BofA SECURITIES

Eli Lilly and Company

Advisory Committee meeting on Alzheimer's unexpected, but not surprising

Maintain Rating: BUY | PO: 1,000.00 USD | Price: 780.16 USD

Breaking News

- FDA announced it plans to hold an Advisory Committee to discuss the safety + efficacy of Lilly's Alzheimer's drug, donanemab
- We don't have a clear line of sight into timing, but expect it will take months for FDA to convene the panel
- While unexpected, we remain confident in a positive outcome, particularly as other a-beta therapies also had panels

Donanemab regulatory delay is just a hiccup

This morning, Lilly announced that FDA plans to hold a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) to discuss its Alzheimer's drug, donanemab, pivotal results in the TRAILBLAZER-ALZ 2 study. At a high level, we remain confident in donanemab's regulatory package and while hosting the Advisory Committee (AdComm) meeting this late in the cycle is unexpected, it's not surprising FDA wants to discuss the safety and efficacy of donanemab given the risk/ benefit of patients and prescriber feedback on Biogen/ Eisai's Leqembi. Indeed, when we caught up with management this morning, they stressed that while an AdComm meeting was unexpected as the PDUFA date was close (sometime in 1Q), given prior anti-amyloid therapies have had AdComms it's not surprising FDA also wanted to host a meeting, particularly given the unique trial design (e.g., tau stratification and the potential to stop dosing upon hitting prespecified targets). Nevertheless, management remains confident in donanemab's regulatory package, especially as FDA has not received any new information. In terms of timing, management expects it will likely take months before a meeting convenes, which makes sense to us based on precedent. While we think donanemab's efficacy is best-in-class, we've remained cautious on the commercial opportunity (see our thoughts on Lilly here) as we'd argue there's still a lot more wood-to-chop in the commercial market (see below), as highlighted by Leqembi's mixed uptake. We maintain Buy and our $1000 PO as this bump in the road doesn't impact Lilly's growth thesis.

Still more work to do commercially

In our view, Lilly has done a good job setting commercial expectations (see our report following Lilly's AAIC presentation), in our view, including the need for 1) cognitive assessment tools + advanced diagnostics, 2) simple commercial access, and 3) ongoing patient monitoring for safety + to determine when to stop therapy. Indeed, we suspect it will take 2-3 years for the commercial opportunity to play out, which has been echoed by Lilly's management team. In fact, we see a net benefit of having two approved Alzheimer's drugs on the market, as the combined commercial might of Lilly + Biogen/ Eisai should accelerate prescriber education + infrastructure build.

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08 March 2024

Equity

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Stock Data

Price	780.16 USD
Price Objective	1,000.00 USD
Date Established	1-Mar-2024
Investment Opinion	B-1-7
52-Week Range	309.32 USD - 800.78 USD
Mrkt Val (mn) / Shares Out (mn)	741,280 USD / 950.2
Free Float	89.4%
Average Daily Value (mn)	2782.86 USD
BofA Ticker / Exchange	LLY / NYS
Bloomberg / Reuters	LLY US / LLY.N
ROE (2024E)	81.8%
Net Dbt to Eqty (Dec-2023A)	205.2%
ESGMeter™	High

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Abbreviations:

PDUFA: Prescription Drug User Fee Act

a-beta: amyloid beta

AAIC: Alzheimer's Association International Conference

Price objective basis & risk

Eli Lilly and Company (LLY)
Our $1000 price objective is based on a probability-adjusted net present value (NPV) analysis of franchise verticals including Endocrinology ($691/share), Oncology ($135/share), Cardiovascular ($4/share), Neuroscience ($14/share), Immunology ($46/share), other pharmaceutical products and early pipeline assets ($128/share), as well as approximately -$17/share in net cash. We use a WACC ranging from 5% for approved products to 8% for pipeline products, depending on the stage of development. We apply terminal values ranging from -12% (cardiology) to 1% (endocrinology) based on projected sales decline following loss of exclusivity within each business vertical.

Risks to our price objective are 1) better-than-expected launches of competing products, 2) emerging clinical data for pipeline assets that does not confirm prior observations, 3) failure to effectively commercialize approved products, 4) potential drug pricing system restructuring in the US.

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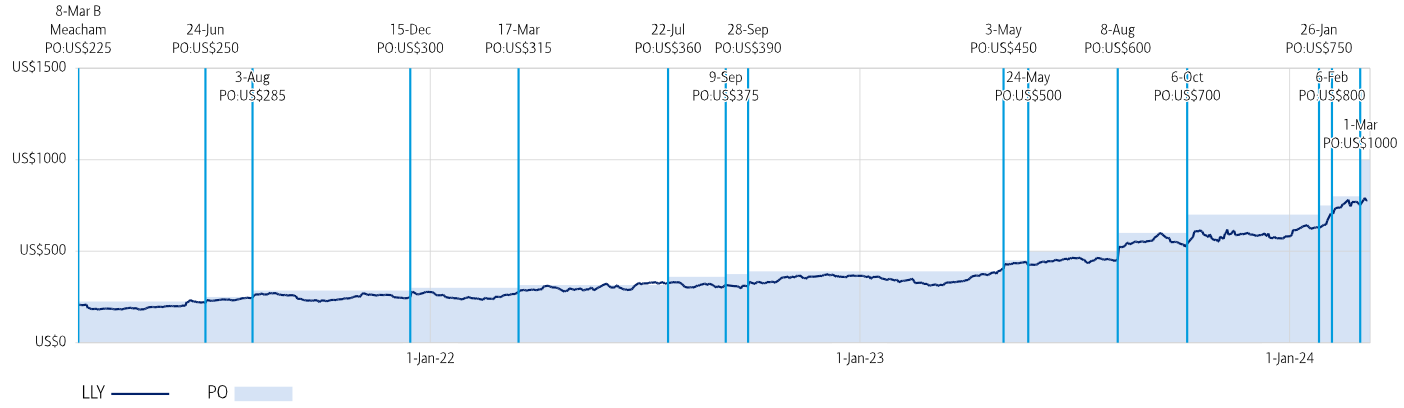
Eli Lilly (LLY) Price Chart



B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

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

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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