



Sample Information

Patient Name: 李傳興
Gender: Male
ID No.: Y100600368
History No.: 14622436
Age: 77

Ordering Doctor: DOC8359H 林暉芸
Ordering REQ.: 0CWBNTM
Signing in Date: 2024/1/22

Path No.: M113-00018
MP No.: F24009
Assay: Oncomine Focus Assay
Sample Type: FFPE
Block No.: S113-90148A
Percentage of tumor cells: 40%

Reporting Doctor: DOC5466K 葉奕成 (Phone: 8#5466)

Note:

Sample Cancer Type: Non-Small Cell Lung Cancer

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Relevant Non-Small Cell Lung Cancer Variants

Gene	Finding	Gene	Finding
ALK	None detected	NTRK1	None detected
BRAF	None detected	NTRK2	None detected
EGFR	EGFR exon 20 insertion	NTRK3	None detected
ERBB2	None detected	RET	None detected
KRAS	None detected	ROS1	None detected
MET	None detected		

Relevant Biomarkers

Tier	Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
IA	EGFR exon 20 insertion epidermal growth factor receptor Allele Frequency: 35.94%	amivantamab ^{1, 2} mobocertinib ¹	None	9

Public data sources included in relevant therapies: FDA¹, NCCN, EMA², ESMO
Tier Reference: Li 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. J Mol Diagn. 2017 Jan;19(1):4-23.

 Alerts informed by public data sources:  Contraindicated,  Resistance

EGFR exon 20 insertion	 gefitinib ²  afatinib, dacomitinib, erlotinib, gefitinib
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Public data sources included in alerts: FDA¹, NCCN, EMA², ESMO

Prevalent cancer biomarkers without relevant evidence based on included data sources

MYC amplification

Variants (Exclude variant in Taiwan BioBank with >1% allele frequency)

DNA Sequence Variants

Gene	Amino Acid Change	Coding	Variant ID	Locus	Allele Frequency	Transcript	Variant Effect	Coverage
EGFR	p.(D770_P772dup)	c.2315_2316insGGAC . AACC		chr7:55249017	35.94%	NM_005228.5	nonframeshift Insertion	1942

Copy Number Variations

Gene	Locus	Copy Number
MYC	chr8:128748885	6

Biomarker Descriptions

MYC amplification

MYC proto-oncogene, bHLH transcription factor

Background: The MYC gene encodes the MYC proto-oncogene (c-MYC), a basic helix-loop-helix transcription factor that regulates the expression of numerous genes that control cell cycle progression, apoptosis, metabolic pathways, and cellular transformation^{1,2,3,4}. MYC is part of the MYC oncogene family that includes related transcription factors MYCN and MYCL that regulate transcription in 10-15% of promoter regions⁵. MYC functions as a heterodimer in complex with the transcription factor MAX^{2,6}.

Alterations and prevalence: Recurrent somatic alterations are observed in both solid and hematological cancers. Recurrent somatic mutations in MYC, including codon T58, are infrequent and hypothesized to increase the stability of the MYC protein^{7,8}. MYC gene amplification is particularly common in diverse solid tumors. MYC amplification is observed in 30% of serous ovarian cancer, 20% of uterine serous carcinoma, 15% of esophageal and breast cancers, and is common (1-10%) in numerous other cancer types^{9,10,11}. MYC is the target of the t(8;14)(q24;32) chromosomal translocation in Burkitt's lymphoma that places MYC coding sequences adjacent to immunoglobulin region regulatory sequences, which results in increased MYC expression^{12,13}.

Potential relevance: B-cell lymphoma with MYC translocations that co-occur with BCL2 or BCL6 are referred to as double hit lymphoma, while co-occurrence with BCL2 and BCL6 rearrangements is referred to as triple-hit lymphoma^{14,15}. MYC translocations are also indicative of high risk for multiple myeloma and is associated with poor risk in acute lymphoblastic leukemia^{16,17}. Currently, no therapies are approved for MYC aberrations. Due to the high frequency of somatic MYC alterations in cancer, many approaches are

Biomarker Descriptions (continued)

being investigated in clinical trials including strategies to disrupt complex formation with MAX, including inhibition of MYC expression and synthetic lethality associated with MYC overexpression^{1,18,19,20}.

EGFR exon 20 insertion

epidermal growth factor receptor

Background: The EGFR gene encodes the epidermal growth factor receptor (EGFR) tyrosine kinase, a member of the ERBB/human epidermal growth factor receptor (HER) family. In addition to EGFR/ERBB1/HER1, other members of the ERBB/HER family include ERBB2/HER2, ERBB3/HER3, and ERBB4/HER4²¹. EGFR ligand induced dimerization results in kinase activation and leads to stimulation of oncogenic signaling pathways including the PI3K/AKT/MTOR and RAS/RAF/MEK/ERK pathways. Activation of these pathways promote cell proliferation, differentiation, and survival^{22,23}.

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^{11,24,25,26}. 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 21²⁷. These mutations constitutively activate EGFR resulting in downstream signaling, and represent 80% of the EGFR mutations observed in lung cancer. A second group of less prevalent activating mutations include E709K, G719X, S768I, L861Q, and short in-frame insertion mutations in exon 20^{28,29,30,31}. EGFR activating mutations in lung cancer tend to be mutually exclusive to KRAS activating mutations³². In contrast, a different set of recurrent activating EGFR mutations in the extracellular domain include R108K, A289V and G598V and are primarily observed in glioblastoma^{27,33}. Amplification of EGFR is observed in several cancer types including 30% of glioblastoma, 12% of esophageal cancer, 10% of head and neck cancer, 5% of bladder cancer, and 5% of lung squamous cell carcinoma^{11,25,26,33,34}. 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^{35,36,37}.

Potential relevance: Approved first-generation EGFR tyrosine kinase inhibitors (TKIs) include erlotinib³⁸ (2004) and gefitinib³⁹ (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 mutations. Second-generation TKIs afatinib⁴⁰ (2013) and dacomitinib⁴¹ (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^{42,43,44,45}. However, in 2021, the irreversible tyrosine kinase inhibitor, mobocertinib⁴⁶ was FDA approved for the treatment of NSCLC with EGFR exon 20 insertion mutations. Additionally, in 2022, the FDA granted breakthrough therapy designation to the irreversible EGFR inhibitors, CLN-081 (TPC-064)⁴⁷ and sunvozertinib⁴⁸, 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 resistance⁴⁹. The primary resistance mutation that emerges following treatment with first-generation TKI is T790M, accounting for 50-60% of resistant cases²⁷. Third generation TKIs were developed to maintain sensitivity in the presence of T790M. Osimertinib⁵⁰ (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. In this case, resistance is associated with the C797S mutation and occurs in 22-44% of cases⁴⁹. 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 versa⁵¹. T790M and C797S can occur in either cis or trans allelic orientation⁵¹. 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 TKIs⁵¹. 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^{51,52}. However, C797S occurring in cis conformation with T790M, confers resistance to first- and third-generation TKIs⁵¹. Fourth-generation TKIs are in development to overcome acquired C797S and T790M resistance mutations after osimertinib treatment. EGFR targeting antibodies including cetuximab (2004), panitumumab (2006), and necitumumab (2016) are under investigation in combination with EGFR-targeting TKIs for efficacy against EGFR mutations. The bispecific antibody, amivantamab⁵³, targeting EGFR and MET was approved (2021) for NSCLC tumors harboring EGFR exon 20 insertion mutations. CPO301⁵⁴ received a fast track designation (2023) from the FDA for EGFR mutations in patients with metastatic NSCLC who are relapsed/refractory or ineligible for EGFR targeting therapy such as 3rd-generation EGFR inhibitors including osimertinib. The Oncoprex immunogene therapy quaratusugene ozeplasmid⁵⁵ in combination with osimertinib received a fast track designation from the FDA (2020) for NSCLC tumors harboring EGFR mutations that progressed on osimertinib alone. BDTX-189⁵⁶ was granted a fast track designation (2020) for the treatment of solid tumors harboring an EGFR exon 20 insertion mutation.

Relevant Therapy Summary

☒ In this cancer type

☐ In other cancer type

☒ In this cancer type and other cancer types

☒ No evidence

EGFR exon 20 insertion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
amivantamab	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
mobocertinib	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
furmonertinib	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/> (III)
chemotherapy	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/> (II/III)
BLU-451	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/> (I/II)
osimertinib	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/> (I/II)
sunvozertinib	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/> (I/II)
zipalertinib	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/> (I/II)
ABBV-400	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/> (I)
AZD-9592, osimertinib	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/> (I)
BAY-2927088	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/> (I)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

Relevant Therapy Details

Current FDA Information

☒ In this cancer type

☐ In other cancer type

☒ In this cancer type and other cancer types

FDA information is current as of 2023-12-13. For the most up-to-date information, search www.fda.gov.

EGFR exon 20 insertion

☒ amivantamab

Cancer type: Non-Small Cell Lung Cancer

Label as of: 2022-11-04

Variant class: EGFR exon 20 insertion

Indications and usage:

RYBREVA[®] is a bispecific EGF receptor-directed and MET receptor directed antibody indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761210s002lbl.pdf

EGFR exon 20 insertion (continued)

● mobocertinib

Cancer type: Non-Small Cell Lung Cancer

Label as of: 2023-09-15

Variant class: EGFR exon 20 insertion

Indications and usage:

EXKIVITY® is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Reference:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215310s003lbl.pdf

Current NCCN Information

☒ In this cancer type ☐ In other cancer type ☐ In this cancer type and other cancer types

NCCN information is current as of 2023-12-01. To view the most recent and complete version of the guideline, go online to NCCN.org.

For NCCN International Adaptations & Translations, search www.nccn.org/global/what-we-do/international-adaptations.

Some variant specific evidence in this report may be associated with a broader set of alterations from the NCCN Guidelines. Specific variants listed in this report were sourced from approved therapies or scientific literature. These therapeutic options are appropriate for certain population segments with cancer. Refer to the NCCN Guidelines® for full recommendation.

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EGFR exon 20 insertion

☒ amivantamab

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR exon 20 insertion

NCCN Recommendation category: 2A

Population segment (Line of therapy):

- Adenocarcinoma, Large Cell, Squamous Cell, Not otherwise specified (NOS); Advanced, Metastatic, Progression (Subsequent therapy)

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 5.2023]

Current EMA Information

☒ In this cancer type ☐ In other cancer type ☐ In this cancer type and other cancer types

EMA information is current as of 2023-12-13. For the most up-to-date information, search www.ema.europa.eu/ema.

EGFR exon 20 insertion

☒ amivantamab

Cancer type: Non-Small Cell Lung Cancer

Label as of: 2023-09-22

Variant class: EGFR exon 20 insertion

Reference:

https://www.ema.europa.eu/en/documents/product-information/rybrevant-epar-product-information_en.pdf

Current ESMO Information

☒ In this cancer type ☐ In other cancer type ☒ In this cancer type and other cancer types

ESMO information is current as of 2023-12-01. For the most up-to-date information, search www.esmo.org.

EGFR exon 20 insertion

☒ amivantamab

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR exon 20 insertion

ESMO Level of Evidence/Grade of Recommendation: III / B

Population segment (Line of therapy):

- Stage IV; Metastatic, Advanced (Subsequent therapy); ESMO-MCBS v1.1 score: 3

Reference: ESMO Clinical Practice Guidelines - ESMO-Oncogene-addicted Metastatic Non-Small-Cell Lung Cancer [Annals of Oncology (2023), doi: <https://doi.org/10.1016/j.annonc.2022.12.009> (Published)]

☒ mobocertinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR exon 20 insertion

ESMO Level of Evidence/Grade of Recommendation: III / C

Population segment (Line of therapy):

- Stage IV; Advanced, Metastatic (Subsequent therapy); ESMO-MCBS v1.1 score: 2

Reference: ESMO Clinical Practice Guidelines - ESMO-Oncogene-addicted Metastatic Non-Small-Cell Lung Cancer [Annals of Oncology (2023), doi: <https://doi.org/10.1016/j.annonc.2022.12.009> (Published)]

Clinical Trials in Taiwan region:

Clinical Trials Summary

EGFR exon 20 insertion		
NCT ID	Title	Phase
NCT05607550	A Global, Phase III, Randomized, Multicenter, Open-Label Study to Investigate the Efficacy and Safety of Furmonertinib Compared to Platinum-Based Chemotherapy as First-Line Treatment for Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer With Epidermal Growth Factor Receptor Exon 20 Insertion Mutations	III
NCT05241873	Phase I/II Study of BLU-451 in Advanced Cancers With EGFR Exon 20 Insertion Mutations	I/II
NCT03974022	A Phase I/II, Open-Label, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics and Anti-tumor Efficacy of DZD9008 in Patients With Advanced Non-Small Cell Lung Cancer (NSCLC) with EGFR or HER2 Mutation	I/II
NCT04036682	A Phase I/II, Open-Label, Multi-Center Trial to Assess Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of CLN-081 in Patients With Locally-Advanced or Metastatic Non-Small Cell Lung Cancer Harboring EGFR Exon 20 Insertion Mutations Who Have Previously Received Platinum-Based Systemic Chemotherapy	I/II
NCT05099172	An Open Label, First-in-human Study of BAY 2927088 in Participants With Advanced Non-small Cell Lung Cancer (NSCLC) Harboring an EGFR and/or HER2 Mutation	I
NCT03178552	A Phase II/III Multicenter Study Evaluating the Efficacy and Safety of Multiple Targeted Therapies as Treatments for Patients With Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC) Harboring Actionable Somatic Mutations Detected in Blood (B-FAST: Blood-First Assay Screening Trial)	II/III
NCT03175224	Phase I/II Multicenter Study of the Safety, Pharmacokinetics, and Preliminary Efficacy of APL-101 in Subjects With Non-Small Cell Lung Cancer With c-Met EXON 14 Skip Mutations and c-Met Dysregulation Advanced Solid Tumors.	I/II
NCT05029882	A Phase I First in Human Study Evaluating Safety, Pharmacokinetics and Efficacy of ABBV-400 in Adult Subjects 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

Alerts Informed By Public Data Sources

Current FDA Information

 Contraindicated  Not recommended  Resistance  Breakthrough  Fast Track

FDA information is current as of 2023-12-13. For the most up-to-date information, search www.fda.gov.

EGFR exon 20 insertion

sunvozertinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR exon 20 insertion

Supporting Statement:

The FDA has granted Breakthrough Therapy Designation to a selective, irreversible, novel epidermal growth factor receptor (EGFR) inhibitor, DZD9008 (Sunvozertinib) for EGFR exon 20 insertion mutation positive locally advanced or metastatic non-small cell lung cancer.

Reference:

<https://www.biospace.com/article/releases/fda-grants-breakthrough-therapy-designation-for-dizal-pharmaceutical-s-dzd9008-in-patients-with-locally-advanced-or-metastatic-non-small-cell-lung-cancer-harboring-egfr-exon20-insertion/>

sunvozertinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR exon 20 insertion

Supporting Statement:

The FDA has granted Breakthrough Designation to a small molecule inhibitor, DZD9008 (sunvozertinib), for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy.

Reference:

<https://www.prnewswire.com/news-releases/fda-grants-breakthrough-therapy-designation-for-dizal-pharmaceuticals-dzd9008-in-patients-with-locally-advanced-or-metastatic-non-small-cell-lung-cancer-harboring-egfr-exon20-insertion-301469692.html>

zipalertinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR exon 20 insertion

Supporting Statement:

The FDA has granted Breakthrough Therapy Designation to an irreversible EGFR inhibitor, zipalertinib (CLN-081), for EGFR exon 20 insertion mutations in locally advanced or metastatic non-small cell lung cancer who have previously received platinum-based systemic chemotherapy.

Reference:

<https://investors.cullinanoncology.com/news-releases/news-release-details/fda-grants-breakthrough-therapy-designation-cullinan-oncologys>

EGFR exon 20 insertion (continued)

A BDTX-189

Cancer type: Solid Tumor

Variant class: EGFR exon 20 insertion

Supporting Statement:

The FDA has granted Fast Track Designation to BDTX-189 for solid tumors harboring a HER2 mutation or an EGFR or HER2 exon 20 insertion after progression on prior therapy.

Reference:

<https://investors.blackdiamondtherapeutics.com/news-releases/news-release-details/black-diamond-therapeutics-granted-fast-track-designation-fda>

A CPO-301

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR mutation

Supporting Statement:

The FDA has granted Fast Track Designation to a first-in-class antibody drug conjugate, CPO301, for EGFR mutations in patients with metastatic non-small cell lung cancer (NSCLC) who are relapsed/refractory to or ineligible for EGFR targeting therapy such as 3rd-generation EGFR inhibitors including Osimertinib.

Reference:

<http://iis.aastocks.com/20230612/10770455-0.PDF>

A osimertinib + quaratusugene ozeplasmid

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR mutation


Supporting Statement:


The FDA has granted Fast Track Designation to the immunogene therapy, quaratusugene ozeplasmid, in combination with EGFR inhibitor osimertinib for the treatment of EGFR mutations in non-small cell lung cancer (NSCLC) patients that progressed after treatment with osimertinib alone.

Reference:

<https://www.genprex.com/news/genprex-receives-u-s-fda-fast-track-designation-for-gene-therapy-that-targets-lung-cancer/>


Current NCCN Information

 Contraindicated

 Not recommended

 Resistance

 Breakthrough

 Fast Track

NCCN information is current as of 2023-12-01. To view the most recent and complete version of the guideline, go online to [NCCN.org](https://www.nccn.org).

For NCCN International Adaptations & Translations, search www.nccn.org/global/what-we-do/international-adaptations.

Some variant specific evidence in this report may be associated with a broader set of alterations from the NCCN Guidelines. Specific variants listed in this report were sourced from approved therapies or scientific literature. These therapeutic options are appropriate for certain population segments with cancer. Refer to the NCCN Guidelines® for full recommendation.

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EGFR exon 20 insertion

afatinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR exon 20 insertion

Summary:

NCCN Guidelines® include the following supporting statement(s):

- "EGFR exon 20 insertions are generally associated with a lack of response to first, second, and third generation tyrosine kinase inhibitors with select exceptions."

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 5.2023]

dacomitinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR exon 20 insertion

Summary:

NCCN Guidelines® include the following supporting statement(s):

- "EGFR exon 20 insertions are generally associated with a lack of response to first, second, and third generation tyrosine kinase inhibitors with select exceptions."

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 5.2023]

erlotinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR exon 20 insertion

Summary:

NCCN Guidelines® include the following supporting statement(s):

- "EGFR exon 20 insertions are generally associated with a lack of response to first, second, and third generation tyrosine kinase inhibitors with select exceptions."

Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 5.2023]

EGFR exon 20 insertion (continued)

gefitinib

Cancer type: Non-Small Cell Lung Cancer

Variant class: EGFR exon 20 insertion

Summary:

NCCN Guidelines® include the following supporting statement(s):

- "EGFR exon 20 insertions are generally associated with a lack of response to first, second, and third generation tyrosine kinase inhibitors with select exceptions."


Reference: NCCN Guidelines® - NCCN-Non-Small Cell Lung Cancer [Version 5.2023]

Current EMA Information

 Contraindicated

 Not recommended

 Resistance

 Breakthrough

 Fast Track

EMA information is current as of 2023-12-13. For the most up-to-date information, search www.ema.europa.eu/ema.

EGFR exon 20 insertion

gefitinib

Cancer type: Non-Small Cell Lung Cancer

Label as of: 2023-07-27

Variant class: EGFR exon 20 insertion

Reference:

https://www.ema.europa.eu/en/documents/product-information/gefitinib-mylan-epar-product-information_en.pdf

gefitinib

Cancer type: Non-Small Cell Lung Cancer

Label as of: 2023-07-17

Variant class: EGFR exon 20 insertion

Reference:

https://www.ema.europa.eu/en/documents/product-information/iressa-epar-product-information_en.pdf

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