LUNG-MAP
A lung cancer precision medicine trial

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New Sub-Study Opens – S1800A

Non-match patients now have another Lung-MAP option

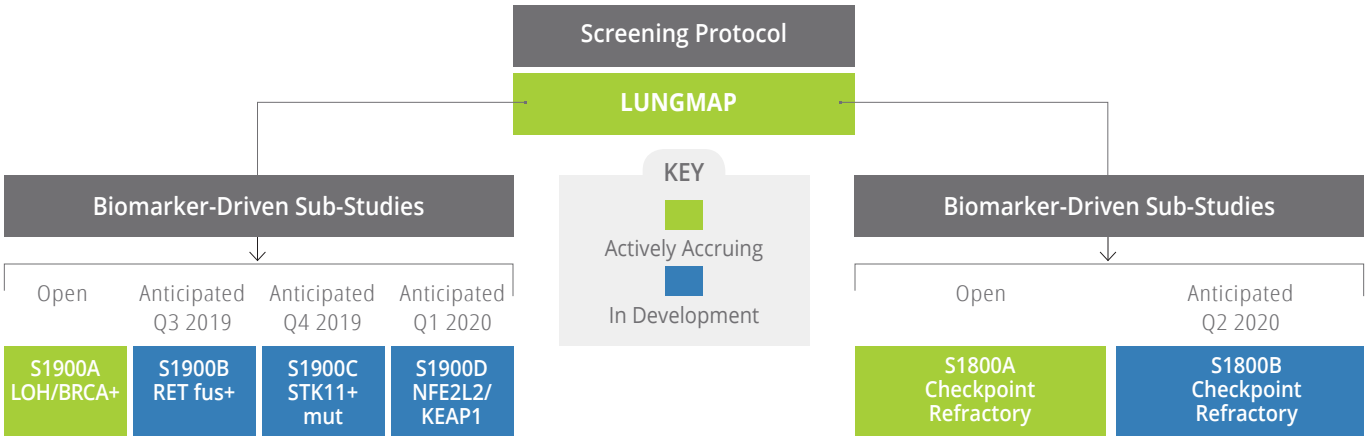
On May 17, a new Lung-MAP sub-study opened to patient enrollment. It compares overall survival between patients treated with two immunotherapies, ramucirumab and pembrolizumab, with patients receiving standard of care. Activation of S1800A offers a new, non-match option in our precision medicine trial and gives patients access to leading-edge immunotherapies.

Patients enrolled in S1800A will be randomly placed into one of two arms.

One group will receive the physician's choice of standard of care treatments, including docetaxel, gemcitabine, pemetrexed, or a combination of ramucirumab and docetaxel. The other group will receive a combination of ramucirumab and pembrolizumab. Ramucirumab, sold as Cyramza, is a VEGFR2 inhibitor while pembrolizumab, sold as Keytruda, is a PD-1 inhibitor.

Patients eligible to join S1800A are those whose non-small cell lung cancer progressed after treatment for at least 84 days with one line of anti-PD-1 or anti-PD-L1 therapy as their most recent line of therapy, either alone or in combination with platinum based therapy. Patients with EGFR, ALK, ROS1, or BRAF alterations who progressed on all standard of care targeted therapy are also eligible.

FOR A FULL LIST OF SUB-STUDIES IN DEVELOPMENT, SEE THE NEXT PAGE



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More Sub-Studies to Come

Two more protocols in development:

- A biomarker-driven sub-study open to all non-small cell lung cancer patients that features a treatment targeting RET fusion-positive cancers; Anticipated opening Q3 2019
- A biomarker-driven sub-study that will feature a drug combination for non-squamous patients with STK11 mutated tumors; Anticipated opening Q4 2019

Two more concepts in development:

- A biomarker-driven sub-study for squamous patients with NFE2L2 or KEAP1 positive tumors; Anticipated opening Q1 2020
- A non-match sub-study that will test combination treatments that include either two immunotherapies or two immunotherapies plus a targeted therapy; Anticipated opening Q2 2020

WHERE WE ARE NOW

LUNGMAP SCREENING PROTOCOL

- Opened January 2019
- 560 sites with IRB approval
- 252 patients enrolled

As of June 11

Tissue Is (Still) The Issue

13.5% of initial tissue submissions on S1400 were inadequate:

- **51% insufficient tissue for analysis**
- **41% less than 20% tumor cells**
- **27% insufficient DNA**
- **12% insufficient tumor size**
- **12% failed sequencing**
- **10% other reasons**
- **2% insufficient tumor cellularity**

For best results, use these specifications:

- **Samples that contain 20% or more of tumor content.** This ensures there is enough DNA needed for sequencing.
- **Samples that contain 80% or more of nucleated cells.** Specimens containing less require greater total volume and may not be suitable to assay. A total of 75,000 to 150,000 nucleated cells are recommended.
- **Sample surface area of at least 25 mm².** The face of the block or slide should be at least 25 mm^2 in area, for example 5x5 mm or 2.5x10 mm.
- **Specimen volume of at least 1 mm.** The total volume (surface area x depth) of the block or stacked slides should be at least 1 mm. If the surface area is 25 mm^2 as recommended, the depth should be at least 40 microns. For this reason, a minimum of 12 slides is required.
- **Specimen type should be FFPE block or 12-20 slides (+H&E slides).** Tissue must be formalin-fixed and paraffin embedded.
- **When sending slides:** Send a required minimum of 12 unstained, charged, and unbaked 4-5 micron slides; 20 slides are highly recommended; Slides should include an additional H&E or Aperio stained slide (If unavailable, submit an extra unstained slide).

Find Our Complete Tissue Spec Sheet on the CTSU website

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