CORPORATE BACKGROUNDER

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

Guardant Health is a leading precision oncology company focused on 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 dedicated to helping patients across the cancer care continuum live longer, healthier lives.

700K+

Advanced Cancer Patients

Guardant360® CDx liquid biopsy

(Estimated number of patients in the US)

15M+

Early-Stage Patients and Survivors

LUNAR-1 program (in development)

65M+

Asymptomatic and High Risk Screening

LUNAR-2 program (in development)

Guardant360® CDx liquid biopsy is poised to bring the promise of precision oncology to more patients

Guardant360® 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® (osimertinib). We believe the ease of our blood test together with approval will help widen adoption of CGP and enable more patients to receive potentially life-changing precision medicines. 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.[1-7] Since then, our Guardant360 LDT has been:

- Clinically validated with more than 150 peer-reviewed publications
- Trusted by more than 7,000 oncologists in more than 150,000 tests to date
- Broadly covered by Medicare and many private payers, representing 170 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 groups most vulnerable like those battling advanced cancer.

With our LUNAR programs, we are making progress toward blood tests that can detect early-stage cancer

Through our work with advanced cancer and the Guardant360 test, we are now poised to transform cancer management in earlier stages through our LUNAR programs. Each blood sample we sequence contributes to real-world data that fuels this progress. For cancer survivors, our LUNAR-1 program aims to detect minimal residual disease and recurrence to inform neoadjuvant and adjuvant treatment decisions. To realize our vision of early cancer detection, our LUNAR-2 program is making progress towards the early detection of cancer in asymptomatic individuals.

- LUNAR-1 studies underway to evaluate clinical utility of test to guide treatment decisions
- LUNAR-2 10,000-patient ECLIPSE trial underway to evaluate performance of test in early-stage colorectal cancer (CRC), our first indication

Helping biopharma partners accelerate precision oncology drug development

Each year, more than 600,000 people die from cancer, many of whom may have benefitted from targeted treatments.[8] 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.

PRODUCTS COVERING THE ENTIRE CANCER CARE CONTINUUM

For oncologists: to match advanced cancer patients with the right precision medicine

Guardant360® 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.

In research and development: LUNAR programs for early-stage cancer management and detection

LUNAR-1 Program

- A blood test that can help guide adjuvant and neoadjuvant treatment decisions by detecting minimal residual disease and recurrence in early-stage cancer patients.
- Available for research use only for biopharmaceutical companies and academic researchers.
- Clinical trials validating the clinical utility of the LUNAR-1 liquid biopsy are underway:

NRG-G1005 COBRA
Study/Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Stage II Colon Cancer (NCT04068103)

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

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.[9]
- 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 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.

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).

Quick Facts

Mission
Conquering cancer with data

Founded
2012

IPO
2018

Headquarters
Redwood City, California

Staff
750+ employees

Stock Listing
NASDAQ: GH

International
Guardant Health AMEA, Inc.
Marketed in 40+ countries

Founders
Helmy Eltoukhy, CEO
AmirAli Talasaz, President and COO

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twitter.com/guardanthealth

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-nsclc/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 https://seer.cancer.gov/statfacts/html/all.html / Accessed online July 1, 2020.

9 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.