About ADVISE

ADapti**V**e Biomarker Trial that **I**nform**S** **E**volution of Therapy

Driving Precision Medicine for Immuno-Oncology Combinations Through an Innovative Study Design

- In Immuno-Oncology (I-O), targeting complementary immune pathways in the tumor microenvironment may yield more robust anti-tumor responses than targeting a single pathway. Given the vast variety of immune pathways researchers have already identified, the potential number of investigational immunotherapy combinations to study is daunting.
- Improved understanding of immune biomarkers may help researchers select the appropriate investigational treatment – or combination of treatments – for each patient based on disease biology, enabling more personalized approaches in I-O.[1]

Immune biomarkers are measurable biological signals which can indicate how a particular mechanism will address a biological effect in a patient, and in turn, predict the likelihood of clinical benefit with I-O therapy.

- However, the clinical feasibility and utility of using real-time biomarker data to study I-O combinations in specific patient populations has not been established.
- Powered by translational medicine – research to further the understanding of cancer biology and identify the patients most likely to benefit from I-O treatment – Bristol-Myers Squibb is working to quickly implement new insights in clinical trials and explore emerging biomarkers and I-O combinations that may help match **the right treatments with the right patients at the right time**.

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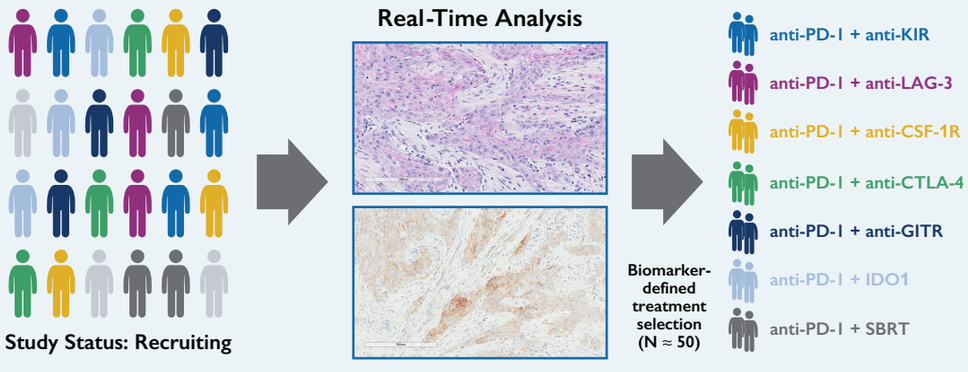
Sponsored by Bristol-Myers Squibb, ADVISE is an early phase trial which uses an innovative approach to assess real-time, biomarker-driven patient selection for I-O combinations.

- During the initial phase of the ADVISE trial, patients will undergo a pretreatment biopsy to inform a biomarker analysis that will determine a personalized treatment approach based on their unique disease biology. The potential regimens include several I-O-based combinations currently under investigation.
- The goal of ADVISE is to determine the real-world feasibility of using biomarkers to guide treatment decisions, while also assessing preliminary clinical activity for multiple I-O-based combinations.

The ongoing trial will assess the logistical capability and clinical utility of real-time biomarker data in tailoring I-O therapy to individual patients across six tumor cohorts.

Through this novel trial design, translational medicine and disease biology can be used to help drive personalized treatment selection for patients, which allows researchers to follow the science and adapt the study as new learnings emerge. In addition, ADVISE offers researchers an opportunity to more closely model how patients are treated in clinical practice, providing an efficient avenue for evaluating investigational treatments.

Investigational Combinations Being Studied in ADVISE



1. Morrissey, et al. Immunotherapy and Novel Combinations in Oncology: Current Landscape, Challenges, and Opportunities. *Clin Transl Sci* (2016) 9, 89–104.

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