innate pharma

ANALYST AND INVESTOR CALL ESMO 2018

MONDAY, OCTOBER 22

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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

J Fayette[7], M Posner, G Lefebvre, J Bauman, S Salas[2], C Even[3], T Seiwert, D Colevas, A Jimeno[5], E Saada, B Burtness, F Calmels, R Zerbib[6], A Boyer-Chammard[6], RB Cohen[1].

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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
- <u>Past positions</u>
  - > 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

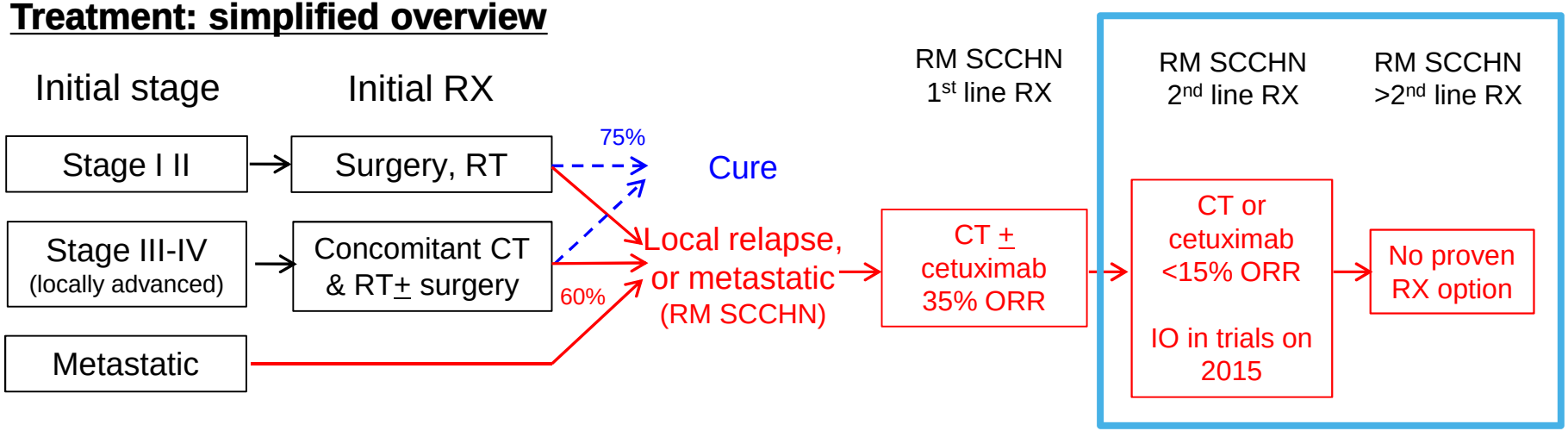
PHASE II STUDY OF MONALIZUMAB IN COMBINATION WITH CETUXIMAB IN HEAD AND NECK CANCER STUDY IPH2201-203

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

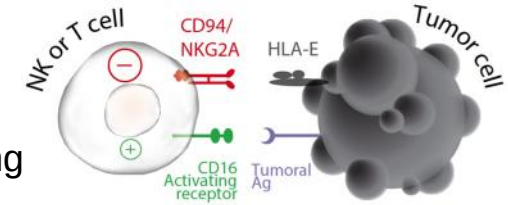


RT: radiotherapy; CT: chemotherapy; RX: treatment; Pt: platinum; ORR: objective response rate
RM SCCHN: locoregionally or metastatic squamous cell of the head and neck

Focus of IPH2201-203 trial

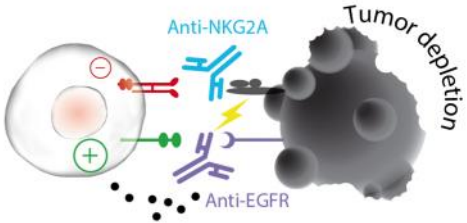
DUAL ANTIBODY TARGETING IN CANCER IMMUNOLOGY CONCEPT

- 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



NK cell and T cell inhibition by NKG2A

+

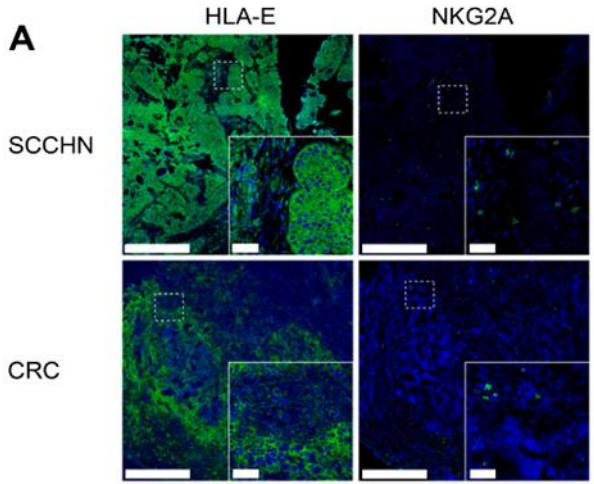


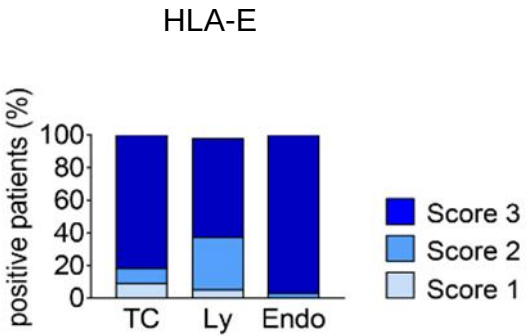
ADCC enhancement by NKG2A blockade

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

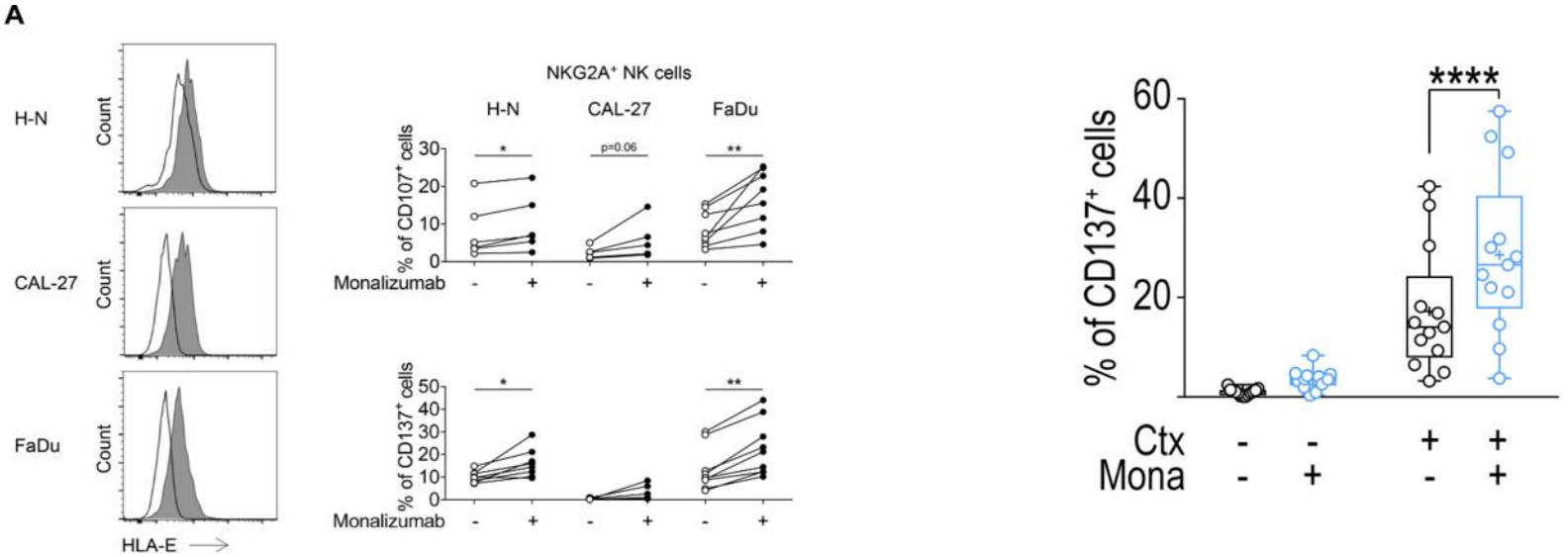




- Representative example of HLA-E and NKG2A expression on frozen sections from head and neck (SCCHN) and colorectal (CRC) cancer samples. Pseudocolors were attributed to each marker (blue for hematoxylin and green for HLA-E or NKG2A).
- Semi-quantitative analysis of HLA-E expression on formalin-fixed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

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

Previous treatment (N=40)		N (%)
Prior lines of overall systemic therapy	1 2 ≥3	20 (50%) 13 (32%) 7 (17%)
	Prior platinum *Platinum resistant**	40 (100%) 21 (53%)
	Prior IO *IO resistant**	17 (42%) 13
	Prior Cetuximab *Cetux resistant**	5 (12%) 0

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

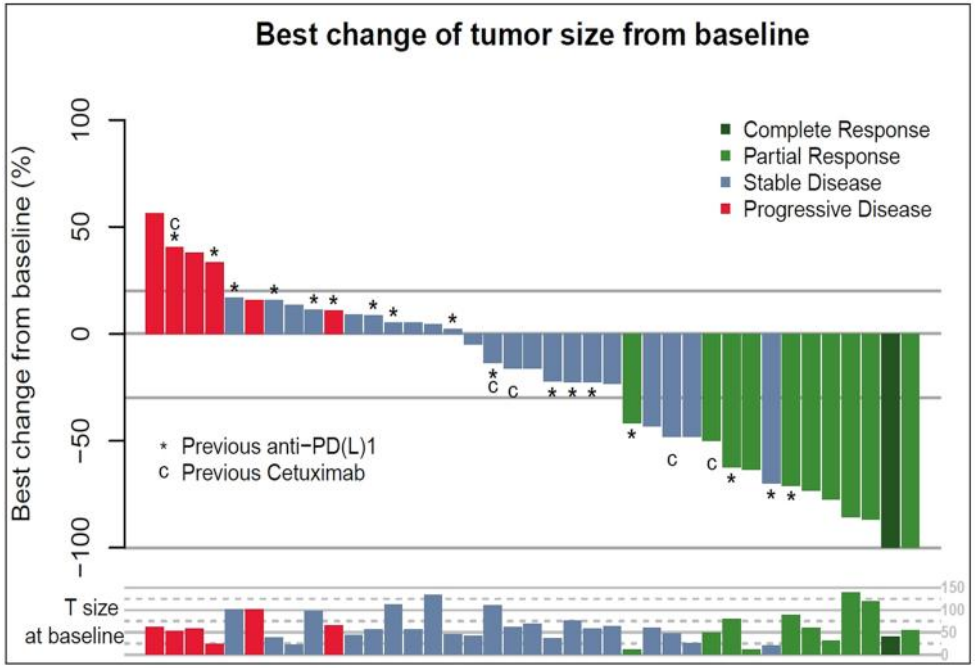
*resistant: PD under treatment or within 6 months after the end of treatment

KEY RESULTS WITH MONALIZUMAB AND CETUXIMAB COMBINATION

RESPONSE DATA

Antitumor response	n (%) CI
Complete Response (CR)	**1 (2.5%)**
Partial response (PR)	**10 (25%)**
Stable disease (SD)	**22 (55%)**
Overall Response Rate (ORR) [95% CI]	**27.5% [16.1-42.8]**

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

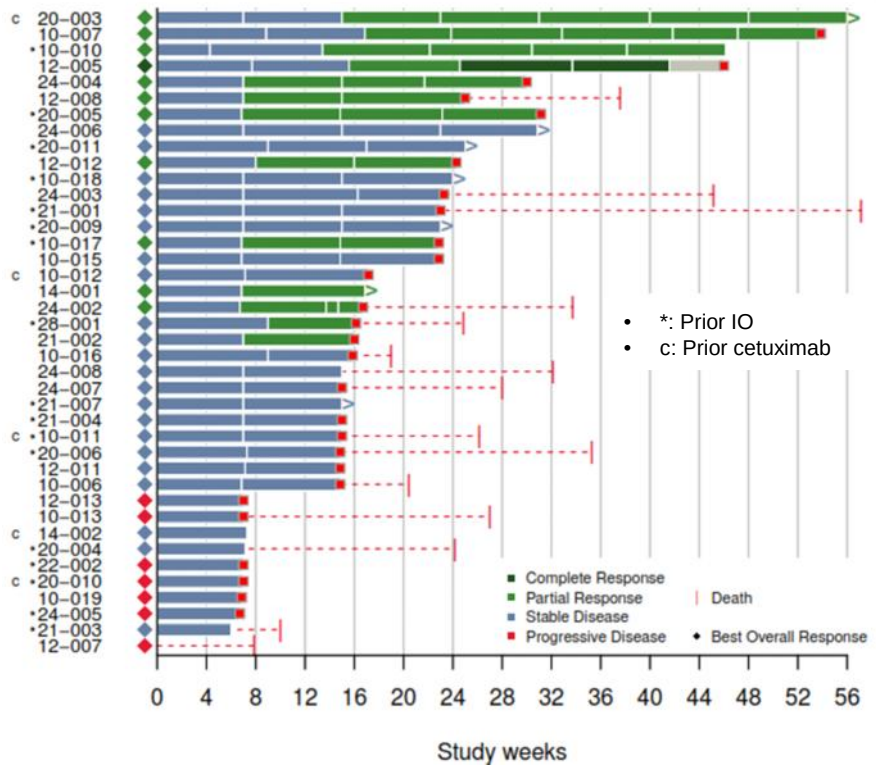


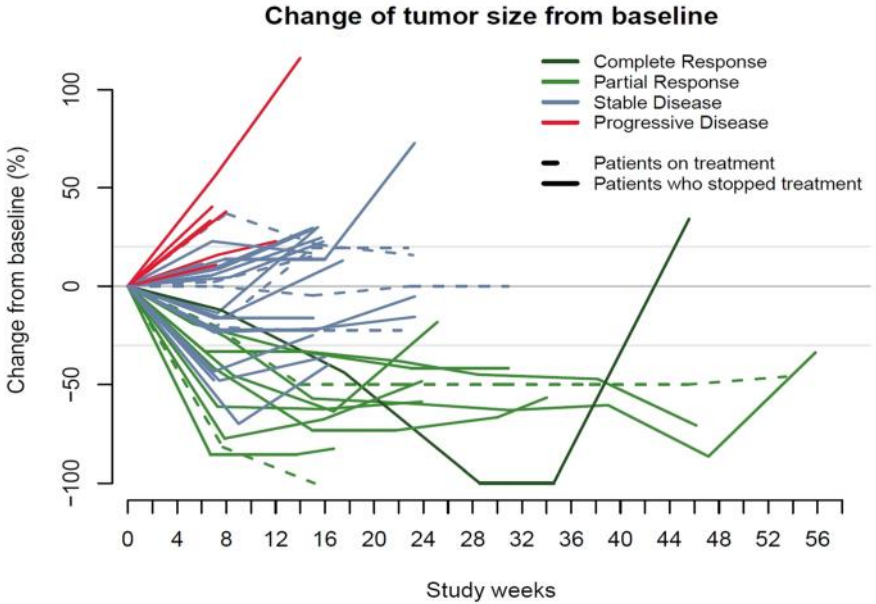
*one patient with death from clinical progression before the 1st post baseline radiological assessment is not represented in the waterfall plot

Cutoff data: Aug 31, 2018

KEY RESULTS WITH MONALIZUMAB AND CETUXIMAB COMBINATION

RESPONSE DATA

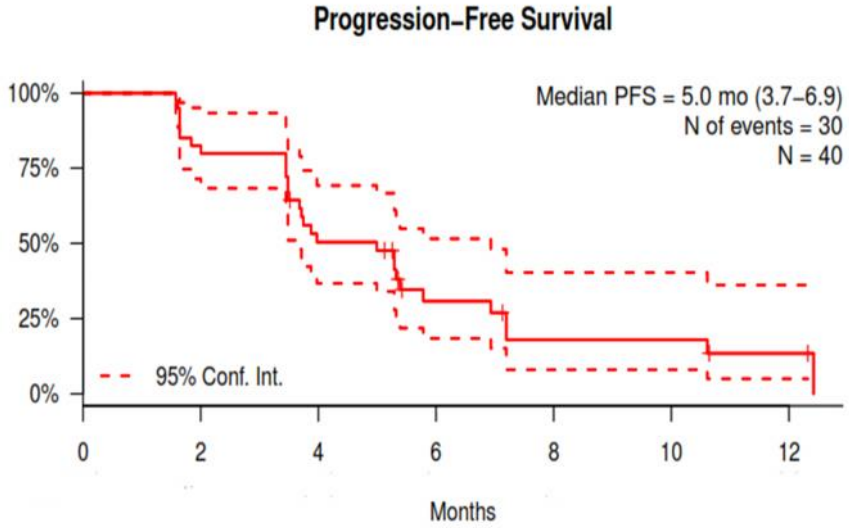


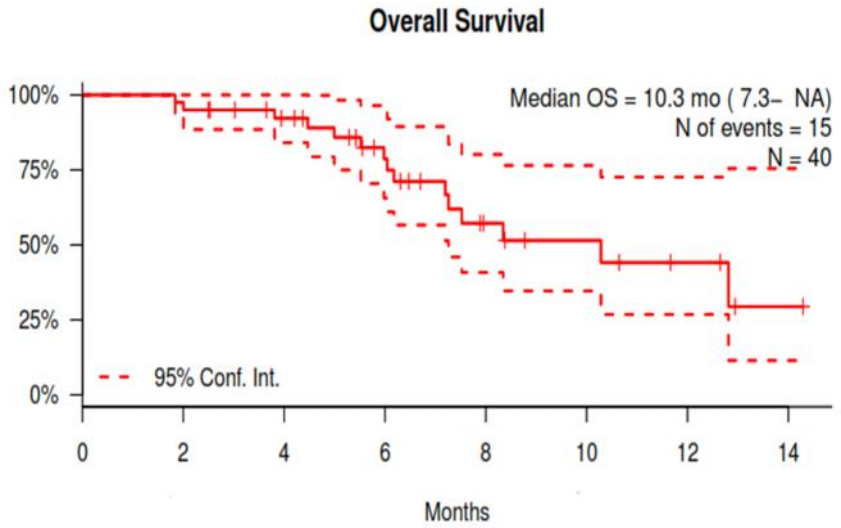


*one patient with death from clinical progression before the 1st post baseline radiological assessment is not represented in these graphs

KEY RESULTS WITH MONALIZUMAB AND CETUXIMAB COMBINATION

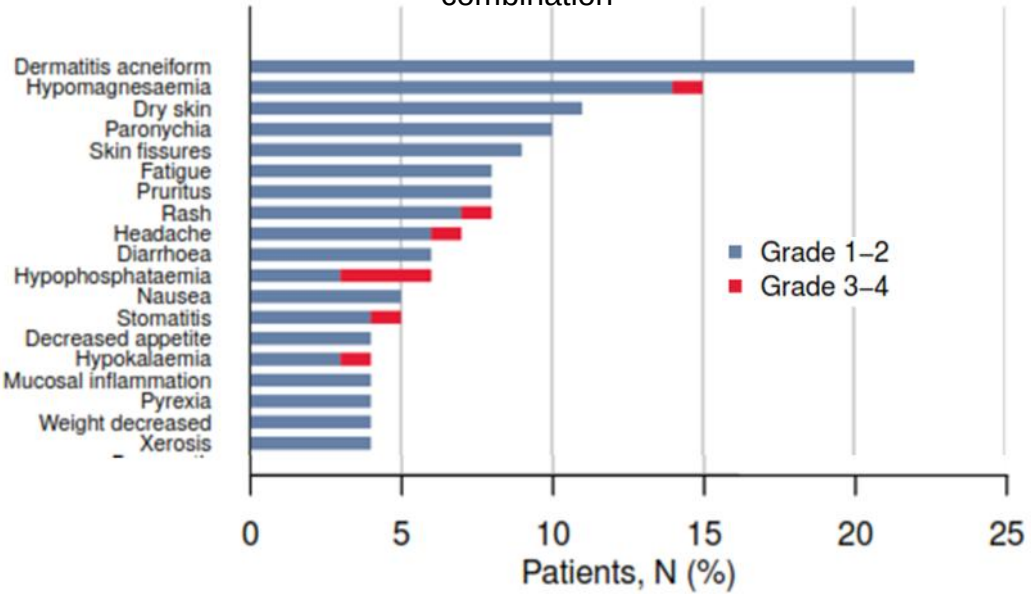
PROGRESSION-FREE AND OVERALL SURVIVAL





KEY RESULTS WITH MONALIZUMAB AND CETUXIMAB COMBINATION
SAFETY DATA

AE related to the monalizumab cetuximab combination



	All TEAE N (%)		Monalizumab related TEAE N (%)	
	Grade			
	All	3-4	All	3-4
AEs	40 (100%)	20 (50%)	30 (75%)	7 (18%)
SAEs	16 (40%)	12 (30%)	3 (8%)	3 (8%)

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

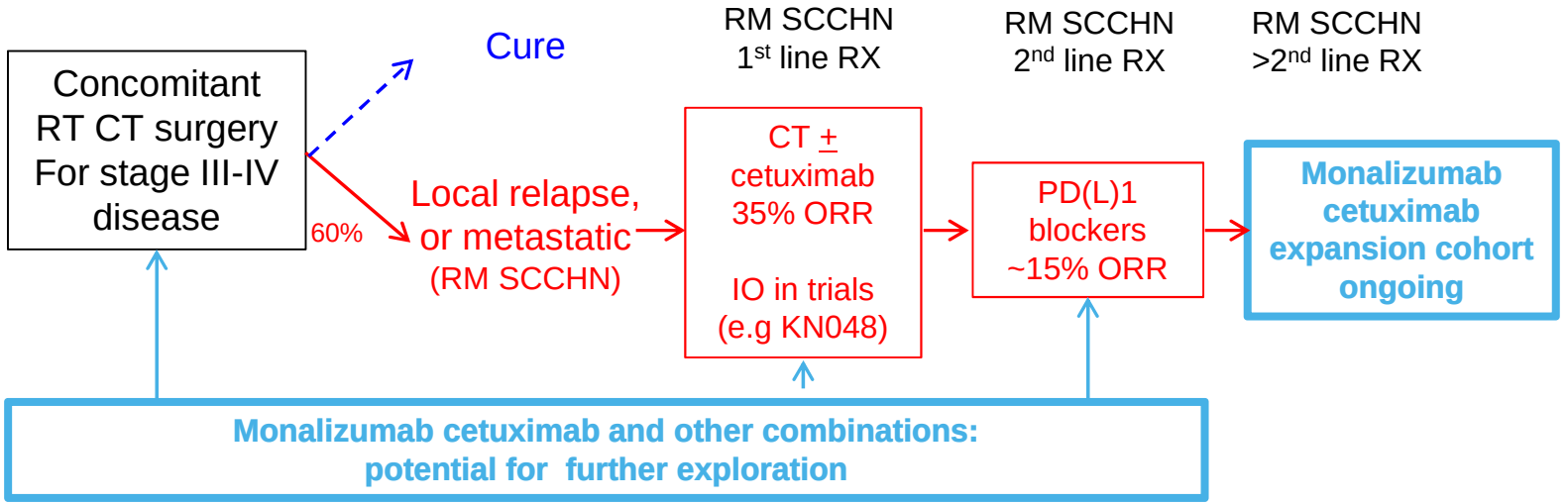
CONCLUSIONS

- 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



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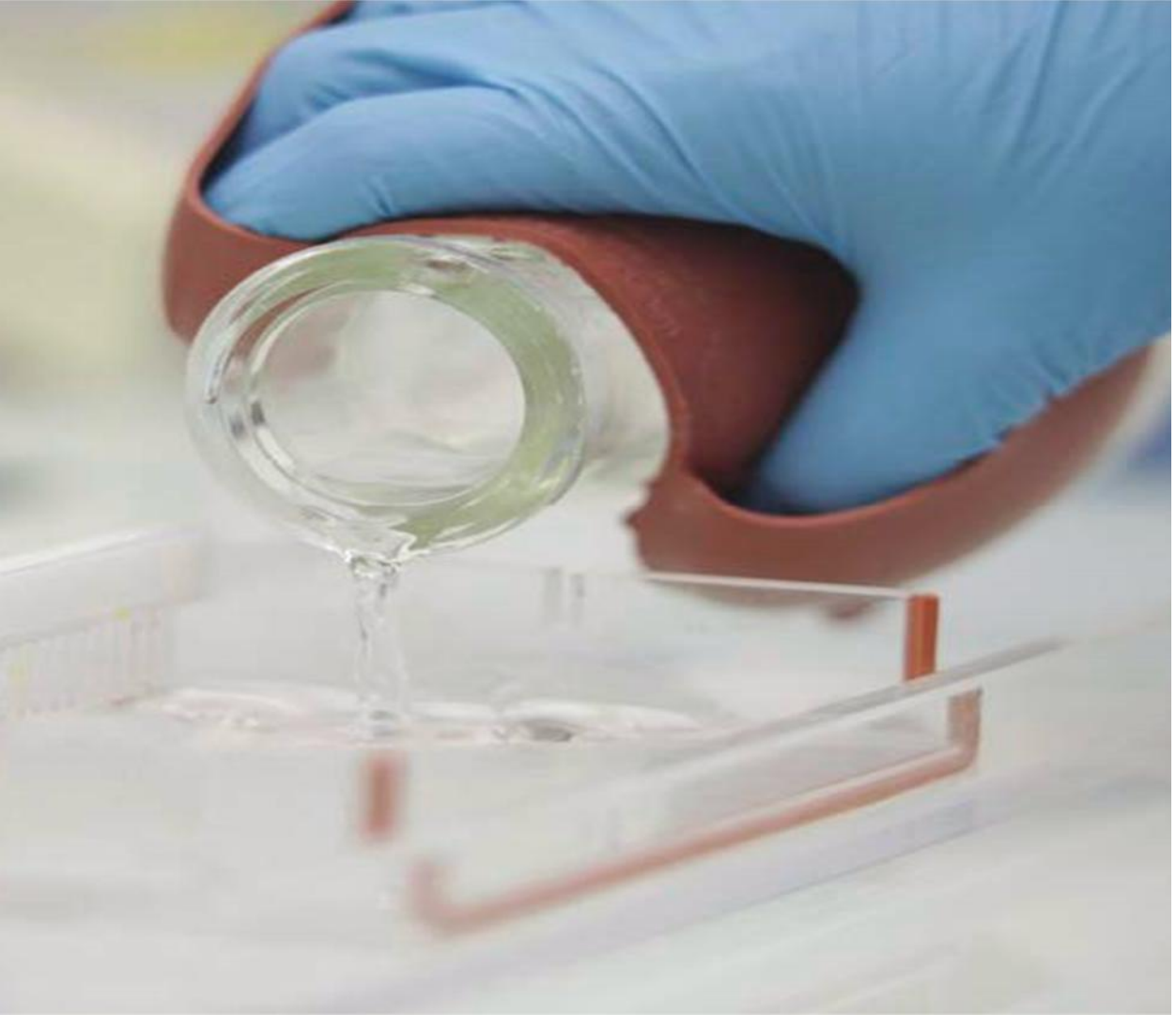
RM SCCHN: locoregionally or metastatic squamous cell of the head and neck



STRATEGIC PERSPECTIVES

INNATE PHARMA

OVERVIEW OF THE MONALIZUMAB PROGRAM IN SCCHN

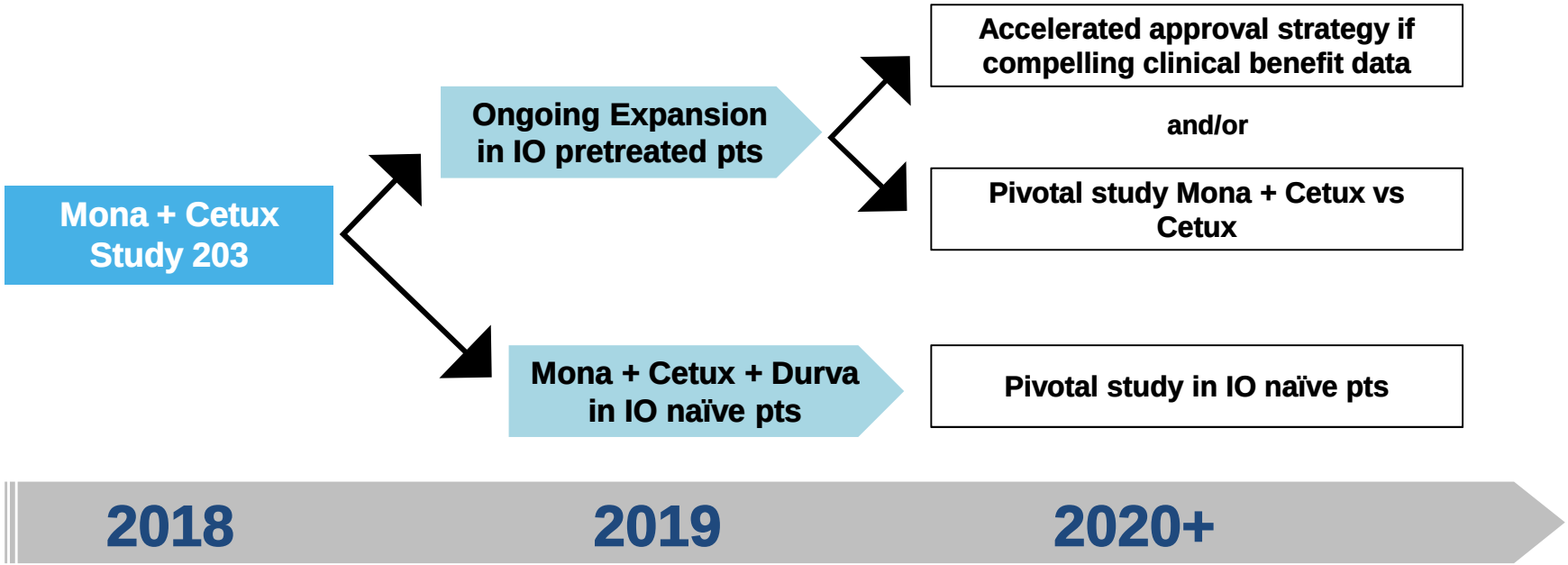
- Strong preclinical rationale for monalizumab in SCCHN
  - > Preclinical data reported for the combination of monalizumab + PD1 blockers
  - > Preclinical data reported for the combination of monalizumab + cetuximab
- Clinical data showing antitumor activity in SCCHN
- Innate and AstraZeneca remain 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

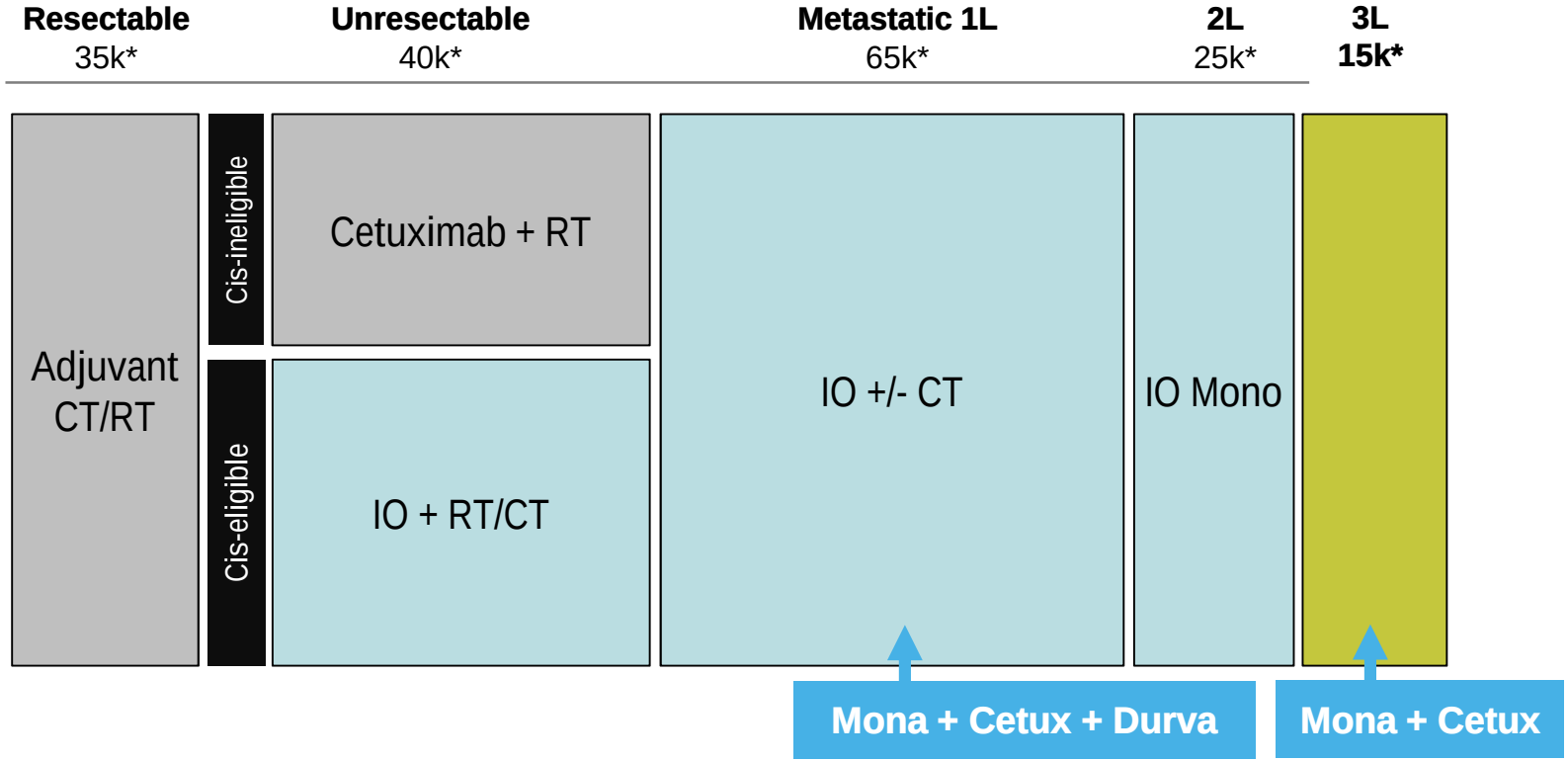
	monalizumab cetuximab	**cetuximab**	**pembrolizumab**	**nivolumab**	**durvalumab**
N patients	40	103	247	240	112
ORR	**27.5%**	**12.6%**	**14.6%**	**13.3%**	**16%**
PFS	**5.0** mo	**2.3** mo	**2.1** mo	**2.0** mo	**2.1** mo
OS	**10.3** mo	**5.8** mo	**8.4** mo	**7.5** mo	**7.1** mo
	Fayette et al, ESMO 2018	Vermorken et al, JCO 2007	Soulieres et al, AACR 2018	Ferris et al, NEJM 2016	Zandberg et al, ESMO 2017

MONALIZUMAB IN COMBINATION WITH CETUXIMAB IN SCCHN
POTENTIAL NEXT STEPS



MONALIZUMAB - COMMERCIAL OPPORTUNITY
SCCHN – FUTURE COMPETITIVE LANDSCAPE

IO SOC
Other SOC



*Drug-treated patients in US/5EU/Jpn & China in 2023. China assumes 20% access to novel therapies
Epidemiology data : Internal best current estimates of patient numbers based on external research

QUESTIONS AND ANSWERS

INVESTOR RELATIONS

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