Akeso

HARMONi-GI1 Positive but OS Upside Capped by Strong Control Arm; SSGJ-707 Supports PD-1/VEGF Class Read-Across

Overweight

9926.HK, 9926 HK
Price (23 Oct 26):HK$86.60

Price Target (Dec-27):HK$125.00

Healthcare

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Akeso's HARMONi-GI1 Ph3 data in 1L BTC (biliary tract cancer) were clinically positive, with ivonescimab-chemo delivering a statistically significant OS benefit vs. durvalumab-chemo. While the OS HR came in below our prior bull-case scenario (see note), the absolute mOS delta of 2.8 months compares favorably with TOPAZ-1's 1.3-month mOS improvement, which was sufficient to support approval and establish durvalumab-chemo as SoC. We also note that Summit and ECOG-ACRIN have initiated the global registrational Ph2/3 EA2251 study of ivonescimab plus chemotherapy versus pembrolizumab- or durvalumab-chemo in 1L advanced BTC, which should help validate global applicability of the China HARMONi-GI1 data. Separately, SSGJ-707/PF'4404's 1L NSCLC Ph2 ESMO data provide supportive PD-1/VEGF class read-across, but given the dataset remains open-label and relatively immature, we would still wait for Ph3 validation before drawing firm conclusions on the competitiveness of PF'4404 versus ivonescimab.

- **Positive HARMONi-GI1 1L BTC readout; OS magnitude below our bull case, but absolute benefit looks meaningful vs. TOPAZ-1:** HARMONi-GI1 randomized 682 patients and showed a statistically significant OS benefit for ivonescimab-chemo vs. durvalumab-chemo, with median OS of 14.9 vs. 12.1 months, HR 0.75, 95% CI 0.61–0.92, P=0.0031. Secondary endpoints were more pronounced, with median PFS of 8.4 vs. 5.8 months, HR 0.61, P<0.0001, and ORR of 53.8% vs. 32.5%, P<0.0001. Overall, we view the data as clinically positive, especially given durvalumab-chemo is an active standard-of-care comparator rather than chemotherapy alone. The magnitude of benefit was below the more bullish scenario in our prior preview, where we saw potential for OS HR of ≤0.6 if the earlier Ph2 signal translated cleanly into Ph3. The ivonescimab arm was broadly in line with expectations, albeit slightly below the Ph2 mOS of 16.8 months, while the control arm performed materially better than the TOPAZ-1 China subgroup benchmark we referenced, where mPFS and mOS were 4.7 and 9.1 months, respectively. This stronger-than-expected control performance likely narrowed the relative treatment effect. That said, the absolute mOS improvement of 2.8 months for ivonescimab-chemo versus durvalumab-chemo appears clinically meaningful, particularly when compared with TOPAZ-1, where the mOS delta was only 1.3 months but still supported approval and established durvalumab-chemo as SoC. We also view the Summit/ECOG-ACRIN global registrational EA2251 study - evaluating ivonescimab plus chemotherapy vs. pembrolizumab- or durvalumab-chemo in 1L advanced BTC - as an important next step to test whether the China HARMONi-GI1 signal can translate globally.
- **SSGJ-707/PF'4404 read-across: supportive for PD-1/VEGF class, but still too early to call Ph3-level competitiveness:** The SSGJ-707 / PF-08634404 1L NSCLC Ph2 ESMO dataset looks supportive for the PD-1/VEGF bispecific class. PF'4404 plus platinum-based chemotherapy showed higher confirmed

See page 5 for analyst certification and important disclosures, including non-US analyst disclosures.

ORR than tislelizumab-chemo in non-squamous NSCLC, at 75.0% vs. 44.7%, and numerically favorable 12-month PFS, at 56.0% vs. 43.0%. In squamous NSCLC, PF'4404 plus carbo/pac achieved cORR of 82.5% and 12-month PFS of 48.0%, while PF'4404 plus carbo/nab-pac showed cORR of 69.2% and 12-month PFS of 54.2%, vs. tislelizumab-chemo cORR of 67.7% and 12-month PFS of 24.5%. This appears comparable vs. HARMONi-6's updated PFS of 12.48mos (see note), though the PF'4404 dataset remains Ph2, open-label and relatively immature, so we would avoid over-extrapolating vs. ivonescimab's more advanced randomized evidence base.



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Investment Thesis, Valuation and Risks

Akeso *(Overweight; Price Target: HK$125.00)*

Investment Thesis

Akeso is a commercial-stage biotech in China and a leader in bispecific antibody. We expect the company's future growth to be driven by: (1) AK104 (PD-1/CTLA-4): Indication expansion into a broad range of large markets in China, which we expect to generate ~Rmb7bn in China peak sales. (2) AK112 (PD-1/VEGF): Successful inclusion in the NRDL, which should unleash solid sales momentum with >Rmb7bn peak sales in China, and its leading position in the PD-(L)1/VEGF space, as well as a highly competitive efficacy profile vs. Keytruda should support ex-China peak sales of US$5+bn.

Valuation

Our Dec-27 PT of HK$125 is based on our DCF valuation. We estimate free cash flow for Akeso until 2034, assuming a terminal growth rate of 3.0% and a WACC of 9.6%.

Figure 2: DCF valuation

WACC Assumptions	
Risk-free rate	3.8%
Market risk	6.6%
Beta	1.0
Cost of equity	**10.4%**
Cost of debt	*3.0%*
Liabilities as a % of EV	*10%*
WACC	**9.6%**

WACC	9.6%
Terminal growth rate	3.0%
Terminal Present Value	61,780
PV Cash Flow	24,180
Enterprise value	**85,961**
+ Cash balance	10,206
- LT Debt	(4,541)
- Minority Interest	(162)
Early pipeline assets	9,000
Akeso equity value (RMB mn)	**100,787**
+ SMMT equity value (Rmb mn)	**3,288**
Total equity value (Rmb mn)	104,075
Shares Outstanding (MM)	**921**
Per Share Value (RMB)	**113.0**
Per Share Value (HKD)	**125**

Source: J.P. Morgan estimates.

Risks to Rating and Price Target

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Key downside risks include: (1) pipeline development setbacks; and (2) sales of AK104 or AK112 are below our expectations.