Changes in cDNA levels as an early indicator of outcomes in advanced NSCLC treated with TKI: Initial findings from a retrospective aggregate analysis of 8 clinical trials

Hilary Street, PhD1, Nevinia Zarifoo, MMkkt, 2, Megan Engel, MD, Edward Goren, PhD, 2, Craig R. E. Espinach, MD, 3, Maksodr Gurnu, PhD, 4, Jonean Ooi, 5, Olga Schulz, Jeurine, PhD, 1, Jean-Francois Martini, PhD, 1, Brittnay McCayle, PhD, 1, Katherine K. Nishimura, MPH, PhD, 2, Gary A. Pavlosto, PhD, 1, Sorena Rahimian, PhD, 1, Adam Rosendahl, MD, 1, Mark Stewart, PhD, 1, Anna Sipikala, PhD, 1, Diana Vega, PhD, 1, Antje Hoering, PhD, 2, Jeff Allen, PhD, 2, and the ctMoniTR Step 2 Working Group


Abstract # 3030


Methods

- **Approach**: Align on evolution
- **Data Submitted**: Randomized
- **Assay Characteristics**: Data from multiple NSCLC trials and patients with TKI treatment

Results

- **Dataset**: Retrospective aggregate analysis of 8 unique clinical trials of patients with advanced NSCLC treated with a tyrosine kinase inhibitor (TKI), i.e. anti-EGFR, anti-HER2, or MEK, n=1950) broken into three research objectives

- **Training/Validation**: We randomly divided the dataset into training (2/3 of the dataset) and validation (1/3 of the dataset) stratified by clinical trial cohort (i.e., age, race, tumor status, and prior therapies) and then ran initial analyses on the training dataset (presented here).

- **Research Objective 1**: Do early changes in cDNA levels associate with long-term clinical outcomes?

- **Research Objective 2**: Do "early" changes in cDNA complement 1st RECIST to assess treatment efficacy? Best overall response?

Conclusions

- **Step 2 Module 2**: aNSCLC with anti-PD-(L)1 and/or chemotherapy

- **Step 2 Module 3**: Solid tumors with anti-PD-(L)1 or TKI

Next Steps

- **Research Objective 1**: In a retrospective aggregate analysis of 8 clinical trials in aNSCLC treated with TKI, non-detected cDNA on treatment (\(d/d\)) associates with better OS compared with patients with detected levels of cDNA on treatment (\(d/d\)).

- **Research Objective 2**: cDNA samples collected within 10 weeks following initial treatment can be used to assess response to treatment and are an indicator of long-term benefit.