Oncomine Cancer Panel Patient Test Report

Life Technologies Clinical Services Lab
910 Riverside Parkway, Suite 60 | West Sacramento, CA 95605
Ph: (888) 734-8588 | Fax: (855) 896-0909
clientservices@lifelabdx.com | lifelabdx.com

SUBJECT INFORMATION

Pre-Screening Subject No.: _____

Subject Initials: _____ (first/middle/last)

Date of Birth: _____ (dd/mmm/yyyy)

Gender: ☐ M ☐ F

SITE INFORMATION

Investigator Name: _____

Site ID: _____

Date of Shipment: _____ (dd/mmm/yyyy)

Phone: _____

Fax: _____

SPECIMEN INFORMATION

Accession No.: _____

Date Specimen Received: _____

Date Reported: _____

TEST RESULTS

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ✖ No evidence available

Mutations

Gene	Amino Acid Change	Geneotype	Classification	Current FDA Information	NCCN Guideline	Number of therapies with clinical trials in this therapies
KRAS	p.Ala146Thr	c.436G>A	Gain of Function	✖	⊘ 2	● 15
KIT	p.Met541Leu	c.1612A>C	Gain of Function	✖	● 1	● 1
MET	p.Asn375Ser	c.1124A>G	Gain of Function	✖	✖	● 3
TP53	p.Arg234Cys	c.700C>T	Loss of Function	✖	✖	● 1
TP53	p.Pro33Arg	c.98C>G	Loss of Function	✖	✖	● 1

Copy Number Variations

Gene	Type	Classification	Current FDA Information	NCCN Guideline	Number of therapies with clinical trials in this therapies
PTEN	Deletion	Loss of Function	✖	✖	● 5

There is no current FDA information, NCCN guidelines, or open clinical trials for the following detected copy number variations: RPS6KB1 Amplification, FLT3 Amplification, ACVRL1 Amplification, PTCH1 Deletion, CDKN2A Deletion, MYC Amplification, TERT Amplification, TET2 Deletion, VHL Deletion.

Other mutations, copy number variations, or fusions of that were detected but not classified by the Oncomine Knowledgebase as a genetic driver of cancer are not listed in the results section of this report. All other genes listed in the Test Description that do not appear in the results section either did not have a detected variant or the variant is not classified as a genetic driver for cancer.

Laboratory director: John E. Glassco, MD, FCAP

CLIA number: 05D1067109

KRAS A146 mutation in Colorectal Cancer

Published therapies summary

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ✖ No evidence available (IV), (III), (II/III), (II), (I/II), (I) Clinical trial phase

Published therapy	Current FDA information	NCCN Guidelines	Open clinical trials for this cancer type*
cetuximab	✖	⊘	✖
panitumumab	✖	⊘	✖
panitumumab + chemotherapy	✖	✖	● (II)
regorafenib + FOLFIRI	✖	✖	● (II)
sorafenib + cetuximab	✖	✖	● (II)
binimetinib + panitumumab	✖	✖	● (I/II)
BVD-523	✖	✖	● (I/II)
navitoclax + trametinib	✖	✖	● (I/II)
palbociclib	✖	✖	● (I/II)
binimetinib + BYL-719	✖	✖	● (I)
BMS-906024	✖	✖	● (I)
buparlisib + irinotecan	✖	✖	● (I)
cobimetinib + RG-7446	✖	✖	● (I)
MEHD-7945A + cobimetinib	✖	✖	● (I)
PD-0325901 + PF-04691502, PF-04691502 + irinotecan, PD-0325901 + irinotecan	✖	✖	● (I)
trametinib + uprosertib	✖	✖	● (I)
vorinostat + hydroxychloroquine	✖	✖	● (I)

* Most advanced phase is shown and multiple clinical trials may be available. See Open clinical trials section in the pages to follow.

Evidence and prevalence summary by class

A class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to unique citations (Current FDA information, NCCN Guidelines, or clinical trial eligibility criteria). An estimate of prevalence of the gene variant in the cancer type is provided.

Class	Evidence items	Prevalence * This cancer type
KRAS mutation status	2	35.5%
↳ KRAS mutation	15	35.5%
↳ KRAS non-G12 mutation	1	8.1%
↳ KRAS A146 mutation	1	<1%

* Source: Oncomine® Cancer Research Panel Knowledgebase (Thermo Fisher Scientific, Ann Arbor, MI)

Published therapies detail

● In this cancer type ○ In other cancer types ◑ In this cancer type and other cancer types ⊘ Contraindicated

NCCN Guidelines

NCCN Guidelines information is current as of 2014-07-01. For the most up-to-date information, go to www.nccn.org.

⊘ **cetuximab**

Cancer type: Colorectal Cancer

Class:
KRAS mutation

Contraindication:
Based upon lower-level evidence, there is uniform NCCN consensus (Category 2A) that patients with any known KRAS or NRAS mutation should not be treated with either cetuximab or pantitumumab. (COL-A 4 of 5, MS-34)

Reference:
NCCN Guideline Version 3.2014 Colon Cancer

⊘ **cetuximab**

Cancer type: Colorectal Cancer

Class:
KRAS mutation

Contraindication:
Based upon lower-level evidence, there is uniform NCCN consensus (Category 2A) that patients with any known KRAS or NRAS mutation should not be treated with either cetuximab or pantitumumab. (REC-A 5 of 6, MS-29 and MS-30)

Reference:
NCCN Guideline Version 3.2014 Rectal Cancer

● In this cancer type ○ In other cancer types ◑ In this cancer type and other cancer types ⊘ Contraindicated

NCCN Guidelines (cont'd)

NCCN Guidelines information is current as of 2014-07-01. For the most up-to-date information, go to www.nccn.org.

⊘ **panitumumab**

Cancer type: Colorectal Cancer

Class:
KRAS mutation

Contraindication:
Based upon lower-level evidence, there is uniform NCCN consensus (Category 2A) that patients with any known KRAS or NRAS mutation should not be treated with either cetuximab or pantitumumab. (COL-A 4 of 5, MS-34)

Reference:
NCCN Guideline Version 3.2014 Colon Cancer

⊘ **panitumumab**

Cancer type: Colorectal Cancer

Class:
KRAS mutation

Contraindication:
Based upon lower-level evidence, there is uniform NCCN consensus (Category 2A) that patients with any known KRAS or NRAS mutation should not be treated with either cetuximab or pantitumumab. (REC-A 5 of 6, MS-29 and MS-30)

Reference:
NCCN Guideline Version 3.2014 Rectal Cancer

Open clinical trials

Clinical trial information is current as of 2014-07-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID.

NCT01312857: A Randomized Phase II Study of Hepatic Arterial Infusion With Intravenous Irinotecan, 5FU and Leucovorin With or Without Panitumumab, in Patients With Wild Type KRAS Who Have Resected Hepatic Metastases From Colorectal Cancer

Class:
KRAS non-G12 mutation

Population segment(s):

First line, Liver mets, Second line or greater/Refractory/Relapsed, Stage IV

Phase:

II

Published therapy:

panitumumab + chemotherapy

Location(s):

NJ, NY

Contact:

Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

Open clinical trials (cont'd)

Clinical trial information is current as of 2014-07-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID.

NCT01298570: Multi-Center, Randomized, Placebo-Controlled Phase II Study of Regorafenib in Combination With FOLFIRI Versus Placebo With FOLFIRI as Second-Line Therapy in Patients With Metastatic Colorectal Cancer

Class:
KRAS mutation

Population segment(s):
Second line or greater/Refractory/Relapsed, Stage IV

Phase:
II

Published therapy:
regorafenib + FOLFIRI

Location(s):
CO, FL, GA, IN, NY, NC, OH, VA, WA

Contact:
Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

NCT00326495: A Phase II Study of BAY 43-9006 (Sorafenib) in Combination With Cetuximab (Erbitux) in EGFR Expressing Metastatic Colorectal Cancer (CRC)

Class:
KRAS mutation

Population segment(s):
Second line or greater/Refractory/Relapsed, Stage IV

Phase:
II

Published therapy:
sorafenib + cetuximab

Location(s):
MD

Contact:
Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

NCT02079740: An Open Label, Two-Part, Phase Ib/II Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Activity of the MEK Inhibitor Trametinib and the BCL2-Family Inhibitor Navitoclax (ABT-263) in Combination in Subjects With KRAS Mutation-Positive Advanced Solid Tumors

Class:
KRAS A146 mutation

Population segment(s):
Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase:
I/II

Published therapy:
navitoclax + trametinib

Location(s):
MA

Contact:
Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

Open clinical trials (cont'd)

Clinical trial information is current as of 2014-07-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID.

NCT01927341: A Phase Ib/II, Open-label, Multi-center, Dose Escalation Study of MEK162 in Combination With Panitumumab in Adult Patients With Mutant RAS or Wild-type RAS Metastatic Colorectal Cancer

Class:
KRAS mutation

Population segment(s):
Second line or greater/Refractory/Relapsed, Stage IV

Phase:
I/II

Published therapy:
binimetinib + panitumumab

Location(s):
CA

Contact:
Novartis Pharmaceuticals [1-888-669-6682]

NCT01781429: Phase I/II Dose-Escalation, Safety, Pharmacokinetic and Pharmacodynamic Study of BVD-523, an ERK 1/2 Inhibitor, in Patients With Advanced Malignancies

Class:
KRAS mutation

Population segment(s):
Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase:
I/II

Published therapy:
BVD-523

Location(s):
FL, TN

Contact:
Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

NCT02022982: Phase I/II Study of the CDK4/6 Inhibitor Palbociclib (PD-0332991) in Combination With the MEK Inhibitor PD-0325901 for Patients With KRAS Mutant Non-Small Cell Lung Cancer and Other Solid Tumors

Class:
KRAS mutation

Population segment(s):
Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase:
I/II

Published therapy:
palbociclib

Location(s):
MA

Contact:
Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

Open clinical trials (cont'd)

Clinical trial information is current as of 2014-07-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID.

NCT01449058: A Phase Ib Open-label, Multi-center, Dose Escalation and Expansion Study of Orally Administered MEK162 Plus BYL719 in Adult Patients With Selected Advanced Solid Tumors

Class:
KRAS mutation

Population segment(s):

HER2 negative, High risk, Second line or greater/Refractory/Relapsed, Stage II, Stage III, Stage IV, Triple receptor negative

Phase:

I

Published therapy:

binimetinib + BYL-719

Location(s):

CA, IL, MA, TX, UT

Contact:

Novartis Pharmaceuticals [1-862-778-8300]

NCT01304602: A Phase I Trial of Irinotecan and BKM120 in Previously Treated Advanced Colorectal Cancer

Class:
KRAS mutation

Population segment(s):

Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase:

I

Published therapy:

buparlisib + irinotecan

Location(s):

KS

Contact:

Stacey Purinton [913-588-2545;spurinton@kumc.edu]

Open clinical trials (cont'd)

Clinical trial information is current as of 2014-07-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID.

NCT01988896: A Phase Ib Study of the Safety and Pharmacology of MPDL3280A Administered with Cobimetinib in Patients with Locally Advanced or Metastatic Solid Tumors

Class:
KRAS mutation

Population segment(s):

Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase:

I

Published therapy:

cobimetinib + RG-7446

Location(s):

NY, NC, TN

Contact:

Reference Study ID Number: GP28363 [888-662-6728; global.rochegenentechtrials@roche.com]

NCT01986166: A Phase Ib, Open-Label, Dose-Escalation Study of The Safety, Tolerability, and Pharmacokinetics Of MEHD7945A and GDC-0973 In Patients with Locally Advanced or Metastatic Solid Tumors with Mutant Kras

Class:
KRAS mutation

Population segment(s):

Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase:

I

Published therapy:

MEHD-7945A + cobimetinib

Location(s):

CA, CO, MI, TN, TX

Contact:

Reference Study ID Number: GO29030 [888-662-6728; global.rochegenentechtrials@roche.com]

Open clinical trials (cont'd)

Clinical trial information is current as of 2014-07-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID.

NCT01347866: A Multi-Arm Phase I Dose Escalation Study Of The Safety, Pharmacokinetics, And Pharmacodynamics Of The Dual PI3K/mTOR Inhibitors PF-04691502 And PF-05212384 In Combination With Experimental Or Approved Anticancer Agents In Patients With Advanced Cancer

Class:
KRAS mutation

Population segment(s):

Second line or greater/Refractory/Relapsed, Stage II, Stage III, Stage IV

Phase:

I

Published therapy:

PD-0325901 + PF-04691502, PF-04691502 + irinotecan, PD-0325901 + irinotecan

Location(s):

CA, CO, SC

Contact:

Pfizer CT.gov Call Center [1-800-718-1021]

NCT01138085: A Phase I Dose Escalation Open-Label Safety, Pharmacokinetic and Pharmacodynamic Study to Determine the Recommended Phase II Dose of GSK1120212 Dosed in Combination With GSK2141795

Class:
KRAS mutation

Population segment(s):

HER2 negative, Recurrent, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase:

I

Published therapy:

trametinib + uprosertib

Location(s):

CO, MA, NJ, TN, TX, UT

Contact:

US GSK Clinical Trials Call Center [877-379-3718; GSKClinicalSupportHD@gsk.com]

Open clinical trials (cont'd)

Clinical trial information is current as of 2014-07-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID.

NCT01292655: Phase I Ascending Multiple-Dose Study to Evaluate the Safety, Pharmacokinetics (PK) and Pharmacodynamics (PD) of BMS-906024 in Subjects With Advanced Solid Tumors

Class:
KRAS mutation status

Population segment(s):

HER2 negative, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase:

I

Published therapy:

BMS-906024

Location(s):

CA, MI, MS, TX

Contact:

Multiple contacts: See www.clinicaltrials.gov for complete list of contacts.

NCT01023737: Inhibition of Autophagy in Solid Tumors: A Phase I Pharmacokinetic and Pharmacodynamic Study of Hydroxychloroquine in Combination With the HDAC Inhibitor Vorinostat for the Treatment of Patients With Advanced Solid Tumors With an Expansion Study in Advanced Renal and Colorectal Cancer.

Class:
KRAS mutation status

Population segment(s):

Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase:

I

Published therapy:

vorinostat + hydroxychloroquine

Location(s):

TX

Contact:

Epp Goodwin [210-450-5798; onctrial@idd.org]

KIT mutation in Colorectal Cancer

Published therapies summary

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ✖ No evidence available (IV), (III), (II/III), (II), (I/II), (I) Clinical trial phase

Published therapy	Current FDA information	NCCN Guidelines	Open clinical trials for this cancer type*
imatinib mesylate	✖	○	✖
imatinib mesylate + ipilimumab	✖	✖	● (I)

* Most advanced phase is shown and multiple clinical trials may be available. See Open clinical trials section in the pages to follow.

Evidence and prevalence summary by class

A class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to unique citations (Current FDA information, NCCN Guidelines, or clinical trial eligibility criteria). An estimate of prevalence of the gene variant in the cancer type is provided.

		Prevalence *
Class	Evidence items	This cancer type
KIT mutation	2	<1%

* Source: Oncomine® Cancer Research Panel Knowledgebase (Thermo Fisher Scientific, Ann Arbor, MI)

Published therapies detail

● In this cancer type ○ In other cancer types ◑ In this cancer type and other cancer types ⊘ Contraindicated

NCCN Guidelines

NCCN Guidelines information is current as of 2014-07-01. For the most up-to-date information, go to www.nccn.org.

○ **imatinib mesylate**

Cancer type: Melanoma

Class:
KIT mutation

NCCN Recommendation category:
2A

Population segment (Line of therapy):
Advanced or metastatic melanoma (Not specified)

Reference:
NCCN Guideline Version 4.2014 Melanoma

Open clinical trials

Clinical trial information is current as of 2014-07-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID.

NCT01738139: A Phase I Trial of Ipilimumab (Immunotherapy) and Imatinib Mesylate (c-Kit Inhibitor) in Patients With Advanced Malignancies

Class:
KIT mutation

Population segment(s):

Metastatic, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Unresectable

Phase:

I

Published therapy:

imatinib mesylate + ipilimumab

Location(s):

TX

Contact:

David S. Hong [713-563-1930]

MET mutation in Colorectal Cancer

Published therapies summary

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ✖ No evidence available (IV), (III), (II/III), (II), (I/II), (I) Clinical trial phase

Published therapy	Current FDA information	NCCN Guidelines	Open clinical trials for this cancer type*
AMG-337	✖	✖	● (I)
crizotinib + dasatinib	✖	✖	● (I)
crizotinib + pazopanib, crizotinib + pemetrexed, crizotinib + pazopanib + pemetrexed	✖	✖	● (I)

* Most advanced phase is shown and multiple clinical trials may be available. See Open clinical trials section in the pages to follow.

Evidence and prevalence summary by class

A class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to unique citations (Current FDA information, NCCN Guidelines, or clinical trial eligibility criteria). An estimate of prevalence of the gene variant in the cancer type is provided.

		Prevalence *
Class	Evidence items	This cancer type
MET positive	0	<1%
↳ MET mutation	3	<1%

* Source: Oncomine® Cancer Research Panel Knowledgebase (Thermo Fisher Scientific, Ann Arbor, MI)

Published therapies detail

Open clinical trials

Clinical trial information is current as of 2014-07-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID.

NCT01253707: A Phase I, First-In-Human Study Evaluating the Safety, Tolerability, and Pharmacokinetics of AMG 337 in Adult Subjects With Advanced Solid Tumors

Class:
MET mutation

Population segment(s):

Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase:

I

Published therapy:

AMG-337

Location(s):

CA, IL, MA, MI, OH, TN, TX

Contact:

Amgen Call Center [866-572-6436]

NCT01744652: A Phase I Trial of Dasatinib in Combination With Crizotinib in Patients With Advanced Malignancies

Class:
MET mutation

Population segment(s):

Aggressive, Classical, Indolent, Nodular lymphocyte-predominant, Second line or greater/Refractory/Relapsed, Stage IV

Phase:

I

Published therapy:

crizotinib + dasatinib

Location(s):

TX

Contact:

Dr. David S. Hong [713-763-1930]

Open clinical trials (cont'd)

Clinical trial information is current as of 2014-07-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID.

NCT01548144: A Two Steps Phase I Trial of Pazopanib or Pemetrexed in Combination With Crizotinib Followed by the Triplet, Crizotinib Plus Pazopanib Plus Pemetrexed in Patients With Advanced Malignancies

Class:
MET mutation

Population segment(s):

Second line or greater/Refractory/Relapsed, Stage IV

Phase:

I

Published therapy:

crizotinib + pazopanib, crizotinib + pemetrexed, crizotinib + pazopanib + pemetrexed

Location(s):

TX

Contact:

Dr Ralph Zinner [713-563-1930, 800-392-1611]

TP53 mutation in Colorectal Cancer

Published therapies summary

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ✖ No evidence available (IV), (III), (II/III), (II), (I/II), (I) Clinical trial phase

Published therapy	Current FDA information	NCCN Guidelines	Open clinical trials for this cancer type*
MK-8242	✖	✖	● (I)

* Most advanced phase is shown and multiple clinical trials may be available. See Open clinical trials section in the pages to follow.

Evidence and prevalence summary by class

A class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to unique citations (Current FDA information, NCCN Guidelines, or clinical trial eligibility criteria). An estimate of prevalence of the gene variant in the cancer type is provided.

		Prevalence *
Class	Evidence items	This cancer type
TP53 mutation	1	70.8%

* Source: Oncomine® Cancer Research Panel Knowledgebase (Thermo Fisher Scientific, Ann Arbor, MI)

Published therapies detail

Open clinical trials

Clinical trial information is current as of 2014-07-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID.

NCT01463696: A Phase I Study to Evaluate the Safety and Tolerability and Pharmacokinetic/Pharmacodynamics of MK-8242 in Patients With Advanced Solid Tumors

Class:
TP53 mutation

Population segment(s):

Locally advanced, Metastatic, Second line or greater/Refractory/Relapsed, Stage III, Stage IV

Phase:

I

Published therapy:

MK-8242

Location(s):

FL, MA, TX

Contact:

Toll Free Number [1-888-577-8839]

PTEN deletion in Colorectal Cancer

Published therapies summary

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ✖ No evidence available (IV), (III), (II/III), (II), (I/II), (I) Clinical trial phase

Published therapy	Current FDA information	NCCN Guidelines	Open clinical trials for this cancer type*
GSK-2636771	✖	✖	● (I/II)
talazoparib	✖	✖	● (I/II)
AZD8186	✖	✖	● (I)
temsirolimus + erlotinib	✖	✖	● (I)
trametinib + uprosertib	✖	✖	● (I)

* Most advanced phase is shown and multiple clinical trials may be available. See Open clinical trials section in the pages to follow.

Evidence and prevalence summary by class

A class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to unique citations (Current FDA information, NCCN Guidelines, or clinical trial eligibility criteria). An estimate of prevalence of the gene variant in the cancer type is provided.

		Prevalence *
Class	Evidence items	This cancer type
PTEN deficiency	2	2.8%
↳ PTEN deletion	3	1.2%

* Source: Oncomine® Cancer Research Panel Knowledgebase (Thermo Fisher Scientific, Ann Arbor, MI)

Published therapies detail

Open clinical trials

Clinical trial information is current as of 2014-07-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID.

NCT01458067: A Phase I/IIa, First Time in Human, Open-label Dose-escalation Study of GSK2636771 in Subjects With Advanced Solid Tumors With PTEN Deficiency

Class:
PTEN deletion

Population segment(s):

HER2 negative, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage II, Stage III, Stage IV, Triple receptor negative

Phase:

I/II

Published therapy:

GSK-2636771

Location(s):

CT, TN, UT

Contact:

US GSK Clinical Trials Call Center [877-379-3718; GSKClinicalSupportHD@gsk.com]

NCT01286987: A Phase I/II, First in Human, Single-arm, Open-label Study of Once a Day, Orally Administered BMN 673 in Patients With Advanced or Recurrent Solid Tumors

Class:
PTEN deletion

Population segment(s):

Hormone refractory, Locally advanced, Metastatic, Second line or greater/Refractory/Relapsed, Stage II, Stage III, Stage IV, Unresectable

Phase:

I/II

Published therapy:

talazoparib

Location(s):

AZ, CA, IN, MI, TX

Contact:

Elva Mazabel [415-506-6662; emazabel@bmrn.com]

Open clinical trials (cont'd)

Clinical trial information is current as of 2014-07-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID.

NCT00770263: Phase I Study of Erlotinib and Temsirolimus in Resistant Solid Malignancies

Class:
PTEN deletion

Population segment(s):

(N/A), Papillary, Second line or greater/Refractory/Relapsed

Phase:

I

Published therapy:

temsirolimus + erlotinib

Location(s):

MO

Contact:

Washington University School of Medicine [800-600-3606; info@ccadmin.wustl.edu]

NCT01884285: A Phase I, Open-label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ascending Doses of AZD8186 in Patients With Advanced Castrate-resistant Prostate Cancer (CRPC), Squamous Non-Small Cell Lung Cancer (sqNSCLC), Triple Negative Breast Cancer (TNBC) and Patients With Known PTEN-deficient Advanced Solid Malignancies, With Expansion to Assess the Pharmacodynamic Activity of AZD8186 Within Prospectively-validated PTEN Deficient Tumours

Class:
PTEN deficiency

Population segment(s):

HER2 negative, Hormone refractory, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase:

I

Published therapy:

AZD8186

Location(s):

MA, WA, WI

Contact:

AstraZeneca Clinical Study Information [800-236-9933; ClinicalTrialTransparency@astrazeneca.com]

Open clinical trials (cont'd)

Clinical trial information is current as of 2014-07-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID.

NCT01138085: A Phase I Dose Escalation Open-Label Safety, Pharmacokinetic and Pharmacodynamic Study to Determine the Recommended Phase II Dose of GSK1120212 Dosed in Combination With GSK2141795

Class:
PTEN deficiency

Population segment(s):

HER2 negative, Recurrent, Second line or greater/Refractory/Relapsed, Stage III, Stage IV, Triple receptor negative

Phase:

I

Published therapy:

trametinib + uprosertib

Location(s):

CO, MA, NJ, TN, TX, UT

Contact:

US GSK Clinical Trials Call Center [877-379-3718; GSKClinicalSupportHD@gsk.com]

Pre-screening subject number: Date Reported:

TEST DESCRIPTION

Oncomine Cancer Panel is a next-generation sequencing (NGS) based test that detects genomic alterations in cancer-related genes.

Test results are intended to aid in patient management when used in conjunction with standard clinical assessment. The test is neither intended nor validated for diagnosis.

Hotspot - Mutations		CDS - Mutations	Copy Number Variations		Fusion Drivers	Fusion Exon Deletion
ABL1	JAK1	APC	ACVRL1	GAS6	ABL1	EGFR
AKT1	JAK2	ATM	AKT1	IGF1R	AKT3	
ALK	JAK3	BAP1	APEX1	IL6	ALK	
AR	KDR	BRCA1	AR	KIT	AXL	
ARAF	KIT	BRCA2	ATP11B	KRAS	BRAF	
BRAF	KNSTRN	CDH1	BCL2L1	MCL1	CDK4	
BTK	KRAS	CDKN2A	BCL9	MDM2	ERBB2	
CBL	MAGOH	FBXW7	BIRC2	MDM4	ERG	
CDK4	MAP2K1	GATA3	BIRC3	MET	ETV1	
CHEK2	MAP2K2	MSH2	CCND1	MYC	ETV4	
CSF1R	MAPK1	NF1	CCNE1	MYCL	ETV5	
CTNNB1	MAX	NF2	CD274	MYCN	FGFR1	
DDR2	MED12	NOTCH1	CD44	MYO18A	FGFR2	
DNMT3A	MET	PIK3R1	CDK4	NKX2-1	FGFR3	
EGFR	MLH1	PTCH1	CDK6	NKX2-8	NTRK1	
ERBB2	MPL	PTEN	CSNK2A1	PDCD1LG2	NTRK3	
ERBB3	MTOR	RB1	DCUN1D1	PDGFRA	PDGFRA	
ERBB4	MYD88	SMAD4	EGFR	PIK3CA	PPARG	
ESR1	NFE2L2	SMARCB1	ERBB2	PNP	RAF1	
EZH2	NPM1	STK11	FGFR1	PPARG	RET	
FGFR1	NRAS	TET2	FGFR2	RPS6KB1	ROS1	
FGFR2	PAX5	TP53	FGFR3	SOX2		
FGFR3	PDGFRA	TSC1	FGFR4	TERT		
FLT3	PIK3CA	TSC2	FLT3	TIAF1		
FOXL2	PPP2R1A	VHL		ZNF217		
GATA2	PTPN11	WT1				
GNA11	RAC1					
GNAQ	RAF1					
GNAS	RET					
HNF1A	RHEB					
HRAS	RHOA					
IDH1	SF3B1					
IDH2	SMO					
IFITM1	SPOP					
IFITM3	SRC					
	STAT3					
	U2AF1					
	XPO1					

Laboratory director: John E. Glassco, MD, FCAP **CLIA number: 05D1067109**

APPENDIX

Report: Information compiled in this report is from publicly available sources. By updating the source database quarterly, LTCSL is making every effort to provide the most accurate and up-to-date information. However, accuracy and completeness are not guaranteed and test reports, once issued, will not be updated.

No Guarantee: By providing drug and clinical trial information for the reported diagnosis, LTCSL is not guaranteeing that any drug or clinical trial is necessarily appropriate for this patient. Healthcare providers should evaluate and interpret the information provided in this report, along with all other available clinical information about this patient, to determine the best treatment decisions in their own independent medical judgment. Patient management decisions should not be based on a single test, including this one, nor solely on the information contained in this report.

Alterations: This test identifies genomic alterations found in the submitted tumor tissue to select cancer-associated genes or portions of genes. While tested alterations were selected for inclusion in the test based on clinical level of evidence, LTCSL makes no claims regarding the clinical actionability of tested and reported alterations. Also note that this test only examines tumor, and not normal, tissue from the patient, and therefore cannot distinguish between somatic and germline (i.e., heritable) alterations.

Drugs: The drugs listed on the report are not ranked in any specific order as to predicted efficacy or appropriateness for this patient. LTCSL makes no guarantee or promise as to the effectiveness or suitability (or lack thereof) of any drug listed on this report. For more detailed information, healthcare providers should refer to the package insert for each FDA-approved drug listed in this report, and go to clinicaltrials.gov for information regarding drugs in clinical trials.

Reimbursement: LTCSL makes no guarantee that any third party payor, including any governmental healthcare program, will pay for this test.