Correction: Society for Immunotherapy of Cancer (SITC) clinical practice guideline on immunotherapy for the treatment of breast cancer

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UPDATE TO THE SITC GUIDELINE ON BREAST CANCER ADDRESSING WITHDRAWAL OF ATEZOLIZUMAB INDICATION FOR ADVANCED TNBC

On August 27, 2021, the indication for atezolizumab in combination with nab-paclitaxel as treatment for patients with triple-negative breast cancer (TNBC) whose tumors express PD-L1 was voluntarily withdrawn by the manufacturer. According to the press release announcing the withdrawal, the decision was not related to any changes in either the efficacy or safety associated with atezolizumab but rather to recent changes in the treatment landscape for TNBC.

In light of the withdrawal, 'Society for Immunotherapy of Cancer (SITC) clinical practice guideline on immunotherapy for the treatment of breast cancer' has been updated. The following changes have been made to the manuscript. Amendments to the original text are shown *in italics*. The amendments below are grouped by the sections in which they appear in the order of the original publication.

Introduction

The following sentences have been modified to include information on the withdrawal of atezolizumab: 'In 2019, the United States (US) Food and Drug Administration (FDA) granted accelerated approval of the PD-L1-directed antibody, atezolizumab, in combination with nanoparticle albumin-bound (nab)-paclitaxel for advanced/metastatic PD-L1-positive (PD-L1+) TNBC,¹⁷ based on the results of the phase III IMpassion130 trial. Furthermore, in 2020, the FDA granted accelerated approval to the PD-L1-directed antibody, pembrolizumab, in combination with chemotherapy for advanced/metastatic PD-L1+ TNBC based on the results of the phase III KEYNOTE-355 trial.'

The updated text now reads: 'In 2019, the United States (US) Food and Drug Administration (FDA) granted accelerated approval of the PD-L1-directed antibody, atezolizumab, in combination with nanoparticle albumin-bound (nab)-paclitaxel for advanced/metastatic PD-L1-positive (PD-L1+) TNBC based on the results of the phase III IMpassion130 trial. Furthermore, in 2020, the FDA granted accelerated approval to the PD-L1-directed antibody, pembrolizumab, in combination with chemotherapy for advanced/metastatic PD-L1+ TNBC based on the results of the phase III KEYNOTE-355 trial. *In 2021, the accelerated approval for pembrolizumab was converted to full approval and the accelerated approval for atezolizumab was voluntarily withdrawn.*'

Immunotherapy with PD-(L)1 inhibitors for the treatment of advanced/metastatic breast cancer

The following sentences have been modified to include information on the withdrawal of atezolizumab: 'At the time of publication, two ICIs were FDA-approved specifically for the treatment of advanced/metastatic TNBC: atezolizumab and pembrolizumab. Both breast cancer-specific approvals are ICIs given in combination with cytotoxic chemotherapy, although the indicated backbone varies between agents and is an ongoing area of investigation.'

The updated text now reads: 'At the time of publication, two ICIs were FDA-approved specifically for the treatment of advanced/metastatic TNBC: atezolizumab and pembrolizumab. *The indication for atezolizumab was withdrawn in 2021.* Both breast cancer-specific approvals *were* for ICIs given in combination with cytotoxic

chemotherapy, although the indicated backbone varied between agents and is an ongoing area of investigation.'

A footnote has been added to **Table 2 - Trials of ICIs for recurrent/metastatic breast cancer and tissue-agnostic indications**, stating, 'The accelerated approval for atezolizumab in combination with nab-paclitaxel was voluntarily withdrawn in 2021.'

The following sentences have been modified to include information on the withdrawal of atezolizumab: 'Accelerated approval was granted in March 2019 for atezolizumab in combination with nab-paclitaxel for treatment of adult patients with PD-L1+ locally advanced or metastatic TNBC, as measured by the VENTANA PD-L1 (SP142) immunohistochemical (IHC) assay and assessed on immune cells (ICs)¹⁷; additional specifics of PD-L1 testing are described in detail in the **Diagnostics and biomarker testing in patients with advanced/metastatic breast cancer** section. Although the approval does not specify line of therapy, data for the clinical activity of atezolizumab beyond the first-line setting is limited.'

The updated text now reads: 'Accelerated approval was granted in March 2019 for atezolizumab in combination with nab-paclitaxel for treatment of adult patients with PD-L1+ locally advanced or metastatic TNBC, as measured by the VENTANA PD-L1 (SP142) immunohistochemical (IHC) assay and assessed on immune cells (ICs)¹⁷; additional specifics of PD-L1 testing are described in detail in the **Diagnostics and biomarker testing in patients with advanced/metastatic breast cancer** section. *The indication for atezolizumab for TNBC was voluntarily withdrawn in 2021.* Although the approval *did* not specify line of therapy, data for the clinical activity of atezolizumab beyond the first-line setting is limited.'

The following expert panel recommendation has been modified to include information on the withdrawal of atezolizumab: 'At the time of this publication, two companion diagnostics were approved by the FDA for PD-L1 testing in metastatic TNBC: the SP142 assay with IC scoring and the 22C3 assay with tumor and IC scoring by combined positive score. Benefit is seen for adding atezolizumab to nab-paclitaxel in patients with tumors expressing PD-L1 on IC occupying $\geq 1\%$ of the tumor area by the SP142 assay, and for adding pembrolizumab to chemotherapy in patients with tumors expressing PD-L1 by CPS score ≥ 10 (LE:2).'

The updated text now reads: '*With the withdrawal of the indication for atezolizumab with nab-paclitaxel in metastatic TNBC, one companion diagnostic is approved by the FDA for PD-L1 testing in metastatic TNBC: the 22C3 assay with tumor and IC scoring by combined positive score. Benefit is seen for adding pembrolizumab to chemotherapy in patients with tumors expressing PD-L1 by CPS score ≥ 10 (LE:2).*'

The following expert panel recommendation has been removed: 'For patients with locally advanced/metastatic TNBC (disease-free interval ≥ 12 months) and PD-L1 IC+ tumors by IC score ≥ 1 using the SP142 assay, atezolizumab plus nab-paclitaxel is recommended as one immunotherapy option for first-line treatment (LE:2), based on clinically meaningful OS improvement in IMpassion130.'

The following expert panel recommendation has been removed: 'For patients with locally advanced/metastatic TNBC, it is recommended that atezolizumab should only be added to nab-paclitaxel if tumor-infiltrating ICs expressing PD-L1 occupy $\geq 1\%$ of the tumor area by the SP142 assay (until PD-L1 assays are harmonized) (LE:2).'

The following expert panel recommendation has been modified to include information on the withdrawal of atezolizumab: 'For patients with locally advanced/metastatic TNBC and PD-L1+ tumors being treated with atezolizumab, nab-paclitaxel is the only chemotherapy backbone that should be used (LE:2).'

The updated recommendation now reads, 'For patients with locally advanced/metastatic TNBC and PD-L1+ tumors being treated with atezolizumab, nab-paclitaxel is the only chemotherapy backbone that *has demonstrated activity in randomized clinical trials* (LE:2). *The indication for atezolizumab in this setting was voluntarily withdrawn in 2021.*'

The following expert panel recommendation has been added to provide guidance on continuation of therapy for patients deriving clinical benefit from atezolizumab based treatment.

The new recommendation reads, *‘Patients deriving clinical benefit from atezolizumab-based treatment in the absence of clinically significant toxicity or disease progression should continue on atezolizumab plus nab-paclitaxel rather than change therapy.’*

Emerging data on immunotherapy with PD-(L)1 inhibitors for early-stage/locally advanced breast cancer

The following sentence has been corrected to reflect that full regulatory approval was granted to pembrolizumab in the neoadjuvant setting: ‘In July 2021, the FDA granted accelerated approval to pembrolizumab for the treatment of patients with high-risk TNBC in combination with chemotherapy as neoadjuvant treatment and then continued as a single agent as adjuvant treatment after surgery.’

The updated text now reads: ‘In July 2021, the FDA granted *regular* approval to pembrolizumab for the treatment of patients with high-risk TNBC in combination with chemotherapy as neoadjuvant treatment and then continued as a single agent as adjuvant treatment after surgery.’

Diagnostics and biomarker testing in patients with advanced/metastatic breast cancer

The following sentence has been modified to include information on the withdrawal of atezolizumab: ‘Three PD-L1 assays have been designated as ‘companion diagnostics’ by the FDA, two of which are indicated for breast cancer: the VENTANA PD-L1 (SP142) assay and the PD-L1 IHC 22C3 pharmDx assay.’

The updated text now reads: ‘Three PD-L1 assays have been designated as ‘companion diagnostics’ by the FDA, *one* of which *is* indicated for breast cancer: the PD-L1 IHC 22C3 pharmDx assay. *The companion diagnostic indication for TNBC for the VENTANA PD-L1 (SP142) assay was withdrawn in 2021.*’

The following sentence has been modified to include information on the withdrawal of atezolizumab: ‘TNBC is considered ‘PD-L1 positive’ and the patient eligible to receive atezolizumab per the FDA-approved indication if the tumor shows PD-L1+ ICs occupying $\geq 1\%$ of the tumor area.’

The updated text now reads, ‘TNBC is considered ‘PD-L1 positive’ and the patient eligible to receive atezolizumab per the *formerly* FDA-approved indication if the tumor shows PD-L1+ ICs occupying $\geq 1\%$ of the tumor area. *The indication for atezolizumab for TNBC was withdrawn in 2021.*’

The following expert panel recommendation has been removed, ‘For patients with TNBC being considered for treatment with atezolizumab in combination with nab-paclitaxel, tumor tissue should be tested for PD-L1 by the VENTANA SP142 assay and scored by the IC scoring system, until PD-L1 assays are harmonized (LE:2). A TNBC is PD-L1+ by SP142, and the patient eligible for atezolizumab, with an IC score $\geq 1\%$.’

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