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Aspyre® Clinical Test in the resectable non-small cell lung cancer stage IB-IIIA, IIIB (T3,N2) setting

Prospective study synopsis

Study Overview

Patients with resectable stage IB-IIIA, IIIB (T3,N2) non-small cell lung cancer (NSCLC) are candidates for limited genomic testing for ALK and EGFR mutations per current treatment guidelines. However, emerging data suggest that early-stage patients may harbor additional genomic alterations with potential clinical relevance, though their impact on targeted treatment strategies in this setting remains to be fully explored. The purpose of this study is to identify genomic alterations in the early-stage resectable patient population. These findings may help inform future clinical trial design for the broader investigation of targeted therapeutic approaches in resectable NSCLC.

Background

NCCN guidelines recommend that patients with resectable stage IB-IIIA should be evaluated for perioperative therapy, with strong consideration for nivolumab, pembrolizumab, durvalumab[1] plus chemotherapy for those patients with tumors ≥4 cm or node positive and no contraindications to immune checkpoint inhibitors. The guidelines support testing for PD-L1 status, EGFR mutations, and ALK rearrangements (stages IB–IIIA, IIIB [T3,N2]), as clinical trials for neoadjuvant nivolumab plus chemotherapy excluded patients harboring EGFR mutations and ALK rearrangements. Exclusion of these biomarkers, at a minimum, is recommended prior to consideration for neoadjuvant nivolumab plus chemotherapy. For patients with completely resected stage II–IIIA or stage IIIB (T3, N2) NSCLC who are positive for ALK rearrangements, Alectinib 600 mg twice daily for 24 months after surgery is approved, and for patients with completely resected stage IB–IIIA or stage IIIB (T3, N2) NSCLC and positive for EGFR (exon 19 deletion, exon 21 L858R) mutations who received previous adjuvant chemotherapy or who are ineligible to receive platinum-based chemotherapy, Osimertinib 80 mg daily for 3 years is recommended.

The primary objective of this study is to identify additional actionable mutations in the early-stage resectable patient population using the Aspyre Clinical Test for Lung tissue assay. This information may be used to design future definitive clinical trials that aim to expand the list of actionable mutations for this patient population, which in turn may offer effective treatment options to a broader community. In addition, Aspyre Clinical Test for Lung may have the potential to improve on the existing gaps in the standard of care for early-stage resectable patients. Current tests for EGFR mutations and ALK rearrangements typically have a turn-around time (TAT) of 10 business days following receipt of the sample, which can result in the delay of clinical decision making (defined as “time to genomic result availability”) regarding upfront surgery vs neoadjuvant therapy with checkpoint inhibitor and chemotherapy. This study will measure the time to genomic result availability of Aspyre Clinical Test for Lung, which is currently advertised as 48 hours.

Aspyre Clinical Test for Lung may also be a solution for other gaps in clinical care that prevent early-stage resectable NSCLC patients from receiving molecular profiling and targeted treatment. Tissue biopsies from early-stage patients are typically small in size. Next generation sequencing (NGS) assays, the typical standard of care for molecular profiling, have strict input requirements, resulting in an undesirable number of samples

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untested due to insufficient quantity[2]. In addition, NGS is sensitive to sample quality, with up to 25% of tissue samples failing assay quality control (QC)[2, 3, 4]. Aspyre Clinical Test for Lung has less stringent sample input requirements compared to most NGS assays, with evidence that Aspyre Clinical Test for Lung can handle low quality samples not amenable to NGS sequencing[5]. Finally, the cost of comprehensive genomic testing when only looking for a small number of actionable mutations is inhibitive. Aspyre Clinical Test for Lung offers a cost-effective and more rapid alternative that overcomes many of the barriers preventing early-stage resectable NSCLC patients from receiving testing and treatment that they can benefit from.

Study Objectives

PRIMARY OBJECTIVE

- To determine the rate at which Aspyre Clinical Test for Lung can detect genomic alterations in samples from patients with resectable stage IB-IIIA, IIIB (T3,N2) NSCLC

SECONDARY OBJECTIVES

- To determine if Aspyre Clinical Test for Lung can expedite the time required for patients with resectable stage IB-IIIA NSCLC to receive biomarker results compared to the historic institutional standard of care assay
- To determine the rate at which Aspyre Clinical Test for Lung can produce definitive clinical results for patients with resectable stage IB-IIIA, IIIB (T3,N2) NSCLC , including for sample types that don't meet Aspyre Clinical Test for Lung assay specifications
- To determine the cost-effectiveness of Aspyre Clinical Test for Lung compared to genomic profiling tests for typically used for patients with resectable stage IB-IIIA, IIIB (T3,N2) NSCLC
- To obtain feedback about the usability of Aspyre Clinical Test for Lung from care teams of patients participating in this study

Study Endpoints

PRIMARY ENDPOINT

- The percentage of samples with Aspyre Clinical Test for Lung results detecting genomic alterations and a breakdown of the targets detected

SECONDARY ENDPOINTS

- Time to genomic result availability for Aspyre Clinical Test for Lung, as defined by: time from specimen receival at Biofidelity to the availability of biomarker testing results
- Assay success rate measured by percentage of QC failures - samples will be run through Aspyre Clinical Test for Lung irrespective of size and tumor content
- Cost-effectiveness of Aspyre Clinical Test for Lung based on the price of performing the assay vs. current standard of care assays at participating institutions. Other health economic endpoints may be explored
- User feedback from care teams of patients participating in this study about their experience with Aspyre Clinical Test for Lung, including sample requisition, collection kits, customer support, results delivery and the clinical report

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Study Design and Eligibility

- Real world, prospective, non-interventional study of 50-75 patients with pathologic confirmation of NSCLC diagnosis
- Treatment naïve patients have been diagnosed with stage IB-IIIA, IIIB (T3,N2) NSCLC and are candidates for genomic testing
- Patients must ≥ 18 years of age and able to provide informed consent for genomic testing
- Basic de-identified demographic information must be available for retrospective collection (gender, ethnicity, diagnosis, staging, date of biopsy)
- Tissue samples submitted to the Biofidelity CAP/CLIA laboratory must meet Aspyre Clinical Test for Lung acceptance criteria—other sample types may be considered upon review
- Biofidelity will engage with care teams to provide user feedback about Aspyre Clinical Test for Lung

To learn more about participating in this study, please contact e.shapiro@biofidelity.com

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