



Name	: Mr.DUMMY REPORT	Centre Details	: DUMMY GURGAON DUMG
Age	: 35 Yrs Sex: Male	Accession.ID	: OQG2510070213
Collection Date	: 07/Oct/2025 11:03AM	Referred By	: SELF
Received Date	: 07/Oct/2025 11:03AM	Report Date	: 31/Oct/2025 02:48PM
Registration Date	: 07/Oct/2025 11:01AM	Ref.No/TRF.No	: /

DEPARTMENT OF MOLECULAR DIAGNOSTICS-II

OncqSol CGP 550+ Next Generation Sequencing

Clinical Indication: Lung Carcinoma
Specimen: Slides from FFPE Block: 4317/22 (6)
Tumor Content & Cellularity: 40%; Adequate
Site: Left Lung Biopsy

Test Result Summary

POSITIVE Clinically relevant actionable Variant was detected in <i>EGFR</i> gene
NEGATIVE No clinically relevant Copy Number Variant (CNV) was detected in this subject

Gene	CDS variant details	Amino acid change/ Exon No.	Overall depth/ Mutant Allele Percentage	Variant Classification (AMP/ASCO/CAP)
EGFR	c.2236_2250delGAATTAAGAGAAGCA	p.Glu746_Ala750del/ Exon 19	586x/ 66.38%	Tier; IA FDA Approved Drug Labels: afatinib, amivantamab + lazertinib, acoitinib, erlotinib + ramucirumab, gefitinib, osimertinib, osimertinib + chemotherapy, amivantamab, chemotherapy and datopotamab deruxtecan-dlnk

Multi-gene Biomarker Results:

Gene	CDS variant details	Amino acid change/ Exon No.
Microsatellite Instability (MSI)	High	High Microsatellite Stability detected
Tumor Mutation Burden (TMB)	9 Mutations/Mb (Low)	Poor response anticipated towards Immuno-Oncology therapy

*Genetic test results are reported based on the recommendations of AMP-ASCO-CAP guidelines. #Correlation of the genetic findings with the clinical condition of the patient is required to arrive at an accurate diagnosis, prognosis or therapeutic decisions.

Additional Biomarkers Detected

This section provides information about variants that do not have any therapeutic value. However, these variants may or may not have a likely oncogenic effect.

Gene	CDS details	Amino acid change/ Exon No.	Overall depth/ Mutant Allele Percentage	Locus	Transcript	Variant Effect
None						

Variant Classification as per AMP-ASCO-CAP Guidelines

Variant	A change in a gene. This could be disease causing (pathogenic) or not disease causing (benign).
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Tier I: Variants of Strong Clinical Significance	Level A , biomarkers that predict response or resistance to US FDA-approved therapies for a specific type of tumor or have been included in professional guidelines as therapeutic, diagnostic, and/or prognostic biomarkers for specific types of tumors; Level B , biomarkers that predict response or resistance to a therapy based on well- powered studies with consensus from experts in the field or have diagnostic and/or prognostic significance of certain diseases based on well-powered studies with expert consensus.
Tier II: Variants of Potential Clinical Significance	Level C , biomarkers that predict response or resistance to therapies approved by FDA or professional societies for a different tumor type (i.e., off-label use of a drug), serve as inclusion criteria for clinical trials, or have diagnostic and/or prognostic significance based on the results of multiple small studies. Level D , biomarkers that show plausible therapeutic significance based on preclinical studies or may assist disease diagnosis and/or prognosis themselves or along with other biomarkers based on small studies or multiple case reports with no consensus.
Tier III: Variants of unknown clinical significance	Not observed at a significant allele frequency in the general or specific subpopulation or pan cancer or tumor specific variant databases. No convincing published evidence of Cancer Association

MSI	Unstable Loci
MSI - Stable	1-18
Intermediate/ No Call	18-19
MSI - Unstable	>19

Test Attributes, Methodology:

- This is a Next Generation Sequencing based test which identifies genetic alterations in a comprehensive panel of >500 genes which can impact response to approved therapy for a particular cancer type. Some of the alterations detected may have bearing on prognosis and/or therapeutic options and may provide relevant information that allows doctor to consider various lines of targeted treatment for the patient.
- Sample preparation and Library preparation: DNA isolated from FFPE or any other fresh tumor tissue source was used to perform targeted gene capture using a custom capture kit. The libraries were sequenced to mean >500X coverage on Thermofisher sequencing platform. The OncoPrint™ Comprehensive Assay Plus is a targeted, next-generation sequencing (NGS) assay that provides a comprehensive genomic profiling solution appropriate for formalin-fixed paraffin-embedded (FFPE) tissues. The assay allows concurrent analysis of DNA and RNA to simultaneously detect multiple biomarkers associated with targeted and immune checkpoint research, including comprehensive targets that are relevant in cancer, in a single workflow.
- Bioinformatics Analysis and Reporting: The sequences obtained are aligned to human reference genome (GRCh37/hg19) and variant analysis is performed using set of Bioinformatics Pipeline. Variant calling, annotation and classification of the variants were done using ion reporter 5.2.0 software. Clinically relevant mutations are annotated using published variants in literature and a set of databases – ClinVar, COSMIC and dbSNP. Common variants are filtered based on allele frequency in 1000 Genome Phase 3, ExAC, EVS, dbSNP147, etc. Non-synonymous variants effect is calculated using multiple algorithms such as PolyPhen-2, SIFT, MutationTaster2, Mutation Assessor and LRT. Silent variations that do not result in any change in amino acid in the coding region are not reported. It enables the identification of SNV, Indels, Gene level copy number variants, TMB score, MSI status, arm level aneuploidy, gene fusions, Homologous recombination deficiency through Genomic instability metric (GIM), Gene LOH for BRCA1/BRCA2 and other HRR genes, full coverage of DNA repair pathways including HRR and MMR Genomic instability metric (GIM) is a novel metric to quantify genomic scars/instability associated with HRD. It is based on genomic segmentation2 using CNV log2 ratios and log odds for SNP allele frequencies, which allows to summarize different unbalanced copy number events across autosomes. It ranges from 0-100, and higher values indicate more genomic instability.
- The performance of the was verified using both commercially sourced reference controls and FFPE samples. Tumor Mutation Burden (TMB) & Microsatellite Instability: study potential response to immunotherapies with measurement of tumor mutational burden





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(TMB), predisposition to genetic hypermutability by comparing microsatellite instability (MSI) regions and analyse mutational signatures for insights into etiological factors in tumorigenesis.

- This kit enables us to detect Genomic instability matrix (GIM). Genetic Instability Metric (GIM) is a proprietary measurement in Ion Reporter™ software that quantifies genomic scarring associated with Homologous Recombination Deficiency (HRD). The GIM is a numeric value between 0 and 100 that summarizes unbalanced copy number changes using genomic segmentation. GIM values are higher in HRD-positive samples than they are in HRD-negative samples in ovarian cancer (GIM values ≥ 16). Higher value correlate with the observation of more genomic instability in the sample. The sensitivity of the assays depends on the quality of the sample and tumor content.

Comprehensive Genomic Panel gene list:

CNV gain and Hotspot Genes (n=185)							TMB only genes** (n=89)		
ABCB1	CD79B*	FGF7*	IKBKB	MYCN	PXDNL	STAT3B	A1CF	KRTAP21-1	OR8U1
ABL1	CDK4	FGF9	IL6ST*	MYD88	RAC1	STAT6	ACSM2B	KRTAP6-2	ORC4
ABL2	CDK6	FGFR1	IL7R	MYO11*	RAF1	TAF1	ADAM18	LRRC7	PAK5
ACVR1*	CHD4	FGFR2	IRF4*	NFE2L2	RARA	TERT	ANO4	MARCO	PCDH17
AKT1	CSF1R*	FGFR3	IRS4*	NRAS	RET	TGFBR1*	ARMC4	NLRCS	PDE1A
AKT2	CTNND1*	FGFR4	KDR	NSD2*	RGS7*	TOP1	AURKB	NOL4	PDE1C
AKT3	CTNND2	FLT3	KIT	NTSC2*	RHEB	TPMT	BRINP3	NRXN1	PLXDC2
ALK	CUL1*	FLT4	KLF4*	NTRK1	RHOA*	TRRAP*	C6	NYAP2	POM121L12
AR	CYSLTR2*	FOXA1	KLF5	NTRK2	RICTOR	TSHR*	C8A	OR10G8	PPFIA2
ARAF	DDR1	FOXL2*	KNSTRN*	NTRK3	RIT1	U2AF1	C8B	OR2G6	RBP3
ATP1A1*	DDR2	FOXO1*	KRAS	NUP93*	ROS1	USP8	CANX	OR2L13	REG1A
AURKA	DGCR8*	FYN	MAGOH	PAX5*	RPL10*	WAS*	CASR	OR2L2	REG1B
AURKC	DROSHA*	GATA2	MAP2K1	PCBP1	RPS6KB1	XPO1	CD163	OR2L8	REG3A
AXL	E2F1*	GLI1*	MAP2K2*	PDGFR4	RPTOR	YAP1	CNTN6	OR2M3	REG3G
BCL2	EGFR	GLI3	MAPK1	PDGFRB	SETBP1	YES1	CNTNAP4	OR2T3	RPTN
BCL2L12	EIF1AX	GNA11*	MAX	PIK3C2B	SF3B1	ZNF217	CNTNAP5	OR2T33	RUNDC38
BCL6	EMSY	GNAQ*	MCL1	PIK3CA	SIX1*	ZNF429	COL11A1	OR2T4	SH3RF2
BCR*	EPAS1*	GNAS	MDM2	PIK3CB	SIX2*		DCAF4L2	OR2W3	SLC15A2
BMP5*	ERBB2	H1-4*	MDM4	PIK3CD*	SLCO1B3		DCDC1	OR4A15	SLC8A1
BRAF	ERBB3	H2BC5*	MECOM	PIK3CG*	SMC1A		GALNT17	OR4C15	SYT10
BTX*	ERBB4	H3-3A	MED12*	PIK3R2	SMO		GPR158	OR4C6	SYT16
CACNA1D*	ESR1	H3-3B	MEF2B	PIM1	SNCAIP*		GRID2	OR4M1	TAPBP
CARD11	EZH2	H3C2*	MET	PLCG1	SOS1*		HCN1	OR4M2	TOP2A
CBL	FAM135B	HIF1A*	MTF	PPP2R1A	SOX2*		HLA-C	OR5D18	TPTE
CCND1	FGF19	HRAS	MPL	PPP6C	SPOP		KCND2	OR5F1	TRHDE
CCND2	FGF23	IDH1*	MTOR	PRKACA	SRC		KCNH7	OR5L1	TRIM48
CCND3	FGF3	IDH2	MYC	PTPN11	SRSF2*		KCNJ5	OR5L2	TRIM51
CCNE1	FGF4	IGF1R	MYCL	PTPRD*	STAT3		KEL	OR6F1	ZIM3
							KIR3DL1	OR6H2	ZNF479
								OR82	ZNF536

CDS genes (n=227)								Gene Fusions (Inter- and Intra-genic) (n=49)	
ABRAXAS1	CASP8	DICER1	FBXW7	MAP3K4	PDIA3	RB1	TAP1	AKT1	NOTCH2
ACVR1B	CBF9	DNMT3A	FUBP1	MAPK8	PCD	RBM10	TAP2	AKT2	NOTCH3
ACVR2A	CD274	DOKK3	GATA3	MEN1	PHF6	RECQL4	TBX3	AKT3	NRG1
ADAMTS12	CD276	DPYD	GNA13	MGA	PIK3R1	RNASEH2A	TCF7L2	ALK	NTRK1
ADAMTS2	CD373	DSC1	GPS2	MLH1	PMS1	RNASEH2B	TET2	AR	NTRK2
AMER1*	CDH1	DSC3	HDAC2	MLH3	PMS2	RNASEH2C	TGFBR2	BRAF	NTRK3
APC	CDH10	ELF3	HDAC9	MRE11	POLD1	RNF43	TMEM132D*	BRCA1	NUTM1
ARHGAP35	CDK12*	ENO1	HLA-A	MSH2	POLE	RPA1	TNFAIP3	CDKN2A	PIK3CA
ARID1A	CDKN1A	EP300	HLA-B	MSH3	POT1	RPL22*	TNFRSF14	EGFR	PIK3CB
ARID1B	CDKN1B	EPCAM	HNF1A	MSH6	PPM1D	RPL5*	TP53	ERBB2	PPARG
ARID5B	CDKN2A	EPHA2	ID3*	MTAP	PPP2R2A	RUNX1	TP63	ERBB4	PRKACA
ASXL1	CDKN2C	ERAP1	INPP4B	MTUS2*	PRDM1	RUNX1T1	TPP2	ERG	PRKACB
ASXL2	CDKN2C	ERAP2	JAK1	MUTYH	PRDM9	SDHA	TSC1	ESR1	RAF1
ATM*	CHEK1*	ERCC2	JAK2	NBN	PRKAR1A	SDHB	TSC2	ETV1	RARA
ATR	CIC	ERCC3	JAK3	NCOR1	PSMB10*	SDHC	UGT1A1*	ETV4	RELA
ATRX	CHIT1*	ERCC4	KDM5C	NF1	PSMB8*	SDHO	USP9X	ETV5	RET
AXIN1	CREBBP	ETV6	KDM6A	NF2	PSMB9*	SETD2	VHL	FGFR1	ROS1
AXIN2	CSMD3	FANCA	KEAP1	NOTCH1	PTCH1	SLX4	WT1	FGFR2	RSP02
B2M	CTCF	FANCC	KLHL13*	NOTCH2	PTEN	SMAD2	XRCC2	FGFR3	RSP03
BAP1	CTLA4	FANCD2	KMT2A	NOTCH3	PTPR	SMAD4	XRCC3	MAP3K8	STAT6
BARD1*	CUL3	FANCE	KMT2B	NOTCH4	RAD50	SMARCA4	ZBTB20*	MET	TERT
BCOR	CUL4A	FANCF	KMT2C	PALB2*	RAD51	SMARCB1	ZFH3	MTAP	TFE3
BLM	CUL4B	FANCG	KMT2D	PARP1	RAD51B*	SOC1	ZMYM3	MYB	TFEB
BMPR2	CYLD	FANCI	LARP4B	PARP2	RAD51C*	SOX9	ZRSR2	MYBL1	YAP1
BRCA1*	CYP2C9	FANCL*	LATS1	PARP3	RAD51D*	SPEN		NOTCH1	
BRCA2*	CYP2D6*	FANCM	MAP2K4	PARP4	RAD52	STAG2			
BRIP1*	DAX1	FAS*	MAP2K7	PBRM1	RAD54L*	STAT1			
CALR*	DGXXK	FAT1	MAP3K1	PDCD1	RASA1	STK11			
				PDCD1LG2	RASA2	SUFU			





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Disclaimer:

DNA studies do not constitute a definitive test for the selected condition(s) in all individuals. It should be realized that there are possible sources of error. Errors can result from trace contamination, rare technical errors, rare genetic variants that interfere with analysis, recent scientific developments, and alternative classification systems. This test should be one of the many aspects used by the healthcare provider to help with a diagnosis and treatment plan. The contents of this test should be carefully assessed by the treating physician and further interpreted along with clinical, histopathological findings, contraindications and guidelines before deciding the course of therapy. Most recent block is recommended for testing as the mutation profile may change in response to treatment and hence differ at different sampling points. Certain genes may not be covered completely, and few mutations could be missed. A negative result cannot rule out the possibility that the tested tumor sample carries mutations not previously associated with cancer and hence not included in the panel. The accuracy and completeness may vary due to variable information available in different databases. The classification of variants of unknown significance can change over time. Synonymous mutations were not considered while preparing this report. The mutations have not been confirmed using Sanger sequencing and/or alternate technologies. To rule out germ line mutations i.e. variant with variant allele frequency at nearly 50% or 100%, whole blood sample is recommended to process along with tissue sample. No other variant that warrants to be pathogenic was detected. Variations with high minor allele frequencies which are benign/likely benign will be given upon request. Due to poor quality of FFPE DNA, indeterminate result due to low gene coverage or low variant depth cannot be ruled out. The sensitivity of the assays depends on the quality of the block, and tumor content

References:

- Li, Marilyn M., et al. "Standards and guidelines for the interpretation and reporting of sequence variants in cancer: a joint consensus recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists." The Journal of Molecular Diagnostics (2017) 19(1): 4-23. PMID: 27993330.
- Richards, Sue, et al. "Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology." Genetics in Medicine (2015) 17(5): 405. PMID: 25741868.
- Forbes, Simon A., et al. "COSMIC: somatic cancer genetics at high-resolution." Nucleic Acids Research (2016) 45(D1): D777-D783. PMID: 27899578.
- Exome Aggregation Consortium et al. "Analysis of Protein-Coding Genetic Variation in 60,706 Humans." Nature (2016) 536(7616): 285–291. PMID: 27535533.
- The 1000 Genomes Project Consortium. "A Global Reference for Human Genetic Variation." Nature (2015) 526(7571): 68–74. PMID: 26432245.

Note: The performance of this Test has been evaluated at Oncquest Laboratories Ltd.

*** End Of Report ***

Disclaimer: All Results released pertain to the specimen submitted to the lab
1. Test results are dependent on the quality of the sample received by the lab
2. Tests are performed as per schedule given in the test listing and in any unforeseen circumstances, report delivery may be delayed
3. Test results may show interlaboratory variations
4. All dispute and claims are subjected to local jurisdiction only. Clinical correlation advised.
5. Test results are not valid for medico legal purposes
6. For all queries, feedbacks, suggestions, and complaints, please contact customer care support +0124 665 0000



Sample Cancer Type: Lung Cancer

Relevant Lung Cancer Findings

Gene	Finding	Gene	Finding
ALK	None detected	NTRK1	None detected
BRAF	None detected	NTRK2	None detected
EGFR	EGFR exon 19 deletion	NTRK3	None detected
ERBB2	None detected	RET	None detected
KRAS	None detected	ROS1	None detected
MET	None detected		

Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
EGFR exon 19 deletion Allele Frequency: 66.38%	afatinib ¹ amivantamab + lazertinib ¹ dacomitinib ¹ erlotinib + ramucirumab ¹ gefitinib ¹ osimertinib ¹ osimertinib + chemotherapy ¹ amivantamab + chemotherapy ¹ datopotamab deruxtecan-dlnk ¹ bevacizumab + erlotinib erlotinib gefitinib + chemotherapy atezolizumab + bevacizumab + chemotherapy	None*	162

* Public data sources included in relevant therapies: NCCN, ESMO, FDA¹

 **Alerts informed by public data sources:**  Contraindicated,  Resistance,  Breakthrough,  Fast Track

EGFR exon 19 deletion
 **izalontamab brengitecan**¹, **patritumab deruxtecan**¹
 **DB-1310**¹

Public data sources included in alerts: NCCN, ESMO, FDA¹

Biomarker Descriptions

EGFR exon 19 deletion

epidermal growth factor receptor

Background: The EGFR gene encodes the epidermal growth factor receptor (EGFR), a member of the ERBB/human epidermal growth factor receptor (HER) tyrosine kinase family¹. In addition to EGFR/ERBB1/HER1, other members of the ERBB/HER family include ERBB2/HER2, ERBB3/HER3, and ERBB4/HER4². EGFR ligand-induced dimerization results in kinase activation and leads to stimulation

Biomarker Descriptions (continued)

of oncogenic signaling pathways, including the PI3K/AKT/MTOR and RAS/RAF/MEK/ERK pathways³. Activation of these pathways promotes cell proliferation, differentiation, and survival^{4,5}.

Alterations and prevalence: Recurrent somatic mutations in the tyrosine kinase domain (TKD) of EGFR are observed in approximately 10-20% of lung adenocarcinoma, and at higher frequencies in never-smoker, female, and Asian populations^{6,7,8,9}. The most common mutations occur near the ATP-binding pocket of the TKD and include short in-frame deletions in exon 19 (EGFR exon 19 deletion) and the L858R amino acid substitution in exon 21¹⁰. These mutations constitutively activate EGFR resulting in downstream signaling, and represent 80% of the EGFR mutations observed in lung cancer¹⁰. A second group of less prevalent activating mutations includes E709K, G719X, S768I, L861Q, and short in-frame insertion mutations in exon 20^{11,12,13,14}. EGFR activating mutations in lung cancer tend to be mutually exclusive to KRAS activating mutations¹⁵. In contrast, a different set of recurrent activating EGFR mutations in the extracellular domain includes R108K, A289V and G598V and are primarily observed in glioblastoma^{10,16}. Amplification of EGFR is observed in several cancer types including 44% of glioblastoma multiforme, 12% of esophageal adenocarcinoma, 10% of head and neck squamous cell carcinoma, 8% of brain lower grade glioma, 6% of lung squamous cell carcinoma, 5% of bladder urothelial carcinoma cancer, lung adenocarcinoma, and stomach adenocarcinoma, 3% of cholangiocarcinoma, and 2% of cervical squamous cell carcinoma, sarcoma, and breast invasive carcinoma^{7,8,9,16,17}. Deletion of exons 2-7, encoding the extracellular domain of EGFR (EGFRvIII), results in overexpression of a ligand-independent constitutively active protein and is observed in approximately 30% of glioblastoma^{18,19,20}. Alterations in EGFR are rare in pediatric cancers^{8,9}. Somatic mutations are observed in 2% of bone cancer and glioma, 1% of leukemia (4 in 354 cases), and less than 1% of B-lymphoblastic leukemia/lymphoma (2 in 252 cases), peripheral nervous system cancers (1 in 1158 cases), and embryonal tumors (3 in 332 cases)^{8,9}. Amplification of EGFR is observed in 2% of bone cancer and less than 1% of Wilms tumor (1 in 136 cases), B-lymphoblastic leukemia/lymphoma (2 in 731 cases), and leukemia (1 in 250 cases)^{8,9}.

Potential relevance: Approved first-generation EGFR tyrosine kinase inhibitors (TKIs) include erlotinib²¹ (2004) and gefitinib²² (2015), which block the activation of downstream signaling by reversible interaction with the ATP-binding site. Although initially approved for advanced lung cancer, the discovery that drug sensitivity was associated with exon 19 and exon 21 activating mutations allowed first-generation TKIs to become subsequently approved for front-line therapy in lung cancer tumors containing exon 19 or exon 21 activating mutations²³. Second-generation TKIs afatinib²⁴ (2013) and dacomitinib²⁵ (2018) bind EGFR and other ERBB/HER gene family members irreversibly and were subsequently approved. First- and second-generation TKIs afatinib, dacomitinib, erlotinib, and gefitinib are recommended for the treatment NSCLC harboring EGFR exon 19 insertions, exon 19 deletions, point mutations L861Q, L858R, S768I, and codon 719 mutations, whereas most EGFR exon 20 insertions, except p.A763_Y764insFQEA, confer resistance to the same therapies^{26,27,28,29}. In 2025, the FDA approved the irreversible EGFR inhibitor, sunvozertinib³⁰, for the treatment of locally advanced or metastatic non-small cell lung cancer in adult patients with EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. In 2022, the FDA granted breakthrough therapy designation to the irreversible EGFR inhibitor, CLN-081 (TPC-064)³¹ for locally advanced or metastatic non-small cell lung cancer harboring EGFR exon 20 insertion mutations. In lung cancer containing EGFR exon 19 or 21 activating mutations, treatment with TKIs is eventually associated with the emergence of drug resistance³². The primary resistance mutation that emerges following treatment with first-generation TKI is T790M, accounting for 50-60% of resistant cases¹⁰. Third generation TKIs were developed to maintain sensitivity in the presence of T790M³². Osimertinib³³ (2015) is an irreversible inhibitor indicated for metastatic EGFR T790M positive lung cancer and for the first-line treatment of metastatic NSCLC containing EGFR exon 19 deletions or exon 21 L858R mutations. Like first-generation TKIs, treatment with osimertinib is associated with acquired resistance, specifically the C797S mutation, which occurs in 22-44% of cases³². The T790M and C797S mutations may be each selected following sequential treatment with a first-generation TKI followed by a third-generation TKI or vice versa³⁴. T790M and C797S can occur in either cis or trans allelic orientation³⁴. If C797S is observed following progression after treatment with a third-generation TKI in the first-line setting, sensitivity may be retained to first-generation TKIs³⁴. If C797S co-occurs in trans with T790M following sequential treatment with first- and third-generation TKIs, patients may exhibit sensitivity to combination first- and third-generation TKIs, but resistance to third-generation TKIs alone^{34,35}. However, C797S occurring in cis conformation with T790M, confers resistance to first- and third-generation TKIs³⁴. Fourth-generation TKIs are in development to overcome acquired resistance mutations after osimertinib treatment, including BDTX-1535³⁶ (2024), a CNS-penetrating small molecule inhibitor, that received fast track designation from the FDA for the treatment of patients with EGFR C797S-positive NSCLC who have disease progression on or after a third-generation EGFR TKI. EGFR-targeting antibodies including cetuximab (2004), panitumumab (2006), and necitumumab (2016) are under investigation in combination with EGFR-targeting TKIs for efficacy against EGFR mutations³⁷. The bispecific antibody, amivantamab³⁸ (2021), targeting EGFR and MET was approved for NSCLC tumors harboring EGFR exon 20 insertion mutations. A small molecule kinase inhibitor, lazertinib³⁹ (2024), was approved in combination with amivantamab as a first-line treatment for adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R mutations. HLX-42⁴⁰, an anti-EGFR-antibody-drug conjugate (ADC) consisting of an anti-EGFR monoclonal antibody conjugated with a novel high potency DNA topoisomerase I (topo I) inhibitor, also received fast track designation (2024) for the treatment of patients with advanced or metastatic EGFR-mutated non-small cell lung cancer whose disease has progressed on a third-generation EGFR tyrosine kinase inhibitor. CPO301⁴¹ (2023) received a fast track designation from the FDA for the treatment of EGFR mutations in patients with metastatic NSCLC who are relapsed/refractory or ineligible for EGFR targeting therapy such as 3rd-generation EGFR inhibitors, including

Biomarker Descriptions (continued)

osimertinib. The OncoPrex immunogene therapy quaratusugene ozeplasmid⁴² (2020), in combination with osimertinib, received fast track designation from the FDA for NSCLC tumors harboring EGFR mutations that progressed on osimertinib alone. Amplification and mutations of EGFR commonly occur in H3-wild type IDH-wild type diffuse pediatric high-grade glioma^{43,44,45}.

Clinical Trials Summary

EGFR exon 19 deletion

NCT ID	Title	Phase
NCT05503667	Neoadjuvant Furmonertinib Plus Bevacizumab or Furmonertinib Monotherapy for Resectable and Potentially Resectable Stage III-IVA EGFR Mutation-Positive Lung Adenocarcinoma: A Randomized, Controlled, Open-label, Single-center Phase II Clinical Trial	II
No NCT ID	A Randomized, Double-Blind, Parallel Controlled Trial for Icotinib Double-Dose First-Line Therapy for EGFR 19 Exon Mutations in Advanced Non-Small Cell Lung Cancer	II
No NCT ID	Study for Efficacy and Safety of Continuing to Treat with TKI Combined with Anlotinib Monotherapy in Advanced NSCLC Patients with T790M Mutation-negative after Tki Treatment Failure	I
No NCT ID	Efficacy And Safety Of Low-Dose Afatinib Combined With Bevacizumab And Pemetrexate In First-Line Treatment Of Stage IV Lung Adenocarcinoma With EGFR Mutation.	IV
No NCT ID	Multi-Center Clinical Study on the Efficacy and Safety of Ametinib Combined with Bevacizumab and Pemetrexed in the First-Line Treatment of EGFR-Mutant Lung Adenocarcinoma Patients with Brain Metastases	IV
NCT07092202	Exploratory Clinical Study on Dynamic Monitoring of cfDNA in Cerebrospinal Fluid and Peripheral Blood Using High-dose Firmonertinib Combined With Intrathecal Injection of Pemetrexed for the Treatment of EGFR Mutant NSCLC With Leptomeningeal Metastases	IV
No NCT ID	The Comparson Of The Gefitinib Combined With Human Recombinant Endostatin And Only Gefitinib In The Treatment Of Advanced NSCLC With EGFR Mutations	IV
NCT04401059	Synergistic Real-World Study and Evidence-based Medicine Evaluation of Elemene Combined With Tyrosine Kinase Inhibitors(TKIs)in the Treatment of Advanced Non-small Cell Lung Cancer (NSCLC): Prospective Study	IV
No NCT ID	Efficacy and Safety of Aumolertinib Combined with Apatinib Versus Aumolertinib as s Single Agent in the First-Line Treatment of Advanced NSCLC with EGFR-Sensitive Mutations: A Multicenter, Randomized, Open, Controlled Phase III Clinical Study	III
NCT04500704	Almonertinib Alone Versus Almonertinib Plus Chemotherapy as First-line Treatment in Patients With Epidermal Growth Factor Receptor (EGFR) Mutation Positive With Concomitant Non-EGFR Driver Gene Mutation Positive, Locally Advanced or Metastatic Non-Small Cell Lung Cancer: A Multicenter, Open-label, Randomized, Control Phase III Study (ACROSS 1)	III
NCT04762459	Efficacy and Safety of Almonertinib Combined With or Without Chemotherapy as an Adjuvant Treatment for EGFR Mutation Positive Stage II-IIIa Non-small Cell Lung Carcinoma Following Complete Tumour Resection: A Multicenter, Randomized Controlled, Open-label Clinical Study	III
NCT05768490	A Prospective, Multicenter, Randomized, Controlled Clinical Study of Early or Delayed Intervention of Brain Radiotherapy Combined With Almonertinib in EGFR Mutated NSCLC With Brain Metastases	III

Clinical Trials Summary (continued)

EGFR exon 19 deletion (continued)

NCT ID	Title	Phase
NCT05800223	Prospective, Multicenter, Randomized Controlled, Phase III Clinical Study of Armatinib Alone or in Combination With Stereotactic Body Radiotherapy (SRT) for First-line Treatment of Brain Metastases From EGFR-mutated Non-small Cell Lung Cancer	III
NCT06041776	A Multicenter, Randomized, Controlled, Double Blind, Double Simulated, Phase III Clinical Study of Befotertinib vs Icotinib for Postoperative Adjuvant Treatment of IB-IIIB (T3N2M0) Stage Non Small Cell Lung Cancer With Positive EGFR Sensitive Mutations	III
NCT06417814	A Phase III, Open-label, Sponsor-blind, Randomized Study of Dato-DXd With or Without Osimertinib Versus Platinum-based Doublet Chemotherapy for Participants With EGFR-mutated Locally Advanced or Metastatic Non-small Cell Lung Cancer Whose Disease Has Progressed on Prior Osimertinib Treatment (TROPION-Lung15)	III
NCT06674343	The Efficacy and Safety of Furmonertinib 160mg as First-line Treatment in Locally Advanced or Metastatic Non-small Cell Lung Cancer (NSCLC) With EGFR Classical Mutations, a Prospective, Single-arm, Multicenter Clinical Study	III
NCT06970639	A Phase III, International, Multicenter, Randomized, Controlled, Open-label Clinical Study Evaluating Furmonertinib Plus Platinum-based Doublet Chemotherapy Versus Osimertinib in Patients With Epidermal Growth Factor Receptor (EGFR) Sensitizing Mutation-Positive Non-squamous Non-Small Cell Lung Cancer (NSCLC) and Brain Metastases	III
NCT03381066	A Phase III, Randomized, Multi-center Study to Determine the Efficacy of the Intercalating Combination Treatment of Chemotherapy and Gefitinib or Chemotherapy as Adjuvant Treatment in NSCLC With Common EGFR Mutations.	III
NCT04797806	Phase III Study Comparing Anlotinib Plus Icotinib to Icotinib in Patients With Untreated Non-squamous NSCLC Harboring EGFR Concomitant Mutations	III
NCT04058704	A Multi-center, Prospective Study to Determine the Efficiency of Icotinib Combined With Radiation Therapy Early Intervention or Late Intervention For NSCLC Patients With Brain Metastases and EGFR(Epidermal Growth Factor Receptor) Mutation	III
No NCT ID	A multicenter study using a regression discontinuity design to determine the optimal dose of osimertinib for patients aged 70 years or older with untreated advanced or recurrent epidermal growth factor receptor mutation-positive non-small cell lung cancer	III
NCT06350097	A Phase III, Open-label, Randomised Study of Osimertinib With or Without Datopotamab Deruxtecan (Dato-DXd), as First-line Treatment in Participants With Epidermal Growth Factor Receptor (EGFR) Mutation-positive, Locally Advanced or Metastatic Non-small Cell Lung Cancer	III
NCT06305754	A Randomized, Open-label, Phase III Study of MK-2870 vs. Platinum Doublets in Participants With EGFR-mutated, Advanced Non squamous Non-small Cell Lung Cancer (NSCLC) Who Have Progressed on Prior EGFR Tyrosine Kinase Inhibitors	III
NCT05261399	A Phase III, Randomised, Open-Label Study of Savolitinib in Combination With Osimertinib Versus Platinum-Based Doublet Chemotherapy in Participants With EGFR Mutated, MET-Overexpressed and/or Amplified, Locally Advanced or Metastatic Non-Small Cell Lung Cancer Who Have Progressed on Treatment With Osimertinib (SAFFRON).	III
NCT06080776	A Phase III, Double-blind, Randomised Study of SH-1028 Tablets Versus Placebo as Adjuvant Therapy in Resected Stage II-IIIB Non-Small Cell Lung Cancer With Sensitizing EGFR Mutations	III

Clinical Trials Summary (continued)

EGFR exon 19 deletion (continued)

NCT ID	Title	Phase
NCT05382728	A Phase III, Randomised, Double-blind, Multi-center Study to Assess the Efficacy and Safety of TY-9591 Tablets Versus Osimertinib as First Line Treatment in Patients With EGFR-sensitive Mutation, Locally Advanced or Metastatic Non Small Cell Lung Cancer.	III
NCT06417008	A Phase Ib/III Clinical Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Immunogenicity of HS-20117 Combined With Aumolertinib in Participants With Advanced Non-Squamous Non-Small Cell Lung Cancer	II/III
No NCT ID	A Phase II/III clinical study evaluating SCTB14 in combination with pemetrexed and cisplatin/ carboplatin versus placebo in combination with pemetrexed and cisplatin/carboplatin in patients with locally advanced or metastatic EGFR-mutated EGFR-mutated lung cancer who have failed transepidermal growth factor receptor tyrosine kinase inhibitor (EGFR-TKI)	II/III
NCT06668103	A Phase II, Open-Label Study to Evaluate the Efficacy and Safety of ABSK043 Combined With Firmonertinib in Patients With EGFR Mutated Locally Advanced or Metastatic Non-small Cell Lung Cancer(NSCLC)	II
No NCT ID	Rechallenge of afatinib for EGFR mutated non-small cell lung cancer previously treated with osimertinib	II
NCT04778800	A Dose Exploration Study of Almonertinib for Epidermal Growth Factor Receptor(EGFR)-Mutant Non-small-cell Lung Cancer(NSCLC) Patients With Newly Diagnosed or Recurrent Brain/Leptomeningeal Metastasis (ARTISTRY)	II
NCT05662813	A Phase II Study to Assess the Efficacy and Safety of Almonertinib Therapy in Patients With Abnormal Liver Function After First/Second Generation TKI Treatment, or Almonertinib First-line Therapy in Patients With Basic Hepatopathy	II
NCT06300424	Neoadjuvant Almonertinib Followed by Adebrelimab-based Chemo-immunotherapy in II-IIIb EGFR-mutant Non-small Cell Lung Cancer, a Single Arm, Phase II Study	II
NCT05754736	Efficacy and Safety of Ametinib Combined With Bevacizumab in First-line Treatment of Non-oligometastatic Advanced NSCLC With EGFR-mutations.	II
NCT04952168	A Single Arm, Prospective, Open Clinical Study of Combination of Almonertinib and Concurrent Chemoradiotherapy in Unresectable Stage III NSCLC With EGFR Mutation	II
NCT05810350	The Efficacy and Safety of Aumolertinib Combined Ommaya Reservoir Intrathecal Chemotherapy With Pemetrexed for Leptomeningeal Metastasis From EGFR-mutated NSCLC and Investigate the Efficacy Prognostic Value of Dynamic Changes of cfDNA	II
NCT04423185	Platform Study of Genotyping Guided Precision Medicine for Rare Tumors in China	II
NCT04636593	Almonertinib With Concurrent Radiotherapy in The Treatment of Unresectable, Stage III Non-small-cell Lung Cancer Harboring EGFR Mutations: A Phase II Cohort Study	II
NCT04905550	An Exploratory Clinical Study of Almonertinib in Combination With Craniocerebral Radiotherapy in First- line Treatment of EGFR Positive Non-Small Cell Lung Cancer(NSCLC) With Brain Metastases.	II
NCT06481566	Efficacy of Almonertinib Combined With Upfront Stereotactic Ablative Body Radiotherapy for Residual Primary Lung Lesions in Advanced EGFR-mutated Non-small Cell Lung Cancer : a Single-arm, Open- label, Phase II Trial	II
NCT05498428	A Phase II, Open-Label, Parallel Cohort Study of Subcutaneous Amivantamab in Multiple Regimens in Patients With Advanced or Metastatic Solid Tumors Including EGFR-mutated Non-Small Cell Lung Cancer	II

Clinical Trials Summary (continued)

EGFR exon 19 deletion (continued)

NCT ID	Title	Phase
No NCT ID	A Prospective, Single-arm Clinical Study of Perioperative Befotertinib in Patients with Stage II-IIIB (N2) EGFR Mutation-Positive Non-Small Cell Lung Cancer	II
No NCT ID	Clinical Study of Camrelizumab Combined With Apatinib in the Treatment of EGFR-TKI Resistance in NSCLC	II
NCT04675008	A Phase II Study of Dacomitinib in Advanced Epidermal Growth Factor Receptor (EGFR)-Mutant Non- small Cell Lung Cancer (NSCLC) Patients Who Have Non-irradiated Brain Metastasis	II
NCT06924398	Postoperative EGFR-TKI Therapy for High-Risk Synchronous Resectable Contralateral Pulmonary Nodules in Patients With EGFR-Mutant Non-Small Cell Lung Cancer (ARMOR2501)	II
NCT06304441	A Clinical Trial of Intra-pemetrexed Plus Third-generation Small Molecule TKI Drugs (e.g. 'Osimertinib') Versus Third-generation Small Molecule TKI Drugs Alone for Leptomeningeal Metastasis From Epidermal Growth Factor Receptor Mutation-Positive Non-Small-cell Lung Cancer	II
NCT02098954	Second Line Erlitinib Combination With Gemcitabine Cisplatinum in Non-small Cell Lung Cancer Patients Who Harbored EGFR Sensitive Mutation Developed Resistance After First Line TKI Treatment	II
NCT05442060	A Randomized, Open-Label, Phase 2 Study to Evaluate OBI-833/OBI-821 in Combination With First-Line Erlotinib in Patients With EGFR-Mutated, Globo H-Positive, Locally Advanced or Metastatic Non-Small Cell Lung Cancer	II
No NCT ID	A Multicenter, Open Label, Single Arm study:Furmonertinib as Neoadjuvant Therapy for Resectable Stage IIIA EGFR Mutant Lung Adenocarcinoma	II
No NCT ID	High-dose Furmonertinib in First-line Treatment of Patients with EGFR Classically Mutated Advanced NSCLC: A Multicenter, Open-label, Single-arm, Clinical Study.	II
NCT05165355	A Phase II, Single-armed Study to Assess the Efficacy and Safety of Furmonertinib in Patients With Epidermal Growth Factor Receptor Mutation Positive Stage IB-IIA Non-small Cell Lung Carcinoma, Following Complete Tumour Resection.	II
NCT05255406	A Prospective, Single-arm, Phase II Clinical Trial of Furmonertinib as the First-line Treatment in EGFR-Mutant, PD-L1+ Patients With Locally Advanced or Metastatic NSCLC	II
NCT05379803	A Single Arm, Multicenter Clinical Study of High-dose Furmonertinib in First-line Treatment of EGFR Mutated NSCLC With Central Nervous System (CNS) Metastases	II
NCT05445310	Adjuvant Furmonertinib in Stage IA With High Risk Factors and Stage IB Non-small Cell Lung Cancer: a Prospective Single-arm Study	II
NCT05465343	Efficacy and Safety of Furmonertinib in Patients With EGFR Mutations in Advanced NSCLC With Brain Metastases: A Single-center, Open-label, Phase II Trial (iFORCE)	II
No NCT ID	A Clinical Study to Evaluate the Efficacy and Safety of Furmonertinib Combined with Bevacizumab or Furmonertinib Monotherapy in Patients with Brain Metastases from Non-squamous Non-small cell Lung Cancer	II
NCT06728865	Evaluation of the Efficacy and Safety of Furmonertinib Combined with Bevacizumab As First-Line Treatment for EGFR-Positive Non-Small Cell Lung Cancer with Brain Metastases: a Single-Arm, Open- Label, Prospective Phase II Clinical Study	II
NCT06812871	A Single-arm, Multicenter, Phase II Study of High-dose Furmonertinib Combined With Bevacizumab and Intrathecal Pemetrexed Chemotherapy in Patients With EGFR-mutated Non-small Cell Lung Cancer and Meningeal Metastasis	II

Clinical Trials Summary (continued)

EGFR exon 19 deletion (continued)

NCT ID	Title	Phase
No NCT ID	A prospective, single-arm, multi-center clinical trial of firmonertinib combined with anlotinib as first-line treatment for advanced NSCLC with EGFR-sensitive mutations and brain metastasis	II
NCT06945705	A Prospective, Single-arm, Multi-center Clinical Trial of Furmonertinib Combined With Anlotinib as First-line Treatment for Advanced NSCLC With EGFR-sensitive Mutations and Brain Metastasis.	II
NCT05430802	Furmonertinib Combined With Cisplatin/Pemetrexed as Neoadjuvant Therapy in EGFR Mutated Stage IIIA-IIIB Resectable Non-small Cell Lung Cancer (FORESEE): a Prospective, Open-label, Single-arm, Phase II Study	II
NCT06339242	A Single-arm, Prospective Clinical Study of Double Dose of Furmonertinib Combined With Lateral Ventricular Chemotherapy in the Treatment of EGFR-mutant Lung Cancer With Leptomeningeal Metastasis After Third-generation EGFR-TKIs Resistance	II
NCT05334277	FurmOnertinib Mesylate With or Without Chemotherapy +/- bevacizUmab as firSt Line Treatment in Advanced Non-small Cell Lung Cancer Patients With Uncleared Epidermal Growth Factor Receptor (EGFR) Mutation Positive Circulating Tumor Cell DNA	II
No NCT ID	Study of Furmonertinib mesylate with Icotinib in EGFR mutant Locally Advanced or Metastatic NSCLC	II
No NCT ID	A Phase II Pilot, Single arm, Open label, Multi-center Study of Gefitinib as Sequential Therapy in Patients with Locally Advanced Non-Small Cell Lung Cancer (Stage III) with Sensitizing EGFR Mutations who have Not Progressed Following Platinum-based, Concurrent Chemoradiation Therapy	II
No NCT ID	Gefitinib Plus Pemetrexed Combined With Bevacizumab Or Carboplatin In First-Line Treatment Of Stage IV EGFR Mutant Non-Squamous Non-Small Cell Lung Cancer	II
No NCT ID	A Phase II Treatment of Gefitinib or Icotinib in lung adenocarcinoma of stage IA.	II
NCT03341494	A Randomized Phase II Study of Gefitinib Alone Versus Gefitinib Plus Thalidomide for Advanced Non-small Cell Lung Cancer With Epidermal Growth Factor Receptor Activating Mutations	II
No NCT ID	A multicenter, randomized, controlled, open Phase II trial of adjuvant ectinib (24 months) after complete resection of non-small cell lung cancer (NSCLC) with high-risk factors in Stage IA	II
No NCT ID	Phase II Clinical Study Of Autologous RAK Cells Combined With Icotinib In The Treatment Of EGFR-Mutated Advanced Non-Small Cell Lung Cancer	II
NCT05536505	Adjuvant Treatment Based on Minimal Residual Disease for Resectable Non-squamous Non-Small-Cell-Lung-Cancer With EGFR Mutations	II
No NCT ID	A Single-Arm, Single-Center, Phase II Clinical Study of Neoadjuvant Treatment of Resectable EGFR-Sensitive Mutant Non-Small Cell Lung Cancer with Ivonescimab (Anti-PD-1 and VEGF Bispecific Antibody) Combination with Chemotherapy	II
NCT06868836	A Phase II Study of JS207 (PD-1/VEGF Bispecific Antibody) in Combination With Pemetrexed and Platinum in Advanced Non-small Cell Lung Cancer With Actionable Genomic Alterations and TKI Therapy Failure	II
NCT05469022	A Phase II, Single Center, Single Arm, Prospective Study of Neoadjuvant Lazertinib Therapy in Resectable EGFR-Mutation Positive Lung Adenocarcinoma Patients Detected by Bronchoalveolar lavage fluid (BALF) Liquid Biopsy (NeolaBAL)	II
NCT06156527	A Randomized Phase II Study of LAZE Rti N ib Alone Versus Lazertinib Plus Beva C Izumab for A Dvanced Non Small Cell Lung Cancer With Epidermal Growth Factor Receptor Activating Mutations and Smoking History	II

Clinical Trials Summary (continued)

EGFR exon 19 deletion (continued)

NCT ID	Title	Phase
No NCT ID	Phase II study of LAZertinib And pemetrexed in EGFR mUtant NSCLC patients with leptomeningeal carcinomatosis	II
NCT06268210	Neoadjuvant Lazertinib With or Without Chemotherapy for Patients With EGFR-mutated Resectable Non-small Cell Lung Cancer (NeoLazer): a Phase II, Randomized, Multi-center Study	II
NCT04322890	Treatment Strategies and Survival Outcome for Non-small Cell Lung Cancer With Oncogenic Mutation.	II
NCT04591002	A Phase II, Study of Osimertinib to Suppress the Progression of Remaining Ground-glass Opacity Nodule (GGN) in Other Lobes After Curative Resection for Actionable EGFR Mutation-positive Stage IB-IIIA Lung Adenocarcinoma	II
NCT05528458	A Phase II Study of Osimertinib to Suppress the Progression of Remaining Ground-glass Opacity Nodule (GGN) for Actionable EGFR Mutation-positive Stage IB-IIIA Lung Adenocarcinoma	II
NCT04769388	The Efficacy and Safety of Osimertinib Plus Carboplatin and Pemetrexed Versus Osimertinib Monotherapy in Metastatic EGFRm NSCLC Patients With EGFRm Persistence in ctDNA at 3 Weeks After 1L Osimertinib: A Multicenter, Randomized Controlled Study	II
No NCT ID	A Randomized Phase II Study Of Consolidative Radiotherapy For Residual Lesions During Osimertinib Monotherapy In Patients With Non-Small Cell Lung Cancer Harboring EGFR Mutation (ORIHALCON Trial/WJOG13920L) (ORIHALCON Trial/WJOG13920L)	II
NCT06574347	A Phase II Study of Vebreltinib Plus PLB1004 as the First-line Therapy for Patients With EGFRm+/MET+ Locally Advanced or Metastatic Non-small Cell Lung Cancer.	II
No NCT ID	Phase II study of rechallenge treatment with ramucirumab plus erlotinib in patients with EGFR-mutated, advanced non-small cell lung cancer	II
NCT06182761	Efficacy and Safety of Sunvozertinib With Anlotinib in EGFR-TKIs Resistant EGFR-sensitive Mutated Locally Advanced or Metastatic Non-small Cell Lung Cancer (NSCLC): a Prospective, Single-arm, Phase II Trial	II
NCT04405674	A Phase II Two Cohorts Prospective Study to Evaluate the Efficacy and Safety of Tislelizumab Combined With Chemotherapy With or Without Bevacizumab in Non-squamous NSCLC With EGFR Sensitizing Mutation Who Failed EGFR TKI Therapy	II
NCT05962021	Neoadjuvant Toripalimab Plus Chemotherapy for Resectable Stage II-IIIB Non-squamous Non-small Cell Lung Cancer With EGFR Mutation: a Multicentre, Multi-cohort, Exploratory Study.	II
NCT06672068	Phase II clinical study of TY-9591 tablets combined with chemotherapy as first-line treatment for locally advanced or metastatic non-small cell lung cancer with EGFR sensitive mutations	II
NCT05948813	A Phase II Study of TY-9591 Tablets in Patients With EGFR-Mutated Non-small Cell Lung Cancer With Brain Metastases	II
NCT05541822	A Phase II Multicenter, Open-Label, Parallel Cohort Expansion Study to Evaluate the Efficacy, Safety, Tolerability and Pharmacokinetic Profile of ABN401 in Patients With Advanced Solid Tumors Harboring c-Mesenchymal-epithelial Transition Factor (c-MET) Dysregulation	II
NCT06107686	A Multicenter, Open-Label, Phase II Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of YL202 in Selected Patients With Advanced Solid Tumors	II
NCT03574402	An Open-label, Multi-center, Phase II Umbrella Study to Assess Efficacy of Targeted Therapy or Immunotherapy Directed by Next Generation Sequencing (NGS) in Chinese Patients With Advanced NSCLC (TRUMP)	II

Clinical Trials Summary (continued)

EGFR exon 19 deletion (continued)

NCT ID	Title	Phase
NCT06940401	A Phase I/II Clinical Study to Evaluate JS111 Capsules in Patients With Locally Advanced, Metastatic, or Recurrent Non-Small Cell Lung Cancer (NSCLC) Harboring Epidermal Growth Factor Receptor (EGFR) Mutations.	I/II
NCT05271916	An Open Label, Multicenter, Phase I/IIB Study of Dacomitinib Plus Anlotinib for Advanced Non-Small Cell Lung Cancer (NSCLC) Harboring Epidermal Growth Factor Receptor (EGFR) 21-L858R Mutations	I/II
NCT05785741	A Phase I/IIa, Multicenter, Open-Label, First in Human Study to Assess the Safety, Tolerability, Pharmacokinetics, and Preliminary Antitumor Activity of DB-1310 in Subjects With Advanced/ Metastatic Solid Tumors	I/II
No NCT ID	A Dose-Escalation And Dose-Expansion Phase I/Phase II Clinical Study On The Safety, Tolerability, Pharmacokinetic Characteristics And Preliminary Efficacy Of Dositinib Mesylate Tablets (90-1408) In The Treatment Of Locally Advanced Or Metastatic Non-Small Cell Lung Cancer With Positive EGFR Mutations.	I/II
NCT05552781	A Phase I/IIa, Open-label, Dose-escalation and Expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetic and Preliminary Anti-tumor Activity of H002 in Patients With EGFR Mutation Locally Advanced or Metastatic NSCLC	I/II
NCT05994131	A Multicenter, Open-label, Phase Ib/II Clinical Trial to Evaluate the Safety, Tolerance, Pharmacokinetics and Anti-tumor Efficacy of IN10018 Combined With Third-generation EGFR-TKI in Patients With Advanced EGFR Mutation-positive NSCLC	I/II
No NCT ID	A Phase I/II Study of Necitumumab plus Osimertinib for Advanced Non-small Cell Lung Cancer with EGFR-mutation (NEO-FORCE study)	I/II
NCT05821933	An Open Single-arm Study to Evaluate the Safety, Tolerability, Efficacy of RC108 in Combination With Furmonertinib and Toripalimab in Patients With Advanced EGFR-mutated NSCLC Ib/II Study	I/II
NCT06195189	Sunvozertinib Combined With Chemotherapy for EGFRm + Locally Advanced or Metastasis NSCLC Patients After EGFR-TKI Treatment Failure (Phase I/II (WU-KONG36)	I/II
NCT06631989	A Phase I/II Multicenter, Open Label, Single-arm Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of WSD0922-FU in the Treatment of Advanced Non-small Cell Lung Cancer	I/II
No NCT ID	A Non-interventional, Single-arm, Prospective Clinical Study for the Efficacy and Safety of Low-dose Afatinib Combined with Pemetrexed and Carboplatin in First-line Treatment of Advanced EGFR Mutant Non-squamous Non-small Cell Lung Cancer	I
NCT05826483	Exploration of the Clinical Application of Almonertinib in the First-line Treatment of Patients With EGFR Mutation-positive Advanced Non-small Cell Lung Cancer With Poor Performance Status	I
NCT06926413	An Open-label, Fixed-sequence Phase I Clinical Study Evaluating the Effect of Multiple Oral Doses of Aumolertinib on the Pharmacokinetics of Midazolam in Patients With Non-small Cell Lung Cancer (NSCLC)	I
NCT05306132	A Phase I, Open, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity of ASKC202 in Patients With Advanced Solid Tumors	I
NCT05647122	A Phase I, Multicenter, Open-label, First-in-Human, Dose Escalation and Expansion Study of AZD9592 as Monotherapy and in Combination With Anti-cancer Agents in Patients With Advanced Solid Tumors	I
No NCT ID	Befotertinib with Icotinib as first line treatment in advanced non-small cell lung cancer patients with epidermal growth factor receptor (EGFR) mutation positive: an exploratory study	I

Clinical Trials Summary (continued)

EGFR exon 19 deletion (continued)

NCT ID	Title	Phase
NCT06362980	An Open-label, Single-arm, Investigator-initiated Phase I Clinical Study Evaluating BPI-1178 Capsules in Combination With Osimertinib Tablets in Patients With Locally Advanced or Metastatic Non-small Cell Lung Cancer With EGFR Mutations	I
NCT06813365	A Phase 1, Open-Label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics, and Anti-tumor Efficacy of DZD6008 in Patients With Advanced Non-Small Cell Lung Cancer (NSCLC) With EGFR Mutation (TIAN-SHAN2)	I
NCT03976856	A Phase Ib Clinical Study With Extension Phase to Evaluate Safety and Efficacy of Genolimzumab (GB226) in Combination With Fruquintinib in the Treatment of Relapsed or Metastatic NSCLC Patients	I
No NCT ID	Study Of Immunologic Factor In Re-Biopsy Specimen, Peritumoral BALF, And The Peripheral Blood For Predicting Response To Osimertinib In NSCLC Patients	I
NCT03260491	A Multicenter, Open-Label Phase 1 Study of U3-1402 in Subjects With Metastatic or Unresectable Non-small Cell Lung Cancer	I
No NCT ID	Clinical Phase I Open trial, EGFR-mutant Advanced Non-small Cell Lung Cancer Patients, with EGFR-TKI Standard Treatment, Combined with the Safety and Tolerability Evaluation of PB101 Immune Cell Preparations	I
NCT05489731	Phase I Clinical Study of VIC-1911 Combined With Osimertinib in the Treatment of Advanced Non-small Cell Lung Cancer With EGRF-TKI Mutation	I
No NCT ID	A phase I clinical study of the safety, tolerability and preliminary antitumor activity of WTS-004 in patients with EGFR mutation-positive advanced non-small cell lung cancer with central nervous system metastases.	I
No NCT ID	Platform trial of dipalertinib in patients with EGFR mutation-positive non-small cell lung cancer	I
No NCT ID	A prospective, single arm, multicenter clinical study of adebrelimab combined with bevacizumab and platinum containing chemotherapy for locally advanced or metastatic non-squamous non-small cell lung cancer patients with EGFR sensitive mutation positive who failed EGFR TKI treatment and EGFR T790M negative, PD-L1 TPS>=1%	IV
NCT06561620	A Prospective Study of Befotertinib Adjuvant Therapy in Patients With Postoperative MRD-positive Non-small Cell Lung Cancer in Stage IA2-IB With High Risk Factors	IV
NCT04116918	Efficacy and Safety of the Combination of Anlotinib and JS001 in EGFR-TKI Resistant T790M-Negative NSCLC	IV
No NCT ID	Gefitinib Combined With Vinorelbine Soft Capsules Vs Gefitinib Monotherapy In The Treatment Of Stage IIIB-IV NSCLC Patients With EGFR-Sensitive Mutation	IV
No NCT ID	Clinical Study of Gefitinib Combined with Recombinant Human Endostatin or Single-agent Gefitinib in The Treatment of EGFR Mutation-Positive Advanced NSCLC	IV
NCT05104281	Osimertinib Combined With Bevacizumab in Patients With Brain Metastasis Epidermal Growth Factor Receptor (EGFR) Mutation Positive Metastatic Non-Small Cell Lung Cancer	III
No NCT ID	Phase III Clinical Study Of The Effectiveness And Safety Of RX518 As The First-line Treatment For Patients With Locally Advanced Or Metastatic Non-small Cell Lung Cancer With EGFR Mutations	III

Clinical Trials Summary (continued)

EGFR exon 19 deletion (continued)

NCT ID	Title	Phase
NCT06829459	A Randomized, Controlled, Open-label Phase III Clinical Study to Evaluate the Efficacy and Safety of Glumetinib Combined With Osimertinib Mesylate Versus Platinum-based Doublet Chemotherapy in Non-Small Cell Lung Cancer Patients With MET Amplification and/or Overexpression After Resistance to EGFR-TKIs	III
No NCT ID	A Multicenter, Randomized, Open-Label, Phase III Clinical Trial Of Icotinib Plus Pemetrexed-Cisplatin Versus Pemetrexed-Cisplatin As Postoperative Adjuvant Treatment In Stage III(N1-N2) Non-Small Cell Lung Cancer(NSCLC) with EGFR-Sensitive Mutation	III
NCT06382116	A Phase III Randomized Controlled Clinical Study Comparing BL-B01D1 With Platinum Based Chemotherapy (First-line of Systemic Treatment) in Patients With Locally Advanced or Metastatic Non-small Cell Lung Cancer After EGFR-TKI Failure	III
NCT06838273	A Phase III Randomized Study of BL-B01D1 in Combination With Osimertinib Versus Osimertinib as First-Line Treatment in Patients With EGFR-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer	III
NCT06735391	A Phase III Clinical Study of JMT101 in Combination With Osimertinib Versus Osimertinib Alone as First-Line Treatment for Patients With Locally Advanced or Metastatic Non-Squamous Non-Small Cell Lung Cancer (NSCLC) Harboring Epidermal Growth Factor Receptor (EGFR) Sensitive Mutations	III
NCT05870319	A Randomized, Open-Label, Multicenter Phase 3 Study to Evaluate SKB264 Monotherapy Versus Pemetrexed in Combination With Platinum in Patients With Locally Advanced or Metastatic Non-squamous Non-small Cell Lung Cancer With EGFR Mutation Who Have Failed to Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor (EGFR-TKI) Therapy	III
NCT06670196	A Randomized, Open-Label, Multicenter, Phase III Clinical Study of SKB264 in Combination with Osimertinib Versus Osimertinib Alone As First-Line Treatment for Patients with Epidermal Growth Factor Receptor (EGFR) Mutations, Locally Advanced or Metastatic Non-Squamous Non-Small Cell Lung Cancer	III
NCT06709859	A Phase II Trial to Evaluate the Efficacy and Safety of Afatinib Combined With Chemotherapy as Conversion Therapy in Unresectable EGFR Sensitive Mutation-positive Stage III Non-small Cell Lung Cancer	II
No NCT ID	Clinical Observation of Aumolertinib in the Treatment of Residual Ground Glass Nodules in Patients with EGFR Mutation Positive after Resection of Lung Cancer	II
NCT06755684	Neoadjuvant Befotertinib Combined Bevacizumab or Platinum-based Double Chemotherapy for Resectable Locally-advanced EGFR Mutation-positive Non-Small Cell Lung Cancer: a Single-center, Randomized Controlled Trial	II
No NCT ID	Bevacizumab combined with Afatinib for First-Line Treatment of Locally Advanced or Advanced EGFR Mutation-Positive NSCLC Patients: The Effectiveness and Safety DataBase Management Platform Construction Project	II
NCT06277674	A Phase II Clinical Trial Evaluating the Efficacy of Cadonilimab in Combination With Pemetrexed and Anlotinib for Treatment of Elderly Patients With T790M-negative Advanced Non-squamous Non-small Cell Lung Cancer Following Resistance to EGFR-TKI.	II
NCT04978753	Phase II Clinical Study of the Efficacy and Safety of Anlotinib Combined With Almonertinib in the First-line Treatment of Patients With Brain Metastases From EGFR Mutation-positive Non-small Cell Lung cancer----a Prospective, Single-arm Exploratory Study	II

Clinical Trials Summary (continued)

EGFR exon 19 deletion (continued)

NCT ID	Title	Phase
No NCT ID	EGFR Tyrosine Kinase Inhibitors combined with Stereotactic Radiotherapy for Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized, Controlled, Open-Label, Multicenter Phase III Study	II
NCT06394674	A Prospective, Randomized, Phase II Clinical Trial of Single-agent Treatment With Different Doses of Sulfamethoxazole Furmonertinib in Patients With Advanced, Metastatic Lung Adenocarcinoma Who Have Progressed After First- or Second-line Treatment With EGFR-TKI Osimertinib	II
NCT06951464	A Phase II Study to Evaluate the Safety and Efficacy of Neoadjuvant Therapy With BL-B01D1 in Combination With Almonertinib Followed by Adjuvant Almonertinib in Patients With Epidermal Growth Factor Receptor Mutation Positive Stage II-IIIb Resectable Non-Small Cell Lung Cancer	II
NCT06498986	A Phase II Clinical Study to Evaluate the Efficacy and Safety of BL-B01D1 in Combination With Osimertinib Mesylate Tablets in Patients With Locally Advanced or Metastatic Non-small Cell Lung Cancer	II
NCT05559645	DZD9008 in Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC) With EGFR Mutations: Cohort Study	II
NCT06295432	A Phase II, Multicenter Study to Assess the Safety, Tolerability and Anti-tumor Efficacy of DZD9008 in Combination With AZD4205 in Standard Treatment Failed Non-Small Cell Lung Cancer (NSCLC) Patients With EGFR Mutations	II
NCT06269211	Neoadjuvant Toripalimab for Clinically Stage II-IIIb Resectable Non-small Cell Lung Cancer with EGFR Mutation and PD-L1 Positive Expression: a Prospective, Open-label, Multicenter, Single-arm Phase II Clinical Study	II
No NCT ID	Toripalimab combined with Clostridium Butyricum and Chemotherapy with or without Bevacizumab regimens for EGFR + Advanced or Metastatic Non-Squamous Non-Small Cell Lung Cancer Who Have Failed Transepidermal Growth Factor Receptor Tyrosine Kinase Inhibitor (EGFR-TKI) Therapy: A Single-Arm, Single-Center, Phase (Study	II
NCT05329298	A Phase I/II Open-label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of BPI-361175 in Subjects With Advanced Solid Tumors	I/II
NCT07070440	A Phase I/II, Open-Label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics, and Anti-tumor Efficacy of DZD6008 Combination Therapy in Patients With Locally Advanced or Metastatic NSCLC With EGFR Mutation (TIAN-SHAN7)	I/II
No NCT ID	A Dose-Escalation, Open-Label Phase I/II Clinical Study Of The Safety, Tolerability, Pharmacokinetics And Efficacy Of DAJH-1050766 Tablets In Patients With Advanced Non-Small Cell Lung Cancer	I/II
NCT06758557	A Multicenter, Open Phase Ib/II Study to Evaluate the Safety, Tolerability, and Preliminary Efficacy of HB0025 Injection Combined With Chemotherapy in Patients With Advanced Solid Tumor	I/II
No NCT ID	A Multi-arm, Open-label, Multi-center, Phase Ib/II Study Evaluating HB0025 Combined With HB0030 Versus HB0025 in the Treatment of Advanced Solid Tumors	I/II
NCT06186076	An Open Label, Multicenter, Phase I/II Study to Explore the Safety, Tolerability, Pharmacokinetics, and Anti-tumor Activity of TRX-221 in the Treatment of Patients With EGFR Mutant NSCLC Who Progressed Following Prior Therapy With EGFR TKI	I/II
No NCT ID	Clinical Study of Anlotinib Hydrochloride Combined with Gefitinib in First-Line Treatment of EGFR- Sensitive I Mutations In Advanced NSCLC	I
NCT04777084	A Prospective, Multi-cohort Clinical Research of Efficacy and Safety of Bispecific Anti-PD-1 / PD-L1 Antibody IBI318 Combined With Lenvatinib in the Treatment of Advanced NSCLC	I

Clinical Trials Summary (continued)

EGFR exon 19 deletion (continued)

NCT ID	Title	Phase
No NCT ID	The Continuous Evaluation of EGFR Mutation in EGFR-mutation Positive Lung Cancer Patients During EGFR TKI Treatment.	IV
NCT04136535	A Multicenter, Randomized, Phase II Study of Pemetrexed and Carboplatin With or Without Anlotinib Hydrochloride for Advanced or Locally-advanced Osimertinib-resistant Non-squamous Non-small Cell Lung Cancer (ALTER-L031)	II
NCT05813522	Efficacy and Safety Analysis of Furmonertinib in Patients With Leptomeningeal Metastases Associated With EGFR Mutated NSCLC (Guiding by Cerebrospinal Fluid ctDNA Detection)	II
NCT06706076	A Phase I/II Open-Label, Multicenter, First-in-Human Study of the Safety, Tolerability, Pharmacokinetics, and Antitumor Activity of BH-30643 in Adult Subjects With Locally Advanced or Metastatic NSCLC Harboring EGFR and/or HER2 Mutations (SOLARA)	I/II
NCT06685718	Phase 1a/1b, Open-Label Study Investigating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Antitumor Activity of a CDAC Degrading EGFR, BG-60366, in Patients With EGFR-Mutant Non-Small Cell Lung Cancer	I
NCT06507306	A Phase I/Ib, Open-label, Multicenter, Dose Escalation and Dose Expansion Study Evaluating the Safety, Tolerability, Pharmacokinetics and Efficacy of KQB198 as Monotherapy and in Combination With Anti-cancer Agents in Participants With Advanced Solid Malignancies	I
NCT07005102	A Phase II/III Randomized Study to Evaluate the Safety, Efficacy, and Optimal Dose of Telisotuzumab Adizutecan in Combination With Osimertinib as First-Line Treatment in Patients With Locally Advanced Unresectable or Metastatic EGFR-Mutated Non-Squamous Non-Small Cell Lung Cancer	II/III
NCT06298058	A Phase I Clinical Study on the Safety, Tolerability, Pharmacokinetics, and Preliminary Efficacy of SIBP-A13 Injection in the Treatment of Advanced Malignant Solid Tumor Patients.	I
NCT07110883	A Phase I Clinical Study Evaluating the Safety, Tolerability, Pharmacokinetic Profiles, and Preliminary Efficacy of SYS6023 in Patients With Advanced Solid Tumors	I

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