



## 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 the 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 blood-based testing can transform cancer care by unlocking insights that will help patients at all stages of the disease. We've made great strides in early-stage and advanced cancer, and we now offer a screening test 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+

### Individuals Eligible for Screening

Shield<sup>™</sup> test\*\*

### Guardant360<sup>®</sup> liquid biopsy technology is bringing precision oncology to more advanced cancer patients

In 2014, we introduced the Guardant360<sup>®</sup> 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 11,000 oncologists with 250,000 tests performed to date
- Broadly covered by Medicare and many private payers representing 200 million+ lives

In 2020, Guardant360 CDx became the first FDA-approved liquid biopsy test for comprehensive genomic profiling (CGP) in advanced cancer patients across all solid cancers, and it is now FDA-approved for use as a companion diagnostic for patients who may benefit from Tagrisso<sup>®</sup> (osimertinib), RYBREVA<sup>™</sup> (amivantamab-vmjw), and LUMAKRAS<sup>™</sup> (sotorasib). We believe the ease of our blood test together with FDA approval will help widen adoption of CGP and enable more patients to receive the best treatment.



### 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 two weeks 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>

- First indication for the test is early-stage colorectal cancer (CRC)
- Interrogates genomic alterations and methylation, to achieve high sensitivity (91%) in a surveillance setting<sup>14</sup>

### Shield<sup>™</sup> detects early signs of cancer in average-risk adults with high sensitivity

Guardant Health has developed highly sensitive technology to detect cancers early, when they are most treatable, using a simple blood draw. The Shield test uses a multimodal approach, integrating genomics, epigenomics and proteomics, to detect early signs of colorectal cancer in the bloodstream. It offers an accurate, easy-to-complete, blood-based approach to cancer screening that has the potential to improve screening rates.\*\*

We are starting with colorectal cancer, but will soon expand into multi-cancer screening, including lung, pancreas and others, where we believe cancer screening can save lives.

**Quick Facts**
**Mission**

Conquering cancer with data

**Founded**

2012

**IPO**

2018

**Headquarters**

Palo Alto, California

**Staff**

1,500+ employees

**Stock Listing**

NASDAQ: GH

**International**

Guardant Health products available in 60+ countries

**Founders**

 Helmy Eltoukhy  
 Chairman and co-CEO  
 AmirAli Talasaz  
 co-CEO

**Contacts**

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 Media: [press@guardanthealth.com](mailto:press@guardanthealth.com)
**Social Media**
[linkedin.com/company/guardant-health](https://www.linkedin.com/company/guardant-health)  
[twitter.com/guardanthealth](https://twitter.com/guardanthealth)
**PRODUCTS COVERING THE ENTIRE CANCER CARE CONTINUUM**
**For patients with advanced cancer: Insights to help inform treatment and improve outcomes**
**Guardant360<sup>®</sup> CDx liquid biopsy:**

- First FDA-approved liquid biopsy for comprehensive genomic profiling.
- Guideline-complete genomic results to help inform treatment plans.
- Approved as a CDx to identify patients with advanced NSCLC who may benefit from specific treatments.
- Results in 7 days from a simple blood draw.

**For patients with early-stage cancer: Identify patients at high risk for recurrence**
**Guardant Reveal<sup>™</sup> liquid biopsy:**

- Informs 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>8-13</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)

**For cancer screening: Find cancer early, when it's most treatable**
**Shield<sup>™</sup> blood test\*\***

- Uses a multimodal approach to detect colorectal cancer signals in the bloodstream, including DNA that is shed by tumors, called circulating tumor DNA (ctDNA).
- Demonstrated sensitivity (true positive rate) of 91% in CRC and 20% in advanced adenoma detection with 92% specificity (true negative rate) in normal cases in validation studies.<sup>16</sup>
- 12,750+-patient ECLIPSE clinical trial underway to support pre-market approval (PMA) submission to the FDA for CRC screening:

**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 comprehensive genomic profiling across all solid tumor cancers and an FDA-approved companion diagnostic for NSCLC. 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 RYBREVANT™ (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.

\* Guardant Reveal, GuardantOMNI, Guardant360 and Shield tests were developed, and their performance characteristics determined, by the Guardant Health Clinical Laboratory in Redwood City, CA USA, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical testing. Guardant360 refers to Guardant360 Laboratory Developed Test (LDT). These tests have not been cleared or approved by the U.S. FDA.

\*\* Shield is currently available for use in the detection of early signs of colorectal cancer in average-risk adults. It is a Laboratory Developed Test (LDT) that is intended to be complementary to and not a replacement for current recommended CRC screening methods.

### References

- 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.
- 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.
- 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.
- 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.
- <https://www.hcp.novartis.com/products/tafinlar-mekinist/metastatic-nscl/efficacy/> Accessed online Jan. 10, 2020.
- 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).
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- Parikh A, Van Seventer 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.
- Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>. Accessed online July 1, 2020.
- 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.