EA4231 Study

Do you have an aggressive B-cell lymphoma that has either come back or persisted after initial therapy?

If so, you may be eligible to participate in this study of a potential new treatment approach.

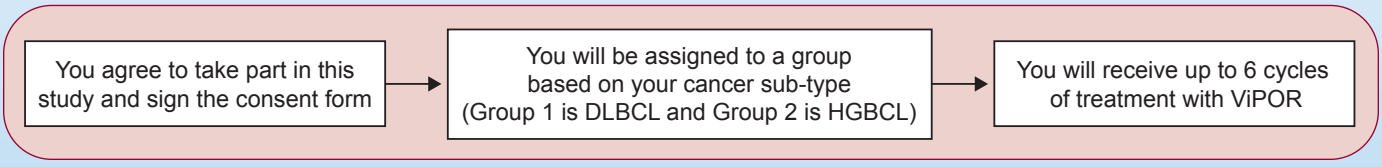
Testing the Effectiveness of a Combination Targeted Therapy (ViPOR) for Patients with Relapsed and/or Refractory Aggressive B-cell Lymphoma

WHY consider participating in this study?

- Research studies are an important way to test the effectiveness of new therapies and approaches to treating cancer.
- The usual approach (i.e., the standard treatment most patients receive) for aggressive B-cell lymphoma that has come back after initial treatment (relapsed) or is resistant to treatment (became refractory), is treatment (or a combination of treatments) using chemotherapy, radiation, and/or immunotherapy. This may include one or more of the targeted therapies being used in EA4231.
- There are different types of aggressive B-cell lymphoma, and this study is specifically for patients with **diffuse-large B-cell lymphoma (DLBCL)** or **high-grade B-cell lymphoma (HGBCL)**. The purpose is to see if treatment with ViPOR (venetoclax, ibrutinib, prednisone, obinutuzumab, and Revlimid [also known as lenalidomide]) might lead to the disappearance of all cancer sites in these patients.
  - Note that the ViPOR drugs are Food and Drug Administration (FDA)-approved for use in other B-cell lymphomas, but not for the treatment of DLBCL or HGBCL.

WHAT does this study involve?

- If you are eligible for this study and choose to participate:
  - You will be assigned to a group based on the type of aggressive B-cell lymphoma you have, but both groups will receive the same treatment, tests, and follow-up:
    - » Approximately 80 participants with DLBCL will be assigned to Group 1
    - » Approximately 40 participants with HGBCL will be assigned to Group 2
  - You will receive up to 6 cycles of treatment with ViPOR (1 cycle = 21 days).
    - » During each cycle:
      - Venetoclax will be taken by mouth (orally) once per day on days 2–14.
      - Ibrutinib and Revlimid will be taken orally once per day on days 1–14.
      - Prednisone will be taken orally once per day on days 1–7.
      - Obinutuzumab will be administered on days 1 and 2 of each cycle by vein (intravenously) in your arm.



- After you finish your study treatment, your doctor/study team will watch you for any side effects from the treatment and for the return of your cancer. They will check you every 6 months for the first 2 years after treatment. After that, they will check you once a year for the third, fourth, and fifth year. This means that you will keep seeing your doctor for at least 5 years after treatment.

WHO will take part in this study?

- Approximately 120 people diagnosed with DLBCL or HGBCL that has relapsed or become resistant to treatment will take part in EA4231.
  - You must not have received certain prior chemotherapy or immunotherapy treatments, including previous treatment with more than one of the study drugs (not including prior prednisone or obinutuzumab).
- You can decide to stop taking part in EA4231 at any time, for any reason, even after you have enrolled.

WHAT are the costs of taking part in this study?

- Just as if you were receiving the usual care for your cancer, you and/or your insurance plan will need to pay for some or all of the costs of medical care you will receive as part of this study. This includes the costs of:
  - Tests, exams, procedures, and medications that you get during the study to monitor your safety, and prevent and treat side effects, if any.
  - Preparing the study drugs (ViPOR) and giving them to you.
- You and/or your insurance plan will **not** have to pay for:
  - Tests, exams, and procedures done for research purposes only or that are covered by the study. These include:
    - » Biopsies
    - » Blood draw(s) for research purposes
  - The costs of the study drugs (venetoclax, ibrutinib, obinutuzumab, and Revlimid).
- Check with your insurance provider to find out what they will pay for.
- Taking part in EA4231 may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer.
- You will not be paid for taking part in this study.

IF you would like more information:

- About the EA4231 study, talk with your doctor, or:
  - Visit www.ecog-acrin.org and search EA4231, then select the link to the EA4231 page.
    - » If you are seeking information about the locations where this study is available, scroll down the page to Locations and Contacts and click the + sign.
  - 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/paying for cancer treatment: www.cancer.gov/clinicaltrials/learningabout/payingfor
- About ECOG-ACRIN:
  - Visit www.ecog-acrin.org
  - For a list of patient resources and links to patient advocacy groups, visit www.ecog-acrin.org/patients/resources

NCI National Clinical Trials Network

ECOG-ACRIN cancer research group