BofA SECURITIES

Moderna

Puts and Takes for mRNA-1345 outlook from our KOL discussions

Maintain Rating: NEUTRAL | PO: 120.00 USD | Price: 91.14 USD

Data presented at RSVVW'24 doesn't paint the full picture

Over the last week, MRNA shares have been weak (YTD: -8%; NBI index: +2%) following a preliminary RSVVW'24 abstract data showing that the efficacy of mRNA-1345 appeared to wane more quickly than competitors with 63.3% (from 83.7%) and 63.0% (from 82.4%) efficacy against RSV-LRTD with ≥2 and ≥3 symptoms at a median follow-up of 8.6 months. That said, following full mrNA-1345 data released today and comparing to Pfizer's and GSK's data from the June ACIP meeting last year, we argue that the overall efficacy as well as degree of waning efficacy fall within comparable ranges for cross-trial studies. Importantly, in our view, the key focus should be on what ACIP's recommendation will be – specifically if there will be a preferential recommendation for mRNA-1345 on the basis of GBS risk, a less favorable recommendation on potential for faster waning efficacy with mRNA-1345, or no preferential recommendation either way. Based on our discussions with KOLs, we think there is still a lot of work to do on growing the RSV market (see our recent 4Q GSK results read-through), and think a call either way ahead of ACIP would be challenging on clinical data presented to date alone. That said, we think the adult RSV market has been more robust than initially forecasted with both GSK and Pfizer's RSV vaccines beating consensus estimates over the last couple of quarters. Overall, we take a more sideline view of mRNA-1345 ahead of ACIP recommendations but are cautiously optimistic about the opportunity for RSV vaccinations over the long term. We anticipate mRNA-1345 will receive approval by April, ahead of the June ACIP later this year. Maintain Neutral on MRNA, $120 PO.

Clinical considerations

In line with Moderna's statement on unreliability of cross-trial comparisons across seasons, multiple experts we spoke to agreed that seasonal variation in RSV infection rates could skew data. A more rigorous approach on viewing the data would require two seasons of data for mRNA-1345 and a level of neutralizing antibody titers, which correlate with vaccine efficacy. Furthermore, we maintain that mRNA vaccine technology has been shown to be associated with a lower risk of GBS as compared to vector vaccine technologies for both COVID-19 and flu. Unlike Pfizer and GSK's trials where GBS cases were reported, Moderna has shared that no cases of GBS have been reported by patients enrolled in the trial. Still, we'd note that some experts pushed back on drawing conclusions on long-term safety and suggested that GBS events could still be reported as more patients are vaccinated with mRNA-1345 in the real world.

Commercial considerations

Beyond clinical data, however, we note that multiple experts we've talked to highlighted the commercial dynamics underlying current uptake. Overall variations in efficacy and safety events seem to play less of a role in uptake than the Street has suggested, with our channel checks suggesting that PBM contracting and access have a far greater influence on market share – assuming ACIP recommendation for all RSV vaccines is at parity. We think, ultimately, RSV vaccine uptake will be influenced more by reimbursement, all other clinical factors fairly comparable. With at least a one-year lead on commercialization and experience with contracting, we think the large pharma companies, GSK and Pfizer, have an advantage in this aspect.

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15 February 2024

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Stock Data

Price	91.14 USD
Price Objective	120.00 USD
Date Established	3-Jan-2024
Investment Opinion	C-2-9
52-Week Range	62.55 USD - 177.37 USD
Mrkt Val (mn) / Shares Out (mn)	34,750 USD / 381.3
Free Float	87.8%
Average Daily Value (mn)	382.70 USD
BofA Ticker / Exchange	MRNA / NAS
Bloomberg / Reuters	MRNA US / MRNA.OQ
ROE (2024E)	-22.2%
Net Dbt to Eqty (Dec-2023A)	-10.8%
ESGMeter™	High

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Abbreviations:
ACIP: Advisory Committee on Immunization Practices
GBS: Guillain-Barré syndrome
KOL: key opinion leader
PBM: pharmacy benefit manager
RSV: Respiratory syncytial virus
RSV-LRTD: RSV-associated lower respiratory tract disease

RSVVW'24: Global Conference on Novel RSV Preventive and Therapeutic Interventions

RSV-LRTD: RSV-associated lower respiratory tract

Price objective basis & risk

Moderna (MRNA)
Our PO of $120 is based on a probability-adjusted NPV of six different parts including prophylactic vaccines ($91/share), systemic secreted cell surface therapeutics ($1/share), cancer vaccines ($4/share), intratumoral immune-oncology ($2/share), cardiovascular diseases ($0/share) and systemic intracellular therapeutics ($1 share), and net cash ($22/share). We estimate sales of 46 pipeline programs that are slated to move forward with probability of success ranging from 6% to 95%. We use a WACC of 10% and terminal growth rate of -30%.

Upside risks to our PO are: 1) faster than expected pipeline development, 2) cleaner than expected safety findings, 3) accelerated product approvals, 4) stronger than expected launches, 5) lower competition, 6) moderating cash burn, and 7) potential upside from coronavirus vaccine program.

Downside risks to our PO are: 1) lower than expected revenues from the COVID-19 program, 2) unexpected safety findings, 3) slower than expected pipeline development/approvals, 4) more intense competition, and 5) accelerating cash burn.

Analyst Certification

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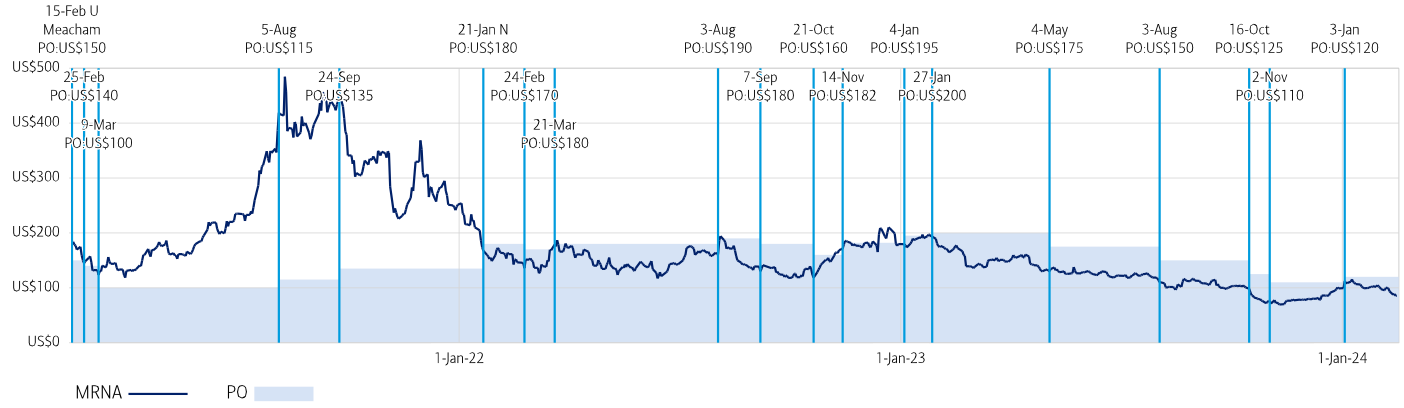
Moderna (MRNA) Price Chart



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

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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
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Sell	807	22.84%	Sell	383	47.46%

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Buy	≥ 10%	≤ 70%
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Underperform	N/A	≥ 20%

[R2]Ratings dispersions may vary from time to time where BofA Global Research believes it better reflects the investment prospects of stocks in a Coverage Cluster.

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