

DESTINY-LUNG04 (Astra Zeneca)

A Study to Investigate the Efficacy and Safety of Trastuzumab Deruxtecan as the First Treatment Option for Unresectable, Locally Advanced/Metastatic Non-Small Cell Lung Cancer With HER2 Mutations

This is the trial summary as assessed on clinicaltrials.gov on 12/04/2022.

Minor changes in the protocol may occur. You can check this on this direct link:

<https://clinicaltrials.gov/ct2/show/NCT05048797?cond=DESTINY+LUNG04&draw=2&rank=1>

Trial Design:

DESTINY-Lung04 will investigate the efficacy and safety of Trastuzumab Deruxtecan (T-DXd) versus Standard of Care (SoC) as first-line treatment of Non-Small Cell Lung Cancer (NSCLC) with HER2 Exon 19 or 20 mutations

This study consists of two open-label treatment arms:

Arm 1: Trastuzumab Deruxtecan

Arm 2: Standard of Care treatment (platinum, pemetrexed and pembrolizumab)

Inclusion criteria:

Participants at least 18 years of age

Locally advanced not amenable to curative therapy, or metastatic disease

Histologically documented non-squamous NSCLC with HER2 mutation in exons 19 or 20 by tissue NGS or ctDNA

Treatment-naïve for palliative intent systemic therapy for locally advanced or metastatic disease

Left ventricular ejection fraction (LVEF) \geq 50%

Measurable disease assessed by Investigator based on RECIST 1.1

Protocol-defined adequate organ function including cardiac, renal, hepatic function ECOG 0-1

Having tumour tissue available for central testing

Exclusion criteria:

Tumors with targetable alterations to EGFR (or other targetable mutations including but not limited to ALK, if routinely tested as a targetable alteration with approved available therapy)

Any clinically active brain metastases; previously treated brain metastases allowed

Active autoimmune or inflammatory disorders

Medical history of myocardial infarction within 6 months prior to randomization

History of non-infectious pneumonitis/ILD, current or suspected ILD

Lung-specific intercurrent clinical significant severe illness

Contraindication to platinum-based doublet chemotherapy or pembrolizumab