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PATIENT INFORMATION	SAMPLE	REFERRING PHYSICIAN
Name: **JOHN SMITH**	Source: **FFFPE**	Name: **Oncologist, M.D.**
Gender: **MALE**	Date Collected: **10/23/2016**	Institution: **Oncology Practice**
Birthday: **04/22/1937**	Date Received: **10/28/2016**	Address: **21 Any Street Any City, Philippines**
Age: **79**	Date of Report: **11/06/2016**	Contact: **+632 123-4567**
Address: **14 Any Street, Any Village Any City, Philippines**	Lab ID: **TGZY160317**	

Tumor Profile for John Smith

ICD-10: C34.11: Malignant neoplasm of upper lobe, right bronchus or lung

OncoGxSelect™
Solid Tumor Genetic Profiling

Result: **POSITIVE**
Mutations Detected: EGFR-E746_A750del, EGFR-T790M

THERAPIES WITH POTENTIAL CLINICAL BENEFIT — SAME TUMOR TYPE

Targeted Therapies	Gene Alteration
Gefitinib, Erlotinib, Afatinib	EGFR-E746_A750del
Dacomitinib	EGFR-E746_A750del
Osimertinib	EGFR-T790M

THERAPIES WITH POTENTIAL CLINICAL BENEFIT — DIFFERENT TUMOR TYPE

Targeted Therapies	Gene Alteration
Erlotinib	EGFR-E746_A750del

LACK OF CLINICAL BENEFIT — SAME TUMOR TYPE

Targeted Therapies	Gene Alteration
Gefitinib, Erlotinib	EGFR-T790M

CLINICAL TRIALS TO CONSIDER

Drug Target	# Clinical Trials
EGFR-Exon19_del	5
EGFR-T790M	5

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KEY FINDINGS

1. **Potential Clinical Benefit** in Non-Small Cell Lung Cancer with **Gefitinib, Erlotinib, Afatinib** due to *EGFR* E746_A750del.
2. **Potential Clinical Benefit** in Non-Small Cell Lung Cancer with **Dacomitinib** due to *EGFR* E746_A750del.
3. **Potential Clinical Benefit** in Non-Small Cell Lung Cancer with **Osimertinib** due to *EGFR* T790M.
4. **Potential Clinical Benefit** in CNS (NSCLC metastases) with **Erlotinib** due to *EGFR* E746_A750del.
5. **Potential Drug Resistance** in Non-Small Cell Lung Cancer with **Gefitinib, Erlotinib** due to *EGFR* T790M.

** The Key Findings section is an overview of potential therapeutic benefit or lack thereof. Please refer to the information below for details.*

Medically Actionable Alterations

THERAPIES WITH POTENTIAL CLINICAL BENEFIT - SAME TUMOR TYPE

Gene	Alteration Detected	Therapies	Tumor Type	Reference
EGFR	E746_A750del	Gefitinib, Erlotinib, Afatinib	Non-Small Cell Lung Cancer	NCCN Guideline
EGFR	E746_A750del	Dacomitinib	Non-Small Cell Lung Cancer	Ramalingam SS, et al. 2012
EGFR	T790M	Osimertinib	Non-Small Cell Lung Cancer	NCCN Guideline

THERAPIES WITH POTENTIAL CLINICAL BENEFIT - DIFFERENT TUMOR TYPE

Gene	Alteration Detected	Therapies	Tumor Type	Reference
EGFR	E746_A750del	Erlotinib	CNS (NSCLC metastases)	NCCN Guideline

THERAPIES WITH POTENTIAL DRUG RESISTANCE - SAME TUMOR TYPE

Gene	Alteration Detected	Therapies	Tumor Type	Reference
EGFR	T790M	Gefitinib, Erlotinib	Non-Small Cell Lung Cancer	NCCN Guideline

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CLINICAL TRIALS TO CONSIDER

1. EGFR-Exon19_del Associated Clinical Trials

Therapies	NCT ID	Title	Phase	Locations#
Afatinib	NCT02514174	A Single Arm Phase IV Study of Afatinib in Elderly Patients With Stage IV or Recurrent Non-Small Cell Lung Cancer Whose Tumors Have Epidermal Growth Factor Receptor (EGFR) Exon 19 Deletions or Exon 21(L858R) Substitution Mutations	4	California, Hawaii
Erlotinib, Gefitinib, ASP8273	NCT02588261	An Open-label, Randomized Phase 3 Efficacy Study of ASP8273 vs Erlotinib or Gefitinib in First-line Treatment of Patients With Stage IIIB/IV Non-small Cell Lung Cancer Tumors With EGFR Activating Mutations	3	California, Oregon
AZD9291	NCT02511106	A Phase III, Double-blind, Randomized, Placebo-controlled Multi-centre, Study to Assess the Efficacy and Safety of AZD9291 Versus Placebo, in Patients With Epidermal Growth Factor Receptor Mutation Positive Stage IB-IIIA Non-small Cell Lung Carcinoma, Following Complete Tumour Resection With or Without Adjuvant Chemotherapy (ADAURA)	3	California, Hawaii
Ramucirumab, Erlotinib	NCT02411448	A Multicenter, Randomized, Double-Blind Study of Erlotinib in Combination With Ramucirumab or Placebo in Previously Untreated Patients With EGFR Mutation-Positive Metastatic Non-Small Cell Lung Cancer	3	California, Hawaii
Erlotinib Hydrochloride	NCT02193282	Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients With Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-small Cell Lung Cancer (NSCLC)	3	California, Hawaii

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2. EGFR-T790M Associated Clinical Trials				
Therapies	**NCT ID**	**Title**	**Phase**	**Locations#**
Erlotinib, Gefitinib, ASP8273	NCT02588261	An Open-label, Randomized Phase 3 Efficacy Study of ASP8273 vs Erlotinib or Gefitinib in First-line Treatment of Patients With Stage IIIB/IV Non-small Cell Lung Cancer Tumors With EGFR Activating Mutations	3	California, Oregon
AZD9291	NCT02511106	A Phase III, Double-blind, Randomized, Placebo-controlled Multi-centre, Study to Assess the Efficacy and Safety of AZD9291 Versus Placebo, in Patients With Epidermal Growth Factor Receptor Mutation Positive Stage IB-IIIA Non-small Cell Lung Carcinoma, Following Complete Tumour Resection With or Without Adjuvant Chemotherapy (ADAURA)	3	California, Hawaii
Afatinib Dimaleate, Cetuximab	NCT02438722	A Randomized Phase II/III Trial of Afatinib Plus Cetuximab Versus Afatinib Alone in Treatment-Naive Patients With Advanced, EGFR Mutation Positive Non-small Cell Lung Cancer (NSCLC)	2,3	California, Washington
INC280, Nivolumab, EGF816	NCT02323126	A Phase II, Multicenter, Open-label Study of EGF816 in Combination With Nivolumab in Adult Patients With EGFR Mutated Non-small Cell Lung Cancer and of INC280 in Combination With Nivolumab in Adult Patients With cMet Positive Non-small Cell Lung Cancer	2	Alabama
Osimertinib	NCT02759835	A Pilot Study of Local Ablative Therapy for Treatment of Oligoprogressive, EGFR-mutated, Non-Small Cell Lung Cancer (NSCLC) After Treatment With Osimertinib (AZD9291, Tagrisso)	2	Maryland

 # The two locations closest to the patient's address based on zip code are shown (for US locations, otherwise show all locations).
Note: Select clinical trials are shown. For a full list of clinical trials, please search the ClinicalTrials.gov website.

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ALTERATION DETAILS WITH THERAPEUTIC IMPLICATIONS BY TUMOR TYPE

EGFR	
Gene: *EGFR* Nucleotide: c.2235_2249del	Pathways: RAS/RAF/MEK/ERK signaling pathway
Alteration Detected: E746_A750del	Variation Type: Deletion
Response to Gefitinib, Erlotinib, Afatinib, Dacomitinib:	➢ Potential Clinical Benefit in Non-Small Cell Lung Cancer
Response to Erlotinib:	➢ Potential Clinical Benefit in CNS (NSCLC metastases)

EGFR	
Gene: *EGFR* Nucleotide: c.2369C>T	Pathways: RAS/RAF/MEK/ERK signaling pathway
Alteration Detected: T790M	Variation Type: Missense
Response to Osimertinib:	➢ Potential Clinical Benefit in Non-Small Cell Lung Cancer
Response to Gefitinib, Erlotinib:	➢ Potential Drug Resistance in Non-Small Cell Lung Cancer

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LIST OF ALL ALTERATIONS AND RESULTS

Gene	Alteration	Alteration Type	Result
ALK	T1151_L1152insT	Indel	Negative(-)
	F1174L	SNV	Negative(-)
	L1196M	SNV	Negative(-)
	G1202R	SNV	Negative(-)
	S1206Y	SNV	Negative(-)
	G1269A	SNV	Negative(-)
	EML4-ALK	Fusion	Negative(-)
	KIF5B-ALK	Fusion	Negative(-)
	TFG-ALK	Fusion	Negative(-)
	STRN-ALK	Fusion	Negative(-)
BRAF	G466V	SNV	Negative(-)
	G469A	SNV	Negative(-)
	G469E	SNV	Negative(-)
	G469L	SNV	Negative(-)
	G469V	SNV	Negative(-)
	D594G	SNV	Negative(-)
	D594V	SNV	Negative(-)
	G596R	SNV	Negative(-)
	L597Q	SNV	Negative(-)
	L597R	SNV	Negative(-)
	L597S	SNV	Negative(-)
	L597V	SNV	Negative(-)
	V600D	SNV	Negative(-)
	V600E	SNV	Negative(-)
	V600G	SNV	Negative(-)
	V600K	SNV	Negative(-)
	V600M	SNV	Negative(-)
	V600R	SNV	Negative(-)
	K601E	SNV	Negative(-)

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Gene	Alteration	Alteration Type	Result
EGFR	G719A	SNV	Negative(-)
	G719C	SNV	Negative(-)
	G719S	SNV	Negative(-)
	K745_A750del	Indel	Negative(-)
	E746_A750del	Indel	Positive(+)
	E746_A750delELREA	Indel	Negative(-)
	E746_S752delinsA	Indel	Negative(-)
	L747_S752del	Indel	Negative(-)
	L747_P753delinsS	Indel	Negative(-)
	A763_Y764insFQEA	Indel	Negative(-)
	G776L	SNV	Negative(-)
	G776_777insVC	Indel	Negative(-)
	A775_G776insYVMA	Indel	Negative(-)
	D770_N771insSVD	Indel	Negative(-)
	T790M	SNV	Positive(+)
	L858R	SNV	Negative(-)
	L861Q	SNV	Negative(-)
	L861R	SNV	Negative(-)
	Exon19_del	Indel	Negative(-)
	Exon19_ins	Indel	Negative(-)
	Exon20_ins	Indel	Negative(-)
	Amplification	CNV	Negative(-)
ERBB2	G776L	SNV	Negative(-)
	A775_G776insYVMA	Indel	Negative(-)
	G776_777insVC	Indel	Negative(-)
	Amplification	CNV	Negative(-)
KIT	W557R	SNV	Negative(-)
	V559A	SNV	Negative(-)
	V559D	SNV	Negative(-)
	L576P	SNV	Negative(-)
	K642E	SNV	Negative(-)
	D816H	SNV	Negative(-)
	Amplification	CNV	Negative(-)

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Gene	Alteration	Alteration Type	Result
KRAS	G12A	SNV	Negative(-)
	G12C	SNV	Negative(-)
	G12D	SNV	Negative(-)
	G12R	SNV	Negative(-)
	G12S	SNV	Negative(-)
	G12V	SNV	Negative(-)
	G13A	SNV	Negative(-)
	G13C	SNV	Negative(-)
	G13D	SNV	Negative(-)
	G13R	SNV	Negative(-)
	G13S	SNV	Negative(-)
	G13V	SNV	Negative(-)
	Q61H	SNV	Negative(-)
	Q61K	SNV	Negative(-)
	Q61L	SNV	Negative(-)
	Q61P	SNV	Negative(-)
	Q61R	SNV	Negative(-)
	A146P	SNV	Negative(-)
	A146T	SNV	Negative(-)
	A146V	SNV	Negative(-)
MAP2K1	C121S	SNV	Negative(-)
MET	Amplification	CNV	Negative(-)
	Exon14_skipping		Negative(-)

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Gene	Alteration	Alteration Type	Result
NRAS	G12A	SNV	Negative(-)
	G12C	SNV	Negative(-)
	G12D	SNV	Negative(-)
	G12R	SNV	Negative(-)
	G12S	SNV	Negative(-)
	G12V	SNV	Negative(-)
	G13A	SNV	Negative(-)
	G13C	SNV	Negative(-)
	G13D	SNV	Negative(-)
	G13R	SNV	Negative(-)
	G13S	SNV	Negative(-)
	G13V	SNV	Negative(-)
	Q61H	SNV	Negative(-)
	Q61K	SNV	Negative(-)
	Q61L	SNV	Negative(-)
	Q61P	SNV	Negative(-)
	Q61R	SNV	Negative(-)
PIK3CA	E542K	SNV	Negative(-)
	E545K	SNV	Negative(-)
	H1047R	SNV	Negative(-)
RET	C634R	SNV	Negative(-)
	C634W	SNV	Negative(-)
	C634Y	SNV	Negative(-)
	M918T	SNV	Negative(-)
	CCDC6-RET	Fusion	Negative(-)
	NCOA4-RET	Fusion	Negative(-)
	KIF5B-RET	Fusion	Negative(-)
ROS1	LRIG3-ROS1	Fusion	Negative(-)
	TPM3-ROS1	Fusion	Negative(-)
	EZR-ROS1	Fusion	Negative(-)
	SDC4-ROS1	Fusion	Negative(-)
	GOPC-ROS1	Fusion	Negative(-)
	SLC34A2-ROS1	Fusion	Negative(-)
	CD74-ROS1	Fusion	Negative(-)

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ABOUT GENES

EGFR

Epidermal growth factor receptor (EGFR) belongs to a family of receptor tyrosine kinases (RTKs) that include EGFR/ERBB1, HER2/ERBB2/NEU, HER3/ERBB3, and HER4/ERBB4. The binding of ligands, such as epidermal growth factor (EGF), induces a conformational change that facilitates receptor homo- or heterodimer formation, thereby resulting in activation of EGFR tyrosine kinase activity. Activated EGFR then phosphorylates its substrates, resulting in activation of multiple downstream pathways within the cell, including the PI3K-AKT-mTOR pathway, which is involved in cell survival, and the RAS-RAF-MEK-ERK pathway, which is involved in cell proliferation.

Mutation location in gene and/or protein
E746_A750del: Kinase domain (exon 19) ; T790M: Kinase domain (exon 20)

Mutation prevalence
EGFR mutation frequency in Non-Small Cell Lung Cancer: 28.10%(21403/76165)
EGFR-E746_A750del mutation frequency from all EGFR mutations in Non-Small Cell Lung Cancer: 8.08%(1729/21403)
EGFR-T790M mutation frequency from all EGFR mutations in Non-Small Cell Lung Cancer: 4.97%(1063/21403)

Effect of mutation
EGFR-E746_A750del is an activating mutation. EGFR activating mutations or amplification may predict sensitivity to Egfr-targeted therapies, including inhibitors of multiple ErbB family members, and several have received FDA approval in some tumor types (Mok et al., 2009, Rosell et al., 2009, Tsao et al., 2005). Egfr activation or overexpression may also lead to activation of the PI3K and MAPK pathway and may confer sensitivity to PI3K and MAPK pathway inhibitors (Bancroft et al., 2002).
EGFR-T790M is an activating mutation. EGFR activating mutations or amplification may predict sensitivity to Egfr-targeted therapies, including inhibitors of multiple ErbB family members, and several have received FDA approval in some tumor types (Mok et al., 2009, Rosell et al., 2009, Tsao et al., 2005). Egfr activation or overexpression may also lead to activation of the PI3K and MAPK pathway and may confer sensitivity to PI3K and MAPK pathway inhibitors (Bancroft et al., 2002). EGFR T790M has been reported to confer resistance to the first generation Egfr TKIs erlotinib and gefitinib (Li et al., 2007). Third generation irreversible Egfr TKIs that target the EGFR T790M mutation, such as rociletinib and osimertinib, have shown efficacy in NSCLC cases that harbor EGFR T790M and are resistant to first generation Egfr TKIs (Yang et al., 2015; IASLC 2015, Abstract 943, Sequist et al., 2015, Mitsudomi et al., 2015; IASLC 2015, Abstract 1406, Jänne et al., 2015). Osimertinib has been approved by the FDA for the treatment of EGFR T790M-mutant metastatic NSCLC (Yang et al., 2015; IASLC 2015, Abstract 943, Mitsudomi et al., 2015; IASLC 2015, Abstract 1406).

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CANCER DRUG INFORMATION

IRESSA® (Gefitinib)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206995s000lbl.pdf

TARCEVA® (Erlotinib)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021743s018lbl.pdf

GILOTRIF® (Afatinib)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/201292s002lbl.pdf

TAGRISSO® (Osimertinib)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208065s000lbl.pdf

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Table 1: OncoGxSelect™ Panel Genes

OncoGxSelect™ is an amplicon-based cancer test panel designed to provide sensitive and accurate genomic analysis on genes frequently mutated in cancers. EGFR, KRAS, BRAF, NRAS, ERBB2, ALK, PIK3CA, MAP2K1, KIT, MET, RET and ROS1. Using Next Generation Sequencing (NGS) based technology, this test detects point mutations, small insertions/deletions for EGFR, KRAS, BRAF, NRAS, ERBB2, ALK, PIK3CA, MAP2K1, KIT and MET, and detects selected known gene fusions for RET, ALK and ROS1, and Exon14 skipping for MET listed in the table below.

HGNC gene name	RefSeq Accession	Detectable Exons
BRAF	NM_004333	E11, E15
EGFR	NM_005228	E2, E3, E18, E19, E20, E21
KRAS	NM_004985	E2, E3, E4
NRAS	NM_002524	E2, E3, E4
ERBB2	NM_004448	E3, E12, E20, E23, E25
ALK	NM_004304	E22, E23, E25
PIK3CA	NM_006218	E9, E20
MAP2K1	NM_002755	E3
KIT	NM_000222	E2, E3, E6, E11, E13, E17
RET	NM_020975	E11, E16
MET	NM_001127500	E1, E2, E16, E17, E18, E20

HGNC gene name	RefSeq Accession	Detectable fusion partner genes
ROS1	NM_002944	CD74, SLC34A2, GOPC, EZR, SDC4, TPM3, LRIG3
ALK	NM_004304	KIF5B, TFG, EML4, STRN
RET	NM_020975	CCDC6, NCOA4, KIF5B

HGNC gene name	RefSeq Accession	Detectable fusion partner genes
MET	NM_001127500	E14 skipping

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References:

- NCCN Biomarkers Compendium at: http://www.nccn.org/professionals/biomarkers/content/
- U.S. Food and Drug Administration, Table of Pharmacogenomic Biomarkers in Drug Labeling. Available online at: http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083378.htm
- My Cancer Genome at: http://www.mycancergenome.org/
- Knowledge Base of Precision Oncology at: https://pct.mdanderson.org/
- Catalogue Of Somatic Mutations In Cancer (COSMIC) at: cancer.sanger.ac.uk
- Ramalingam SS, et al. Randomized phase II study of dacomitinib (PF-00299804), an irreversible pan-human epidermal growth factor receptor inhibitor, versus erlotinib in patients with advanced non-small-cell lung cancer. J Clin Oncol. 2012 Sep 20;30(27): 3337-44. (PMID: 22753918)
- Mok TS, et al. Gefitinib or carboplatin-paclitaxel in pulmonary adenocarcinoma. N Engl J Med. 2009 Sep 3;361(10):947-57. (PM ID: 19692680)
- Rosell R, et al. Screening for epidermal growth factor receptor mutations in lung cancer. N Engl J Med. 2009 Sep 3;361(10):958 -67. (PMID: 19692684)
- Tsao MS, et al. Erlotinib in lung cancer - molecular and clinical predictors of outcome. N Engl J Med. 2005 Jul 14;353(2):133-44. (PMID: 16014883)
- Bancroft CC, et al. Effects of pharmacologic antagonists of epidermal growth factor receptor, PI3K and MEK signal kinases on NF-kappaB and AP-1 activation and IL-8 and VEGF expression in human head and neck squamous cell carcinoma lines. Int J Cancer. 2002 Jun 1;99(4):538-48. (PMID: 11992543)
- Li D, et al. Bronchial and peripheral murine lung carcinomas induced by T790M-L858R mutant EGFR respond to HKI-272 and r apamycin combination therapy. Cancer Cell. 2007 Jul;12(1):81-93. (PMID: 17613438)
- Sequist LV, et al. Rociletinib in EGFR-mutated non-small-cell lung cancer. N Engl J Med. 2015 Apr 30;372(18):1700-9. (PMID: 25923550)
- Jänne PA, et al. AZD9291 in EGFR inhibitor-resistant non-small-cell lung cancer. N Engl J Med. 2015 Apr 30;372(18):1689-99. (PMID: 25923549)

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Test Methodology and Limitations for OncoGxSelect™:
Target regions of interest were constructed using an amplicon library and sequenced by massive parallel sequencing method (Illumina platform). The detected mutations are annotated based on hg19 reference genome assembly. The OncoGxSelect™ test was developed by Admera Health, including determination and validation of performance characteristics. The sensitivity and specificity of this test is greater than 99% and 99%, respectively, when a minimum of 10% tumor tissue is present in the sample. This test has not been approved by the U.S. Food and Drug Administration (FDA) but the FDA has determined that such clearance or approval is not necessary. The OncoGxSelect™ test is used for clinical purposes. It should not be regarded as investigational or for research. The Admera Health clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), accredited by the College of American Pathologists, and is qualified to perform high complexity clinical laboratory testing.

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The information contained in this report is provided as a service and does not constitute medical advice. At the time of report generation this information is believed to be current and is based upon published research; however, research data evolves and amendments to the prescribing information of the drugs listed will change over time. While this report is believed to be accurate and complete as of the date issued, THE DATA IS PROVIDED "AS IS", WITHOUT WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. As medical advice must be tailored to the specific circumstances of each case, the treating health care professional has ultimate responsibility for all treatment decisions made with regard to a patient including any made on the basis of a patient's genotype.

Signatures:

James J. Dermody, Ph.D.
Laboratory Director
Admera Health LLC
ABMG Certified, Clinical Molecular Genetics

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