

## News Release

### Title

#### **A novel biomarker for predicting clinical efficacy of PD-1 blockade therapies**

### Key Points

- A research team mainly based at National Cancer Center identified a novel biomarker which can predict the clinical efficacy of PD-1 blockade therapies. Precision medicine utilizing the biomarker predicting clinical efficacy of immunotherapy is anticipated.
- The team developed an evaluation system to measure the biomarker from phenotypes of tumor-infiltrating lymphocytes, a technical challenge, in collaboration with Nippon Becton Dickinson Company. The breakthrough will promote the development of diagnostic kits for use in clinical settings.
- Clinical trials to validate the developed biomarker will follow towards realizing precision medicine in cancer immunotherapy.

### Summary

We have identified a novel biomarker that predicts the therapeutic effects of PD-1 blockade therapies and have also developed a new measuring tool for evaluating the biomarker. Clinical trials will follow to realize the clinical application of this biomarker.

### Research Background

Immunotherapies with immune checkpoint inhibitors have been deployed for the treatment of various types of cancer. However, there are many issues; patients showing therapeutic effects are limited to only 20-30%, serious adverse effects are observed in some patients, and it is expensive.

### Research Results

In this study, we utilized pre-treatment tissue samples from patients with malignant melanoma, lung cancer and gastric cancer treated with PD-1/PD-L1 blockade (nivolumab, pembrolizumab or atezolizumab) to evaluate immunological phenotypes of tumor-infiltrating lymphocytes (TILs). As a result, PD-1 expression balance between tumor-infiltrating effector and regulatory T cells correlated with antitumor effects of the treatment, and predicted the clinical efficacy with high accuracy.

For identifying the biomarker, the research team collaborated with Ono Pharmaceutical. For clinical application of this biomarker, Nippon Becton Dickinson Company has jointly developed a new measuring tool for evaluating PD-1 expression balance in TILs, which was considered technically difficult. National Cancer Center continues to evaluate the biomarker in clinical settings.

The results of the research were published in the electronic version of the American scientific journal *Nature Immunology* on August 31, 2020.

## **Publication**

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