Abstract 6043: Palbociclib in patients with head and neck cancer with CDKN2A loss or mutation: Results from the Targeted Agent and Profiling Utilization Registry (TAPUR) Study

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Palbociclib has anti-tumor activity in heavily pre-treated patients with head and neck cancer with CDKN2A loss or mutation and no RB mutations treated with palbociclib are reported.

Future Direction: Additional study is warranted to confirm the efficacy of palbociclib in this patient population.

Background:
- TAPUR is a phase II basket study that evaluates anti-tumor activity of commercially available targeted agents in patients (pts) with advanced cancers with specific genomic alterations.
- Results of a cohort of head and neck cancer (HNC) pts with CDKN2A loss or mutation and no RB mutations treated with palbociclib are reported.

Methods:

Study Design:
- Eligible pts: Advanced HNC, no standard treatment (tx) options, ECOG PS 0-2, adequate organ function, measurable disease. Tx assigned according to pre-specified matching rules based on genomic tests selected by sites.
- Pts received palbociclib at 125 mg orally once daily for 21 days, followed by 7 days off until disease progression. Tumor evaluations performed at 8 and 16 wks then Q12 wks after treatment initiation.
- Primary endpoint: Disease control (DC) defined as objective response (OR) or stable disease (SD) at 16+ wks per RECIST v1.1. Secondary endpoints: Progression-free survival (PFS), overall survival (OS), and toxicity per CTCAE. Grade 3-5 adverse events (AEs) or serious adverse events (SAEs) at least possibly related to palbociclib are reported.

Statistical Methods:
- Simon’s optimal two-stage design used to test null hypothesis of 15% DC rate vs. alternative of 35% Power = 85%; 1-sided α = 10%.
- At least 7 of 28 pts must achieve DC to reject null hypothesis and consider treatment worthy of further study.

Results:
- 28 pts enrolled June 2016 to Sept 2019. 20 pts (71%) had CDKN2A loss; 8 (29%) had CDKN2A mutation.
- Demographics: Median age 58 y (range 33-80); 64% male.
- Clinical characteristics: 25% PS 0, 68% PS 1, 7% PS 2; 75% received ≥3 prior systemic regimens; 21% received 1-2 prior regimens; 4% received 0 prior regimens. Histology (# pts): squamous cell carcinoma (11); adenocarcinoma (7); poorly differentiated carcinoma (4); esthesioneuroblastoma (3); myxofibrosarcoma (1); acinic cell carcinoma (1); myoepithelial carcinoma (1)
- Outcomes: 10 pts (37%) SD16+ and 0 OR (Table 1 and Figure 1). Time on palbociclib among pts with SD16+ is shown in Figure 2.
- Safety: 14 pts (50%) had ≥1 SAE or Grade 3-5 AE at least possibly related to palbociclib and consistent with known safety profile.

Table 1: Efficacy Outcomes (N=28)

<table>
<thead>
<tr>
<th>DC rate, % (95% CI)</th>
<th>OR rate, % (95% CI)</th>
<th>Median PFS, wks (95% CI)</th>
<th>Median OS, wks (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>37 (21, 50)</td>
<td>0 (0, 12)</td>
<td>9.4 (8.0, 20.3)</td>
<td>42.0 (22.9, 68.1)</td>
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</table>

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Figure 1: Best Percent Change from Baseline in Target Lesion Size (N=28)

Figure 2: Time on Treatment in Pts with SD16+ (N=10)

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