NEWS RELEASE

Media Contact: Emma Nash (650) 467-6800
Advocacy Contact: Cem Mangir (202) 251-4037
Investor Contacts: Loren Kalm (650) 225-3217
Karl Mahler 011 41 61 687 8503

[Ad hoc announcement pursuant to Art. 53 LR]

PHASE III STUDY SHOWS GENENTECH’S POLIVY PLUS R-CHP IS THE FIRST REGIMEN IN 20 YEARS TO SIGNIFICANTLY IMPROVE OUTCOMES IN PREVIOUSLY UNTREATED AGGRESSIVE FORM OF LYMPHOMA COMPARED TO STANDARD OF CARE

– Pivotal Phase III POLARIX trial comparing Polivy in combination with chemotherapy regimen R-CHP versus the standard of care R-CHOP in treatment of first-line diffuse large B-cell lymphoma (DLBCL) met its primary endpoint of investigator assessed progression-free survival –

– Prolonging survival without disease advancement could be transformative for newly diagnosed DLBCL patients, as currently 40% of patients relapse after disease progression –

– Data will be submitted to health authorities globally as soon as possible and presented at an upcoming medical meeting –

SOUTH SAN FRANCISCO, Calif. – August 8, 2021 – Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), today announced that the pivotal Phase III POLARIX trial investigating Polivy® (polatuzumab vedotin) in combination with Rituxan® (rituximab) plus cyclophosphamide, doxorubicin and prednisone (R-CHP) versus Rituxan plus cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP) met its primary endpoint by demonstrating significantly improved and clinically meaningful progression-free
survival in people with previously untreated diffuse large B-cell lymphoma (DLBCL). Safety outcomes were consistent with those seen in previous trials.

“Since 40% of people with DLBCL relapse after initial therapy, achieving meaningful treatment effects in the front-line setting has the potential to be transformative,” said Levi Garraway, M.D., Ph.D., chief medical officer and head of Global Product Development. “This Polivy regimen is the first in two decades to improve progression-free survival in DLBCL compared to the standard of care, and we look forward to sharing these results with health authorities to bring this important potential new treatment option to patients as soon as possible.”

Today’s POLARIX results will be presented at an upcoming medical meeting and submitted to health authorities as part of Genentech’s commitment to transforming the treatment of DLBCL by providing options tailored to patient and healthcare professional needs. Genentech would like to thank all investigators, academic partners and people with DLBCL who participated in the study.

Currently, Polivy is used as an off-the-shelf, fixed-duration treatment option in the relapsed or refractory (R/R) DLBCL setting, and is approved in combination with bendamustine and Rituxan for the treatment of R/R DLBCL in more than 60 countries worldwide, including in the EU and in the U.S. Genentech continues to explore areas of unmet need where Polivy has the potential to deliver benefit, with ongoing studies investigating combinations of Polivy with the CD20xCD3 T cell-engaging bispecific antibodies mosunetuzumab and glofitamab, with Venclexta® (venetoclax), which is being developed by AbbVie and Genentech, and with Rituxan in combination with gemcitabine and oxaliplatin in the Phase III POLARGO study.
About the POLARIX study

POLARIX [NCT03274492] is an international Phase III, randomized, double-blind, placebo-controlled study evaluating the efficacy, safety and pharmacokinetics of Polivy® (polatuzumab vedotin) plus Rituxan® (rituximab), cyclophosphamide, doxorubicin and prednisone (R-CHP) versus Rituxan, cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP) in people with previously untreated diffuse large B-cell lymphoma (DLBCL). Eight hundred and seventy-nine patients were randomized 1:1 to receive either Polivy plus R-CHP plus a vincristine placebo for six cycles, followed by Rituxan for two cycles; or R-CHOP plus a Polivy placebo for six cycles, followed by two cycles of Rituxan. The primary outcome measure is progression-free survival as assessed by the investigator using the Lugano Response Criteria for malignant lymphoma. POLARIX is being conducted in collaboration with The Lymphoma Study Association (LYSA) and The Lymphoma Academic Research Organisation (LYSARC).

About Polivy® (polatuzumab vedotin-piiq)

Polivy is a first-in-class anti-CD79b antibody-drug conjugate (ADC). The CD79b protein is expressed specifically in the majority of B cells, an immune cell impacted in some types of non-Hodgkin’s lymphoma (NHL), making it a promising target for the development of new therapies. Polivy binds to CD79b and destroys these B cells through the delivery of an anti-cancer agent, which is thought to minimize the effects on normal cells. Polivy is being developed by Genentech using Seagen ADC technology and is currently being investigated for the treatment of several types of NHL.

About DLBCL

DLBCL is the most common form of non-Hodgkin’s lymphoma (NHL), accounting for about one in three cases of NHL. DLBCL is an aggressive (fast-growing) type of NHL. While it is generally responsive to treatment in the frontline, as many as 40% of patients will relapse or
have refractory disease, at which time salvage therapy options are limited and survival is short. Approximately 150,000 people worldwide are estimated to be diagnosed with DLBCL each year.

**Polivy U.S. Indication**

Polivy is a prescription medicine used with other medicines, bendamustine and a rituximab product, to treat diffuse large B-cell lymphoma in adults who have progressed after at least two prior therapies.

The accelerated approval of Polivy is based on a type of response rate. There are ongoing studies to confirm the clinical benefit of Polivy.

**Important Safety Information**

**Possible serious side effects**

Everyone reacts differently to Polivy therapy, so it’s important to know what the side effects are. *Some people who have been treated with Polivy have experienced serious to fatal side effects.* A patient’s doctor may stop or adjust a patient’s treatment if any serious side effects occur. *Patients must contact their healthcare team if there are any signs of these side effects.*

- **Nerve problems in arms and legs:** This may happen as early as after the first dose and may worsen with every dose. If a patient already has nerve pain, Polivy may make it worse. The patient’s doctor will monitor for signs and symptoms, such as changes in sense of touch, numbness or tingling in hands or feet, nerve pain, burning sensation, any muscle weakness, or changes to walking patterns.

- **Infusion-related reactions:** A patient may experience fever, chills, rash, breathing problems, low blood pressure, or hives within 24 hours of the infusion.

- **Infections:** Patients should contact their healthcare team, if they experience a fever of 100.4°F or higher, chills, cough, or pain during urination. Also, a patient’s doctor may
give medication before giving Polivy, which may prevent some infections, and monitor blood counts throughout treatment with Polivy. Treatment with Polivy can cause severe low blood cell counts

- **Rare and serious brain infections**: A patient’s doctor will monitor the patient closely for signs and symptoms of these types of infections. Patients should contact their doctor if they experience confusion, dizziness or loss of balance, trouble talking or walking, or vision changes

- **Tumor lysis syndrome**: Caused by the fast breakdown of cancer cells. Signs include nausea, vomiting, diarrhea, and lack of energy

- **Potential harm to liver**: Some signs include tiredness, weight loss, pain in the abdomen, dark urine, and yellowing of the skin or the white part of the eyes. Patients may be at higher risk if they already have liver problems or are taking other medication

**Side effects seen most often**

The most common side effects during treatment were

- Low blood cell counts (platelets, red blood cells, white blood cells)
- Nerve problems in arms and legs
- Tiredness or lack of energy
- Diarrhea
- Nausea
- Fever
- Decreased appetite
- Infections

**Polivy may not be for everyone. A patient should talk to their doctor if they are**
• **Pregnant or may be pregnant:** Data have shown that Polivy may harm an unborn baby

• **Planning to become pregnant:** Women should avoid getting pregnant while taking Polivy. Women should use effective contraception during treatment and for at least 3 months after their last Polivy treatment. Men taking Polivy should use effective contraception during treatment and for at least 5 months after their last Polivy treatment

• **Breastfeeding:** Women should not breastfeed while taking Polivy and for at least 2 months after the last dose

These may not be all the side effects. Patients should talk to their healthcare provider for more information about the benefits and risks of Polivy treatment.

**Report side effects to the FDA at (800) FDA-1088 or [http://www.fda.gov/medwatch](http://www.fda.gov/medwatch). Report side effects to Genentech at (888) 835-2555.**

Please visit [http://www.Polivy.com](http://www.Polivy.com) for the full Prescribing Information for additional Important Safety Information.

**About Genentech in Hematology**

For more than 20 years, Genentech has been developing medicines with the goal to redefine treatment in hematology. Today, we’re investing more than ever in our effort to bring innovative treatment options to people with diseases of the blood. For more information visit [http://www.gene.com/hematology](http://www.gene.com/hematology).

**About Genentech**
Founded more than 40 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious and life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, California. For additional information about the company, please visit http://www.gene.com.

###