Roche presents new data for TECENTRIQ® (atezolizumab) and updates from across its cancer immunotherapy development programme at ASCO 2017

- Data evaluated TECENTRIQ in novel combinations across a broad range of tumours including lung, kidney and melanoma
- Promising Phase II combination data with TECENTRIQ plus Avastin (bevacizumab) in advanced kidney cancer
- First treatment-beyond-progression data from a Phase III study of cancer immunotherapy in advanced lung cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new data for TECENTRIQ and updates from across its extensive cancer immunotherapy clinical development programme will be presented during the American Society of Clinical Oncology (ASCO) Annual Meeting on 2 June – 6 June in Chicago, Illinois, United States. Data from phase I, II and Phase III studies presented at ASCO 2017 suggest that TECENTRIQ has the potential to be used as a foundational combination partner with cancer immunotherapies, targeted medicines and various chemotherapies across a broad range of cancers.

Data from a study of TECENTRIQ plus Avastin in metastatic Renal Cell Carcinoma (mRCC) supports a scientific rationale for combining TECENTRIQ with Avastin including its potential to increase infiltration (trafficking) of T-cells into tumours and other immune-modulatory properties. New data will also be presented for TECENTRIQ as a monotherapy from the OAK trial, which represent the first treatment-beyond-progression data from a Phase III study of cancer immunotherapy in advanced lung cancer (NSCLC). Updated data will also be presented from the Phase Ib study of TECENTRIQ in combination with chemotherapy for people with advanced NSCLC. Two Phase Ib studies in melanoma combining TECENTRIQ plus Cotelic® (cobimetinib) and TECENTRIQ plus Cotelic plus Zelboraf® (vemurafenib) showed that the addition of Zelboraf and/or Cotelic may alter the tumour micro environment, enhancing the anti-tumour activity of TECENTRIQ.
“By applying our seminal research in immune tumour profiling within the framework of the Roche-devised cancer immunity cycle, we are accelerating and expanding the transformative benefits with TECENTRIQ to a greater number of people living with cancer,” said Sandra Horning, MD, Chief Medical Officer and Head of Global Product Development. “Our cancer immunotherapy development programme takes a comprehensive approach in pursuing the goal of restoring cancer immunity to improve outcomes for patients, and at ASCO 2017 we are presenting data from a range of medicines and combinations that we believe have this potential.”

Kidney cancer (Renal Cell Carcinoma RCC)

IMmotion150 is a global, multicentre Phase II study that was designed to evaluate the efficacy and safety of TECENTRIQ plus Avastin, TECENTRIQ alone or sunitinib alone in 305 patients with previously untreated, locally advanced or mRCC. After progression on the sunitinib or TECENTRIQ arms of the study, 77% and 75% of patients crossed over to TECENTRIQ plus Avastin treatment, respectively.

Clinical activity of TECENTRIQ plus Avastin was seen in crossover patients regardless of first line TECENTRIQ or sunitinib therapy or response to first line therapy, further supporting this combination as a potential treatment option. Specifically, TECENTRIQ plus Avastin resulted in an Overall Response Rate (ORR) of 26% in all-crossover patients (28% in crossover post-sunitinib; 24% in crossover post-TECENTRIQ patients) with a median Progression Free Survival (PFS) of 8.8 months in all-crossover patients. There were no new safety signals observed in the crossover treated patients.

A Phase III study, IMmotion151, in a similar population is expected to provide initial results in early 2018.

IMmotion150: A Phase II trial in untreated metastatic renal cell carcinoma (mRCC) patients (pts) of atezolizumab (atezo) and bevacizumab (bev) vs and following atezo or sunitinib (sun). Oral abstract 4505 Monday 5 June, 08:00 – 11:00 CDT

Lung cancer

In the Phase III OAK trial, which studied the impact of TECENTRIQ treatment beyond radiologic disease progression (PD), showed that a continuation of TECENTRIQ treatment after PD resulted in promising clinical benefit. The study design allowed patients randomised to TECENTRIQ to continue treatment beyond PD, as assessed by Response Evaluation Criteria in Solid Tumours (RECIST) v1.1, if the patient was considered to be deriving clinical benefit from treatment. TECENTRIQ could be continued until there was loss of clinical benefit according to the investigator’s clinical judgement.
Patients in the TECENTRIQ arm who continued TECENTRIQ therapy beyond PD had a prolonged clinical benefit, 12.7 months Overall Survival (OS) (95% CI 9.3–14.9) compared with 8.8 months OS (6.0 - 12.1) for those treated with other anti-cancer treatments post PD. Tumour target lesion responses and stabilisation post-PD were seen across all subgroups of programmed death-ligand 1 (PD-L1) expression. These data support the treatment strategy of continuing TECENTRIQ beyond PD until loss of clinical benefit in patients, regardless of the level of PD-L1 expression.

Impact of atezolizumab (atezo) treatment beyond disease progression (TBP) in advanced NSCLC: Results from the randomised phase III OAK study. Oral abstract TPS5090
Tuesday 6 June, 09:45 – 12:45 CDT

The updated efficacy and safety data for Arms C–E of our phase Ib GP28328 study are encouraging for TECENTRIQ in combination with various chemotherapies. The primary endpoint of the study was safety and TECENTRIQ was well tolerated when combined with various chemotherapies.

<table>
<thead>
<tr>
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<th>Arm C (carboplatin /paclitaxel) (n=25)</th>
<th>Arm D (carboplatin/pemetrexed) (n=25)</th>
<th>Arm E (carboplatin /nab-paclitaxel) (n=26)</th>
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<tbody>
<tr>
<td>Confirmed response rate</td>
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<tr>
<td>ORR, n (%)</td>
<td>9 (36)</td>
<td>17 (68)</td>
<td>12 (46)</td>
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<tr>
<td>CR, n (%)</td>
<td>0</td>
<td>1 (4)</td>
<td>4 (15)</td>
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<tr>
<td>PR, n (%)</td>
<td>9 (36)</td>
<td>16 (64)</td>
<td>8 (31)</td>
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<td>SD, n (%)</td>
<td>12 (48)</td>
<td>4 (16)</td>
<td>9 (35)</td>
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<td>PD, n (%)</td>
<td>3 (12)</td>
<td>3 (12)</td>
<td>3 (12)</td>
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<tr>
<td>Median PFS (95% CI), months</td>
<td>7.1 (4.2–8.3)</td>
<td>8.4 (4.7–11.0)</td>
<td>5.7 (4.4–14.8)</td>
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<tr>
<td>Median OS (95% CI), months</td>
<td>12.9 (8.8–21.3)</td>
<td>18.9 (9.9–27.4)</td>
<td>17.0 (12.7–NE)</td>
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</table>

The confirmed ORRs and mature OS data provide further evidence for a synergy between the anti-tumour activity of TECENTRIQ and chemotherapy.

Abstract 9092, Poster Board: #418. Lung Cancer—Non-Small Cell Metastatic
Saturday 6 June, 08:00 – 11:30 CDT
Melanoma

Updated study results from two Phase Ib studies combining TECENTRIQ plus Cotellic (cobimetinib) and, TECENTRIQ plus Cotellic plus Zelboraf (vemurafenib) showed improved ORR and PFS after a longer follow up. Both combination studies demonstrated a manageable safety profile.

Based on the results of the Phase 1b studies both combinations are now in Phase III clinical trials. The TECENTRIQ plus Cotellic plus Zelboraf combination will be investigated in people with untreated BRAFV600-mutant unresectable metastatic melanoma while the TECENTRIQ plus Cotellic combination will be studied in people with untreated, unresectable metastatic BRAF wild-type melanoma.

Atezolizumab (A) + cobimetinib (C) + vemurafenib (V) in BRAFV600-mutant metastatic melanoma (mel): Updated safety and clinical activity. Abstract 3063
Monday 5 June, 08:00 – 11:30 CDT

Atezolizumab (A) + cobimetinib (C) in metastatic melanoma (mel): Updated safety and clinical activity. Abstract 3057
Monday 5 June, 8:00 - 11:30CDT

Pipeline

Data from two studies will be presented that demonstrate the potential of TECENTRIQ in combination with novel cancer immunotherapies. These studies include a Phase I dose escalation study evaluating the T-cell bispecific (CEA-TCB) antibody as a single agent or in combination with TECENTRIQ in patients with metastatic colorectal cancer and a Phase Ib dose-escalation study evaluating the combined inhibition of TECENTRIQ plus IDO1 (GDC-0919) in patients with locally advanced or metastatic solid tumours and Monotherapy data will also be presented from a Phase Ia study of TECENTRIQ in advanced/recurrent endometrial cancer (rEC), a patient population for whom the prognosis remains poor. The study is evaluating clinical activity and safety. Results show that TECENTRIQ has a favourable safety profile in rEC, with durable clinical benefit seen in some patients. Clinical benefit appeared to increase with higher PD-L1 expression, suggesting a link between PD-L1 status and response.
To learn more about Roche’s personalised cancer immunotherapy programme and Roche’s contribution to ASCO 2017, please follow Roche on Twitter via @Roche. You can keep up to date with ASCO 2017 Annual Meeting news and updates by using the hashtag #ASCO17.

**Overview of Roche cancer immunotherapy data being presented at ASCO 2017**

<table>
<thead>
<tr>
<th>Therapy area/track</th>
<th>Abstract title</th>
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<tr>
<td>Lung cancer</td>
<td>Impact of atezolizumab (atezo) treatment beyond disease progression (TBP) in advanced NSCLC: Results from the randomized phase III OAK study.</td>
<td>Oral abstract 9001 Tuesday 6 June 09:45 – 12:45 CDT</td>
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<td></td>
<td>Atezolizumab (atezo) plus platinum-based chemotherapy (chemo) in non-small cell lung cancer (NSCLC): Update from a phase Ib study.</td>
<td><strong>Abstract 9092</strong> Poster #418 Lung Cancer—Non-Small Cell Metastatic Saturday 3 June 08:00 – 11:30 CDT</td>
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<tr>
<td>Genitourinary cancers</td>
<td>IMmotion150: A phase II trial in untreated metastatic renal cell carcinoma (mRCC) patients (pts) of atezolizumab (atezo) and bevacizumab (bev) vs and following atezo or sunitinib (sun).</td>
<td>Oral abstract 4505 Monday 5 June 08:00 – 11:00 CDT</td>
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<td>Atezolizumab (atezo) in platinum-treated locally advanced or metastatic urothelial carcinoma (mUC): Safety analysis from an expanded access study.</td>
<td><strong>Abstract 4532/Poster #210</strong> Sunday 4 June 08:00 – 11:30 CDT</td>
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<tr>
<td>Cancer Type</td>
<td>Treatment Description</td>
<td>Abstract/Clinical Event Details</td>
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| **Melanoma**          | Atezolizumab (A) + cobimetinib (C) + vemurafenib (V) in BRAFV600-mutant metastatic melanoma (mel): Updated safety and clinical activity. | Abstract 3063/Poster #158  
Monday 5 June  
08:00 – 11:30 CDT                                                   |
|                       | Atezolizumab (A) + cobimetinib (C) in metastatic melanoma (mel): Updated safety and clinical activity. | Abstract 3057/Poster #152  
Monday 5 June  
08:00 – 11:30 CDT                                                   |
| **Colorectal cancer** | Phase Ia and Ib studies of the novel carcinoembryonic antigen (CEA) T-cell bispecific (CEA CD3 TCB) antibody as a single agent and in combination with atezolizumab: Preliminary efficacy and safety in patients with metastatic colorectal cancer (mCRC). | Oral abstract 3002  
Monday 5 June  
13:15 – 16:15 CDT                                                   |
| **Gynaecological cancers** | Clinical activity, safety and biomarker results from a phase Ia study of atezolizumab (atezo) in advanced/recurrent endometrial cancer (rEC). | Abstract 5585/Poster #407  
Saturday 3 June  
13:15 – 16:15 CDT                                                   |
| **Solid tumours**     | A phase Ib dose escalation study of combined inhibition of IDO1 (GDC-0919) and PD-L1 (atezolizumab) in patients (pts) with locally advanced or metastatic solid tumors. | Abstract 105/  
Sunday 4 June  
09:45 – 11:15 CDT                                                   |
|                       | Pharmacokinetics (PK) and pharmacodynamics (PD) of a novel carcinoembryonic antigen (CEA) T-cell bispecific antibody (CEA CD3 TCB) for the treatment of CEA-expressing solid tumors. | Abstract 2549/Poster #41  
Monday 5 June  
08:00 – 11:30 CDT                                                   |
| **Haematological tumours** | A phase I/II study of Atezolizumab in pediatric and young adult patients with refractory/relapsed solid tumours (Imatriz-Atezolizumab) | Abstract 10524/Poster #281  
Sunday 4 June  
08:00 – 11:30 CDTC                                                  |

**About Roche in 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 Roche cancer immunotherapy research and development programme comprises more than 20 investigational candidates, 11 of which are in clinical trials.
The aim of personalised cancer immunotherapy (PCI) is to provide patients and physicians with treatment options tailored to the specific immune biology associated with a person’s individual tumour. The purpose is to inform treatment strategies that provide the greatest number of people with a chance for transformative benefit. PCI encompasses the search for reliable biomarkers that correlates with clinical benefit either as a monotherapy or in combination, and across a broad range of cancers.

PCI is an essential component of how Roche delivers on the broader commitment to personalised healthcare. To learn more about the Roche approach to cancer immunotherapy please follow this link: http://www.roche.com/research_and_development/what_we_are_working_on/oncology/cancer-immunotherapy.htm

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 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.

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. 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 for improving patient access to medical innovations by working with all relevant stakeholders. 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 eight years in a row by the Dow Jones Sustainability Indices (DJSI).
The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 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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