Media Release

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Green light for advanced bladder cancer patients whose disease has progressed following chemotherapy

NICE says patients with 'forgotten cancer' that has progressed following chemotherapy can access Tecentriq® ▼ (atezolizumab) via the NHS

17th May 2018, Welwyn Garden City – Patients with advanced bladder cancer whose disease has progressed during or after treatment with platinum-containing chemotherapy, can now access the new immunotherapy Tecentriq (atezolizumab) via routine NHS funding in England and Wales.[1] Atezolizumab is recommended if it is stopped at two years of uninterrupted treatment or earlier, or if the disease progresses and Roche provides atezolizumab with the discount agreed in the patient access scheme. This provides clinicians and relapsed bladder cancer patients with an additional treatment option on the NHS.[1]

Allen Knight, Chairman of Action Bladder Cancer UK said, "Bladder cancer affects around 10,000 people each year in the UK and in its advanced form leads to poor outcomes; with only 15% of patients surviving more than five years. Bladder cancer has been seriously neglected for a long time and until recently there has been no significant new treatment options for patients in over 30 years. We welcome this news for patients with advanced bladder cancer."

The decision is based on the totality of evidence from the Phase II/III IMvigor210 and IMvigor211 studies, demonstrating the clinical efficacy and safety of atezolizumab compared to therapies currently provided to patients in this setting.[2,3,4] Atezolizumab side-effects were manageable. Around 1 in 5 patients experienced Grade 3 or 4 adverse events (AEs), but only 7% and 8% stopped treatment because of side-effects in IMvigor211 and IMvigor210 respectively.[2,4]

Simon Eayrs, Cancer Immunotherapy Franchise Lead at Roche Products UK, commented, "We welcome the news that more bladder cancer patients will now be able to access atezolizumab via the NHS. Atezolizumab has received three out of three positive NICE recommendations, one of these within the Cancer Drugs Fund. We at Roche believe this demonstrates the importance of working collaboratively and flexibly with NICE and NHS England. We're incredibly proud that patients are able to access the medicines we've worked so hard to develop."

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Editor's Notes

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About atezolizumab

Atezolizumab is a cancer immunotherapy. It disarms the cancer of its cloak, which allows the body's smartest medicine - the immune system - to detect and destroy it. Atezolizumab blocks PD-L1 – an important ligand found on the surface of cancer cells that camouflage them from detection and destruction by the immune system.[5]

This latest guidance is the Final Appriasal Determination (FAD) from NICE recommending the reimbursement of atezolizumab in the NHS for patients with advanced bladder cancer whose disease has progressed during or after treatment with platinum-containing chemotherapy.[1] Following Marketing Authorisation in late September 2017,[6] NICE also recommended the use of atezolizumab via the Cancer Drugs Fund (CDF) in November 2017 for previously untreated people with advanced bladder cancer who are not suitable for cisplatin-based chemotherapy.[7] Last month NICE also recommended atezolizumab as an option for treating locally advanced or metastatic non-small-cell lung cancer after chemotherapy.[8] Atezolizumab is currently being trialled in 9 other types of cancer.

About bladder cancer

About 1 in 10 bladder cancers have already spread by the time they are diagnosed.[9] Current methods to treat bladder cancer include chemotherapy, radiotherapy and surgical intervention.[10] Overall survival is around 50% after five years, but with advanced bladder only around 15% of patients are still alive five years later. Bladder cancer has a high rate of recurrence - up to 78% of patients with non-invasive bladder cancer may relapse within five years.[11] The National Cancer Patient Experience Survey showed that patients with urological cancers (including bladder cancer) report the worst experiences of their care.[12] Bladder cancer can affect mental health as well as sexual, urinary and bowel functions, impacting on a patient's quality of life.[13]

About IMvigor 210 and IMvigor 211

IMvigor210 is an open-label, multicentre, single-arm phase II study that evaluated the safety and efficacy of atezolizumab in people with locally advanced or metastatic urothelial carcinoma (mUC), regardless of PD-L1 expression.[2,3] People in the study were enrolled into one of two cohorts. Cohort 1 consisted of people who had not received a prior treatment (first-line) and who were ineligible for cisplatin-based chemotherapy.[14] Cohort 2 included people whose disease had progressed during or following previous treatment with platinum-containing chemotherapy (second-line).[3] IMvigor 210 cohort 2 study results showed patients who had previously been treated with platinum-containing chemotherapy (n=311) demonstrated a median overall survival of 7.9 months and indicated atezolizumab shrank tumours (objective response rate, ORR) in 15 percent of people.[3]

Atezolizumab side-effects were generally manageable in IMvigor210, cohort 2. Around 1 in 5 patients experienced Grade 3 or 4 AEs, but only 4% stopped treatment because of side-effects.[3]

IMvigor211 is a phase III study of atezolizumab in patients with mUC whose disease progressed during or after treatment with a platinum-based chemotherapy (second-line).[4] While the study did not meet its primary endpoint of overall survival (OS) compared to chemotherapy in a particular sub-group of patients with high levels of PDL-1, thought at the time of the study design to be a good predictor of atezolizumab benefit, the performance of atezolizumab was consistent with improving efficacy results seen in previously reported studies; it showed durable responses across all patient subgroups and clinical benefit versus chemotherapy in the intention to treat (ITT) population, with 12-month overall survival of 39% vs 32%, and a significantly longer duration of response (21.7 vs 7.4 months on chemotherapy).[4]

Patients receiving atezolizumab had fewer grade 3–4 treatment-related adverse events than did those receiving chemotherapy and fewer adverse events leading to treatment discontinuation.[4]

The chemotherapy medicine used in the trial (vinflunine) outperformed protocol assumptions and thus atezolizumab did not demonstrate a significant efficacy difference, but did demonstrate more favourable safety and much longer lasting responses than those produced by chemotherapy. The totality of data demonstrates a favourable benefit/risk profile for atezolizumab in mUC.

About Roche

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases and neuroscience. Roche is also the world leader in *in-vitro* diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life, safety and survival of patients. Thirty medicines developed by Roche are included in the WHO Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy. Roche in the UK employs over 2,000 people in pharmaceuticals and diagnostics. For more information: www.roche.co.uk

Adverse reaction reporting

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme: website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44(0)1707 367554.

References

[1] National Institute for Health and Care Excellence (2018) Final Appraisal Determination: Atezolizumab for treating metastatic urothelial cancer after platinum-based chemotherapy. May 2018

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[2] Bellmunt et al. IMvigor210: updated analyses of first-line (1L) atezolizumab (atezo) in cisplatin (cis)-ineligible locally advanced/metastatic urothelial carcinoma. Poster 782PD Presented at the European Society for Medical Oncology (ESMO 2016) – October 7-11, 2016, Copenhagen, Denmark.
[3] Hoffman-Censits JH, Grivas P, Van Der Heijden MS, et al. IMvigor 210, a phase II trial of atezolizumab (MPDL3280A) in platinum-treated locally advanced or metastatic urothelial carcinoma (mUC). J Clin Oncol 34, 2016 (suppl 2S; abstr 355).
[4] Powles T et al. IMvigor211: A Phase III Randomized Study Examining Atezolizumab vs. Chemotherapy for Platinum-Treated Advanced Urothelial Carcinoma. Presented at the 2nd special conference EACR AACR SIC. EAS 2017.
[5] Inman, B, et al. (2017). Atezolizumab: A PD-L1–Blocking Antibody for Bladder Cancer. *Clinical Cancer Research*. Vol 23. No. 8 DOI: 10.1158/1078-0432.CCR-16-1417
[6] European Marketing Authorisation Assessment report Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004143/human_med_002166.jsp&mid=WC0b01ac058001d124
[7] National Institute for Health and Care Excellence (2018) Final Appraisal Determination: Atezolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable. November 2017
[8] National Institute for Health and Care Excellence (2018) Final Appraisal Determination: Atezolizumab for treating locally advanced or metastatic non-small-cell lung cancer after chemotherapy
[9] National Cancer Institute. SEER Stat Fact Sheets: Bladder Cancer; 2017. Available at: http://seer.cancer.gov/statfacts/html/urinb.html. [Accessed May 2018]
[10] NHS Choices (2016). Bladder cancer – Treatment. [online] Available at: www.nhs.uk/conditions/cancer-of-the-bladder/pages/treatment.aspx [Accessed May 2018]
[11] Ramachandran, K., Gordian, E., Singal, R. (2011). 5-Azacytidine Reverses Drug Resistance in Bladder Cancer Cells. *Anticancer Research*. vol. 31 no. 11 3757-3766.
[12] Macmillan (2014). Cancer patient experience survey: insight report and league table 2014. [online] Available at: http://www.macmillan.org.uk/documents/aboutus/research/keystats/2014-cpes-insight-briefing.pdf [Accessed May 2018]
[13] Sanchez, A and Wszolek, M.F. (2015). Bladder cancer: Quality of life in patients with non-muscle-invasive bladder cancer. Nature Reviews Urology. 12,186–188.
[14] Bellmunt et al. (2016). 782PD- IMvigor210: updated analyses of first line (1L) atezolizumab (atezo) in cisplatin (cis)-ineligible locally advanced/metastatic urothelial carcinoma…

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