

AFT-42: Safety, Activity, and Pharmacology of Nivolumab in Patients with Advanced
Non-Small Cell Lung Cancer and Pre-existing Autoimmune Disease

Rebecca S. Heist, MD, MPH, Massachusetts General Hospital

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Despite the clear evidence of benefit of anti-PD1 agents such as nivolumab in NSCLC, there are very limited data regarding the safety of immunotherapies in patients with pre-existing autoimmune disease, as clinical trials have excluded such patients.



A recent evaluation of over 200,000 patients contained in the National Cancer Data Base by Khan et al. demonstrates that patients with autoimmune diseases collectively may comprise as many as 10-15% of the lung cancer population. By their evaluation approximately 6% had rheumatoid arthritis, 3% psoriasis, 2% polymyalgia rheumatic and 1% each SLE, ulcerative colitis, and giant cell arteritis. Given the inevitability that such patients will be seen with advanced lung cancer, it is essential to determine the safety, efficacy and appropriate dosing for these individuals.



Primary

- To determine the safety and tolerability of nivolumab in patients with specific autoimmune diseases and NSCLC

Secondary

- To evaluate the activity of nivolumab in this population

Translational/Correlative Science

- To evaluate the pharmacokinetics of nivolumab in this population
- To characterize changes in circulating immune cells by flow cytometry
- To characterize TCR diversity and clonality in tumor-infiltrating lymphocytes (TILs)

RATIONALE

OBJECTIVE

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rationale/
objective

study
details

study
design

key eligibility
criteria

follow up

Study Number
AFT-42

Study Phase
Phase IB

Clinical Indication
**Advanced NSCLC
with coexisting
autoimmune disease**

Number of Trial Patients
70

Study Design
**Safety run in
with expansion**

STUDY DETAILS

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The purpose of this study is to explore the safety, tolerability and activity of PD-1 inhibition with nivolumab in cohorts of patients with autoimmune disease. Two cohorts of patients will be enrolled, based on autoimmune disease type (Table 1). Entry into cohorts 1 and 2 will start simultaneously and enroll independently.

The FDA approved dose of nivolumab is 240 mg IV every two weeks. All patients will be started at this dose, and there will be no escalation past this dose level. An initial safety run-in will be conducted in each cohort, with decision rules for continuing or stopping enrollment. If the safety run-in is completed and the decision is to go forward with enrollment, enrollment will proceed with a total of 35 evaluable patients in each cohort.

STUDY DESIGN

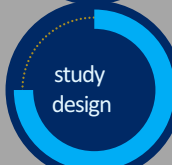


Table 1. Cohorts of Autoimmune Conditions

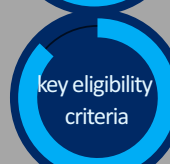
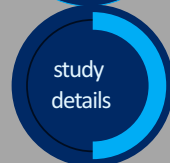
Cohort 1	Rheumatoid arthritis, psoriasis, giant cell arteritis/polymyalgia rheumatica, systemic lupus erythematosus
Cohort 2	Other autoimmune diseases (ulcerative colitis, Crohn's disease, multiple sclerosis) Patients must be discussed with PI prior to enrollment

KEY ELIGIBILITY CRITERIA

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FUNDING SUPPORT

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