CheckMate 77T: A Double-Blind Phase 3 Trial of Neoadjuvant Nivolumab Plus Chemotherapy Followed by Adjuvant Nivolumab in Non-Small Cell Lung Cancer

Jhanelle Gray,1* Tina Cascone,1 Mariano Provenzio,2 Boris Sepesi,3 Shun Lu,4 Nivedita Aanur,5 Sunny Li,6 Jonathan Spicer4

1 Moffitt Cancer Center, Tampa, FL, USA; 2 The University of Texas MD Anderson Cancer Center, Houston, TX, USA; 3 Hospital Universitario Puerta de Hierro, Madrid, Spain; 4 Shanghai Lung Cancer Center, Shanghai Chest Hospital, Shanghai Jiao Tong University, Shanghai, China; 5 Bristol Myers Squibb, Princeton, NJ, USA; 6 McGill University, Montreal, Quebec, Canada

On behalf of the authors

CheckMate 77T (NCT04025879) is a phase 3, randomized, double-blind phase trial evaluating neoadjuvant nivolumab plus chemotherapy followed by adjuvant nivolumab vs neoadjuvant placebo plus chemotherapy followed by adjuvant placebo in resectable early stage NSCLC (Figure 3)

Study Design

1. Primary endpoint
2. EFS by BICR
3. Secondary endpoints
   a. OS by BICR
   b. MRR rate by BICR
   c. Safety and tolerability

Study Sites and Dates

1. 115 study sites in 21 countries (Figure 4)
2. Study start date: September 2019
3. Estimated primary completion date: May 2023
4. Estimated study completion date: September 2024

Figure 4. CheckMate 77T study sites

Figure 3. CheckMate 77T study design

Table 1. Select CheckMate 77T inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
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<tbody>
<tr>
<td>Histologically confirmed, stage IA-IIIA, resectable NSCLC</td>
<td>EGFR or ALK mutations</td>
</tr>
<tr>
<td>ECOG PS 0-1</td>
<td>Brain metastasis</td>
</tr>
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<td>Eligibility for complete lung cancer resection</td>
<td>Prior systemic anti-cancer treatment or radiotherapy in NSCLC</td>
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Acknowledgments

The patients and families for making this trial possible.

Study Rationale

Nivolumab combined with chemotherapy as peroperative therapy

- Combining cytotoxic chemotherapy with a PD-1 inhibitor may augment the antitumor immune response through cell death-induced increased tumor antigenicity and reduction of T-regulatory immune suppression.4,5
- Early phase trials using major histopathologic response (mPR) ≤ 10% viable tumor in resected tumor specimens indicate that nivolumab-based regimens have the potential to deepen pathological responses and extend survival in this setting.2
- Neoadjuvant nivolumab plus chemotherapy followed by adjuvant nivolumab exhibited encouraging response and preliminary survival outcomes in patients with resectable stage IIIA NSCLC in the single-arm phase 2 NADIM trial (Figure 2)7
- Neoadjuvant nivolumab plus chemotherapy followed by adjuvant nivolumab in stage IIIA resectable NSCLC (NADIM study)8

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