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FDA grants Roche's cancer immunotherapy Tecentriq (atezolizumab) accelerated approval for people with a specific type of advanced bladder cancer

- **First and only anti-PD-L1 cancer immunotherapy approved by the FDA**
- **First FDA-approved treatment for people with a specific type of bladder cancer in more than 30 years**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) granted accelerated approval to Tecentriq® (atezolizumab) for the treatment of people with locally advanced or metastatic urothelial carcinoma (mUC) who have disease progression during or following platinum-based chemotherapy, or whose disease has worsened within 12 months of receiving platinum-based chemotherapy before surgery (neoadjuvant) or after surgery (adjuvant). Urothelial carcinoma accounts for 90% of all bladder cancers and can also be found in the renal pelvis, ureter and urethra.

“Tecentriq is a new medicine that can work with the immune system to treat people with a type of bladder cancer that progressed after platinum-based chemotherapy,” said Sandra Horning, MD, Chief Medical Officer and Head of Global Product Development. “We thank the scientists, doctors, patients and their families who made it possible to bring Tecentriq to people with advanced urothelial carcinoma.”

The FDA's Accelerated Approval Program allows conditional approval of a medicine that fills an unmet medical need for a serious condition, based on early evidence suggesting clinical benefit. The indication for Tecentriq is approved under accelerated approval based on tumour response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Today's approval of Tecentriq is based on the phase II IMvigor 210 study.

Roche is also evaluating Tecentriq in a confirmatory phase III study (IMvigor 211), which compares Tecentriq to chemotherapy in people whose bladder cancer has progressed on at least one prior platinum-containing regimen.

About the IMvigor 210 study

IMvigor 210 is an open-label, multicenter, two-cohort Phase II study that evaluated the safety and efficacy of Tecentriq in people with locally advanced or mUC, regardless of PD-L1 expression. People in a cohort of the study whose disease had progressed during or following previous treatment with a platinum-based chemotherapy regimen, or who had disease progression within 12 months of treatment with a platinum-based neoadjuvant or adjuvant chemotherapy regimen (n=310) received a 1200-mg intravenous dose of Tecentriq on day one of 21-day cycles until unacceptable toxicity or either radiographic or clinical progression. The primary endpoint of the study was objective response rate (ORR) as assessed by an independent review facility (IRF) using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. Secondary endpoints included duration of response (DOR). A summary of the efficacy and safety data from the IMvigor 210 study that supports this accelerated approval is included below. The median follow-up time for this cohort was 14.4 months

	All patients	PD-L1 expression subgroups	
	n=310	PD-L1 expression of < 5% in ICs¹ (n=210)	PD-L1 expression of ≥ 5% in ICs¹ (n=100)
Number of IRF-assessed Confirmed responders	46	20	26
ORR (%) (95% CI)	14.8% (11.1, 19.3)	9.5% (5.9, 14.3)	26.0% (17.7, 35.7)
Complete response (CR) (%)	5.5%	2.4%	12.0%
Partial response (PR) (%)	9.4%	7.1%	14.0%
Median DOR, months (range)	Not reached (2.1+, 13.8+)	12.7 months (2.1+, 12.7)	Not reached (4.2, 13.8+)
¹ PD-L1 expression in tumour-infiltrating immune cells (ICs) + Denotes a censored value			

In a subset of people in the IMvigor 210 study with disease progression following neoadjuvant or adjuvant platinum-containing therapy (n=59), Tecentriq shrank tumors (ORR) in 22.0 percent (95 percent CI: 12.3, 34.7) of people.

The most common Grade 3-4 adverse reactions (≥ 2 percent) were: urinary tract infection (9 percent), anemia (8 percent), fatigue (6 percent), dehydration, intestinal obstruction (partial or complete blockage of the bowel), urinary obstruction, hematuria (blood in the urine; 3 percent), dyspnea (difficulty breathing; 4 percent), acute kidney injury, abdominal pain (pain in stomach area; 4 percent), venous thromboembolism (blood clots in the vein), sepsis (blood infection) and pneumonia (lung infection). Three people (0.9 percent) experienced either sepsis, pneumonitis (lung problems) or intestinal obstruction, which led to death. Tecentriq was discontinued for adverse reactions in 3.2 percent (10) of the 310 patients.

About metastatic urothelial cancer

Metastatic urothelial cancer (mUC) is associated with a poor prognosis and limited treatment options. It is a disease that has seen no major advances for more than 30 years. UC is the ninth most common cancer worldwide, with 430,000 new cases diagnosed in 2012, and it results in approximately 145,000 deaths globally each year. Men are three times more likely to suffer from UC, compared with women, and the disease is three times more common in developed countries than in less developed countries.

About Tecentriq® (Atezolizumab)

Tecentriq is a monoclonal antibody designed to bind with a protein called PD-L1. Tecentriq is designed to directly bind to PD-L1 expressed on tumour cells and tumour-infiltrating immune cells, blocking its interactions with both PD-1 and B7.1 receptors. By inhibiting PD-L1, atezolizumab may enable the activation of T cells. Tecentriq may also affect normal cells.

About personalised cancer immunotherapy

For more than 50 years, Roche has been developing medicines with the goal to redefine treatment in oncology. Today, we're investing more than ever in our effort to bring innovative treatment options that help a person's own immune system fight cancer.

The aim of personalised cancer immunotherapy (PCI) is to provide individual patients with treatment options that are tailored to their specific needs. Our PCI research and development programme comprises more than 20 investigational candidates, nine of which are in clinical trials. All studies include the prospective evaluation of biomarkers to determine which people may be appropriate candidates for our medicines.

In the case of atezolizumab, PCI begins with the PD-L1 (programmed death ligand-1) IHC assay based on the SP142 antibody developed by Roche Tissue Diagnostics. The goal of PD-L1 as a biomarker is to identify those people most likely to experience clinical benefit with atezolizumab as a single agent versus those who may benefit more from combination approaches; the purpose is to inform treatment strategies which will give the greatest number of patients a chance for transformative benefit. The ability to combine atezolizumab with multiple chemotherapies may provide new treatment options to people across a broad range of tumours regardless of their level of PD-L1 expression.

Personalised Cancer Immunotherapy is an essential component of how Roche delivers on the broader commitment to personalised healthcare.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

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. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine 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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 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

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