Treatment Patterns and Clinical Outcomes in Patients With First-Line nab-Paclitaxel Plus Gemcitabine: Analysis of US Electronic Health Records From the Flatiron Health Database

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INTRODUCTION

The phase III MPACT trial in patients with metastatic pancreatic cancer (mPCa) demonstrated superior benefit (1L nab-PG) vs 0L gemcitabine (nab-PG) for all efficacy outcomes tested, including the primary endpoint, overall survival (OS). Median OS: 6.7 vs 6.0 months; HR 0.72; P = 0.001. Median progression-free survival (PFS): 5.6 vs 3.7 months; HR 0.69; P = 0.002. Although MPACT demonstrated promising results, the relevance of clinical trial data to real-world results is often questioned.

PATIENTS AND METHODS

Study Design and Data Source

The Flatiron Health database consists of ~2 million patients treated at ~265 cancer clinics, which translates to > 800 sites of care across the United States. Data for patients with mPCa who were diagnosed between 01 March 2015 and 31 October 2015 and treated with 1L nab-PG (initiated within 60 days of metastatic diagnosis) were electronically and manually extracted from the EHR via technology-enabled chart extraction (Figure 1).

Statistical Analysis

Kaplan-Meier methods were used to calculate median PFS, median OS, and 95% confidence intervals for all patients and those who received any subsequent 5-fluorouracil (5-FU)- or capetebine (cape)-based therapy (second line or beyond).

Sensitivity analyses were performed restricted to patients who initiated 1L nab-PG treatment within 30 days after diagnosis of metastatic disease to evaluate potential survival bias from the 60-day treatment initiation inclusion criterion.

Endpoints are described in Table 1.

RESULTS

Patient Characteristics

Table 1. Effectiveness Endpoints

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Definition</th>
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<tbody>
<tr>
<td>OS</td>
<td>Start date of 1L nab-PG treatment to date of death; patients who were still alive were censored at the last contact date before or on the date of death on 31 July 2017</td>
</tr>
<tr>
<td>PFS</td>
<td>Start date of 1L nab-PG treatment to the earliest date of documented disease progression or death or patients who were still alive or without PD were censored at the last contact date before or on the date of death on 31 January 2017</td>
</tr>
</tbody>
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- 1L nab-PG treatment duration was measured from date of first administration of either nab-PG or G until the last documentation date. >> 7 days at last visit date, whichever was later, but was not in excess of the date of death.

Figure 1. Patient Flowchart*<br> Table 3. Disease Characteristics*<br> Table 4. Treatment Duration and Clinical Outcomes

STRENGTHS AND LIMITATIONS

- The Flatiron Health EHR database represents one of the largest community-based oncology EHR databases in the United States.
- A real-world population, such as that presented herein, is likely more representative of the general mPCa population than patients enrolled in a clinical trial.
- The median age in this study (68 years) is higher than that of patients in the MPACT trial (63 years) and is closer to the median age of patients diagnosed with all stages of pancreatic cancer (70 years).
- Limitations to the EHR database may include missing or erroneous data and bias due to a lack of protocol-mandated treatment and response criteria.

CONCLUSIONS

- This study is supported by Celgene Corporation, Summit, NJ. The authors received editorial and production support in the preparation of this poster from MediTech Media, Ltd. funded by Celgene Corporation. The authors are fully responsible for all content and editorial decisions for this poster.

REFERENCES


ACKNOWLEDGMENTS

The authors received editorial and production support in the preparation of this poster from MediTech Media, Ltd. funded by Celgene Corporation. The authors are fully responsible for all content and editorial decisions for this poster.

DISCLOSURES

EDF, AS, JSL, GUL, MO, MN, SF, HL, JPM, CUL: employment, leadership position, and stock ownership, Celgene; FI: employment, leadership position, Celgene.