (0.21) | (0.10) | 0.03 | N/A | N/A | -18% |
| Gross Margin | 80.00% | 82.00% | 83.00% | 80.00% | 82.00% | 83.00% | +0.00 ppt | +0.00 ppt | +0.00 ppt |

Source: Company data, CMBIS estimates

Figure 7: CMBIS estimates vs consensus

| RMB mn | CMBIS | | | Consensus | | | Diff (%) | | |
|------------------|--------|--------|--------|-----------|--------|--------|-----------|-----------|-----------|
| | FY21E | FY22E | FY23E | FY21E | FY22E | FY23E | FY21E | FY22E | FY23E |
| Revenue | 116 | 305 | 668 | 183 | 492 | 1,618 | -37% | -38% | -59% |
| Gross Profit | 93 | 250 | 555 | 143 | 415 | 1,364 | -35% | -40% | -59% |
| Operating Profit | (308) | (149) | 51 | (526) | (445) | 73 | N/A | N/A | -31% |
| Net profit | (309) | (150) | 42 | (482) | (336) | 431 | N/A | N/A | -90% |
| EPS (RMB) | (0.21) | (0.10) | 0.03 | (0.35) | (0.25) | 0.29 | N/A | N/A | -90% |
| Gross Margin | 80.00% | 82.00% | 83.00% | 78.28% | 84.22% | 84.33% | +1.72 ppt | -2.22 ppt | -1.33 ppt |

Source: Company data, 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 | 1 | 116 | 305 | 668 | Profit before tax | (2,150) | (464) | (309) | (150) | 49 |
| Orelabrutinib - risk adjusted | 0 | 0 | 116 | 305 | 598 | Depreciation and amortization | 9 | 4 | 4 | 4 | 4 |
| ICP-192 - risk adjusted | 0 | 0 | 0 | 0 | 70 | Change in working capital | 21 | (39) | 19 | (22) | (42) |
| ICP-105 - risk adjusted | 0 | 0 | 0 | 0 | 0 | Others | 2,040 | 78 | (68) | (88) | (127) |
| R&D services | 2 | 2 | 0 | 0 | 0 | Net income tax paid | 0 | 0 | 0 | 0 | (7) |
| Cost of sales | 0 | 0 | (23) | (55) | (114) | Net operating cash flow | (80) | (421) | (354) | (256) | (115) |
| Gross profit | 1 | 1 | 93 | 250 | 555 | Interest received | 0 | 97 | 101 | 122 | 119 |
| Other income | 104 | 271 | 203 | 153 | 151 | Purchases of PP&E | (45) | (200) | (100) | (60) | (60) |
| Selling & distribution expenses | (3) | (68) | (100) | (153) | (187) | Purchases of other intangible assets | (0) | 0 | 0 | 0 | 0 |
| R&D expenses | (213) | (403) | (400) | (275) | (334) | Net purchases of financial assets | 85 | 0 | 0 | 0 | 0 |
| Administrative expenses | (64) | (89) | (70) | (92) | (134) | Others | 8 | 32 | 2 | 2 | 2 |
| Other expenses | (160) | (34) | (34) | (34) | 0 | Net investing cash flow | 47 | (72) | 3 | 63 | 61 |
| Operating profit (loss) | (334) | (322) | (308) | (149) | 51 | Net proceeds from shares issued | 422 | 2,053 | 2,555 | 0 | 0 |
| Fair value changes of convertible redeemable preferred shares | (1,814) | (142) | 0 | 0 | 0 | Bank borrowing, net | (50) | 0 | 0 | 0 | 0 |
| Finance costs | (2) | (1) | (1) | (1) | (1) | Acquisition of non-controlling interests | 0 | 0 | 0 | 0 | 0 |
| Pre-tax profit (loss) | (2,150) | (464) | (309) | (150) | 49 | Others | (9) | (1) | (1) | (1) | (1) |
| Income tax | 0 | 0 | 0 | 0 | (7) | Net financing cash flow | 363 | 2,052 | 2,554 | (1) | (1) |
| Minority interests | 9 | 0 | 0 | 0 | 0 | FX changes | 18 | 0 | 0 | 0 | 0 |
| Attributable net profit (loss) | (2,141) | (464) | (309) | (150) | 42 | Net change in cash | 331 | 1,560 | 2,203 | (194) | (56) |
| | | | | | | Cash at the beginning | 1,245 | 2,292 | 3,970 | 6,172 | 5,978 |
| | | | | | | Cash at the end | 1,594 | 3,970 | 6,172 | 5,978 | 5,923 |

| 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 | 207 | 445 | 542 | 598 | 654 | Sales mix (%) | | | | | |
| PP&E | 48 | 306 | 405 | 463 | 522 | Orelabrutinib - risk adjusted | 0 | 0 | 100 | 100 | 89 |
| Goodwill | 3 | 3 | 3 | 3 | 3 | ICP-192 - risk adjusted | 0 | 0 | 0 | 0 | 11 |
| Other intangible assets | 37 | 37 | 37 | 36 | 36 | ICP-105 - risk adjusted | 0 | 0 | 0 | 0 | 0 |
| Right-of-use assets | 86 | 97 | 95 | 93 | 91 | R&D services | 100 | 100 | 0 | 0 | 1 |
| Investment in JVs | 1 | 1 | 1 | 1 | 1 | Total | 100 | 100 | 100 | 100 | 101 |
| Other non-current assets | 31 | 1 | 1 | 1 | 1 | | | | | | |
| Current assets | 2,409 | 4,092 | 6,192 | 6,031 | 6,036 | Profit & loss ratios (%) | | | | | |
| Inventories | 0 | 2 | 4 | 11 | 22 | Gross margin | 100 | 100 | 80 | 82 | 83 |
| Trade receivables | 0 | 0 | 13 | 33 | 73 | EBITDA margin | NA | NA | NA | NA | NA |
| Prepayments, other receivables & other assets | 37 | 121 | 3 | 8 | 18 | Pre-tax margin | NA | NA | NA | NA | 7 |
| Cash and cash equivalents | 2,292 | 3,970 | 6,172 | 5,978 | 5,923 | Net margin | NA | NA | NA | NA | 6 |
| Others | 80 | 0 | 0 | 0 | 0 | Effective tax rate | 0 | 0 | 0 | 0 | 15 |
| Current liabilities | 66 | 104 | 21 | 32 | 51 | Balance sheet ratios | | | | | |
| Trade payables | 8 | 6 | 6 | 15 | 31 | Current ratio (x) | 37 | 39 | 293 | 191 | 119 |
| Loans and borrowings | 0 | 0 | 0 | 0 | 0 | Trade receivables turnover days | NA | 40 | 40 | 40 | 40 |
| Other payables and accruals | 42 | 85 | 1 | 3 | 6 | Trade payables turnover days | NA | 100 | 100 | 100 | 100 |
| Lease liabilities | 6 | 0 | 0 | 0 | 0 | Net debt to total equity ratio (%) | Net cash | Net cash | Net cash | Net cash | Net cash |
| Loans from a related party | 9 | 7 | 7 | 7 | 7 | | | | | | |
| Others | 1 | 7 | 7 | 7 | 7 | Returns (%) | | | | | |
| Non-current liabilities | 5,498 | 1,273 | 1,307 | 1,340 | 1,340 | ROE | NA | NA | NA | NA | NA |
| Convertible redeemable preferred shares | 4,214 | 0 | 0 | 0 | 0 | ROA | (82) | (10) | (5) | (2) | 1 |
| Convertible loan | 1,117 | 1,150 | 1,183 | 1,217 | 1,217 | | | | | | |
| Loans and borrowings | 0 | 0 | 0 | 0 | 0 | | | | | | |
| Others | 167 | 123 | 123 | 123 | 123 | | | | | | |
| Total net assets | (2,948) | 3,161 | 5,406 | 5,256 | 5,298 | | | | | | |
| Minority interest | 57 | 56 | 56 | 56 | 55 | | | | | | |
| Shareholders' equity | (3,005) | 3,104 | 5,350 | 5,201 | 5,243 | | | | | | |

Source: Company data, CMBIS estimates

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