

## **Roche provides update on Tecentriq US indication for previously untreated metastatic bladder cancer**

Basel, 29 November 2022

Roche today announced that the company is voluntarily withdrawing the US indication of Tecentriq® (atezolizumab) for the treatment of adults with locally advanced or metastatic urothelial carcinoma (mUC, bladder cancer) who are not eligible for cisplatin-containing chemotherapy and whose tumours express PD-L1 (PD-L1-stained tumour-infiltrating immune cells covering  $\geq 5\%$  of the tumour area) or are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.

Roche made this decision following consultation with the US Food and Drug Administration (FDA), in accordance with the requirements of the US FDA's Accelerated Approval Program. The Phase III IMvigor130 trial was designed to evaluate Tecentriq plus platinum-based chemotherapy for the first-line treatment of people with previously untreated advanced bladder cancer. IMvigor130 was the designated postmarketing requirement (PMR) to convert the accelerated approval to regular approval, and did not meet the co-primary endpoint of overall survival for Tecentriq plus chemotherapy compared with chemotherapy alone. These data will be presented at an upcoming medical meeting.

“While we are disappointed with this withdrawal, we understand the need to uphold the principles of the US FDA’s Accelerated Approval Program, which brings innovative medicines to patients sooner. We remain confident in the benefit Tecentriq offers to people diagnosed with some of the most difficult-to-treat forms of cancer,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “There is a considerable unmet need for effective and tolerable treatments for people living with advanced bladder cancer and so we regret that the IMvigor130 trial did not cross the statistical threshold for overall survival.”

This decision does not affect other approved indications for Tecentriq in the US.

Roche will work with the US FDA over the coming weeks to complete the withdrawal process and notify healthcare professionals in the US about this withdrawal. Patients in the US being treated with Tecentriq for previously untreated mUC should discuss their care with their healthcare provider.

### **About Roche**

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world’s largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and

develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavour to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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