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Phase II study of monalizumab, a first-in-class NKG2A monoclonal antibody, in combination with cetuximab in previously treated recurrent or metastatic squamous cell carcinoma of the head and neck (R/M SCCHN)

Study IPH2201-203

ESMO POSTER ID: 1049PD


1 Abramson Cancer Center, Philadelphia, US; 2 Aix Marseille University, Early Phases Cancer Trial Center, Assistance Publique-Hôpitaux de Marseille, France; 3 Institut Gustave Roussy, Villejuif, France; 4 Centre Oscar Lambret, Lille, France; 5 University of Colorado Cancer Center, Aurora, US; 6 Innate Pharma, Marseille, France; 7 Centre Léon Bérard, Lyon, France.
PROF. ROGER B COHEN

• Professor of Medicine at the University of Pennsylvania and Associate Director for Clinical Research for the Abramson Cancer Center.

• Active investigator on a number of clinical trials in the field of novel therapies, including monoclonal antibodies, immune therapies, and small molecule cell-signaling pathway inhibitors.

• Particular interest in lung and head and neck cancer

• Principal investigator for trial IPH2201-203

• Past positions
  > Medical officer at the FDA Center for Biologics from 1989-1994 where he was Deputy Director, Division of Monoclonal Antibodies
  > Director of the Clinical Trials Office at the University of Virginia Cancer Center in Charlottesville
  > Director of the Phase 1 Program and interim Medical Oncology Department Chair at the Fox Chase Cancer Center
PHASE II STUDY OF MONALIZUMAB IN COMBINATION WITH CETUXIMAB IN HEAD AND NECK CANCER
STUDY IPH2201-203

PROF. RB COHEN
ABRAMSON CANCER CENTER, PHILADELPHIA
SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK (SCCHN)
OVERVIEW AND TREATMENT PARADIGMS IN 2015

- 6th most frequent tumor type – 300,000 new cases and 76,000 deaths every year in US + EU
- Most frequent histology: squamous cell carcinoma
- Most important risk factors: smoking, alcoholism, HPV infection, betel nuts

Treatment: simplified overview

<table>
<thead>
<tr>
<th>Initial stage</th>
<th>Initial RX</th>
<th>RM SCCHN 1st line RX</th>
<th>RM SCCHN 2nd line RX</th>
<th>RM SCCHN &gt;2nd line RX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage I II</td>
<td>Surgery, RT</td>
<td>75%</td>
<td>CT or cetuximab</td>
<td>No proven RX option</td>
</tr>
<tr>
<td>Stage III-IV (locally advanced)</td>
<td>Concomitant CT &amp; RT± surgery</td>
<td>60%</td>
<td>&lt;15% ORR</td>
<td></td>
</tr>
<tr>
<td>Metastatic</td>
<td></td>
<td></td>
<td>IO in trials on 2015</td>
<td></td>
</tr>
</tbody>
</table>

RT: radiotherapy; CT: chemotherapy; RX: treatment; Pt: platinum; ORR: objective response rate
RM SCCHN: locoregionally or metastatic squamous cell of the head and neck
Focus of IPH2201-203 trial
**DUAL ANTIBODY TARGETING IN CANCER IMMUNOLOGY**

**CONCEPT**

- **Monalizumab**
  - First-in-class humanized IgG4 targeting NKG2A on NK and tumor infiltrating CD8+ T cells
  - Blocks binding of CD94/NKG2A to HLA-E reducing inhibitory signaling and thereby unleashing NK and T cell responses

**Hypothesis:**
Dual targeting with the combination of monalizumab and cetuximab will provide greater antitumor activity than cetuximab alone
DUAL ANTIBODY TARGETING IN CANCER IMMUNOLOGY

KEY PRECLINICAL DATA: HLA-E AND NKG2A EXPRESSION IN SCCHN

- Representative example of HLA-E and NKG2A expression on frozen sections from head and neck (SCCHN) and colorectal (CRC) cancer samples. Pseudocolors were attributed to each marker (blue for hematoxylin and green for HLA-E or NKG2A).

- Semi-quantitative analysis of HLA-E expression on formalin-fixed paraffin-embedded (FFPE) SCCHN samples (n=65). HLA-E expression was assessed on tumor cells (TC), lymphocytes (Ly) and endothelial cells (endo). Score 1 = 1 - 33%; Score 2 = 34 - 66%; Score 3 ≥ 66% of positive cells.

Soulas et al, AACR, 2018; Andre et al, 2018 in press
MONALIZUMAB ENHANCES HUMAN NK CELL-MEDIATED ADCC AND ANTI-TUMOR ACTIVITY OF MONALIZUMAB AND CETUXIMAB

(A) FACS profiles showing HLA-E expression at the cell surface in SCCHN cell lines. White histograms: isotype control; gray histograms: anti-HLA-E mAb. NK cells were co-cultured with the cell line indicated, in the presence or absence of monalizumab. The frequencies of CD107- and CD137-producing NKG2A+ NK cells are shown. Each donor = a single dot. Wilcoxon matched-pairs signed-rank test, * = p<0.05, ** = p<0.01.

(B) NK cells from healthy donors were co-cultured with the CAL-27 SCCHN cell line in the presence or absence of monalizumab (Mona) or cetuximab (Ctx). The data shown are the frequencies of CD137-expressing NKG2A+ NK cells after 24 hours. N=13. Student t-test comparing Mona+Ctx combination with Ctx as single agent ****p<0.0001.

Soulas et al, AACR, 2018; Andre et al, 2018 in press
IPH2201-203 STUDY DESIGN

- Multicenter single arm study to evaluate the combination of monalizumab and cetuximab
- Cohort expansion in recurrent and/or metastatic SCCHN patients (NCT02643550)
- N= 40 patients enrolled. Data cut-off August 31, 2018

Key eligibility criteria
- R/M SCCHN, HPV(+) or HPV(-)
- PD after platinum-based CT
- Maximum of 2 prior systemic regimens for R/M disease
- prior IO allowed*

Treatment
- **monalizumab** (10mg/kg Q2W) + **cetuximab** (approved dosage) until progression or unacceptable toxicity

Primary objective
- ORR (RECIST 1.1)
- Secondary objectives
  - Safety,
  - DoR, PFS, OS
- Exploratory objectives
  - Translational analyses

* prior cetuximab allowed if for locally advanced disease with no PD for at least 4 months
### KEY BASELINE CHARACTERISTICS

<table>
<thead>
<tr>
<th>Characteristics (N=40)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>Median [range]</td>
<td>64 [34-76]</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>12 (30%)</td>
</tr>
<tr>
<td>Male</td>
<td>28 (70%)</td>
</tr>
<tr>
<td><strong>ECOG</strong></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>14 (35%)</td>
</tr>
<tr>
<td>1</td>
<td>26 (65%)</td>
</tr>
<tr>
<td><strong>HPV status</strong></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>6 (15%)</td>
</tr>
<tr>
<td>Negative</td>
<td>30 (75%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>4 (10%)</td>
</tr>
<tr>
<td><strong>Smoking history</strong></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>7 (18%)</td>
</tr>
<tr>
<td>Former/current</td>
<td>32 (82%)</td>
</tr>
<tr>
<td><strong>Tumor site</strong></td>
<td></td>
</tr>
<tr>
<td>Oral cavity</td>
<td>17 (42%)</td>
</tr>
<tr>
<td>Oropharynx</td>
<td>13 (32%)</td>
</tr>
<tr>
<td>Other</td>
<td>10 (25%)</td>
</tr>
<tr>
<td><strong>Type of recurrence</strong></td>
<td></td>
</tr>
<tr>
<td>Local</td>
<td>21 (52%)</td>
</tr>
<tr>
<td>Distant</td>
<td>19 (48%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Previous treatment (N=40)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prior lines of overall</strong></td>
<td></td>
</tr>
<tr>
<td>systemic therapy</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>20 (50%)</td>
</tr>
<tr>
<td>2</td>
<td>13 (32%)</td>
</tr>
<tr>
<td>≥3</td>
<td>7 (17%)</td>
</tr>
<tr>
<td><strong>Prior platinum</strong></td>
<td></td>
</tr>
<tr>
<td>Platinum resistant*</td>
<td>40 (100%)</td>
</tr>
<tr>
<td>Platinum resistant*</td>
<td>21 (53%)</td>
</tr>
<tr>
<td><strong>Prior IO</strong></td>
<td></td>
</tr>
<tr>
<td>IO resistant*</td>
<td>17 (42%)</td>
</tr>
<tr>
<td>IO resistant*</td>
<td>13</td>
</tr>
<tr>
<td><strong>Prior Cetuximab</strong></td>
<td></td>
</tr>
<tr>
<td>Cetux resistant*</td>
<td>5 (12%)</td>
</tr>
<tr>
<td>Cetux resistant*</td>
<td>0</td>
</tr>
</tbody>
</table>

* For oropharynx (n=13), 4 HPV +, 9 HPV -

*resistant: PD under treatment or within 6 months after the end of treatment
KEY RESULTS WITH MONALIZUMAB AND CETUXIMAB COMBINATION
RESPONSE DATA

<table>
<thead>
<tr>
<th>Antitumor response</th>
<th>n (%) CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete Response (CR)</td>
<td>1 (2.5%)</td>
</tr>
<tr>
<td>Partial response (PR)</td>
<td>10 (25%)</td>
</tr>
<tr>
<td>Stable disease (SD)</td>
<td>22 (55%)</td>
</tr>
<tr>
<td>Overall Response Rate (ORR) [95% CI]</td>
<td>27.5% [16.1-42.8]</td>
</tr>
</tbody>
</table>

Median duration of response: 5.6 months [3.8-NR]

Cutoff data: Aug 31, 2018

*one patient with death from clinical progression before the 1st post baseline radiological assessment is not represented in the waterfall plot
KEY RESULTS WITH MONALIZUMAB AND CETUXIMAB COMBINATION RESPONSE DATA

• *: Prior IO
• c: Prior cetuximab

one patient with death from clinical progression before the 1st post baseline radiological assessment is not represented in these graphs
KEY RESULTS WITH MONALIZUMAB AND CETUXIMAB COMBINATION

PROGRESSION-FREE AND OVERALL SURVIVAL

**Progression-Free Survival**

- Median PFS = 5.0 mo (3.7–6.9)
- N of events = 30
- N = 40

**Overall Survival**

- Median OS = 10.3 mo (7.3–NA)
- N of events = 15
- N = 40

95% Conf. Int.
KEY RESULTS WITH MONALIZUMAB AND CETUXIMAB COMBINATION

SAFETY DATA

- No new safety signals for monalizumab
- Only one patient stopped treatment for an AE
- No potentiation of cetuximab side-effects

<table>
<thead>
<tr>
<th>All TEAE N (%)</th>
<th>Monalizumab related TEAE N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade</td>
<td>All</td>
</tr>
<tr>
<td>AEs</td>
<td>40 (100%)</td>
</tr>
<tr>
<td>SAEs</td>
<td>16 (40%)</td>
</tr>
</tbody>
</table>

AE related to the monalizumab cetuximab combination
CONCLUSIONS

- The combination of monalizumab and cetuximab results in early, deep and durable responses
  - Encouraging PFS and OS
  - Combination has activity in platinum-resistant and in HPV-positive and negative patients
  - Activity appears higher than that of cetuximab alone historical data
- Combination is safe & well tolerated with no potentiation of cetuximab adverse events
- These results warrant further development of the combination of monalizumab and cetuximab in SCCHN patients who have failed platinum-based chemotherapy and PD-(L)1 inhibitors
  - A patient population with a very high unmet medical need
  - Ongoing expansion cohort to confirm observed clinical benefit
**SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK (SCCHN) CURRENT TREATMENT PARADIGMS IN 2018**

**Treatment: simplified overview**

- **Cure**
  - Concomitant RT CT surgery
- For stage III-IV disease

- **Local relapse, or metastatic (RM SCCHN)**

- **RM SCCHN 1st line RX**
  - CT ± cetuximab
  - 35% ORR
  - IO in trials (e.g. KN048)

- **RM SCCHN 2nd line RX**
  - PD(L)1 blockers
  - ~15% ORR

- **RM SCCHN >2nd line RX**

**Monalizumab cetuximab and other combinations: potential for further exploration**

RT: radiotherapy; CT: chemotherapy; RX: treatment; Pt: platinum; ORR: objective response rate
RM SCCHN: locoregionally or metastatic squamous cell of the head and neck
STRATEGIC PERSPECTIVES
INNATE PHARMA
OVERVIEW OF THE MONALIZUMAB PROGRAM IN SCCHN

• Strong preclinical rationale for monalizumab in SCCHN
  > Preclinical data reported for the combination of monalizumab + PD1 blockers
  > Preclinical data reported for the combination of monalizumab + cetuximab

• Clinical data showing antitumor activity in SCCHN

• Innate and AstraZeneca remain committed to advancing the SCCHN development program to further investigate potential therapeutic benefits
  > Ongoing expansion cohort testing the monalizumab + cetuximab combination in patients with prior exposure to both platinum based chemotherapy and PD(L)1 blockers (3rd line setting)
  > Other investigational trial collaboration (e.g. EORTC program)
MONALIZUMAB IN COMBINATION WITH CETUXIMAB IN SCCHN
KEY CLINICAL DATA IN 2L R/M SCCHN

<table>
<thead>
<tr>
<th></th>
<th>monalizumab cetuximab</th>
<th>cetuximab</th>
<th>pembrolizumab</th>
<th>nivolumab</th>
<th>durvalumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>N patients</td>
<td>40</td>
<td>103</td>
<td>247</td>
<td>240</td>
<td>112</td>
</tr>
<tr>
<td>ORR</td>
<td>27.5%</td>
<td>12.6%</td>
<td>14.6%</td>
<td>13.3%</td>
<td>16%</td>
</tr>
<tr>
<td>PFS</td>
<td>5.0 mo</td>
<td>2.3 mo</td>
<td>2.1 mo</td>
<td>2.0 mo</td>
<td>2.1 mo</td>
</tr>
<tr>
<td>OS</td>
<td>10.3 mo</td>
<td>5.8 mo</td>
<td>8.4 mo</td>
<td>7.5 mo</td>
<td>7.1 mo</td>
</tr>
</tbody>
</table>

Ferris et al, NEJM 2016
Vermorken et al, JCO 2007
Soulieres et al, AACR 2018
Fayette et al, ESMO 2018
Zandberg et al, ESMO 2017
MONALIZUMAB IN COMBINATION WITH CETUXIMAB IN SCCHN
POTENTIAL NEXT STEPS

- Ongoing Expansion in IO pretreated pts
- Accelerated approval strategy if compelling clinical benefit data
- and/or
- Pivotal study Mona + Cetux vs Cetux
- Mona + Cetux + Durva in IO naïve pts
- Pivotal study in IO naïve pts

2018
2019
2020+
**MONALIZUMAB - COMMERCIAL OPPORTUNITY**
**SCCHN - FUTURE COMPETITIVE LANDSCAPE**

<table>
<thead>
<tr>
<th>Resectable</th>
<th>Unresectable</th>
<th>Metastatic 1L</th>
<th>2L</th>
<th>3L</th>
</tr>
</thead>
<tbody>
<tr>
<td>35k*</td>
<td>40k*</td>
<td>65k*</td>
<td>25k*</td>
<td>15k*</td>
</tr>
</tbody>
</table>

- **Adjuvant CT/RT**
  - Cis-eligible
    - Cetuximab + RT
  - Cis-ineligible
    - IO + RT/CT

- **IO Mono**
- **IO +/- CT**
- **IO SOC**
- **Other SOC**


Epidemiology data: Internal best current estimates of patient numbers based on external research.
QUESTIONS AND ANSWERS