REPORTING

Report Date:	MAY-27-2024
Receipt Date:	MAY-21-2024
Collection Date:	MAY-20-2024
Specimen:	Blood
Status:	FINAL

PHYSICIAN

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Additional Recipient: N/A

Complete Tumor Response Map on page 2

Summary of Detected Somatic Alterations, Immunotherapy Biomarkers & Associated Treatment Options

KEY ✓ Approved in indication ~ Approved in other indication ⊗ Lack of response

Detected Alteration(s) / Biomarker(s)	Associated FDA-approved therapies	Clinical trial availability (see page 3)	% cfDNA or Amplification
ATM R2832H	~ Olaparib, Talazoparib	Yes	0.4%

Synonymous Alterations
MAPK3 I272I (6.9%)
This sequence change does not alter the amino acid at this position and is unlikely to be a therapeutic target. Clinical correlation is advised.

Comments

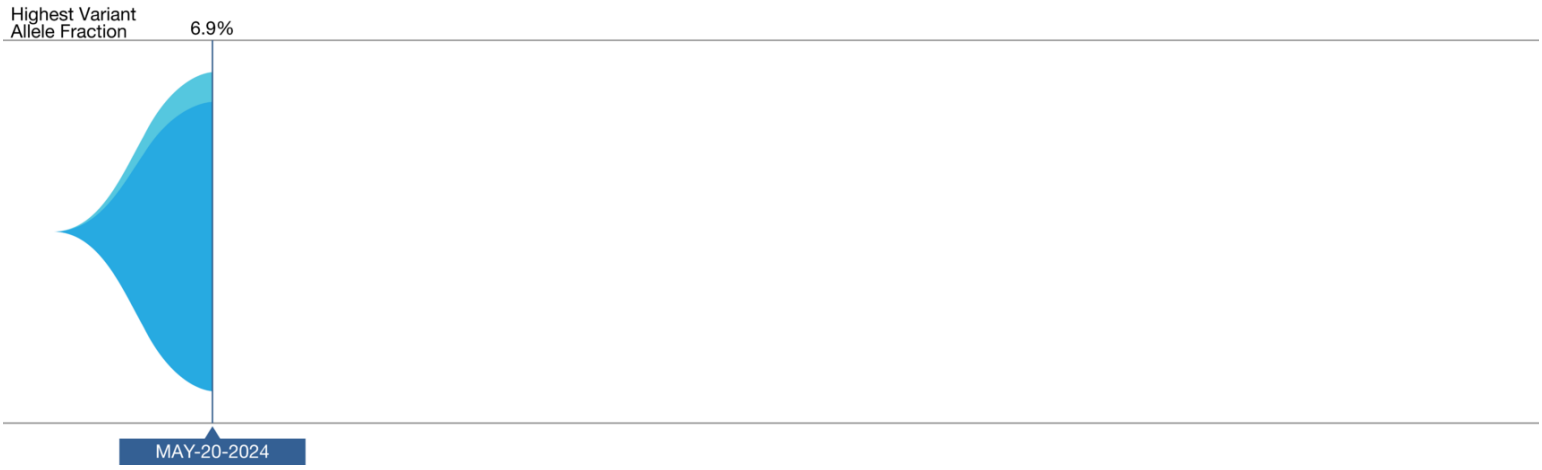
Reported by: HM8

Additional Biomarkers

Biomarker	Additional Details
MSI-High	NOT DETECTED

Guardant360 Tumor Response Map

The Guardant360 Tumor Response Map illustrates the variant allele fraction (% cfDNA) of observed somatic variants at each sample submission. Amplifications are not plotted, and only the first and last five test dates are plotted. Please see the Physician Portal (portal.guardanthealth.com) for the Tumor Response Map with all test dates.



Detected Alteration(s) / Biomarker(s)	% cfDNA or Amp	
MAPK3 I272I	6.9%	Synonymous Alteration §
ATM R2832H	0.4%	

The table above annotates the variant allele fraction (% cfDNA) detected in this sample, listed in descending order.
§ See definitions section for more detail

Available Clinical Trials (within the same state as the ordering physician)

There may be additional trials not listed here. Visit: **portal.guardanthealth.com** or email **clientservices@guardanthealth.com** with A1050686 in the subject line of the email, for additional trials.

Alteration	Trial ID / Contact	Title	Phase	Site(s)
ATM R2832H	NCT04434482 Min Song,min.song@impacttherapeutics.com,021 68411121	IMP4297 in Combination With Temozolomide in Patients With Advanced Solid Tumors and Small Cell Lung Cancer	Phase 1 /Phase 2	Taipei, Taiwan Taoyuan, Taiwan Taichung, Taiwan Tainan, Taiwan (2)
	NCT05269316 Xiangna Chen,xiangna.chen@impacttherapeutics.com,+86-021-68411121	Study to Evaluate IMP9064 as a Monotherapy or in Combination in Patients With Advanced Solid Tumors	Phase 1	Taipei, Taiwan
	NCT05489211 AstraZeneca Clinical Study Information Center,information.center@astrazeneca.com,1-877-240-9479	Study of Dato-Dxd as Monotherapy and in Combination With Anti-cancer Agents in Patients With Advanced Solid Tumours (TROPION-PanTumor03)	Phase 2	Taoyuan, Taiwan Liou Ying Township, Taiwan Taipei, Taiwan (3)
	NCT05797168 AstraZeneca Clinical Study Information Center,information.center@astrazeneca.com,1-877-240-9479	Phase I/IIa Study for AZD5335 as Monotherapy and in Combination With Anti-cancer Agents in Participants With Solid Tumors	Phase 1 /Phase 2	Tainan City, Taiwan Taichung, Taiwan Taipei, Taiwan (2)
	Visit **portal.guardanthealth.com** for trials not within the same state as the physician's office			

More clinical trial options available at **portal.guardanthealth.com**

Definitions

Synonymous Alteration: This sequence change does not alter the amino acid at this position and is unlikely to be a therapeutic target. Clinical correlation is advised.

Interpretation

Somatic alterations were detected in the circulating cell-free DNA isolated from this patient's blood specimen. These genomic alterations are cancer-associated somatic variants, some of which have been associated with either increased or reduced clinical response to specific treatments. The percentage of altered cell-free DNA circulating (% cfDNA) in blood is related to the unique tumor biology of each patient. Factors that may affect the % cfDNA of detected somatic alterations include tumor growth, turn over, size, heterogeneity, vascularization, disease progression, and treatment.

Method and Limitations

Guardant360 sequences 74 cancer-associated genes to identify somatic alterations. Cell-free DNA (cfDNA) is extracted from plasma, enriched for targeted regions, and sequenced using the Illumina platform and hg19 as the reference genome. All exons are sequenced in some genes; only clinically significant exons are sequenced in other genes. The types of genomic alterations detected by Guardant360 include single nucleotide variants, gene amplifications, fusions, short insertions/deletions (longest detected, 70 base pairs), and splice site disrupting events (see Table 1). Microsatellite Instability (MSI) is assessed for all cancer types by evaluating somatic changes in the length of repetitive sequences on the Guardant360 panel. A "Not Detected" result in samples where the highest % cfDNA is < 0.2% is an inconclusive result because it does not preclude MSI-High status in tissue. MSI status is currently not reported for earlier panel versions. This version of the Guardant360 test is not validated for the detection of other types of genomic alterations, such as complex rearrangements or gene deletions. Certain sample or variant characteristics, such as low cfDNA concentration, may result in reduced analytic sensitivity. Guardant360 cannot discern the source of circulating cfDNA, and for some variants in the range of ~40 to 60% cfDNA, the test cannot easily distinguish germline variants from somatic alterations. Guardant360 is not validated for the detection of germline or de novo variants that are associated with hereditary cancer risk. Tissue genotyping should be considered when plasma genotyping is negative, if clinically appropriate.

Table 1: Genes on the Guardant360 Panel

Guardant360 reports single nucleotide variants, splice site mutations, and insertion and deletion variants (indels) in all clinically relevant exons in 74 genes and reports other variant types in select genes as indicated below.

AKT1	*ALK* #	*APC*	*AR* †	*ARAF*	*ARID1A*	*ATM*	*BRAF* †	*BRCA1*
BRCA2	*CCND1* †	*CCND2* †	*CCNE1* †	*CDH1*	*CDK12*	*CDK4* †	*CDK6* †	*CDKN2A*
CTNNB1	*DDR2*	*EGFR* †	*ERBB2* †	*ESR1*	*EZH2*	*FBXW7*	*FGFR1* †	*FGFR2* # †
FGFR3 #	*GATA3*	*GNA11*	*GNAQ*	*GNAS*	*HNF1A*	*HRAS*	*IDH1*	*IDH2*
JAK2	*JAK3*	*KIT* †	*KRAS* †	*MAP2K1*	*MAP2K2*	*MAPK1*	*MAPK3*	*MET* †
MLH1	*MPL*	*MTOR*	*MYC* †	*NF1*	*NFE2L2*	*NOTCH1*	*NPM1*	*NRAS*
NTRK1 #	*NTRK3*	*PDGFRA* †	*PIK3CA* †	*PTEN*	*PTPN11*	*RAF1* †	*RB1*	*RET* #
RHEB	*RHOA*	*RIT1*	*ROS1* #	*SMAD4*	*SMO*	*STK11*	*TERT* ‡	*TP53*
TSC1	*VHL*							

‡ Guardant360 reports alterations in the promoter region of this gene.

Guardant360 reports fusion events involving this gene.

† Guardant360 reports amplifications of this gene.

About the Test

The Guardant360 assay was developed and its performance characteristics were determined by Guardant Health, Inc. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test may be used for clinical purposes and should not be regarded as investigational or for research only. Guardant Health's clinical reference laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing. The laboratory report should be interpreted in the context of other clinical information and laboratory, pathology, and imaging studies by a qualified medical professional prior to initiating or changing a patient's treatment plan. The selection of any, all, or none of the drugs associated with potential clinical benefit (or potential lack of clinical benefit) is entirely at the discretion of the treating medical professional. Drug and trial information are based on the diagnosis written on the submitted test request form; this information is not based on any supplemental information provided by the requesting medical professional, including pathology reports or other molecular studies. Some drugs listed in this report may not be approved or cleared by the FDA for the indicated use. Guardant Health makes no endorsement, express or implied, of any product, physician, or procedure contained in this report. This report makes no promises or guarantees that a particular medication will affect (or not affect) the clinical outcome of any patient.

Testing Performed at: Guardant Health

Laboratory Director: Martina Lefterova, MD PhD | CLIA ID: 05D2070300 | CAP #: 8765297 | 505 Penobscot Drive, Redwood City, CA, 94063, USA

Additional information is available

Any therapeutic annotations are based on publicly available information. This information is described in the "Detailed Therapy Results" and "Relevance of Detected Alterations" sections.

Visit **portal.guardanthealth.com** or email **clientservices@guardanthealth.com** with A1050686 in the subject line of the email for:

- Additional clinical trials
- Detailed Therapy Results
- Relevance of Detected Alterations
- References

If you would like to receive this additional information with every Guardant360 report, please call client services at **855.698.8887** to opt-in.

Additional information begins on the next page.

List of Available Clinical Trials

Alteration	Trial ID / Contact	Title	Phase	Site (number in parenthesis is count of trial sites)
ATM R2832H	NCT02925234 E.E. Voest, prof.,DRUP@nki.nl, 0031205129111	The Drug Rediscovery Protocol (DRUP Trial)	Phase 2	Netherlands (35)
	NCT03742895 Toll Free Number,Trialsites@merck.com, 1-888-577-8839	Efficacy and Safety of Olaparib (MK-7339) in Participants With Previously Treated, Homologous Recombination Repair Mutation (HRRm) or Homologous Recombination Deficiency (HRD) Positive Advanced Cancer (MK-7339-002 / LYNK-002)	Phase 2	Harrison, NY; Seattle, WA; New York, NY; Baltimore, MD; Middletown, NJ; Colombia; Argentina; United Kingdom; Canada; Ireland; Denmark; Israel; Australia; Spain (2); Turkey (7); Korea, Republic of (2); Guatemala (4); Mexico (2); France (2); Peru (5)
	NCT04042831 See https://clinicaltrials.gov/ct2/show /NCT04042831	Olaparib in Treating Patients With Metastatic Biliary Tract Cancer With Aberrant DNA Repair Gene Mutations	Phase 2	Houston, TX; Rochester, MN; Scottsdale, AZ; New York, NY
	NCT04434482 Min Song,min.song@impacttherapeutics.com,021 68411121	IMP4297 in Combination With Temozolomide in Patients With Advanced Solid Tumors and Small Cell Lung Cancer	Phase 1 /Phase 2	Evergreen Park, IL; Canton, OH; Columbus, OH; Tennessee, TN; China (4); Taiwan (5); Korea, Republic of (4); Australia (4)
	NCT04657068 Sarah Cannon Development Innovations, SCRI.InnovationsMedical@scri.com,844-710-6157	A Study of ART0380 for the Treatment of Advanced or Metastatic Solid Tumors	Phase 1 /Phase 2	Denver, CO; Oklahoma City, OK; Philadelphia, PA; West Palm Beach, FL; Fort Myers, FL; Dallas, TX; Birmingham, AL; Sarasota, FL; Nashville, TN; Little Rock, AR; Fairfax, VA; Chattanooga, TN; France; United Kingdom (3); Spain (18)
	NCT05222971 Changhoon Yoo,yooc@amc.seoul.kr, +821099006798	Olaparib With or Without Durvalumab for DDR Gene Mutated Biliary Tract Cancer Following Platinum-based Chemotherapy	Phase 2	Korea, Republic of
	NCT05269316 Xiangna Chen,xiangna.chen@impacttherapeutics.com,+86-021-68411121	Study to Evaluate IMP9064 as a Monotherapy or in Combination in Patients With Advanced Solid Tumors	Phase 1	Greenville, SC; New York, NY; Dallas, TX; Hackensack, NJ; China; Taiwan; Australia (2)
	NCT05489211 AstraZeneca Clinical Study Information Center,information.center@astrazeneca.com,1-877-240-9479	Study of Dato-Dxd as Monotherapy and in Combination With Anti-cancer Agents in Patients With Advanced Solid Tumours (TROPION-PanTumor03)	Phase 2	Los Angeles, CA; Albuquerque, NM; Houston, TX; Santa Rosa, CA; Madison, WI; East Brunswick, NJ; Boston, MA; Grand Rapids, MI; Commack, NY; Cincinnati, OH; Columbus, OH; Muncie, IN; Nashville, TN; Canada (3); Turkey (7); Japan (6); China (8); Taiwan (5); Poland (3); Korea, Republic of (4); United Kingdom (5); Italy (3); France (3); Spain (6)
	NCT05797168 AstraZeneca Clinical Study Information Center,information.center@astrazeneca.com,1-877-240-9479	Phase I/IIa Study for AZD5335 as Monotherapy and in Combination With Anti-cancer Agents in Participants With Solid Tumors	Phase 1 /Phase 2	Houston, TX; Duarte, CA; Louisville, KY; Boston, MA; Columbus, OH; Irvine, CA; Portland, OR; Aurora, CO; Providence, RI (2); Canada (5); Japan (2); China (5); Taiwan (4); United Kingdom (4); Israel (2); Australia (2); Spain (4)

Detailed Therapy Results

Alteration	Drug	Trade Name	Target	Current Status
ATM R2832H	AMXI-5001		Dual PARP1/2 and microtubule polymerization inhibitor.	Phase 2 (Solid Tumor)
	ART0380		Atr inhibitor.	Phase 2 (Solid Tumor) Phase 2 (Brain and Central Nervous System Tumors)
	ATG-018		Atr inhibitor.	Phase 1 (Solid Tumor) Phase 1 (Marginal zone lymphoma (MZL), Diffuse large B-cell lymphoma (DLBCL))
	ATRN-119		Atr inhibitor.	Phase 2 (Solid Tumor) Phase 2 (Brain and Central Nervous System Tumors)
	AZD9574		PARP1 inhibitor (brain penetrant).	Phase 2 (Glioma, Pancreatic carcinoma, Prostate carcinoma, Ovarian carcinoma, Breast carcinoma)
	Berzosertib		Atr inhibitor.	Phase 1 (Solid Tumor) Phase 2 (Gastric carcinoma, Neuroendocrine carcinoma, Small cell carcinoma, Osteosarcoma, Non-small cell lung carcinoma (NSCLC), Prostate carcinoma, Ovarian carcinoma, Small cell lung carcinoma (SCLC), Gastroesophageal junction carcinoma, Urothelial carcinoma, Bladder carcinoma, Leiomyosarcoma, Renal pelvis carcinoma, Lung cancer)
	Camonsertib		Atr inhibitor.	Phase 1 (Solid Tumor) Phase 1 (Brain and Central Nervous System Tumors)
	Ceralasertib		Atr inhibitor.	Phase 2 (Gallbladder carcinoma) Phase 3 (Non-small cell lung carcinoma (NSCLC), Lung cancer)
	Elimusertib		Atr inhibitor.	Phase 1 (Solid Tumor) Phase 1 (Head and neck squamous cell carcinoma (HNSCC))
	Fluzoparib		PARP inhibitor.	Phase 1 (Solid Tumor) Phase 3 (Pancreatic carcinoma, Ovarian carcinoma, Breast carcinoma)
	IDX-1197		PARP inhibitor.	Phase 2 (Solid Tumor) Phase 2 (Brain and Central Nervous System Tumors)
	IMP9064		Atr inhibitor.	Phase 1 (Solid Tumor)
	Niraparib	Zejula	PARP inhibitor.	Phase 1 (Solid Tumor) FDA Approved in other indications (Prostate carcinoma with BRCA1/2 mutation, Ovarian carcinoma with BRCA1/2 mutation)
	Nivolumab+ipilimumab	Opdivo+Yervoy	Anti-PD-1 monoclonal antibody + anti-CTLA-4 monoclonal antibody combination.	Phase 2 (Gallbladder carcinoma) FDA Approved in other indications (NSCLC with high PD-L1 expression, Hepatocellular carcinoma (HCC), Melanoma, Non-small cell lung carcinoma (NSCLC), Renal cell carcinoma, Esophageal squamous cell carcinoma, CRC with MSI-H or dMMR, Mesothelioma)
	NMS-03305293		PARP inhibitor.	Phase 1 (Solid Tumor) Phase 2 (Glioblastoma)
	Olaparib	Lynparza	PARP inhibitor.	Phase 2 (Gallbladder carcinoma) FDA Approved in other indications (Pancreatic adenocarcinoma with germline BRCA1/2

Detailed Therapy Results

Alteration	Drug	Trade Name	Target	Current Status
				mutation, Prostate cancer with HRR gene mutation, Ovarian carcinoma with BRCA1/2 mutation, Breast carcinoma with germline BRCA1/2 mutation)
	Pamiparib		PARP inhibitor.	Phase 1 (Solid Tumor) Phase 3 (Gastric carcinoma, Gastroesophageal junction carcinoma)
	RP12146		PARP inhibitor.	Phase 1 (Gastric carcinoma, Pancreatic carcinoma, Prostate carcinoma, Endometrial carcinoma, Ovarian carcinoma, Small cell lung carcinoma (SCLC), Breast carcinoma, Cholangiocarcinoma, Colorectal carcinoma (CRC))
	Rucaparib	Rubraca	PARP inhibitor.	Phase 2 (Gallbladder carcinoma) FDA Approved in other indications (Prostate carcinoma with BRCA1/2 mutation, Ovarian carcinoma)
	Saruparib		PARP1 inhibitor.	Phase 2 (Solid Tumor)
	Senaparib		PARP inhibitor.	Phase 1 (Solid Tumor) Phase 2 (Small cell lung carcinoma (SCLC))
	Stenoparib		PARP inhibitor.	Phase 1 (Pancreatic carcinoma, Non-small cell lung carcinoma (NSCLC), Endometrial carcinoma, Ovarian carcinoma, Breast carcinoma, Colorectal carcinoma (CRC))
	Talazoparib	Talzenna	PARP inhibitor.	Phase 1 (Solid Tumor) FDA Approved in other indications (Prostate cancer with HRR gene mutation, Breast carcinoma with germline BRCA1/2 mutation)
	Tuvusertib		Atr inhibitor.	Phase 1 (Solid Tumor) Phase 2 (Merkel cell carcinoma, Non-small cell lung carcinoma (NSCLC), Prostate carcinoma, Endometrial carcinoma, Ovarian carcinoma, Colorectal carcinoma (CRC))
	Veliparib		PARP inhibitor.	Phase 1 (Gallbladder carcinoma) Phase 3 (Glioblastoma, Non-small cell lung carcinoma (NSCLC), Ovarian carcinoma, Ovarian carcinosarcoma, Breast carcinoma, Lung cancer)

Relevance of Detected Alterations

Alteration	Role in Disease	Effect on Drug Sensitivity	Effect on Drug Resistance
ATM R2832H	ATM deficiency in cells has been reported to result in progression through the cell cycle even in the presence of DNA damage, resulting in the accumulation of DNA errors and genomic instability that can lead to cancer. (1).	Based on preclinical and clinical evidence, ATM-deficient tumors may be sensitive to poly(ADP-ribose) polymerase (PARP) inhibitors, Atr inhibitors, and DNA-PKcs inhibitors, which are under investigation in clinical trials. PARP inhibitors have been approved in multiple indications in the context of mutations in homologous recombination repair genes. (2-8). The PARP inhibitor olaparib has been approved by the FDA for castration-resistant adult prostate cancer patients with tumors harboring germline or somatic alteration in one or more homologous recombination repair genes, including ATM mutation. (9-17). In addition, talazoparib in combination with enzalutamide has been FDA-approved for the treatment of metastatic castration-resistant prostate cancer patients with tumors harboring germline or somatic alteration in one or more homologous recombination repair genes, including ATM mutation. (18-20).	

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