



Personalized Gene Profile

Patient Name: _____			Client Name: _____		Lims ID: _____	
					2-17778	
DoB: _____	Age: _____	Gender: _____	Ordering Physician: _____		Collection Date: _____	Date Received: _____
Indication: _____			Client ID: _____		Date Reported: _____	
Colorectal Cancer						

Sequence Variants: 6

GENE	ALTERATION	MUTANT FRACTION	FDA GUIDANCE (for indication)	FDA GUIDANCE (for other indications)	TRIALS (details below)
KRAS	c.38G>A; p.G13D	21.0%	Cetuximab Contraindicated Panitumumab Contraindicated		22
KRAS	c.34G>A; p.G12S	3.2%	Cetuximab Contraindicated Panitumumab Contraindicated		22
KRAS	c.34G>T; p.G12C	1.7%	Cetuximab Contraindicated Panitumumab Contraindicated		22
PIK3CA	c.3140A>G; p.H1047R	36.3%			4
BRAF	c.1799T>G; p.V600G	1.8%			16
BRAF	c.1799T>A; p.V600E	5.7%		Melanoma (V600E): Dabrafenib, Trametinib & Vemurafenib	16
NRAS	No Reported Mutation				8

*Variants are reported if sequence coverage is greater than 100x, quality is greater than 10, variant frequency is greater than 1%.

FDA Biomarker Guidance

KRAS Cetuximab Colorectal Cancer KRAS codon 12 and 13 mutation negative

GUIDANCE

Cetuximab is indicated for KRAS wild-type, EGFR-expressing, metastatic colorectal cancer as determined by FDA-approved tests. Cetuximab is not indicated for the treatment of patients with colorectal cancer that harbor somatic mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of either K-Ras or N-Ras.

KRAS Panitumumab Colorectal Cancer KRAS codon 12 and 13 mutation negative

GUIDANCE

Panitumumab is indicated for the treatment of wild-type KRAS metastatic colorectal cancer as determined by an FDA-approved test. Panitumumab is not indicated for the treatment of patients with colorectal cancer that harbor somatic mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of either KRAS or NRAS

FDA BIOMARKER INFORMATION

The Information compiled in this report is from the FDA's Table of Pharmacogenomic Biomarkers in Drug Labeling, augmented with information extracted from the drug label at the FDA. The list does not represent a listing of all drugs that might be approved for the indication, but only those drugs approved for the specific biomarker, indication and referenced subgroup.



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Colorectal Cancer

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Date Reported:

Open Clinical Trials : 50

NCT01960023

A Phase I/II Dose-Escalation Study Evaluating the Combination of Neratinib and Cetuximab in Patients With "Quadruple Wild-Type" (KRAS/NRAS/BRAF/PIK3CA Wild-Type) Metastatic Colorectal Cancer Resistant to Cetuximab

GENE

PIK3CA

INTERVENTION(S)

Drug:Cetuximab; Drug:Neratinib;

SUMMARY CONDITION(S)

Colorectal Cancer;

PHASE

Phase 1/Phase 2

STATUS

Recruiting

STATE(S) FL; ID; IL; MI; NC; PA

NCT00897429

Correlative Science Studies in Colon Cancer a Companion Study to CALGB 9581 and 89803

GENE

PIK3CA

INTERVENTION(S)

Procedure:laboratory biomarker analysis;

SUMMARY CONDITION(S)

Colorectal Cancer;

PHASE

N/A

STATUS

Recruiting

STATE(S) MA

NCT01928459

A Phase Ib, Open-label Study of Oral BGJ398 in Combination With Oral BYL719 in Adult Patients With Select Advanced Solid Tumors

GENE

PIK3CA

INTERVENTION(S)

Drug:BGJ398; Drug:BYL719;

SUMMARY CONDITION(S)

Advanced Solid Tumors.; Metastatic Solid Tumors;

PHASE

Phase 1

STATUS

Recruiting

STATE(S) FL; MI; MO; TN; TX; MI; MO

NCT01282502

Phase I Study of Chemoradiation With Midostaurin (PKC412) For Locally Advanced Rectal Cancer

GENE

PIK3CA

INTERVENTION(S)

Drug:Midostaurin;

SUMMARY CONDITION(S)

Adenocarcinoma of the Rectum;

PHASE

Phase 1

STATUS

Recruiting

STATE(S) MA

Lab Director: Dr. Kathryn Clary

Client Services: 205-278-1601 Fax: 205-278-1651 3125 Independence Drive, Suite 301, Birmingham, AL 35209 support@circulogene.com

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Colorectal Cancer

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Date Reported:

Open Clinical Trials : 50

NCT01960023

A Phase I/II Dose-Escalation Study Evaluating the Combination of Neratinib and Cetuximab in Patients With "Quadruple Wild-Type" (KRAS/NRAS/BRAF/PIK3CA Wild-Type) Metastatic Colorectal Cancer Resistant to Cetuximab

GENE

KRAS

INTERVENTION(S)

Drug:Cetuximab; Drug:Neratinib;

SUMMARY CONDITION(S)

Colorectal Cancer;

PHASE

Phase 1/Phase 2

STATUS

Recruiting

STATE(S) FL; ID; IL; MI; NC; PA

NCT02278133

A Phase Ib/II Multi-center, Open Label, Dose Escalation Study of WNT974, LGX818 and Cetuximab in Patients With BRAFV600-mutant KRAS Wild-type Metastatic Colorectal Cancer Harboring Wnt Pathway Mutations

GENE

KRAS

INTERVENTION(S)

Drug:WNT974; Drug:LGX818; Biological:Cetuximab;

SUMMARY CONDITION(S)

Metastatic Colorectal Cancer;

PHASE

Phase 1/Phase 2

STATUS

Recruiting

STATE(S) FL; SC; TX; WI; MI

NCT01309126

A Phase 3 Open-Label, Randomized, Multicenter Study of Imprime PGG^Å in Combination With Cetuximab (Erbitux^Å) in Subjects With Recurrent or Progressive KRAS Wild Type Colorectal Cancer

GENE

KRAS

INTERVENTION(S)

Biological:Imprime PGG + cetuximab; Drug:Cetuximab;

SUMMARY CONDITION(S)

Colorectal Cancer;

PHASE

Phase 3

STATUS

Recruiting

STATE(S) AL; AR; CA; FL; HI; IL; IN; KY; LA; MA; MI; MN; MO; NE; NY; OH; OR; SC; TN; TX; UT; VA

NCT01274624

A Multicenter Phase 1 Study of Intravenous Administration of REOLYSIN^Å (Reovirus Type 3 Dearing) in Combination With Irinotecan/Fluorouracil/Leucovorin (FOLFIRI) and Bevacizumab in FOLFIRI Naive Patients With KRAS Mutant Metastatic Colorectal Cancer

GENE

KRAS

INTERVENTION(S)

Biological:REOLYSIN^Å; Drug:Irinotecan; Drug:Leucovorin; Drug:Fluorouracil (5-FU); Drug:Bevacizumab;

SUMMARY CONDITION(S)

KRAS Mutant Metastatic Colorectal Cancer;

PHASE

Phase 1

STATUS

Recruiting

STATE(S) NY

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Indication:

Colorectal Cancer

Client ID:

Date Reported:

Open Clinical Trials : 50

NCT02292758

A Randomized, Double-blind, Placebo-Controlled Phase II Trial of Irinotecan, Cetuximab, and Bevacizumab Compared With Irinotecan, Cetuximab, and Placebo in KRAS-Wildtype, Irinotecan-Refractory, Metastatic Colorectal Cancer

GENE

KRAS

INTERVENTION(S)

Drug:Bevacizumab; Drug:Irinotecan; Drug:Cetuximab;

SUMMARY CONDITION(S)

Metastatic Colorectal Cancer;

PHASE

Phase 2

STATUS

Recruiting

STATE(S) IA; KS; LA; MA; MN; MO; NH; NY; WI

NCT02008383

Cabozantinib (XL184) With Panitumumab in Subjects With KRAS Wild-Type Metastatic Colorectal Cancer and Cabozantinib Monotherapy in Subjects With MET Amplified Treatment-Refractory Colorectal Cancer

GENE

KRAS

INTERVENTION(S)

Biological:Panitumumab; Drug:Cabozantinib;

SUMMARY CONDITION(S)

Colorectal Cancer;

PHASE

Phase 1

STATUS

Recruiting

STATE(S) NC

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

GENE

KRAS

INTERVENTION(S)

Drug:panitumumab; Drug:Randomization to No Panitumumab;

SUMMARY CONDITION(S)

Metastatic Colorectal Cancer;

PHASE

Phase 2

STATUS

Recruiting

STATE(S) NJ; NY

NCT02448810

A Phase 2a Randomized, Open-label Study to Assess the Safety, Tolerability, and Efficacy of BAX69 in Combination With 5-FU/Leucovorin or Panitumumab Versus Standard of Care in Subjects With Metastatic Colorectal Cancer

GENE

KRAS

INTERVENTION(S)

Biological:BAX69 + infusional 5-FU/LV; Biological:BAX69 + panitumumab; Biological:BAX69 + 5-FU/LV; Biological:BAX69 + panitumumab; Drug:Standard of Care; Biological:Standard of Care;

SUMMARY CONDITION(S)

Metastatic Colorectal Cancer;

PHASE

Phase 2

STATUS

Recruiting

STATE(S) IL

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Indication:

Colorectal Cancer

Client ID:

Date Reported:

Open Clinical Trials : 50

NCT01079780

A Randomized Phase II Study of Irinotecan and Cetuximab With or Without the Anti-Angiogenic Antibody, Ramucirumab (IMC -1121B), in Advanced, K-ras Wild-Type Colorectal Cancer Following Progression on Bevacizumab-Containing Chemotherapy

GENE

KRAS

INTERVENTION(S)

Biological: cetuximab; Biological: ramucirumab; Drug: irinotecan hydrochloride;

SUMMARY CONDITION(S)

Colorectal Cancer;

PHASE

Phase 2

STATUS

Recruiting

STATE(S) AL; CO; CT; GA; IL; IN; IA; KS; LA; MD; MA; MI; MN; NE; NJ; NM; ND; OH; OK; PA; SD; TX; VA; WV; WI

NCT01814501

A Phase II Study of Panitumumab in Combination With FOLFIRI After Progression on FOLFIRI Plus Bevacizumab in KRAS(Kirsten Rat Sarcoma) and NRAS Wild-Type Metastatic Colorectal Cancer.

GENE

KRAS

INTERVENTION(S)

Biological: panitumumab; Drug: irinotecan hydrochloride; Drug: fluorouracil; Drug: leucovorin calcium;

SUMMARY CONDITION(S)

Mucinous Adenocarcinoma of the Colon; Mucinous Adenocarcinoma of the Rectum; Recurrent Colon Cancer; Recurrent Rectal Cancer; Signet Ring Adenocarcinoma of the Colon; Signet Ring Adenocarcinoma of the Rectum; Stage IV Colon Cancer; Stage IV Rectal Cancer;

PHASE

Phase 2

STATUS

Recruiting

STATE(S) OH; TN

NCT02199223

Combination Study of Panitumumab and Regorafenib in Advanced or Metastatic KRAS Wild Type Colorectal Cancers

GENE

KRAS

INTERVENTION(S)

Drug: regorafenib + panitumumab;

SUMMARY CONDITION(S)

KRAS Wild-type Colorectal Cancer;

PHASE

Phase 1

STATUS

Recruiting

STATE(S) UT

NCT01719380

A Phase Ib/II Multi-center, Open-label, Dose Escalation Study of LGX818 and Cetuximab or LGX818, BYL719, and Cetuximab in Patients With BRAF Mutant Metastatic Colorectal Cancer

GENE

KRAS

INTERVENTION(S)

Drug: LGX818; Drug: Cetuximab; Drug: BYL719;

SUMMARY CONDITION(S)

Colorectal Cancer;

PHASE

Phase 1/Phase 2

STATUS

Recruiting

STATE(S) CA; CT; MA; NJ; OH; TN; UT; MO

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Ordering Physician:

Collection Date:

Date Received:

Indication:

Colorectal Cancer

Client ID:

Date Reported:

Open Clinical Trials : 50

NCT01871311

A Phase I Study of the BCR-ABL Tyrosine Kinase Inhibitor Nilotinib and Cetuximab in Patients With Solid Tumors That Can be Treated With Cetuximab

GENE

KRAS

INTERVENTION(S)

Drug:Nilotinib + Cetuximab;

SUMMARY CONDITION(S)

Colorectal Cancer; Head and Neck Cancer;

PHASE

Phase 1

STATUS

Recruiting

STATE(S) DC

NCT01787500

A Phase I Trial of Vemurafenib in Combination With Cetuximab and Irinotecan in Patients With BRAF V600 Mutant Advanced Solid Malignancies

GENE

KRAS

INTERVENTION(S)

Drug:Vemurafenib; Drug:Cetuximab; Drug:Irinotecan;

SUMMARY CONDITION(S)

Advanced Cancers;

PHASE

Phase 1

STATUS

Recruiting

STATE(S) TX

NCT02248805

A Phase 1, First-in-Human, Open Label, Dose Escalation Study of MGD007, A Humanized gpA33 x CD3 Dual-Affinity Re-Targeting (DART[®]) Protein in Patients With Relapsed/Refractory Metastatic Colorectal Carcinoma

GENE

KRAS

INTERVENTION(S)

Drug:MGD007;

SUMMARY CONDITION(S)

Colorectal Carcinoma;

PHASE

Phase 1

STATUS

Recruiting

STATE(S) MD; MA; NC; OR

NCT01729923

A Phase II Trial of Maintenance ADAPT Therapy With Capecitabine and Celecoxib in Patients With Metastatic Colorectal Cancer

GENE

KRAS

INTERVENTION(S)

Drug:capecitabine; Drug:celecoxib; Radiation:radiation therapy; Radiation:intensity-modulated radiation therapy; Radiation:stereotactic radiosurgery; Procedure:therapeutic conventional surgery; Other:quality-of-life assessment; Other:laboratory biomarker analysis;

SUMMARY CONDITION(S)

Recurrent Colon Cancer; Recurrent Rectal Cancer; Stage IVA Colon Cancer; Stage IVA Rectal Cancer; Stage IVB Colon Cancer; Stage IVB Rectal Cancer;

PHASE

Phase 2

STATUS

Recruiting

STATE(S) WA

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DoB:

Age:

Gender:

Ordering Physician:

Collection Date:

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Indication:

Colorectal Cancer

Client ID:

Date Reported:

Open Clinical Trials : 50

NCT00897429

Correlative Science Studies in Colon Cancer a Companion Study to CALGB 9581 and 89803

GENE

KRAS

INTERVENTION(S)

Procedure:laboratory biomarker analysis;

SUMMARY CONDITION(S)

Colorectal Cancer;

PHASE

N/A

STATUS

Recruiting

STATE(S) MA

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

GENE

KRAS

INTERVENTION(S)

Drug:Regorafenib (BAY 73-4506); Drug:FOLFIRI; Drug:Placebo; Drug:FOLFIRI;

SUMMARY CONDITION(S)

Colorectal Cancer Metastatic;

PHASE

Phase 2

STATUS

Recruiting

STATE(S) CO; FL; GA; IL; IN; KY; NJ; NY; NC; OH; SC; VA

NCT01740648

A Phase I Trial of MEK Inhibitor Trametinib in Combination With Neoadjuvant 5-Fluorouracil Chemoradiation in the Treatment of KRAS, BRAF, and NRAS-MUTANT Rectal Cancers

GENE

KRAS

INTERVENTION(S)

Drug:trametinib; Drug:fluorouracil; Radiation:radiation therapy;

SUMMARY CONDITION(S)

Recurrent Rectal Cancer; Stage IIA Rectal Cancer; Stage IIB Rectal Cancer; Stage IIC Rectal Cancer; Stage IIIA Rectal Cancer; Stage IIIB Rectal Cancer; Stage IIIC Rectal Cancer;

PHASE

Phase 1

STATUS

Recruiting

STATE(S) MO; OH

NCT02318901

A Phase Ib/II Study of Pembrolizumab and Monoclonal Antibody Therapy in Patients With Advanced Cancer (PembroMab

GENE

KRAS

INTERVENTION(S)

Drug:Pembrolizumab; Drug:Trastuzumab; Drug:ado-trastuzumab emtansine; Drug:Cetuximab;

SUMMARY CONDITION(S)

Advanced Cancer; Breast Cancer; Gastric Cancer; Esophageal Cancer; Colorectal Cancer;

PHASE

Phase 1/Phase 2

STATUS

Recruiting

STATE(S) AZ

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Gender:

Ordering Physician:

Collection Date:

Date Received:

Indication:

Colorectal Cancer

Client ID:

Date Reported:

Open Clinical Trials : 50

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

GENE

KRAS

INTERVENTION(S)

Other:Laboratory Biomarker Analysis; Biological:Navitoclax; Other: Pharmacological Study; Drug:Trametinib;

SUMMARY CONDITION(S)

Adult Solid Neoplasm; Extensive Stage Small Cell Lung Carcinoma; Recurrent Colon Carcinoma; Recurrent Non-Small Cell Lung Carcinoma; Recurrent Pancreatic Carcinoma; Recurrent Rectal Carcinoma; Recurrent Small Cell Lung Carcinoma; Stage III Pancreatic Cancer; Stage IIIA Colon Cancer; Stage IIIA Non-Small Cell Lung Cancer;

PHASE

Phase 1/Phase 2

STATUS

Recruiting

STATE(S) MA

NCT01282502

Phase I Study of Chemoradiation With Midostaurin (PKC412) For Locally Advanced Rectal Cancer

GENE

KRAS

INTERVENTION(S)

Drug:Midostaurin;

SUMMARY CONDITION(S)

Adenocarcinoma of the Rectum;

PHASE

Phase 1

STATUS

Recruiting

STATE(S) MA

NCT01750918

An Open-Label, Four-Part, Phase I/II Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Activity of the MEK Inhibitor GSK1120212, BRAF Inhibitor GSK2118436 and the Anti-EGFR Antibody Panitumumab in Combination in Subjects With BRAF-mutation V600E Positive Colorectal Cancer and in Subjects With CRC With Secondary Resistance to Prior Anti-EGFR Therapy

GENE

BRAF

INTERVENTION(S)

Drug:Dabrafenib; Drug:Trametinib; Drug:Panitumumab; Drug:5-fluorouracil;

SUMMARY CONDITION(S)

Cancer;

PHASE

Phase 2

STATUS

Recruiting

STATE(S) AZ; CA; MA; NC; PA; TN

NCT01960023

A Phase I/II Dose-Escalation Study Evaluating the Combination of Neratinib and Cetuximab in Patients With "Quadruple Wild-Type" (KRAS/NRAS/BRAF/PIK3CA Wild-Type) Metastatic Colorectal Cancer Resistant to Cetuximab

GENE

BRAF

INTERVENTION(S)

Drug:Cetuximab; Drug:Neratinib;

SUMMARY CONDITION(S)

Colorectal Cancer;

PHASE

Phase 1/Phase 2

STATUS

Recruiting

STATE(S) FL; ID; IL; MI; NC; PA

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Indication: Colorectal Cancer		Client ID:	Date Reported:	

Open Clinical Trials : 50

NCT02164916 Randomized Phase II Study of Irinotecan and Cetuximab With or Without Vemurafenib in BRAF Mutant Metastatic Colorectal Cancer

GENE BRAF	INTERVENTION(S) Biological:cetuximab; Drug:irinotecan hydrochloride; Drug:vemurafenib;	SUMMARY CONDITION(S) Colorectal Cancer;
PHASE Phase 2		
STATUS Recruiting	STATE(S) AZ; CA; CO; CT; DE; FL; GA; HI; ID; IL; IN; IA; KS; KY; LA; ME; MD; MA; MI; MN; MS; MO; NE; NH; NJ; NY; NC; ND; OH; OK; PA; SC; SD; TN; TX; WA; WV; WI; WY	

NCT02278133 A Phase Ib/II Multi-center, Open Label, Dose Escalation Study of WNT974, LGX818 and Cetuximab in Patients With BRAFV600-mutant KRAS Wild-type Metastatic Colorectal Cancer Harboring Wnt Pathway Mutations

GENE BRAF	INTERVENTION(S) Drug:WNT974; Drug:LGX818; Biological:Cetuximab;	SUMMARY CONDITION(S) Metastatic Colorectal Cancer;
PHASE Phase 1/Phase 2		
STATUS Recruiting	STATE(S) FL; SC; TX; WI; MI	

NCT01719380 A Phase Ib/II Multi-center, Open-label, Dose Escalation Study of LGX818 and Cetuximab or LGX818, BYL719, and Cetuximab in Patients With BRAF Mutant Metastatic Colorectal Cancer

GENE BRAF	INTERVENTION(S) Drug:LGX818; Drug:Cetuximab; Drug:BYL719;	SUMMARY CONDITION(S) Colorectal Cancer;
PHASE Phase 1/Phase 2		
STATUS Recruiting	STATE(S) CA; CT; MA; NJ; OH; TN; UT; MO	

NCT02508077 A Prospective Study of FOLFIRI Plus Panitumumab in Extended RAS Wild Type and BRAF Wild Type Metastatic Colorectal Cancer With Acquired Resistance to Prior Cetuximab (or Panitumumab) Plus Irinotecan-Based Therapy and Who Failed at Least One Subsequent Non-anti-EGFR Containing Regimen

GENE BRAF	INTERVENTION(S) Drug:Fluorouracil; Drug:Irinotecan Hydrochloride; Other:Laboratory Biomarker Analysis; Drug:Leucovorin Calcium; Biological:Panitumumab;	SUMMARY CONDITION(S) Recurrent Colorectal Carcinoma; Stage IVA Colorectal Cancer; Stage IVB Colorectal Cancer;
PHASE Phase 2		
STATUS Not yet recruiting	STATE(S) CA	

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Indication:

Colorectal Cancer

Client ID:

Date Reported:

Open Clinical Trials : 50

NCT01876511

Phase 2 Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors

GENE

BRAF

INTERVENTION(S)

Drug:MK-3475;

SUMMARY CONDITION(S)

MSI Positive Colorectal Cancer; MSI Negative Colorectal Cancer; MSI Positive Non-Colorectal Cancers;

PHASE

Phase 2

STATUS

Recruiting

STATE(S) CA; MD; OH; OR; PA

NCT01787500

A Phase I Trial of Vemurafenib in Combination With Cetuximab and Irinotecan in Patients With BRAF V600 Mutant Advanced Solid Malignancies

GENE

BRAF

INTERVENTION(S)

Drug:Vemurafenib; Drug:Cetuximab; Drug:Irinotecan;

SUMMARY CONDITION(S)

Advanced Cancers;

PHASE

Phase 1

STATUS

Recruiting

STATE(S) TX

NCT00897429

Correlative Science Studies in Colon Cancer a Companion Study to CALGB 9581 and 89803

GENE

BRAF

INTERVENTION(S)

Procedure:laboratory biomarker analysis;

SUMMARY CONDITION(S)

Colorectal Cancer;

PHASE

N/A

STATUS

Recruiting

STATE(S) MA

NCT01351103

A Phase I, Open-label, Dose Escalation Study of Oral LGK974 in Patients With Malignancies Dependent on Wnt Ligands

GENE

BRAF

INTERVENTION(S)

Drug:LGK974;

SUMMARY CONDITION(S)

Pancreatic Adenocarcinoma; BRAF Mutant Colorectal Cancer; Other Tumor Types With Documented Genetic Alterations Upstream in the Wnt Signaling Pathway;

PHASE

Phase 1

STATUS

Recruiting

STATE(S) MD; MA; MI; TX

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Indication: _____		Client ID: _____	Date Reported: _____	
Colorectal Cancer				

Open Clinical Trials : 50

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

GENE

BRAF

PHASE

Phase 2

STATUS

Recruiting

INTERVENTION(S)

Drug:Regorafenib (BAY 73-4506); Drug:FOLFIRI; Drug:Placebo; Drug:FOLFIRI;

SUMMARY CONDITION(S)

Colorectal Cancer Metastatic;

STATE(S) CO; FL; GA; IL; IN; KY; NJ; NY; NC; OH; SC; VA

NCT02313012 Phase 1A Multicenter, Open-Label Safety, Tolerability and Pharmacokinetic Study of CC-90003, A Selective Extracellular Signal-Regulated Kinase (ERK) Inhibitor, In Subjects With Locally-Advanced or Metastatic, Relapsed, or Refractory BRAFV600 or RAS-Mutated Malignancies

GENE

BRAF

PHASE

Phase 1

STATUS

Recruiting

INTERVENTION(S)

Drug:CC-90003;

SUMMARY CONDITION(S)

Neoplasm Metastasis;

STATE(S) CA; CT; NC; TN

NCT01740648 A Phase I Trial of MEK Inhibitor Trametinib in Combination With Neoadjuvant 5-Fluorouracil Chemoradiation in the Treatment of KRAS, BRAF, and NRAS-MUTANT Rectal Cancers

GENE

BRAF

PHASE

Phase 1

STATUS

Recruiting

INTERVENTION(S)

Drug:trametinib; Drug:fluorouracil; Radiation:radiation therapy;

SUMMARY CONDITION(S)

Recurrent Rectal Cancer; Stage IIA Rectal Cancer; Stage IIB Rectal Cancer; Stage IIC Rectal Cancer; Stage IIIA Rectal Cancer; Stage IIIB Rectal Cancer; Stage IIIC Rectal Cancer;

STATE(S) MO; OH

NCT02318901 A Phase Ib/II Study of Pembrolizumab and Monoclonal Antibody Therapy in Patients With Advanced Cancer (PembroMab

GENE

BRAF

PHASE

Phase 1/Phase 2

STATUS

Recruiting

INTERVENTION(S)

Drug:Pembrolizumab; Drug:Trastuzumab; Drug:ado-trastuzumab emtansine; Drug:Cetuximab;

SUMMARY CONDITION(S)

Advanced Cancer; Breast Cancer; Gastric Cancer; Esophageal Cancer; Colorectal Cancer;

STATE(S) AZ

Lab Director: Dr. Kathryn Clary

Client Services: 205-278-1601 Fax: 205-278-1651 3125 Independence Drive, Suite 301, Birmingham, AL 35209 support@circulogene.com

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Personalized Gene Profile

Patient Name: _____		Client Name: _____	Lims ID: _____	
			2-17778	
DoB: _____	Age: _____	Gender: _____	Ordering Physician: _____	Collection Date: _____
				Date Received: _____
Indication: _____		Client ID: _____	Date Reported: _____	
Colorectal Cancer				

Open Clinical Trials : 50

NCT01524978 An Open-label, Phase II Study of Vemurafenib in Patients With BRAF V600 Mutation-positive Cancers

GENE		
BRAF	INTERVENTION(S)	SUMMARY CONDITION(S)
PHASE	Drug:cetuximab; Drug:vemurafenib [Zelboraf]; Drug:vemurafenib [Zelboraf];	Multiple Myeloma, Neoplasms;
Phase 2		
STATUS		
Recruiting	STATE(S) AZ; CO; MA; MI; MO; TN; TX; WA	

NCT01282502 Phase I Study of Chemoradiation With Midostaurin (PKC412) For Locally Advanced Rectal Cancer

GENE		
BRAF	INTERVENTION(S)	SUMMARY CONDITION(S)
PHASE	Drug:Midostaurin;	Adenocarcinoma of the Rectum;
Phase 1		
STATUS		
Recruiting	STATE(S) MA	

NCT01960023 A Phase I/II Dose-Escalation Study Evaluating the Combination of Neratinib and Cetuximab in Patients With "Quadruple Wild-Type" (KRAS/NRAS/BRAF/PIK3CA Wild-Type) Metastatic Colorectal Cancer Resistant to Cetuximab

GENE		
NRAS	INTERVENTION(S)	SUMMARY CONDITION(S)
PHASE	Drug:Cetuximab; Drug:Neratinib;	Colorectal Cancer;
Phase 1/Phase 2		
STATUS		
Recruiting	STATE(S) FL; ID; IL; MI; NC; PA	

NCT02448810 A Phase 2a Randomized, Open-label Study to Assess the Safety, Tolerability, and Efficacy of BAX69 in Combination With 5-FU/Leucovorin or Panitumumab Versus Standard of Care in Subjects With Metastatic Colorectal Cancer

GENE		
NRAS	INTERVENTION(S)	SUMMARY CONDITION(S)
PHASE	Biological:BAX69 + infusional 5-FU/LV; Biological:BAX69 + panitumumab; Biological:BAX69 + 5-FU/LV; Biological:BAX69 + panitumumab; Drug:Standard of Care; Biological:Standard of Care;	Metastatic Colorectal Cancer;
Phase 2		
STATUS		
Recruiting	STATE(S) IL	

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Personalized Gene Profile

Patient Name:

Client Name:

Lims ID:

2-17778

DoB:

Age:

Gender:

Ordering Physician:

Collection Date:

Date Received:

Indication:

Colorectal Cancer

Client ID:

Date Reported:

Open Clinical Trials : 50

NCT01814501

A Phase II Study of Panitumumab in Combination With FOLFIRI After Progression on FOLFIRI Plus Bevacizumab in KRAS(Kirsten Rat Sarcoma) and NRAS Wild-Type Metastatic Colorectal Cancer.

GENE

NRAS

PHASE

Phase 2

STATUS

Recruiting

INTERVENTION(S)

Biological:panitumumab; Drug:irinotecan hydrochloride; Drug: fluorouracil; Drug:leucovorin calcium;

SUMMARY CONDITION(S)

Mucinous Adenocarcinoma of the Colon; Mucinous Adenocarcinoma of the Rectum; Recurrent Colon Cancer; Recurrent Rectal Cancer; Signet Ring Adenocarcinoma of the Colon; Signet Ring Adenocarcinoma of the Rectum; Stage IV Colon Cancer; Stage IV Rectal Cancer;

STATE(S) OH; TN

NCT02199223

Combination Study of Panitumumab and Regorafenib in Advanced or Metastatic KRAS Wild Type Colorectal Cancers

GENE

NRAS

PHASE

Phase 1

STATUS

Recruiting

INTERVENTION(S)

Drug:regorafenib + panitumumab;

SUMMARY CONDITION(S)

KRAS Wild-type Colorectal Cancer;

STATE(S) UT

NCT02205398

A Phase Ib, Open-label, Multicenter, Dose Escalation and Expansion Study, to Evaluate the Safety, Pharmacokinetics and Activity of INC280 in Combination With Cetuximab in c-MET Positive CRC and HNSCC Patients Who Have Progressed After Anti-EGFR Monoclonal Antibody Therapy.

GENE

NRAS

PHASE

Phase 1/Phase 2

STATUS

Recruiting

INTERVENTION(S)

Drug:INC280; Drug:cetuximab;

SUMMARY CONDITION(S)

Squamous Cell Carcinoma of Head and Neck;; Metastatic Colorectal Cancer;

STATE(S) MA; UT; MI

NCT01740648

A Phase I Trial of MEK Inhibitor Trametinib in Combination With Neoadjuvant 5-Fluorouracil Chemoradiation in the Treatment of KRAS, BRAF, and NRAS-MUTANT Rectal Cancers

GENE

NRAS

PHASE

Phase 1

STATUS

Recruiting

INTERVENTION(S)

Drug:trametinib; Drug:fluorouracil; Radiation:radiation therapy;

SUMMARY CONDITION(S)

Recurrent Rectal Cancer; Stage IIA Rectal Cancer; Stage IIB Rectal Cancer; Stage IIC Rectal Cancer; Stage IIIA Rectal Cancer; Stage IIIB Rectal Cancer; Stage IIIC Rectal Cancer;

STATE(S) MO; OH

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Lims ID:

2-17778

DoB:

Age:

Gender:

Ordering Physician:

Collection Date:

Date Received:

Indication:

Colorectal Cancer

Client ID:

Date Reported:

Open Clinical Trials : 50

NCT02318901

A Phase Ib/II Study of Pembrolizumab and Monoclonal Antibody Therapy in Patients With Advanced Cancer (PembroMab)

GENE

NRAS

INTERVENTION(S)

Drug:Pembrolizumab; Drug:Trastuzumab; Drug:ado-trastuzumab
emtansine; Drug:Cetuximab;

SUMMARY CONDITION(S)

Advanced Cancer; Breast Cancer; Gastric Cancer;
Esophageal Cancer; Colorectal Cancer;

PHASE

Phase 1/Phase 2

STATUS

Recruiting

STATE(S) AZ

NCT01282502

Phase I Study of Chemoradiation With Midostaurin (PKC412) For Locally Advanced Rectal Cancer

GENE

NRAS

INTERVENTION(S)

Drug:Midostaurin;

SUMMARY CONDITION(S)

Adenocarcinoma of the Rectum;

PHASE

Phase 1

STATUS

Recruiting

STATE(S) MA

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Colorectal Cancer

Client ID:

Date Reported:

Open Clinical Trials : 50

DISCLAIMER

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The test report incorporates analyses of peer-reviewed studies and other publicly available information. Every effort is made to provide the most accurate and up-to-date information through FDA and PubMed, to exclude germline alterations via COSMIC and dbSNP. Identification of cancer associated mutations does not necessarily indicate good response to therapy; while absence of a cancer associated mutation does not necessarily indicate poor response to therapy. This report makes no promises or guarantees that a particular drug will be effective in the treatment of disease in any patient. This report also makes no promises or guarantees that a drug with potential lack of clinical benefit will in fact provide no clinical benefit.

Drugs referenced in this report may not be suitable for a particular patient. The selection of any, all or none of the drugs associated with potential clinical benefit (or potential lack of clinical benefit) resides entirely within the discretion of the treating physician. Indeed, the information in this report must be considered in conjunction with all other relevant information regarding a particular patient, before the patient's treating physician recommends a course of treatment.

Decisions on patient care and treatment must be based on the independent medical judgment of the treating physician, taking into consideration all applicable information concerning the patient's condition, such as patient and family history, physical examinations, information from other diagnostic tests, and patient preferences, in accordance with the standard of care in a given community. A treating physician's decisions should not be based on a single test, such as this test, or the information contained in this report.

CirculoGene Theranostics makes no promises or guarantees that a healthcare provider, insurer or other third party payor, whether private or governmental, will reimburse a patient for the cost of our tests.

CGT's tests target specific gene mutations and does not detect mutations that are outside of the targeted area. Testing does not completely sequence every exon of each one of the 50 genes. The limit of detection is 5% at 500X coverage and 10% at 200X coverage. This technology cannot reliably detect mutations at coverage below 100X.

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