MEDICATION GUIDE
COLUMVI™ (ko-loom-vee)
(glofitamab-gxbm)
injection, for intravenous infusion

What is the most important information I should know about COLUMVI?

COLUMVI can cause Cytokine Release Syndrome (CRS), a serious side effect that is common during treatment with COLUMVI, and can also be serious and lead to death.

- **Call your healthcare provider or get emergency medical help right away if you develop any signs or symptoms of CRS, including:**
  - fever of 100.4°F (38°C) or higher
  - chills or shaking
  - fast or irregular heartbeat
  - dizziness or light-headedness
  - trouble breathing
  - shortness of breath
- **Due to the risk of CRS, you will receive COLUMVI on a "step-up dosing schedule".**
  - A single dose of a medicine called obinutuzumab will be given to you on the first day of your first treatment cycle (Day 1 of Cycle 1).
  - You will start the COLUMVI step-up dosing schedule a week after the obinutuzumab dose. The step-up dosing schedule is when you receive smaller "step-up" doses of COLUMVI on Day 8 and Day 15 of Cycle 1. This is to help reduce your risk of CRS. You should be hospitalized during your infusion and for 24 hours after receiving the first step-up dose on Day 8. You should be hospitalized during your infusion and for 24 hours after receiving the second step-up dose on Day 15 if you experienced CRS during the first step-up dose.
  - You will receive your first full dose of COLUMVI a week after the second step-up dose (this will be Day 1 of Cycle 2).
  - If your dose of COLUMVI is delayed for any reason, you may need to repeat the "step-up dosing schedule".
  - If you had more than mild CRS with your previous dose of COLUMVI, you should be hospitalized during and for 24 hours after receiving your next dose of COLUMVI.
  - Before each dose of COLUMVI, you will receive medicines to help reduce your risk of CRS and infusion-related reactions.
  - See **"How will I receive COLUMVI?"** for more information about how you will receive COLUMVI.
- Your healthcare provider will monitor you for CRS during treatment with COLUMVI and may treat you in a hospital if you develop signs and symptoms of CRS. Your healthcare provider may temporarily stop or completely stop your treatment with COLUMVI if you have severe side effects.
- **Carry the COLUMVI Patient Wallet Card with you at all times and show it to all of your healthcare providers.** The COLUMVI Patient Wallet Card lists the signs and symptoms of CRS you should get emergency medical help for right away.

See **"What are the possible side effects of COLUMVI?**" for more information about side effects.

What is COLUMVI?

COLUMVI is a prescription medicine used to treat adults with certain types of diffuse large B-cell lymphoma (DLBCL) or large B-cell lymphoma (LBCL) that has come back (relapsed) or that did not respond to previous treatment (refractory), and who have received 2 or more prior treatments for their cancer.

It is not known if COLUMVI is safe and effective in children.

Before receiving COLUMVI, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- have kidney problems
- are pregnant or plan to become pregnant. COLUMVI may harm your unborn baby.
  Females who are able to become pregnant:
  - Your healthcare provider should do a pregnancy test before you start treatment with COLUMVI.
  - You should use effective birth control (contraception) during treatment and for 1 month after your last dose of COLUMVI. Talk to your healthcare provider about what birth control method is right for you during this time.
  - Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with COLUMVI.
- are breastfeeding or plan to breastfeed. It is not known if COLUMVI passes into your breastmilk. Do not breastfeed during treatment and for 1 month after your last dose of COLUMVI**.**

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive COLUMVI?

- COLUMVI will be given to you by your healthcare provider by infusion through a needle placed in your vein (intravenous infusion).
- Your COLUMVI treatment schedule is divided into cycles that are 21 days (3 weeks) long.

- On Day 1 of Cycle 1, your healthcare provider will give you a single dose of a medicine called obinutuzumab by intravenous infusion. You will then receive COLUMVI on Day 8 and Day 15 of Cycle 1. Starting with Cycle 2, you will receive COLUMVI 1 time every three weeks.

Your healthcare provider will decide how many treatment cycles you will receive of COLUMVI. See **"What is the most important information I should know about COLUMVI?"** for more information about how you will receive COLUMVI.

What should I avoid while receiving COLUMVI?

Do not drive, operate heavy machinery, or do other dangerous activities if you develop dizziness, confusion, shaking (tremors), sleepiness, or any other symptoms that impair consciousness until your signs and symptoms go away. These may be signs and symptoms of neurologic problems.

See "**What are the possible side effects of COLUMVI?"** for more information about signs and symptoms of neurologic problems.

What are the possible side effects of COLUMVI?

COLUMVI may cause serious side effects, including:

- **Cytokine Release Syndrome**. See **"What is the most important information I should know about COLUMVI?"**
- **Neurologic problems.** COLUMVI can cause serious neurologic problems that may lead to death. Your healthcare provider will monitor you for neurologic problems during treatment with COLUMVI. Your healthcare provider may also refer you to a healthcare provider who specializes in neurologic problems. Tell your healthcare provider right away if you develop any signs or symptoms of neurologic problems, including:
  - headache
  - confusion and disorientation
  - difficulty paying attention or understanding things
  - trouble speaking
  - sleepiness
  - memory problems
  - numbness, tingling, or weakness of the hands or feet
  - dizziness
  - shaking (tremors)
- **Serious infections.** COLUMVI can cause serious infections that may lead to death. Your healthcare provider will monitor you for signs and symptoms of infection and treat you as needed. Tell your healthcare provider right away if you develop any signs of infection, including: fever, chills, weakness, cough, shortness of breath, or sore throat.
- **Growth in your tumor or worsening of tumor related problems (tumor flare).** Tell your healthcare provider if you get any of these signs or symptoms of tumor flare:
  - tender or swollen lymph nodes
  - pain or swelling at the site of the tumor
  - chest pain
  - cough
  - trouble breathing

Your healthcare provider may temporarily stop or completely stop treatment with COLUMVI if you develop certain side effects.

The most common side effects of COLUMVI include: CRS, muscle and bone pain, rash, and tiredness.

The most common severe abnormal lab test results with COLUMVI include: decreased white blood cells, decreased phosphate (an electrolyte), increased uric acid levels, and decreased fibrinogen (a protein that helps with blood clotting).

These are not all the possible side effects of COLUMVI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of COLUMVI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your healthcare provider or pharmacist for information about COLUMVI that is written for health professionals.

What are the ingredients in COLUMVI?

Active ingredient: glofitamab-gxbm

Inactive ingredients: histidine, histidine hydrochloride monohydrate, methionine, polysorbate 20, sucrose, and Water for injection.

Manufactured by: **Genentech, Inc.**, A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990
U.S. License No.: 1048
For more information, go to www.COLUMVI.com or call 1-877-436-3683.

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