Case Study

Companion Diagnostics

at NeoGenomics Laboratories

A focus on personalized medicines and immune-modulating drugs has given rise to biomarker-focused oncology clinical studies. The use of biological signatures to identify patients that will benefit from a particular therapy has greatly accelerated the pace of drug development and approval. For this reason, there has been increased use of biomarkers and more specifically companion diagnostics, in current oncology drug development. With more than 30 active programs with pharmaceutical sponsors and IVD companies NeoGenomics has been a key player in this new approach to oncology drug development.

As the development of personalized/precision medicine gains momentum, pharmaceutical companies are creating partnerships with device and diagnostic organizations for the development of companion diagnostics to accompany novel therapeutics in clinical trials. By definition a companion diagnostic is a medical device, most often an in vitro device, that by design provides critical information that can predetermine the safe and effective use of an established therapeutic in three major ways.

- **Identify patients that will have optimal beneficial response to the drug**
- **Identify patients that will not respond or may be at risk with the drug and should not receive treatment**
- **Monitor responses to drug treatment for the purpose of adjusting treatment to potentially improve safety or effectiveness.**

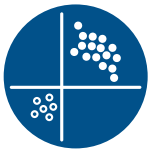
Because companion diagnostics are regulated devices, there are additional development requirements beyond those for biomarker or clinical assays used in clinical trials. Careful consideration must be given to the regulatory strategy and design of the assay and supporting technology platform to ensure that the device can be successfully commercialized. As a global organization, NeoGenomics is notably resourced with strong clinical and scientific expertise in multiple biomarker technologies that can develop, initiate and deliver companion diagnostic programs worldwide from clinical trials all the way through commercialization.

NeoGenomics has extensive experience working directly with large oncology IVD manufacturers across a multitude of platforms. These include Hoffmann-La Roche AG (Switzerland), Becton Dickinson, Agilent Technologies, Inc. (US), QIAGEN N.V. (acquired by Thermo Fisher Scientific) (Germany), Abbott Laboratories, Inc. (US), Danaher Corporation (US), Illumina, Inc. (US), NanoString (US), and Thermo Fisher Scientific Inc. (US). Because of these strategic relationships, NeoGenomics can engage in a collaborative enterprise with pharmaceutical organizations who are seeking to develop a companion diagnostic biomarker.

The global nature of clinical trials and drug development requires networks of harmonized laboratories and partners to ensure that assays developed in early phase development are scalable to the rest of the world. With NeoGenomics' recent expansion into Singapore and China (laboratory) with a focus on supporting real-time companion diagnostic testing and established partnerships with global manufacturing partners, NeoGenomics is well positioned to continue our efforts in the global market to develop and commercialize companion diagnostics.

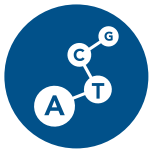
As the largest oncology-focused clinical reference laboratory in the United States, NeoGenomics uses a multitude of platforms and resources that not only supports companion diagnostic development but also commercial launch. Our Day One Launch program ensures that physicians and patients have access to companion diagnostic testing immediately following FDA approval of the drug/device combination.

Anatomic Pathology



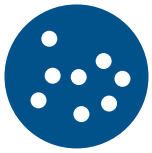
Flow Cytometry

Immunoassay



Molecular

Multiplexed IF



FISH & Cytogenetics

In recent case studies associated with Merck and Novartis, NeoGenomics lead all other diagnostic companies in the development and commercialization of at least two successful companion diagnostics for targeted cancer therapies, KeyTruda and Piqray to support drug launch.

With known development and regulatory expertise NeoGenomics has created defined processes associated with each aspect of the program that involves coordinated efforts in the areas of Consultation; Customization; Commercialization; and Consolidation. Development of companion diagnostics is complex and time consuming. Our team of scientists, pathologists and business development professionals are here to help.

Consultation	• Platform and technology selection • Study design • Regulatory support and submission • Pathology • Commercial Strategy
Customization	• Assay Development • Fit for purpose assay design and validation • Global harmonization. Clinical trial testing (Phase 1–3) • Project management • Data management
Commercialization	• IVD Partnerships • Single-site FDA approved test • USA commercial launch • Partnerships for Ex-US launch • Day One Launch Program • Sponsored testing program • Data services
Consolidation	• Consolidate specialty testing with one CRO

Novartis CDx Case Study – Piqray.

NeoGenomics Becomes First to Launch PIK3CA CDx as Part of 'Day One' Program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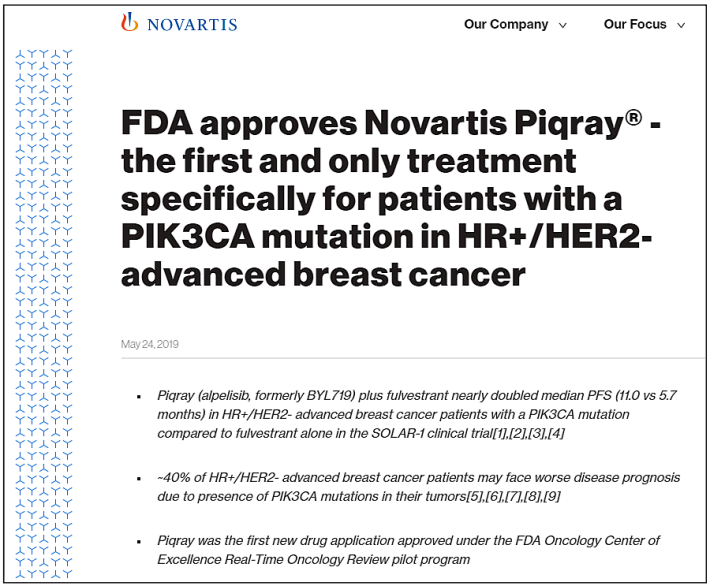
NeoGenomics and QIAGEN Collaborate to Offer Companion Diagnostic Test for HR+/HER2 - Advanced Breast Cancer Patients to Detect a PIK3CA Mutation

FT. MYERS, FL / May 28, 2019 / NeoGenomics, Inc. (NASDAQ: NEO), a leading provider of cancer-focused genetic testing services, today announced availability of the QIAGEN therascreen® PIK3CA RGQ PCR test from QIAGEN N.V. (NYSE: QGEN, Frankfurt Stock Exchange: QIA) for post-menopausal women, and men, with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer following progression on or after an endocrine-based regimen. This PIK3CA assay is a companion diagnostic test recently approved by the FDA to aid clinicians in identifying breast cancer patients suitable for treatment with Piqray®* (alpelisib), a newly approved therapy developed and marketed by Novartis. Piqray is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.


NOVARTIS

Our Company · Our Focus

FDA approves Novartis Piqray® - the first and only treatment specifically for patients with a PIK3CA mutation in HR+/HER2- advanced breast cancer

May 24, 2019

- *Piqray (alpelisib, formerly BYL719) plus fulvestrant nearly doubled median PFS (11.0 vs 5.7 months) in HR+/HER2- advanced breast cancer patients with a PIK3CA mutation compared to fulvestrant alone in the SOLAR-1 clinical trial[1],[2],[3],[4]*
- *~40% of HR+/HER2- advanced breast cancer patients may face worse disease prognosis due to presence of PIK3CA mutations in their tumors[5],[6],[7],[8],[9]*
- *Piqray was the first new drug application approved under the FDA Oncology Center of Excellence Real-Time Oncology Review pilot program*

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