

AstraZeneca

GILD fails in 2L lung; Helps competitive debate; Still confident TL01

Maintain Rating: BUY | PO: 14,500 GBp | Price: 10,508 GBp

GILD's EVOKE-01 Trodelvy 2L lung misses OS; Helps AZN

Gilead Trodelvy's PIII EVOKE-01 data (2nd line lung study, equivalent to AstraZeneca's (AZN) datopotamab TL01) has missed its OS primary endpoint, largely as we had expected, a directional positive for AZN's datopotamab. Forming conclusions is difficult pending detailed data (highlights discussed in paragraph below), but some initial headline thoughts include: 1) We had flagged risk to the EVOKE study given AZN's study also missed OS. AZN's TL01 had dual co-primary PFS and OS endpoints, while for EVOKE-01, OS was the only primary; 2) There is no PFS data available for GILD, with positive PFS data the basis for AZN's filing. As a reminder, no detriment in OS is all that AZN communicate is needed for approval, though AZN is close to stat sig OS benefit in the non-squamous subgroup, the subgroup most likely approved; 3) GILD does note a benefit in both squamous and non-squamous patients, with AZN's benefit entirely driven by non-squamous with an adverse trend in sq. The differences will be a focus for detailed data; 4) GILD does cite a >3m OS benefit in a subgroup (60% of patients) non-responsive to prior IO, though we need to understand this better vs a 2L population in TL01 of which c90% had prior IO; 5) GILD regulatory pathway commentary is non-committal with only discussion of data with regulators; 6) GILD sees Trodelvy differentiated vs Dato on ILD and stomatitis, but we flag Trodelvy generally viewed by physician's as tougher safety. Maintain Buy. *See thesis below.*

We remain confident TL-01 approval and launch in totality

We see GILD mixed data as positive for AZN as delaying a potential key competitor, and particularly in light of recent GILD commentary on upcoming data. Next TL01 milestones include: 1) Acceptance of filing 1Q24; 2) Clarification of final OS timing 1H24, in our opinion; 3) Final approval 2H24, with our focus the non-squamous subgroup; 5) Commercial launch to confirm >\$2bn sales potential.

Dato TL-01 likely approval in non squam; usage in majority

As a reminder, we hosted a [lung cancer doc on Friday](#) (see report link). with feedback below. Our KOL was directionally positive Dato TL-01, with non-squamous PFS HR solid, and saw likely approval in the non-squamous population. If OS continues to mature at a similar Hazard Ratio (0.77) would be sufficient to see usage in the majority of patients given clin meaningful PFS (HR 0.63), and safety directionally better than docetaxel. Our KOL raised questions on the EVOKE-01 competition given OS primary endpoint. Reasons for potentially different data in squamous patients was also discussed.

Optimistic Dato opp in 1L, with PII data strong

Overall, our KOL was optimistic the Dato opp in 1L lung cancer, seeing TROPION-Lung02, and TROPION-Lung04 data (Dato combo Imfinzi and Keytruda NSCLC) data supportive of confidence. Saw TROPION-Lung02 response rates promising and durable, though focus more on PFS and OS data. Target was a 3-4m PFS benefit for 1L data, higher than the 1.9m benefit in TL-01, which he sees as entirely possible.

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Timestamp: 22 January 2024 09:53AM EST

22 January 2024

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Stock Data

Price (Common / ADR)	10,508 GBp / 66.54 USD
Price Objective	14,500 GBp / 88.00 USD
Date Established	5-Dec-2022 / 5-Dec-2022
Investment Opinion	A-1-7 / B-1-7
52-Week Range	9,851 GBp-12,390 GBp
Market Value (mn)	162,891 GBP
Shares Outstanding (mn)	1,550.2 / 3,100.3
Average Daily Value (mn)	153.29 USD
Free Float	100.0%
BofA Ticker / Exchange	AZNCF / LSE
BofA Ticker / Exchange	AZN / NYS
Bloomberg / Reuters	AZN LN / AZN.L
ROE (2023E)	28.5%
Net Dbt to Eqty (Dec-2022A)	58.8%
ESGMeter™	High

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Best GARP with Best pipe. 24 guide & catalyst path debate

Maintain Buy on AZN for attractive valuation (14.5x 25E PE) for premium growth prospect (12% FY25-28 EPS CAGR), with best-in-class mid-stage pipeline. We see two near-term clearing events; 1) 24 EPS guide (which we now see as less risky, as above), and 2) Dato filing and approval. While the catalyst path is quieter than FY23; 1) We believe lack of binary events attractive for investors to re-engage; 2) The catalyst path is still busy relative to EU pharma broadly and discussed below (with most important Imfinzi and Capivasertib beats, Dato 2L lung launch, Enhertu DB06, Tagrisso LAURA). From mid-year we see a big FY25 path coming into focus: Enhertu DB09/11, Camizestrant SERENA-6, first Eplontersen data and potential Dato 1L lung read.

Glossary

PIII = Phase 3

ESMO = European Society of medical Oncology

OS = Overall Survival

TL = TROPION-Lung

IO = Immuno-oncology

GILD = Gilead

PFS = Progression Free Survival

HR = Hazard Ratio

KOL = Key Opinion Leader

1L = First line

NSCLC = Non small cell lung cancer

G5 = Grade 5

AE = Adverse Events

Price objective basis & risk

AstraZeneca (AZNCF / AZN)

Our PO of GBP145 (US\$88) is based on c19x FY25E PE, ahead of our target sector multiple of c16x due to potential for premium growth (11% 25-28E EPS CAGR vs sector c7%) and significant pipeline optionality.

Our target sector multiple of c16x 25E PE is based on: 1) A 40% premium to the market average multiple which implies c15x 25E PE, a premium which is in line with the long-term historical trend for periods of growth for the sector during times of broader market uncertainty, 2) Regression analysis of historical sector forward PEs and three-year-forward EPS CAGR implies a target PE of c16x 25E PE based on sector growth of c7%, 3) Our DCF valuations imply c17x 25E PE

Upside risks to our PO are better-than-expected EPS momentum driven by better execution on product launches and pipeline success.

Downside risks to our PO are pipeline failure, risk of litigation, adverse currency moves, greater margin pressure driving EPS miss and a failure to inflect key product launches.

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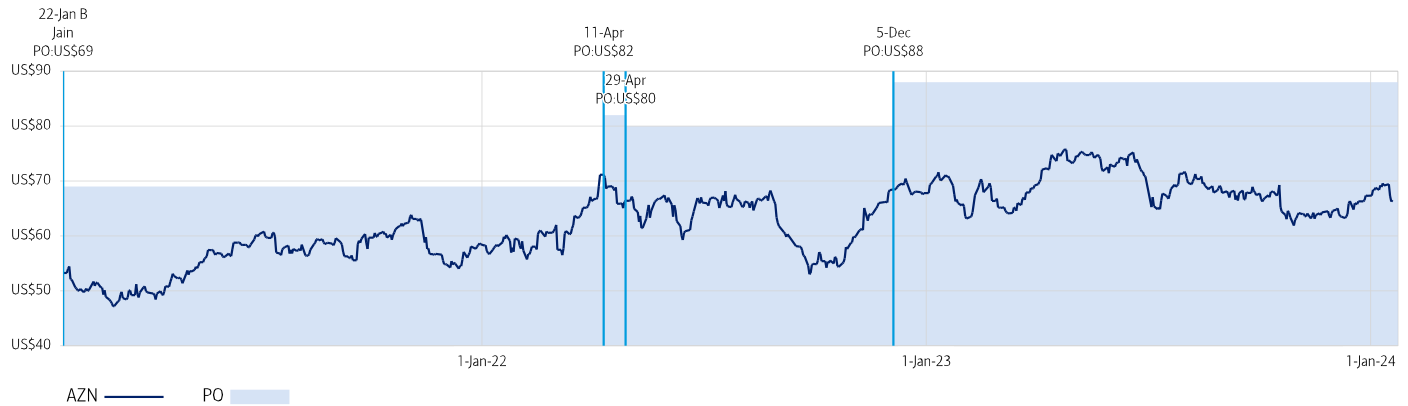
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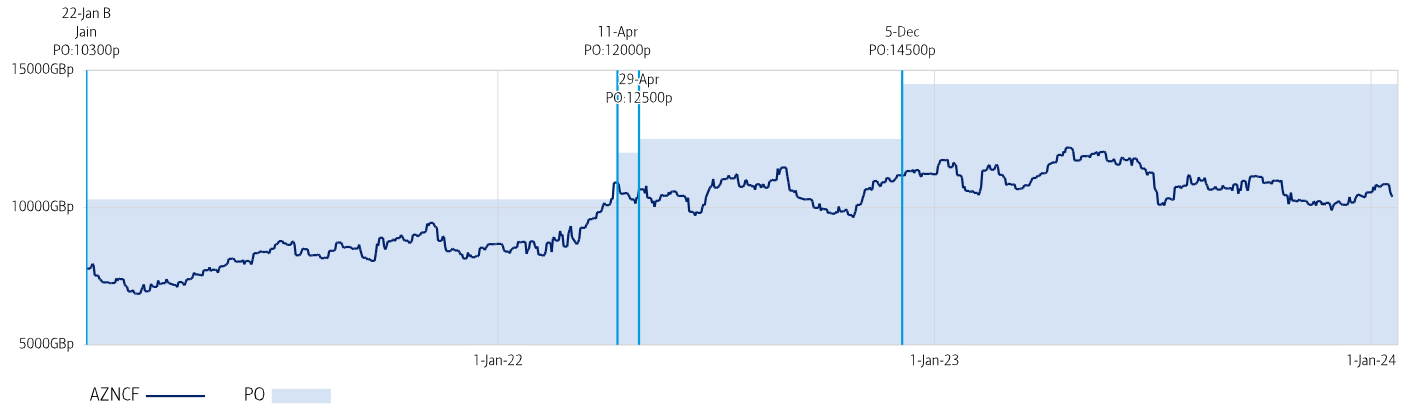
AstraZeneca (AZN) Price Chart



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

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AstraZeneca (AZNCF) 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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