

## AstraZeneca

# 3 lung positives: Tagrisso Laura hits, TL01 file accepted, FLAURA2 OS and approval

Maintain Rating: BUY | PO: 14,500 GBp | Price: 10,094 GBp

## Tagrisso Laura hits, TL01 file accepted, FLAURA2 approval

There are 3 pieces of positive and important newsflow this morning, which should help shares from recent lows. As a reminder, we recently hosted a bull-bear debate on AZN, [see report summarising debate](#). Key newsflow includes: 1) Tagrisso LAURA (stage III unresectable EGFRm NSCLC post CRT) "overwhelming" positive and a c\$1bn opportunity. We see LAURA as underpinning cons, not necessarily upside, helping offset multiple competitive debates; 2) Datopotamab TL01 file accepted, a small positive with a 4Q24 PDUFA. Importantly, AZN indicating no request for an adcom at this stage and final OS continues to be expected within review cycle. As a reminder, no detriment in OS all that needed according to AZN, and FDA comfortable looking at non-squamous subgroup; 3) Tagrisso FLAURA 2 (chemo combo 1L) approved and added to NCCN guidelines at category 1, with more mature OS now much better (HR 0.75 vs 0.9, and likely significant at final analysis). Time advantage vs JNJ Mariposa and OS higher hurdle. Maintain Buy, *see thesis overleaf*.

## TL01 file accepted, no adcom indicated, 4Q24 PDUFA

Datopotamab TL01 file accepted, a small positive with a 4Q24 PDUFA, with no adcom requested/ signaled as yet. As a reminder, as part of our bull/bear debate, investor concerns on datopotamab 2L lung approval remain the biggest debate on the stock, in our opinion. Investors see three drivers of risk of approval; a) OS, where some investors believe stat sig improvement needed, contrary to AZN commentary of no detriment needed; b) Non squamous wasn't a prespecified subgroup (although a stratification factor), with our understanding that FDA comfortable looking at non-squamous c) GILD Trodelvy data showing different subgroup efficacy, driving potential biology debate at FDA (though we believe simply linked to different linker/potency).

## Tagrisso LAURA PIII hits. \$1bn opp, underpins cons

AZN also announced its Tagrisso LAURA PIII trial demonstrated a statistically significant and highly clinically meaningful improvement in PFS. LAURA is a PIII trial assessing Tagrisso in stage III unresectable EGFRm NSCLC post CRT. A favourable trend towards OS was demonstrated, although data was not mature.

## Tagrisso FLAURA2 FDA approved. Big improvement in OS

Tagrisso FLAURA2 (chemo combo 1L) received FDA approval post priority review, important as competitive rebuttal vs Amivantamab MARIPOSA. As a reminder, [our KOL feedback](#) (see note) still favours Tagrisso monotherapy, with use in c50% or more patients, with c30% MARIPOSA, and remainder FLAURA2. Updated OS data was still immature, but demonstrated a big improvement vs initial interim (0.9) with HR now 0.75, and upper end of confidence interval below 1 (0.97). We think this takes away OS debate vs MARIPOSA (updated OS from mid-year). Our KOL also doesn't expect MARIPOSA OS data to change the commercial debate, even if HR improves to around 0.75, given weak PFS and safety issues.

19 February 2024

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### Stock Data

Price (Common / ADR)	10,094 GBp / 64.27 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	9,461 GBp-12,390 GBp
Market Value (mn)	156,476 GBP
Shares Outstanding (mn)	1,550.2 / 3,100.4
Average Daily Value (mn)	194.00 USD
Free Float	100.0%
BofA Ticker / Exchange	AZNCF / LSE
BofA Ticker / Exchange	AZN / NYS
Bloomberg / Reuters	AZN LN / AZN.L
ROE (2024E)	29.6%
Net Dbt to Eqty (Dec-2023A)	54.7%
ESGMeter™	High

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**Refer to important disclosures on page 3 to 6. Analyst Certification on page 2. Price Objective Basis/Risk on page 2.**

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Timestamp: 19 February 2024 03:14AM EST

## Best GARP with Best pipe. Big FY25 catalyst path

Buy for attractive valuation (13.5x 25E PE vs NOV and ROG at c13x) for premium growth prospect (13% FY25-28 EPS CAGR), with best-in-class mid-stage pipeline, a big FY25 catalyst path, and May investor day to confirm mid-term growth prospects above cons. Shorter-term, we see the Dato 2L path as most important post filing approval.

## Glossary

TL01 = TROPION-Lung01

PIII = Phase 3

PFS = Progression Free Survival

EGFRm = Epidermal Growth Factor Receptor Mutation

NSCLC = Non-small cell lung cancer

CRT = Chemoradiation

OS = Overall Survival

KOL = Key Opinion Leader

## 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.

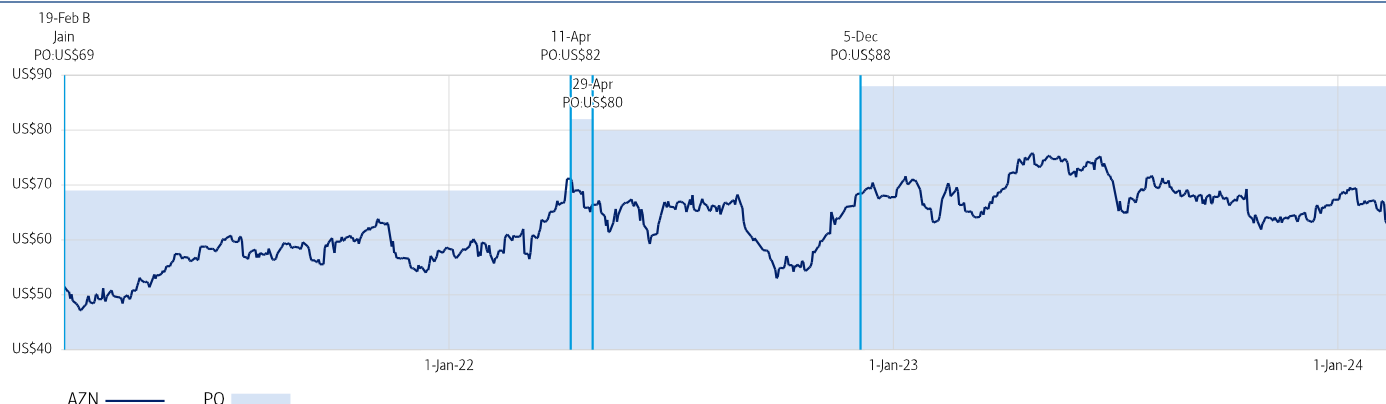
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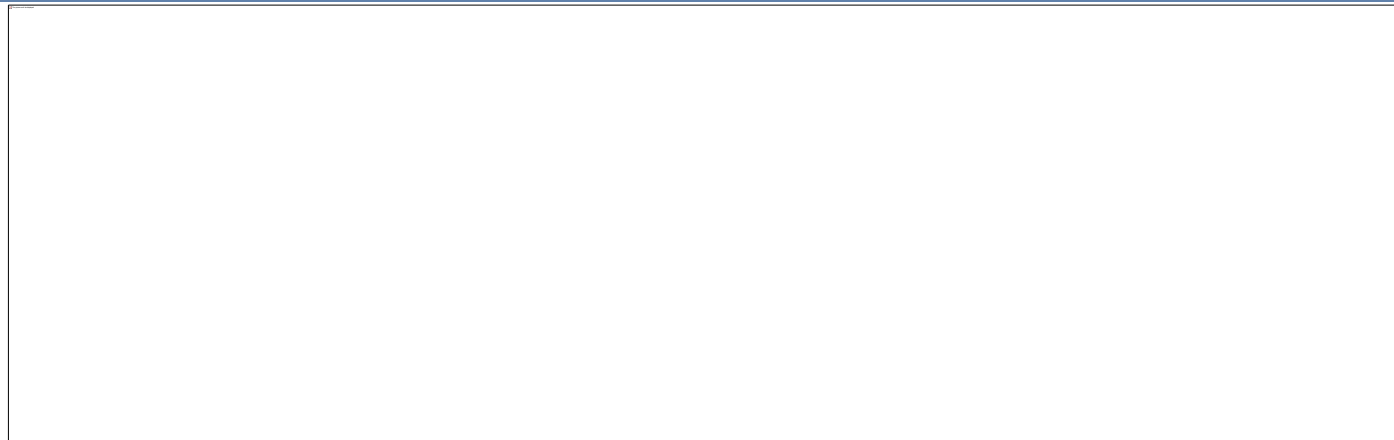
### AstraZeneca (AZN) Price Chart



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

The Investment Opinion System is contained at the end of the report under the heading "Fundamental Equity Opinion Key". Dark grey shading indicates the security is restricted with the opinion suspended. Medium grey shading indicates the security is under review with the opinion withdrawn. Light grey shading indicates the security is not covered. Chart is current as of a date no more than one trading day prior to the date of the report.

### AstraZeneca (AZNCF) Price Chart



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Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	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%

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Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	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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