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CMB International Global Markets | Equity Research | Company Report

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ImmuneOnco (1541.HK)

Promising results of IMM01 released at ASCO

NOT RATED

Current Price	**HK$14.44**

China Healthcare

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ImmuneOnco is a clinical-stage biotech company focusing on innate immune systems. It has built a differentiated CD47-based portfolio with favourable safety and efficacy profiles. The Company has a rich pipeline with 8 drug candidates in clinical studies. The key product asset Timdarpacept (IMM01), a SIRPα-Fc Fusion protein targeting CD47, has moved to Ph3 studies, with three clinical-stage CD47-based bispecific molecules in clinical studies, including MM0306 (CD47×CD20), IMM2902 (CD47×HER2) and IMM2520 (CD47×PD-L1). Additionally, IMM2510（VEGF x PD-L1) and IMM27M (CTLA-4 ADCC+) are also being investigated in clinical studies. At 2024 ASCO meeting, ImmuneOnco had two oral presentations for IMM01, including 1) the latest Ph2 results of IMM01 combined with azacitidine (AZA) as the first-line treatment in adults with higher risk myelodysplastic syndromes (MDS, link), and 2) the latest Ph2 results of IMM01 in combination with tislelizumab in prior anti-PD-1 failed classical Hodgkin lymphoma (cHL, link).

- **Robust response of IMM01+AZA for 1L high-risk MDS**. Among the 51 efficacy evaluable MDS patients, IMM01+AZA demonstrated an ORR of 64.7%, including 33.3% CR, 15.7% mCR with hematologic improvement, 11.8% mCR and 3.9% HI alone. Among the 34 efficacy evaluable patients who received initial treatment ≥ 4 months, ORR increased to 85.3%, with 50.0% CR rate. For the 29 efficacy evaluable patients who received initial treatment ≥6 months, ORR further improved to 89.7%, with 58.6% CR rate. The median time to response was 1.9 months and the median DoR was not reached. 12-month OS rate was 71.1%. IMM01+AZA combination treatment led to significant recoveries of HGB and PLT, as well as the significant reduction in RBC or PLT transfusions. In terms of safety, in this Ph2 trial, TRAEs leading to treatment discontinuation occurred in 3 patients (5.3%) and only 1 patient had Grade 3 hemolysis reported but resolved after treatment.
- **Strong efficacy signals of IMM01+tislelizumab in anti-PD-1 failed cHL**. In 33 efficacy evaluable anti-PD-1 failed cHL patients (n=33), with a median follow-up of 6.87 months, IMM01+tislelizumab achieved ORR of 66.7% (22/33) with 24.2% (8/33) CR. 87.9% (29/33) of patients had target lesion size reduction. mPFS and mDOR were not reached. IMM01+tislelizumab also demonstrated a tolerated safety profile for cHL, with most of the TRAEs being grade 1-2 hematologic toxicities. The most common 3-4 TRAEs included WBC decreased (12.1%), PLT decreased (12.1%), ANC decreased (12.1%) and anemia (6.1%), which were full recovery or recovery to grade 1/baseline level after symptomatic treatment. There was no hemolysis event reported, and no patients experienced TRAEs leading to the study drug discontinuation or death.
- **Ph3 studies on the way for further validation.** The promising efficacy and well-tolerated safety profile observed in the Ph2 trials of IMM01 warrants the initiation of Ph3 studies to further validate its potential. IMM01 has recently received approvals from CDE to conduct Ph3 clinical trials in 1L high-risk MDS (+AZA), PD-1-failed cHL (+tislelizumab), as well as in combination with AZA for the first-line chronic myelomonocytic leukemia (CMML). We expect the Company to file a BLA for IMM01 for treatment of cHL in 2026, with potential to become the first CD47 targeted therapy in China.

Earnings Summary

(YE 31 Dec) (RMB mn)	FY21A	FY22A	FY23A
Revenue	5	1	0
R&D expenses	(176)	(277)	(292)
Admin expenses	(48)	(93)	(80)
Net profit/loss	(733)	(403)	(379)
Year-end cash balance	676	635	609

Source: Company data

Stock Data

Mkt Cap (HK$mn)	5,403
Avg 3-mths t/o (HK$mn)	4.04
52w High/Low (HK$)	32.15/13.58
Total Issued Shares (mn)	229

Source: FactSet

Shareholding Structure

Tian Wenzhi	15.35%
Halo Biomedical Investment	7.88%

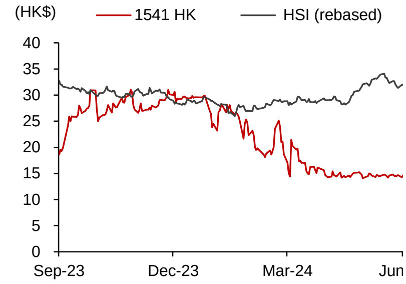
Source: Bloomberg

Share Performance

	Absolute	Relative
1-mth	4.3%	4.6%
3-mth	-2.5%	-14.5%
6-mth	-52.2%	-57.6%

Source: FactSet

12-mth Price Performance



Source: FactSet

Website: http://cn.immuneonco.com/

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