BAF_FRontier-1

A Phase 1 Clinical Research Study on B-Cell Activating Factor Receptor (BAFF-R) T-Cell Engager Bispecific Antibody, an Antibody That Links Cancer Cells to Immune Cells to Help the Body Eliminate the Cancer, for People With Previously Treated B-Cell Cancers

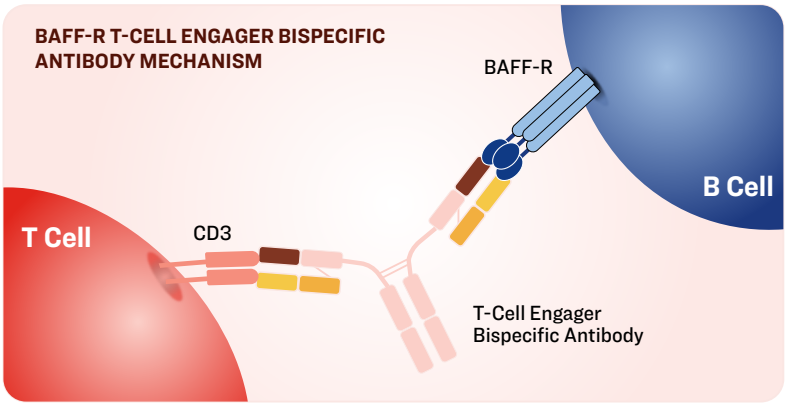
Actively enrolling

What is the Purpose of this Study?

To learn if a new antibody can help the immune system treat B-cell cancers.

What is BAFF-R?

- BAFF-R stands for B-cell activating factor receptor[1]
- It helps B cells, a type of white blood cell that fights infections, to grow and survive[1]
- BAFF-R is found on most B cells. In B-cell cancer, there may be more BAFF-R than usual, which helps the cancer cells to stay alive and grow[2,3]



What are T Cells and CD3?

T cells are a type of white blood cell that helps find foreign proteins like viruses, bacteria, and cancer cells that enter your body, with the help of CD3 proteins found on T cells. CD3 acts like a switch that turns T cells on when it detects something harmful. Once CD3 finds such foreign proteins, specific T cells called killer T cells can be activated to destroy, in this case, cancer cells.[4]

What is the BAFF-R T-Cell Engager Bispecific Antibody?

- The BAFF-R T-cell engager bispecific antibody is a lab-made antibody that helps the immune system fight cancer by acting as a bridge between killer T cells and cancer cells. It attaches to BAFF-R on cancer cells and CD3 on T cells, bringing them together and turning on the T cell to kill the cancer[4,5]
- Many treatments for B cell cancers target CD20 or CD19 proteins found on B cells. Over time, these treatments may stop working because the cancerous B cells lose CD19 or CD20. The BAFF-R T-cell engager bispecific antibody can now attach to BAFF-R on the cancer cells and bring in killer T cells to destroy them[5]

What is the Main Goal of the Study?

To learn about the safety, side effects, and preliminary effectiveness of BAFF-R T-cell engager bispecific antibody.

Can I Change My Mind About Taking Part in the Study?

Taking part in the study is your choice. If you decide to discontinue, you may leave the study at any time for any reason.

Who can Participate in the Study?

This study is for patients:

- Who are 18 years or older
- Who has a type of B-cell cancer that has returned after treatment (relapsed) or did not respond to atleast two prior treatments (refractory)
- Eligible cancers include:
  - Diffuse large B-cell lymphoma (DLBCL)
  - Follicular lymphoma (FL) - Grades 1 to 3a
- Who have already received treatment for cancer
- Who are able to follow inpatient/outpatient treatment, laboratory monitoring, and clinic visits during trial participation
- Who have adequate organ function

What is the Plan for the Study?

- This is an open-label study, meaning both the doctors and patients will know what treatment is being given
- All patients will receive BAFF-R T-cell engager bispecific antibody. No placebo (meaning, a treatment that looks like real treatment, but does not have any therapeutic effect) will be given in this study
- BAFF-R T-cell engager bispecific antibody is a medication that may be given either through a vein (intravenous infusion) or injected just under the skin (subcutaneous)

What are the Possible Benefits and Risks of Taking Part in the Study?

The benefits of taking part in the study are:

- Getting actively involved in medical research
- Helping others by advancing medical research

You do not need to have health insurance to take part. You may be refunded for travel costs related to study participation.

If you choose to take part, you will receive the following at no cost:

- All study-related medicine
- All study-related care and check-ins
- Access to specialized doctors and researchers

The main known risks that you should be aware of are:

- Cytokine Release Syndrome (CRS): This is a reaction that can happen when your immune system becomes too active and releases too many chemical signals (called cytokines). It may cause symptoms like fever, low blood pressure, and trouble breathing. Not all cases of CRS are severe, your medical team will monitor you closely for this potential risk
- Treatment Response: Your cancer may or may not respond to the study drug. This means the treatment might work well for some patients, but not for others

Abbreviations: BAFF-R=B-cell activating factor receptor; CD=cluster of differentiation; CRS=cytokine release syndrome.

References: 1. Rodig SJ, et al. *Hum Pathol*. 2005;36(10):1113-1119. 2. Dong Z, et al. *Blood Adv*. 2023;7(6):918-932. 3. Qin H, et al. *Sci Transl Med*. 2019;11(511):eaaw9414. 4. Cech P, et al. *Cancers*. 2024; 16(8):1580. 5. Yang W, et al. Abstract presented at: American Society of Hematology; December 7-10, 2024; San Diego, CA. Abstract 2785.

For more information, please visit the study website:

https://clinicaltrials.gov/study/NCT07101328

Lilly Trials Support:
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The use of the investigational medicine is experimental.
Not all risks are known. There is no guarantee that a participant's cancer will improve when taking part in this study.

There may be multiple sites in this clinical trial. If you have further questions or interest in this clinical trial, please contact -
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