Roche's Gazyvaro shorter 90-minute infusion time approved in Europe for people with previously treated or untreated follicular lymphoma

- **Short duration infusion of Gazyvaro® (obinutuzumab) is administered with a target infusion time of 90 minutes, compared to the current standard infusion time of approximately three to four hours**
- **Results from the phase IV GAZELLE study showed no new safety signals with the shorter infusion of Gazyvaro**
- **Shorter infusions could be more convenient for patients by reducing time in hospital and easing pressure on healthcare systems**[1]

Basel, 14 October 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced European Medicines Agency (EMA) approval of a new, shorter 90-minute Gazyvaro® (obinutuzumab) infusion time, administered in combination with chemotherapy in patients with previously treated or untreated advanced follicular lymphoma (FL). The approval is based on a positive opinion from the EMA's Committee for Medicinal Products for Human Use (CHMP). The regular rate of infusion can take approximately three to four hours, so administering over a shorter time period can result in time savings for patients and could also reduce pressure on healthcare systems. This is especially important given the ongoing challenges for healthcare systems around the world brought about by the COVID-19 pandemic.[1]

"Gazyvaro has improved outcomes for people with follicular lymphoma, and now has the additional benefit of a shorter infusion time," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Reducing the amount of time patients need to be in hospital has the potential to improve their treatment experience whilst also increasing efficiency for institutions and healthcare systems."

The approval is based on the phase IV GAZELLE study and other supportive studies investigating Gazyvaro in previously treated and untreated FL patients. The efficacy and safety of the GAZELLE study were consistent with that demonstrated by Gazyvaro administered at the regular rate of infusion. The trial showed that no patients experienced Grade 3 or higher infusion-related reactions during treatment cycle 2 with short duration infusion Gazyvaro, and no unexpected safety findings were found, supporting its use. Following this approval, Gazyvaro's label update is being implemented immediately and Roche is aiming to launch short duration infusion Gazyvaro for patients in the EU with previously treated and untreated advanced FL as soon as possible. Gazyvaro is already approved for the treatment of FL, and now shorter duration infusion Gazyvaro will offer another more convenient option to enhance FL patients' treatment experiences.

In the US, Europe and multiple other countries, Gazyva®/Gazyvaro is currently approved in combination with chlorambucil for patients with previously untreated chronic lymphocytic leukaemia (CLL). It is also approved in combination with bendamustine, followed by Gazyva/Gazyvaro maintenance for the treatment

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of FL patients who did not respond to a MabThera®/Rituxan® (rituximab)-containing regimen, or whose FL returned after such treatment and in combination with chemotherapy for previously untreated advanced FL.

About the GAZELLE study
GAZELLE [NCT03817853] is an open-label, international, multicentre, single arm, phase IV study investigating the safety and efficacy of the short duration infusion (SDI; target 90-minute infusion) of Gazyvaro® (obinutuzumab) administered in combination with chemotherapy in patients with previously untreated advanced follicular lymphoma (FL). Patients who did not experience Grade 3 or higher infusion-related reactions were eligible to receive short duration infusion Gazyvaro from cycle 2. The primary endpoint of the study was the proportion of patients who experience Grade 3 or higher infusion-related reactions associated with short duration infusion during cycle 2 (the first treatment cycle with short duration infusion).

About Gazyvaro® (obinutuzumab)
Gazyvaro is an engineered monoclonal antibody designed to attach to CD20, a protein expressed on B-cells, including malignant B-cells, but not on stem cells or plasma cells. Gazyvaro is designed to attack and destroy targeted B-cells both directly and together with the body's immune system. Gazyvaro is marketed as Gazyva® in the US.

In the US, Europe and multiple other countries, Gazyva/Gazyvaro is currently approved in combination with chlorambucil for patients with previously untreated chronic lymphocytic leukaemia (CLL). It is also approved in combination with bendamustine, followed by Gazyva/Gazyvaro maintenance for the treatment of FL patients who did not respond to a MabThera®/Rituxan® (rituximab)-containing regimen, or whose FL returned after such treatment and in combination with chemotherapy for previously untreated advanced FL.

Additional combination studies investigating Gazyvaro with other approved or investigational medicines, including cancer immunotherapies and small molecule inhibitors, are underway across a range of blood cancers.

About follicular lymphoma
Follicular lymphoma (FL) is the most common indolent (slow-growing) form of non-Hodgkin lymphoma (NHL), accounting for about one in five cases of NHL.[2] It is considered incurable and relapse is common. It is estimated that more than 100,000 people are diagnosed with FL each year worldwide, including over 30,000 people in Europe.[3]

About Roche in haematology
Roche has been developing medicines for people with malignant and non-malignant blood diseases for over

20 years; our experience and knowledge in this therapeutic area runs deep. Today, we are investing more than ever in our effort to bring innovative treatment options to patients across a wide range of haematologic diseases. Our approved medicines include MabThera®/Rituxan® (rituximab), Gazyva®/Gazyvaro® (obinutuzumab), Polivy® (polatuzumab vedotin), Venclexta®/Venclyxto® (venetoclax) in collaboration with AbbVie, and Hemlibra® (emicizumab). Our pipeline of investigational haematology medicines includes T-cell engaging bispecific antibodies, glofitamab and mosunetuzumab, targeting both CD20 and CD3, and cevostamab, targeting FcRH5 and CD3; Tecentriq® (atezolizumab), a monoclonal antibody designed to bind with PD-L1; and crovalimab, an anti-C5 antibody engineered to optimise complement inhibition. Our scientific expertise, combined with the breadth of our portfolio and pipeline, also provides a unique opportunity to develop combination regimens that aim to improve the lives of patients even further.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics, as well as growing capabilities in the area of data-driven medical insights, help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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