



## CORPORATE BACKGROUNDER

# LIQUID BIOPSY IS AT THE CORE OF OUR MISSION TO CONQUER CANCER WITH DATA

Guardant Health is a leading precision oncology company dedicated to helping conquer cancer globally through use of our proprietary blood tests, vast data sets, and advanced analytics.

### A company uniquely positioned to help patients across the entire cancer care continuum

At Guardant Health, we believe liquid biopsy is at the center of transforming cancer care by unlocking data that will help patients at all stages of the disease. While we've made great strides to help advanced cancer patients, our vision since inception has been to detect cancer early, when patient survival rates can be impacted most. We are committed to helping patients across the cancer care continuum live longer, healthier lives.

700K+ *(Estimated number of patients in the US)*

#### Advanced Cancer Patients

Guardant360<sup>®</sup> CDx liquid biopsy

15M+

#### Early-Stage Patients and Survivors

Guardant Reveal<sup>™</sup> liquid biopsy

100M+

#### Asymptomatic Individuals

LUNAR-2 program (in development)

### Guardant360<sup>®</sup> CDx liquid biopsy is helping to bring precision oncology to more advanced cancer patients

Guardant360<sup>®</sup> CDx is the first FDA-approved liquid biopsy for comprehensive genomic profiling (CGP) in advanced cancer patients across all solid cancers, and for use as a companion diagnostic for patients who may benefit from Tagrisso<sup>®</sup> (osimertinib), RYBREVANT<sup>™</sup> (amivantamab-vmjw), and LUMAKRAS<sup>™</sup> (sotorasib). We believe the ease of our blood test together with approval will help widen adoption of CGP and enable more patients to receive the best treatment.

In 2014, we introduced the Guardant360 laboratory developed test (LDT), the first-in-kind liquid biopsy to comprehensively sequence a patient's cancer to reveal actionable mutations. Our test enables doctors to match patients with the right targeted therapy, which can significantly extend survival compared to chemotherapy alone.<sup>1-7</sup> Since then, our Guardant360 LDT has been:

- Clinically validated with more than 200 peer-reviewed publications
- Trusted by more than 9,000 oncologists in more than 150,000 tests to date
- Broadly covered by Medicare and many private payers representing 200 million+ lives

During COVID-19, the value that liquid biopsy brings to cancer care is more important than ever. Non-invasive blood testing can be done using in-home services, minimizing health risks for those battling advanced cancer.

### Guardant Reveal<sup>™</sup> liquid biopsy enables residual disease and recurrence monitoring for early-stage patients

Guardant Reveal<sup>™</sup> is the first blood-only liquid biopsy test that detects residual and recurrent disease in 7 days from a simple blood draw. For oncologists, the test improves the management of early-stage patients by detecting circulating tumor DNA (ctDNA) in blood after surgery to identify patients with residual disease who may benefit most from adjuvant therapy, and by detecting recurrence months earlier than current standard-of-care methods like carcinoembryonic antigen (CEA) tests or imaging.<sup>8-13</sup>

- The first indication of the test is early-stage colorectal cancer (CRC)
- Interrogates genomic alterations and methylation, to achieve high sensitivity (91%)<sup>14</sup>

### LUNAR-2 is making progress toward a blood test that can screen for cancer in asymptomatic individuals

To help identify cancer at the earliest stages, we are developing a blood test that seeks to increase screening rates and overcome the challenges of current methods. By leveraging data from the tens of thousands of cancer patients already tested through our work with advanced cancer and the Guardant360 test, we are developing a test with high sensitivity and specificity for early cancer detection. We are collaborating with multiple investigators at cancer centers around the world in pursuit of this goal.

- 10,000-patient ECLIPSE trial underway to evaluate performance of test in early-stage CRC, the first indication

**Quick Facts**
**Mission**

Conquering cancer with data

**Founded**

2012

**IPO**

2018

**Headquarters**

Redwood City, California

**Staff**

1000+ employees

**Stock Listing**

NASDAQ: GH

**International**

 Guardant Health AMEA, Inc.  
Marketed in 40+ countries

**Founders**

 Helmy Eltoukhy, CEO  
AmirAli Talasaz, President  
and COO

**Contacts**

 Customer Service: 855.698.8887  
Investors: investors@guardanthealth.com  
Media: press@guardanthealth.com

**Social Media**

 linkedin.com/company/guardant-health  
twitter.com/guardanthealth

**PRODUCTS COVERING THE ENTIRE CANCER CARE CONTINUUM**
**For oncologists: to match advanced cancer patients with the right precision medicine**
**Guardant360<sup>®</sup> CDx liquid biopsy:**

- First FDA-approved comprehensive liquid biopsy.
- Guideline-complete genomic results to inform first-line treatment plans.
- A simple blood draw.
- Fast results in only 7 days.

**For oncologists: to improve management of early-stage colorectal cancer patients**
**Guardant Reveal<sup>™</sup> liquid biopsy:**

- Guides adjuvant treatment decisions by detecting minimal residual disease and detects recurrence months earlier than current standard-of-care methods for early-stage cancer patients.<sup>9-13</sup>
- Clinical trials underway to validate the clinical utility of the Guardant Reveal liquid biopsy:

**NRG-G1005 COBRA**

Study/Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Stage II Colon Cancer (NCT04068103)

**SU2C**

Study/Circulating Tumor DNA to identify Micrometastatic Disease for Treatment in Stage III Colon Cancer (NCT03803553)

**PEGASUS**

Trial/Post-Surgical Liquid Biopsy-Guided Treatment of Stage III and High-Risk Stage II Colon Cancer Patients (NCT04259944)

**In research and development: LUNAR-2 program for early-stage cancer screening from blood**
**LUNAR-2 Program**

- A multi-cancer blood test for early detection of cancer in asymptomatic individuals.
- Test has demonstrated high sensitivity and specificity in detecting colorectal cancer (CRC), our first indication for early cancer detection.<sup>16</sup>
- 10,000-patient ECLIPSE clinical trial underway to support pre-market approval (PMA) submission to the FDA:

**ECLIPSE**

Evaluation of the ctDNA LUNAR Test in an Average Patient Screening Episode (NCT04136002)

## For biopharma companies: solutions to help accelerate precision oncology drug development

### Biopharma Solutions

Our **GuardantOMNI® 500-gene test** delivers performance comparable to our Guardant360 test but with greater breadth, incorporating most genes evaluated in cancer drug development pipelines plus biomarkers for immuno-oncology applications.

Our **Guardant360® CDx** offers partners an FDA-approved companion diagnostic across all solid tumor cancers. We are currently collaborating with companies including Amgen, Janssen, and Radius Health, Inc. to add CDx claims to our validated platform. Guardant360 CDx is already FDA approved as a CDx to identify patients who may benefit from treatment with AstraZeneca's Tagrisso® (osimertinib) and Janssen's RYBREVA™ (amivantamab-vmjw).

Our **GuardantINFORM™ platform** is an in-silico platform that combines de-identified longitudinal clinical information and genomic data collected from our Guardant360 test. This real-world clinical-genomic dataset of advanced cancer patients is one of the largest in oncology. Notable applications include targeted drug development, clinical trial optimization, and post-marketing studies.

## Helping biopharma partners accelerate precision oncology drug development

Each year, more than 600,000 people die from cancer,<sup>15</sup> many of whom may have benefitted from targeted treatments. Guardant Health is proud to work with biopharmaceutical companies, more than 60+ to date, to help inform new precision oncology drug opportunities that can benefit more patients, through our extensive clinical-genomic datasets, advanced analytics, and comprehensive suite of biopharma solutions.

### References

- 1 Shaw AT, Riely GJ, Bang Y-J, et al. Crizotinib in ROS1-rearranged advanced non-small-cell lung cancer (NSCLC): updated results, including overall survival, from PROFILE 1001. *Annals of Oncology*. 2019;30(7):1121-1126.
- 2 Ramalingam SS, Gray JE, Ohe Y, et al. Osimertinib vs comparator EGFR-TKI as first-line treatment for EGFRm advanced NSCLC (FLAURA): Final overall survival analysis. *Annals of Oncology*. 2019;30(5):v851-v934.
- 3 Garon EB, Hellmann MD, Costa EC, et al. Five-year long-term overall survival for patients with advanced NSCLC treated with pembrolizumab: Results from KEYNOTE-001. *J Clin Oncol*. 2019;37(28):2518-2527.
- 4 Camidge DR, Dziadziuszko R, Peters S, et al. Updated Efficacy and Safety Data and Impact of the EML4-ALK Fusion Variant on the Efficacy of Alectinib in Untreated ALK-Positive Advanced Non-Small Cell Lung Cancer in the Global Phase III ALEX Study. *J Thorac Oncol*. 2019;14(7):1233-1243.
- 5 <https://www.hcp.novartis.com/products/tafinlar-mekinist/metastatic-nscl/efficacy/> Accessed online Jan. 10, 2020.
- 6 Gadgeel SM, Garassino MC, Esteban E, et al. KEYNOTE-189: Updated OS and progression after the next line of therapy (PFS2) with pembrolizumab (pembro) plus chemo with pemetrexed and platinum vs placebo plus chemo for metastatic nonsquamous NSCLC. *J Clin Oncol*. 2019;37(suppl; abstr 9013).
- 7 Sandler A, Gray R, Perry MC, et al. Paclitaxel-carboplatin alone or with bevacizumab for non-small-cell lung cancer. *N Engl J Med*. 2006;14;355(24):2542-2550.
- 8 Reinert T, Henriksen TV, Christensen E, et al. Analysis of Plasma Cell-Free DNA by Ultradeep Sequencing in Patients With Stages I to III Colorectal Cancer. *JAMA Oncology*. 2019; 5 (8): 1125-1131.
- 9 Tie J, Wang Y, Tomasetti C, Li L, Springer S, et al. Circulating tumor DNA analysis detects minimal residual disease and predicts recurrence in patients with stage II colon cancer. *Science Translational Medicine*. 2016; 8 (346): 346ra92.
- 10 Tie J, Cohen J, Wang Y, et al. Circulating Tumor DNA Analyses as Markers of Recurrence Risk and Benefit of Adjuvant Therapy for Stage III Colon Cancer. *JAMA Oncology*. 2019; 5(12): 1710-1717.
- 11 Peng J, Li Y, Mo S, Ma X, Hu X, Zhang L, et al. Prognostic value of circulating tumor DNA (ctDNA) detection during adjuvant chemotherapy in patients with stage III colorectal cancer: The interim report of a prospective, observational study. *Journal of Clinical Oncology*. 2020; 38, no.4\_suppl.
- 12 Tarazona N, Gimeno-Valiente F, Gambardella V, et al. Targeted next-generation sequencing of circulating-tumor DNA for tracking minimal residual disease in localized colon cancer. *Annals of Oncology*. 2019; 30 (11): 1804-1812.
- 13 Reece M, Saluja H, Hollington P, Karapetis C, et al. The Use of Circulating Tumor DNA to Monitor and Predict Response to Treatment in Colorectal Cancer. *Frontiers in Genetics*. 2019; 10: 1118.
- 14 Parikh A, Van Severter E, Siravegna G, Hartwig A, et al Minimal Residual Disease Detection using a Plasma-Only Circulating Tumor DNA Assay in Colorectal Cancer Patients. Under Review. Data on file.
- 15 Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>. Accessed online July 1, 2020.
- 16 Kim ST, Raymond VM, Park JO, et al. Combined genomic and epigenomic assessment of cell-free circulating tumour DNA (ctDNA) improves assay sensitivity in early stage colorectal cancer (CRC). Proceedings: AACR Annual Meeting 2019; March 29-April 3, 2019; Atlanta, GA, DOI: 10.1158/1538-7445.AM2019-916.