

Takeda Pharm. (4502)

Positive take on TAK-861 meeting primary endpoint in P2b NT1 trial

Maintain Rating: BUY | PO: 5,000 JPY | Price: 4,199 JPY

TAK-861 shows efficacy and safety in P2b trial in NT1

Before the start of trade on 9 February, Takeda Pharmaceutical issued a press release concerning topline results from a Phase 2b study evaluating TAK-861, an oral orexin receptor 2 (OX2R) agonist, in patients with narcolepsy type 1 (NT1). The study met its primary endpoint, with TAK-861 found to be generally safe and well tolerated. This will allow Takeda to rapidly initiate Phase 3 trials, which we view as a positive. We maintain our ¥5,000 price objective (PO) and Buy rating.

Primary endpoint of MWT met, with TAK-861 demonstrating clinically meaningful improvement

The primary endpoint in the Phase 2b study (TAK-861-2001) was the Maintenance of Wakefulness Test (MWT), on which the drug demonstrated statistically significant and clinically meaningful improvement compared to placebo at week 8. Improvements in key secondary endpoints including Epworth Sleepiness Scale (ESS) and Weekly Cataplexy Rate (WCR) also were statistically significant and clinically meaningful, consistent with the primary endpoint.

Safety profile: No reports of hepatotoxicity or visual disturbances

Development of an earlier narcolepsy drug, TAK-994, had been halted owing to reports of severe hepatotoxicity. In the Phase 2b study of TAK-861, however, there were no reports of hepatotoxicity or visual disturbances. The study enrolled 112 participants, and the absence of safety concerns in this relatively high number is reassuring.

Takeda estimates peak sales potential of \$3–4bn in NT1

For drugs in its narcolepsy program, Takeda estimates peak sales potential of \$3–4bn for the indication of NT1 and \$1–2bn for NT2 and idiopathic hypersomnia (IH). In the press release, while Takeda reported favorable results for NT1, it does not plan to advance TAK-861 in NT2. The company did not explain the reason behind this decision; we need to wait for release of the full set of data at an academic conference. Takeda did note that there is a lack of orexin in NT1, while orexin levels are generally normal in NT2. It accordingly believes OX2R agonist development for NT2 could be more challenging.

09 February 2024

Equity

Koichi Mamegano >>
Research Analyst
BofAS Japan
koichi.mamegano@bofa.com

Haruhiko Yokota >>
Research Analyst
BofAS Japan
haruhiko.yokota@bofa.com

Stock Data

Price (Common / ADR)	4,199 JPY / 14.00 USD
Price Objective	5,000 JPY / 17.20 USD
Date Established	25-Oct-2023/ 25-Oct-2023
Investment Opinion	A-1-7 / B-1-7
52-Week Range	3,900-4,873 JPY
Market Value (mn)	6,591,872 JPY
Market Value (\$mn)	44,116 USD
Shares Outstanding (mn)	1,569.9
Average Daily Value (\$mn)	125.0 USD
Free Float	95.6%
BofA Ticker / Exchange	TKPHF / TYO
BofA Ticker / Exchange	TAK / NYS
Bloomberg / Reuters	4502 JP / 4502.T
ROE (2024E)	3.7%
Net Dbt to Eqty (Mar-2023A)	60.0%

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Timestamp: 08 February 2024 09:06PM EST

Price objective basis & risk

Takeda Pharm. (4502 / TKPHF / TAK)

We base our JPY5,000 PO (ADR: \$17.20) on our 12-year DCF model and also taking into account valuations such as P/E and P/B. Our DCF assumptions are risk-free rate 1.0%, equity risk premium 5.5%, terminal growth 1.0% and tax rate 40%. Individual company FCF risk is reflected in the stock beta, which takes into account quantitative risk based on new drug development scenario analysis and qualitative risk based on factors such as management strategies, and is set at a tiered level within the sector. We use the Bloomberg two-year adjusted beta of 0.68, and base our price objective for the company on a stock beta of 0.76, and WACC of 3.9%. Our PO equates to a P/E of 11x our FY3/24 Core EPS forecast. Upside risks are favorable new drug pipeline data and better-than-expected progress in cost reductions. Downside risks are a cancellation or postponement of new product development or changes in product evaluation, inaccuracy in our DCF assumptions and higher-than-expected impairment losses on intangible assets.

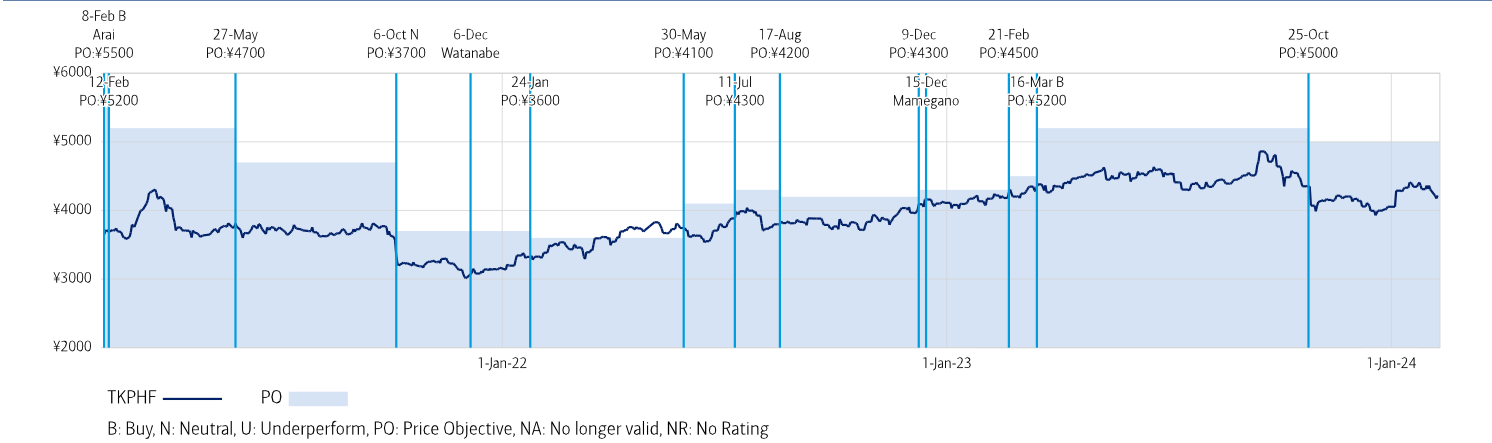
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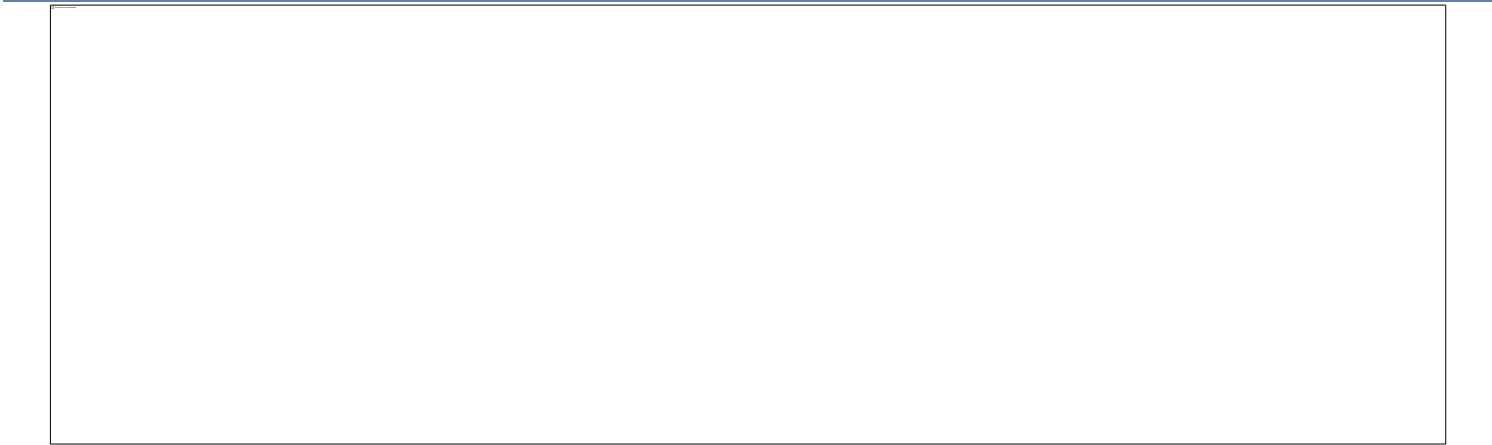
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Takeda Pharm. (TKPHF) Price Chart



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Takeda Pharm. (TAK) Price Chart



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Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	Count	Percent
Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18.23%	Sell	29	41.43%

Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

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Investment rating	Total return expectation (within 12-month period of date of initial rating)	Ratings dispersion guidelines for coverage cluster ^{R2}
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Underperform	N/A	≥ 20%

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