

A lung cancer precision medicine trial

VOLUME 18 | FALL 2021 NEWSLETTER WWW.LUNG-MAP.ORG

S1800D, Non-Match Sub-Study, on the Way!

S1800D "A Phase II/III Study of N-803 (ALT-803) Plus Pembrolizumab Versus Standard of Care in Participants with Stage IV or Recurrent Non-Small Cell Lung Cancer Previously Treated with Anti-PD-1 or Anti-PD-L1 Therapy (Lung-MAP Non-Match Sub-Study)" is set to launch this fall. <u>A recording of an S1800D preview</u> from the spring 2021 SWOG virtual group meeting is online.

Primary Objective: Patients will be enrolled into two cohorts – primary resistance versus acquired resistance to prior anti-PD-(L)1 containing therapy. Within each cohort, overall survival will be compared between participants randomized to N-803 + pembrolizumab and those randomized to standard of care therapy.

Industry Partner: ImmunityBio

Accrual Goal: 478

Study chairs **John M. Wrangle, MD**, **MPH**, of the Medical University of South Carolina, and **Hatim Husain**, **MD**, of the University of California San Diego, say:

"We are incredibly excited about \$1800D serving unmet needs for patients in lung cancer therapy after immunotherapy. This trial will compare standard-of-care chemotherapy to a new combination of immunotherapies in the hopes that a





WRANGLE

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non-chemotherapy option will improve survival in our patients. The experimental combination adds a cytokine therapy, N-803, to immune checkpoint therapy. N-803 is based on IL-15 and acts as a growth factor for the lymphocytes responsible for killing cancer. The hope is that this therapy can restore a response to immunotherapy or deliver a response when initial immunotherapy failed to do so."

4,000+
patients
genetically
screened



1,000 patients enrolled to sub-studies

Since 2014, Lung-MAP has genetically screened more than 4,000 patients with non-small cell lung cancer. Almost 1,000 of these patients have enrolled in a Lung-MAP sub-study.

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Sub-Studies S1400F and S1400I Publish Results

 "Phase II Study of Durvalumab Plus Tremelimumab as Therapy for Patients with Previously Treated Anti-PD-1/PD-L1 Resistant Stage IV Squamous Cell Lung Cancer (Lung-MAP Substudy S1400F, NCT03373760)," by Natasha B. Leighl, MD, and colleagues, was published in the Journal for

ImmunoTherapy of Cancer.

 "Nivolumab Plus Ipilimumab vs Nivolumab for Previously Treated Patients With Stage IV Squamous Cell Lung Cancer: The Lung-MAP S1400I Phase 3 Randomized Clinical Trial," by Scott N. Gettinger, MD, et al., appeared in JAMA Oncology.

As of 9/28/2021, the *new* LungMAP protocol has logged:

2190 screening registrations1013 sub-study assignments305 sub-study registrations

TOP-ACCRUING SITES

I. UPMC Hillman Cancer (Center,
Pittsburgh, PA	133

UNM Comprehensive Cancer Center, Albuquerque, NM 42

41

38

25

24

24

23

23

23

3. Wilmot Cancer Institute, Rochester, NY

4. Mercy Medical Center, Canton, OH

5. Missouri Baptist Medical Center, St. Louis, MO **32**

6. Roswell Park Comprehensive Cancer Center, Buffalo, NY **27**

7. Markey Cancer Center,	
Lexington, KY	

8. Good Samaritan Hospital, Cincinnati, OH

8. Stephenson Cancer Center	
Oklahoma City, OK	

9. Baystate Medical Center, Springfield, MA

9. Essentia Health, Duluth, MN

9. Virginia Cancer Institute, Richmond, VA

10. Eastern Maine Medical Center Cancer Care, Brewer, ME **22**

Lung-MAP's Annual Update Meeting

Lung-MAP held its annual update meeting July 12th.

The drug selection committee reported talks with seven companies with active concepts, as well as discussions of a multidrug combination trial with several firms.

The translational medicine (TM) committee update included an inventory of some of the TM resources available, including genetic sequencing data from more than 1,600 patients, about 800 stained slides, residual DNA extracted from submissions of circulating tumor DNA, and digital images of slides. For researchers looking to work with these resources, the TM committee is planning a webinar and developing a request form.

Lung-MAP statistician **Mary Redman**, **PhD**, spoke of a formal analysis now underway looking at the diversity

of patients recruited to the trial. Analysis results are expected this fall.

The group also heard from Vali
Papadimitrakopoulou, MD, one
of the three original Lung-MAP PIs
(along with Roy Herbst, MD, PhD,
and David Gandara, MD), who
applauded how the project has
grown and said that a great strength
of the trial is its ability to reach
patients in community settings.

Finally, while addressing challenges of identifying sub-studies for Lung-MAP, **Roy Herbst**, **MD**, **PhD**, emphasized that the trial's ability to obtain tissue and to look at targeted biomarkers also offers great opportunities for industry and academic researchers to propose sub-studies.

CONTACT US

General Medical Questions <u>LUNGMAP@swog.org</u>

Protocol & Regulatory Questions lgildner@swog.org or jbeeler@swog.org

Eligibility & Data Submission Questions LUNGMAPQuestion@crab.org Central Monitoring Questions centralmonitorquestion@crab.org

Quality Assurance Auditing Questions qamail@swog.org Funding Questions funding@swog.org

S1900E Study Chairs S1900EMedicalQuery@swog.org