Testing Pembrolizumab with Existing Cancer Therapy in Patients with Evidence of Residual CML

**WHY consider participating in this study?**

- Research studies are an important way to test the effectiveness of new drugs for treating CML.

- All study participants will receive the usual treatment for this cancer, which is continuous therapy with tyrosine kinase inhibitors (TKIs) (i.e., imatinib [Gleevec], dasatinib [Sprycel], bosutinib [Bosulif], or nilotinib [Tasigna]). In addition, all participants will also receive the study drug, pembrolizumab (Keytruda), by vein (intravenously).

- The purpose of the EA9171/BLAST MRD CML 1 study is to determine the effects of adding pembrolizumab to the usual treatment.
  - Researchers hope to learn if pembrolizumab will shrink the cancer/prevent it from returning.

**WHAT does this study involve?**

- All study participants who decide to enroll in this study will be on Arm A and will receive pembrolizumab by vein once every 3 weeks for 18 doses (total duration of 54 weeks). During this time, you will continue to take the TKI you were on prior to joining the study.

- After completing 54 weeks of treatment, a decision regarding your further treatment strategy will be made depending on whether a fusion gene product, called bcr-abl, remains detectable in your blood. This is referred to as minimal residual disease (MRD) testing.
  - **If bcr-abl is undetectable (referred to as undetectable MRD, or UMRD), you will stop receiving pembrolizumab and will only continue the TKI.**
    - If bcr-abl remains undetectable in your blood for a year, then you would stop taking your TKI and your bcr-abl levels will be monitored for 2 years.
    - If bcr-abl becomes detectable in your blood again, you will start back on a TKI and will come off the study.
  - **If bcr-abl remains detectable (you have minimal residual disease), after the first year in the study, you will continue to Arm B and receive both TKI and pembrolizumab for another year. Then, your bcr-abl levels will be checked.**
    - If there is no evidence of bcr-abl, you will stop taking your TKI and you will be monitored for an additional 2 years. Or, if you still have detectable bcr-abl in your blood, you will come off the study.

- After you finish your study treatment, your doctor will continue to follow your condition at least every 6 months. You will continue to see your doctor for up to 6 years.
WHO will take part in this study?

- Participants must be at least 18 years old, and must not have had a previous allogeneic transplant, or received prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent.
- Please note, you can decide to stop taking part in this study at any time, even after you have enrolled.

WHAT are the costs of taking part in this study?

- You/your insurance provider will not have to pay for pembrolizumab or scheduled MRD assessments while you take part in this study.
- You and/or your insurance plan will need to pay for some or all of the costs of medical care you get as part of this study, just as you would if you were getting the usual care for your cancer. Check with your insurance company to find out what they will pay for.

IF you would like to know more

- About the EA9171/BLAST MRD CML 1 study, talk with your doctor, or:
  - Visit www.ecog-acrin.org and search EA9171, then select the link to EA9171.
    » For information about medical facilities where the study is available, scroll down this page to Locations and Contacts
  - Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237)
- About clinical trials:
  - General cancer information: visit the NCI website at www.cancer.gov
  - Insurance coverage: visit www.cancer.gov/clinicaltrials/learningabout/payingfor
- About ECOG-ACRIN:
  - Visit www.ecog-acrin.org