

Amcenestrant bound to Estrogen Receptor

Sanofi Oncology ASCO Event

Play to Win





June 4, 2021



Forward looking statements

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Agenda- Sanofi oncology ASCO event

Introduction	Dietmar Berger	Global Head of Development, CMO	
Amcenenstrant	Chris Soria	Global Project Head, Amcenenstrant	
SAR'245	Peter Adamson	Global Oncology Development Head	
Conclusion	Dietmar Berger	Global Head of Development, CMO	
Q&A session			



Introduction

Dietmar Berger

Global Head of Development, CMO



Significant progress made in oncology since ASCO 2020

Key achievements

- ✓ Amcenestrant AMEERA-1 combination data further supports potential best-in-class profile
- ✓ SAR'245 HAMMER interim data shows clinical activity in monotherapy and combination
- ✓ FDA and EU approve Sarclisa® Kd combination⁽¹⁾
- ✓ Libtayo® cervical cancer positive overall survival⁽²⁾
- ✓ Libtayo® FDA approval in 2L locally advanced basal cell carcinoma⁽³⁾ and 1L advanced NSCLC mono⁽⁴⁾
- ✓ Libtayo® positive EMA CHMP opinion in 1L advanced NSCLC mono⁽⁵⁾ and 2L locally advanced or metastatic BCC⁽⁶⁾

Acquisitions / collaborations



Oncology pipeline expansion: 17 molecules in development compared to only 5 in 2017

Amcenestrant and SAR'245 (formerly known as THOR707, full SAR444245) are assets under investigation, not approved by regulators; Libtayo® is in collaboration with Regeneron; Kd: carfilzomib and dexamethasone;

(1) Sarclisa® was FDA approved in combination with carfilzomib and dexamethasone for patients with relapsed or refractory multiple myeloma (MM) who have received 1-3 prior lines of therapy. Sarclisa® was EC approved in combination with carfilzomib and dexamethasone for the treatment

of adult patients with relapsed MM who have received at ≥1 prior therapy

(2) Libtayo® not yet licensed in cervical cancer, pivotal trial stopped early for positive result on OS (3) Libtayo® was FDA approved for patients with locally advanced basal cell carcinoma previously treated with a hedgehog pathway

inhibitor (HHI) or for whom a HHI is not appropriate

(4) Libtayo® was FDA approved as monotherapy for patients with first-line advanced NSCLC with PD-L1 expression of ≥50% with no EGFR, ALK, or ROS1 aberrations

(5) CHMP positive opinion for first-line treatment of adults with metastatic or locally advanced disease that is not a candidate for definitive chemoradiation with PD-L1 expression ≥50% with no EGFR, ALK or ROS1 aberrations.

(6) CHMP positive opinion for patients who have progressed on or are intolerant to a HHI



Amcenstrant

Chris Soria

Global Project Head, Amcenstrant



Large unmet need remains for improved therapies in ER+ breast cancer



Breast cancer is the most commonly diagnosed cancer⁽¹⁾

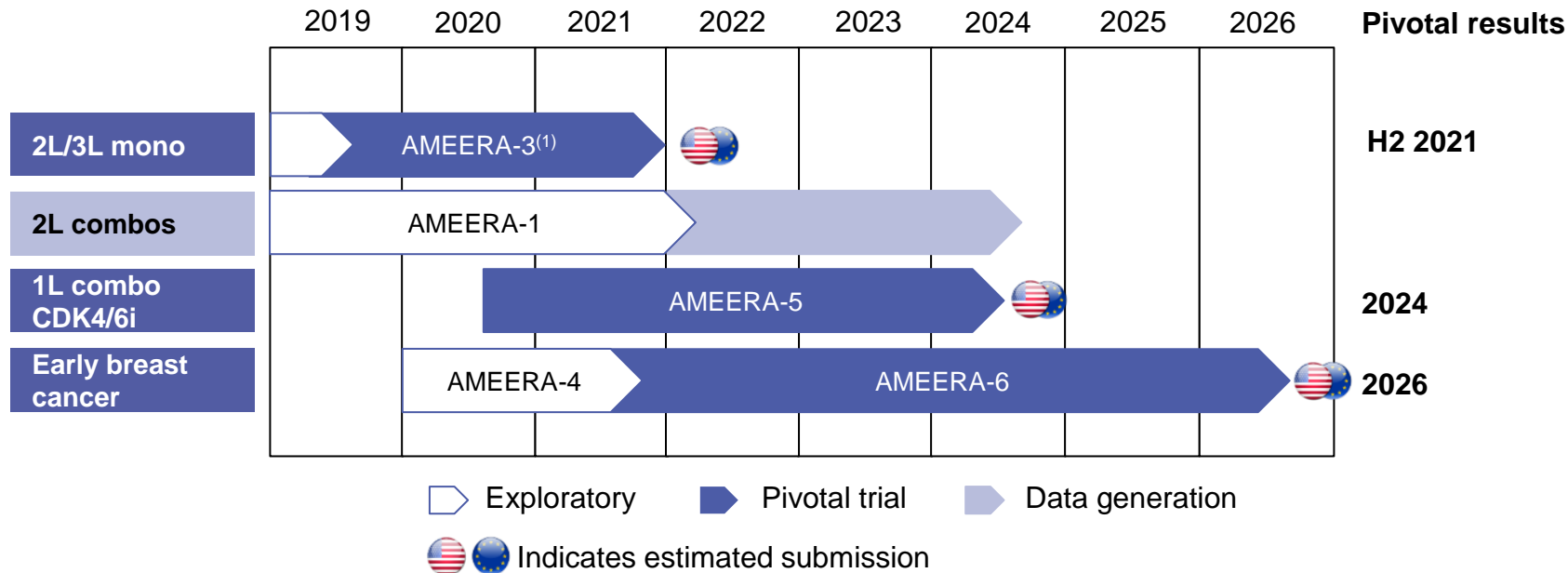
- Leading cause of cancer death in women globally
- ~70% of breast cancers are ER+⁽²⁾
- ~30% of patients with early BC progress to metastatic disease⁽³⁾
- Median overall survival for patient with ER+ metastatic disease is still only ~5 years⁽²⁾

Amcenestrant is a potent, oral selective estrogen receptor α (ER α) degrader

- Amcenestrant is dosed once daily
- FDA fast-track designation

Amcenestrant emerging profile positions it as the endocrine backbone for all lines of ER+ BC

Broad global clinical development program across all lines of ER+/HER2- breast cancer



AMEERA-1 combination data shows safety profile of amcenestrant consistent with monotherapy

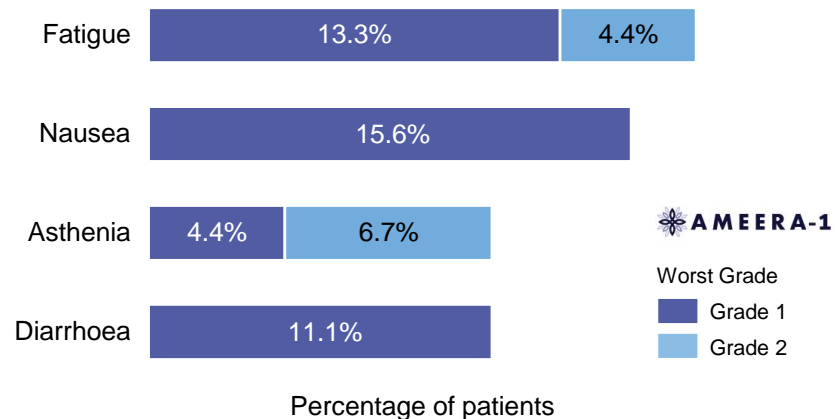
Phase 1/2 Parts C and D: amcenestrant + palbociclib

Potential class leading safety & tolerability profile

- No dose-limiting toxicities
- Consistent safety profile in combination similar to monotherapy
- Neutrophil count decrease consistent with expected safety profile of ET in combination with palbociclib

No clinically significant bradycardia, QTc prolongation, or ocular toxicity

Most frequent non-hematological TRAEs (≥10%) related to amcenestrant

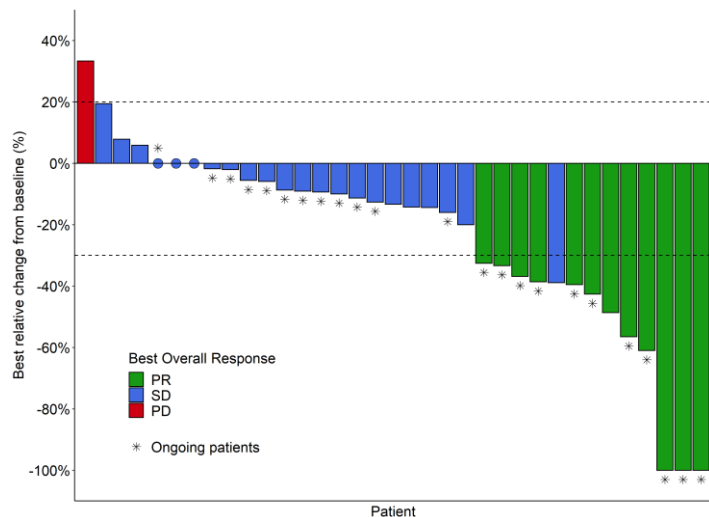


Amcenestrant's favorable safety profile continues to support backbone potential

Amcenestrant plus palbociclib shows meaningful anti-tumor activity with ORR of 34.3% and CBR of 74.3%

Objective response rate (ORR) = 34.3%

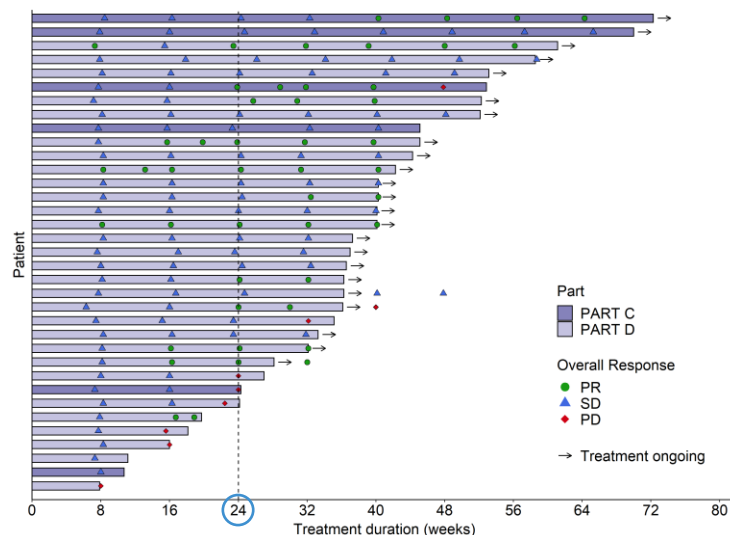
80% of patients with tumor shrinkage, with 3 at 100%



Patient relative change from baseline by Best Overall Response (N=35)


Clinical benefit rate (CBR) = 74.3%

Long duration of benefit (majority >6 months);
23 of 35 patients still on treatment



Duration of Treatment in weeks (N= 35)

AMEERA-1 demonstrated favorable activity in context of instructive historical data

	Trial	Regimen	N	ORR	CBR
2L+ setting endocrine resistant	 AMEERA-1	Amcenestrant + palbociclib	35	34%	74%
	Paloma-3 ⁽¹⁾	Fulvestrant + palbociclib	268	25%	64%
	Paloma-3 ⁽¹⁾	Fulvestrant monotherapy	138	11%	36%

Amcenestrant is an asset under investigation, not approved by regulators; Not based on head to head data. Limited conclusions should be derived from this indirect comparison given the variability of study designs. Clinical relevance of these differences is still under investigation; Antitumor activity assessed in the response-evaluable population receiving amcenestrant 200mg daily (N = 35), comprising a subset of patients from Part C without prior CDK4/6i or mTORi and all evaluable patients from Part D.

(1) Cristofanilli M, et. Al. Lancet Oncol 2016; 17:425-39

First oral SERD to start a pivotal trial in the adjuvant setting with key academic partners

AMEERA-6

Fast-to-market approach

- Amcenestrant vs tamoxifen in patients with **high-risk adjuvant disease not able to tolerate AI therapy**
- Global partnership with leading academic research networks



AMEERA-6 Phase 3 adjuvant, monotherapy trial planned to start in H2 2021

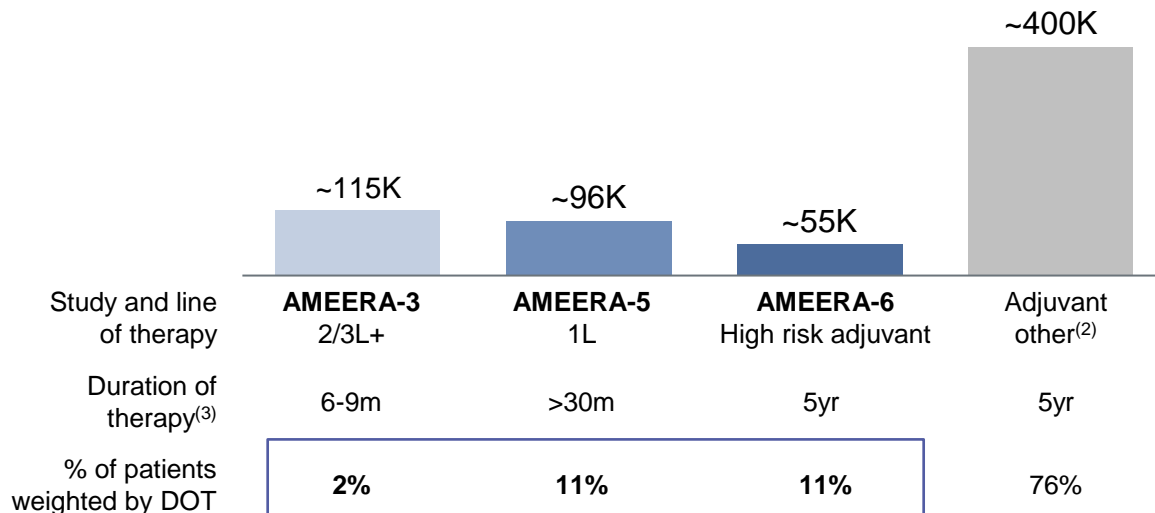
Amcenenstrant has the potential to capture significant share in ER+ breast cancer



- Fast-to-market approach across all breast cancer lines
- Potential to be first-to-market in 2L+ monotherapy
- Earlier line therapy represents the possibility of extended treatment duration
- Favorable results from AMEERA-6 and AMEERA-5 could represent significant market potential

Addressable patient population in current AMEERA registration studies

(patients in thousands⁽¹⁾)



Amcenenstrant is an asset under investigation, not approved by regulators

(1) 2022 projection estimates - Sanofi internal data, Kantar Health & Synix – CancerMpact 2021 (U.S. Japan, EU5)

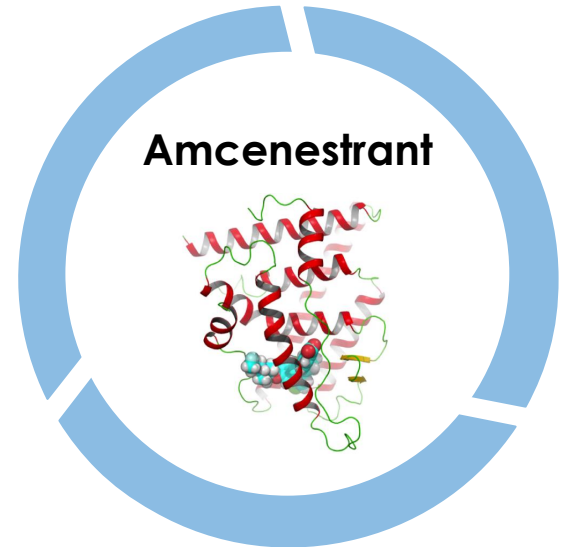
(2) Includes adjuvant & neoadjuvant

(3) Sanofi internal data

Potential best-in-class endocrine backbone in ER+ breast cancer across treatment lines

Amcenestrant demonstrating potential best-in-class antitumor activity and safety / tolerability profile

- ✓ **NO** dose limiting toxicities
- ✓ **NO** safety findings of bradycardia, QTc prolongation or ocular toxicity
- ✓ **IMPRESSIVE** antitumor activity with ORR of 34.3% and CBR of 74.3% (combination data ASCO 2021)
- ✓ **FIRST** oral SERD in adjuvant setting with leading academic research groups





SAR'245

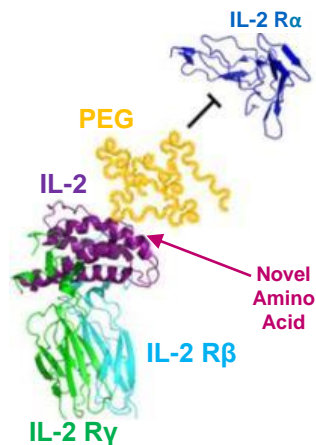
Peter Adamson

Global Oncology Development Head



SAR'245: Potential best-in-class IL-2

SAR'245 'non-alpha' IL-2



- PEG blocks engagement of IL-2R α chain
- Selectively expands anti-tumor CD8+ T and NK cells
- No expansion of immune-suppressive CD4+ reg T cells
- No activation of eosinophils responsible for VLS

	SAR'245 ⁽³⁾	ALKS 4320 ⁽¹⁾	NKTR-214 ⁽²⁾
	Site-specific pegylation	Fusion protein	Random and cleavable lysine pegylation
Dose	24 µg/kg	6 µg/kg	6 µg/kg
Schedule	Q3W	Daily for 5 days	Q3W
Non-Alpha	✓	✓	○
Expansion of CD8+T-cells ⁽⁴⁾	✓✓	✓	✓
Expansion of NK cells ⁽⁵⁾	✓✓	✓✓	✓
No expansion of CD4-Tregs	✓	✓	○
No meaningful increase in EOS	✓	N/A	○
No anti-drug antibodies	✓	N/A	✓

SAR'245 is an asset under investigation, not approved by regulators, formerly known as THOR707; 24ug/kg is the projected RP2D: recommended Phase 2 dose Q3W: every three weeks; NK: Natural killer. (1) Lopes et al, Journal for ImmunoTherapy of Cancer 2020; medication package insert (2) Benteibibel et al, Cancer discovery, 2019; Charych et al, PLOS One 2017 (3) Synthorx data (4) ✓✓ are a >2 fold increase, ✓ is ~1.5 fold increase For illustrative purposes. Table represents target profile. Not based on head to head data. Limited conclusions should be derived from this indirect comparison given the variability of study designs. Clinical relevance of these differences is still under investigation. Green check in table ✓ = attribute present; Red circle in table ○:attribute not present.

Compelling CD8 T-cell and NK cell expansion (AACR 2021)

HAMMER study

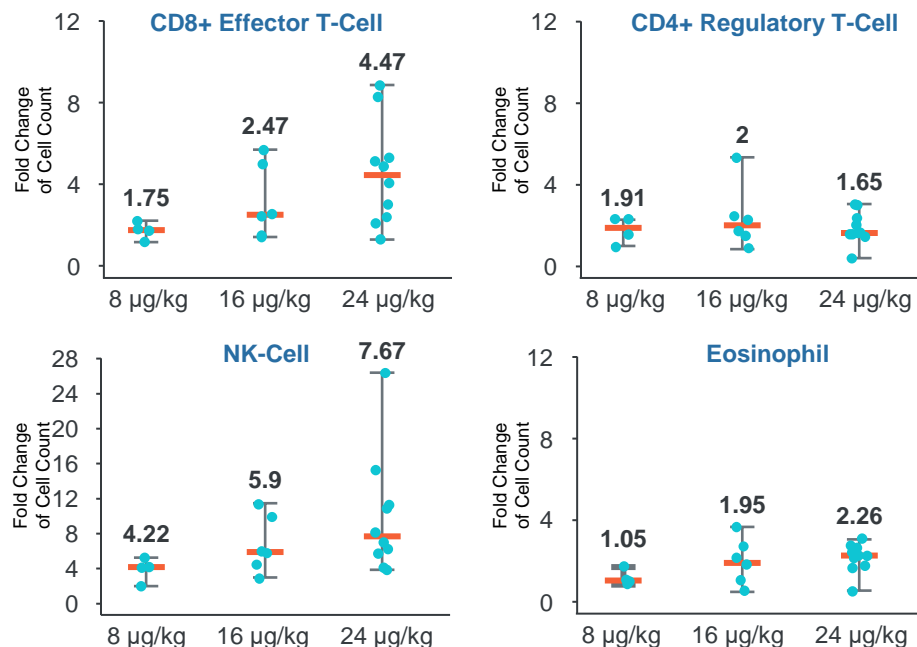
- Phase 1/2 open-label, dose escalation and dose expansion study of SAR'245
- Monotherapy and combination cohorts with advanced or metastatic solid tumors

No dose limiting toxicities^(1,2)

SAR'245 Dose level	# Evaluable / # Enrolled	# DLT
8 µg/kg		
Monotherapy Q2W	3/4	0
Monotherapy Q3W	3/4	0
+ pembrolizumab	4/4	0
16 µg/kg		
Monotherapy Q2W	2/3	0
Monotherapy Q3W	6/6	0
+ pembrolizumab	6/6	0
24 µg/kg		
Monotherapy Q3W	10/11	0

Dose dependent increase in CD8+ and NK Cells⁽¹⁾

Importantly, no increase in CD4+ Reg or eosinophils observed



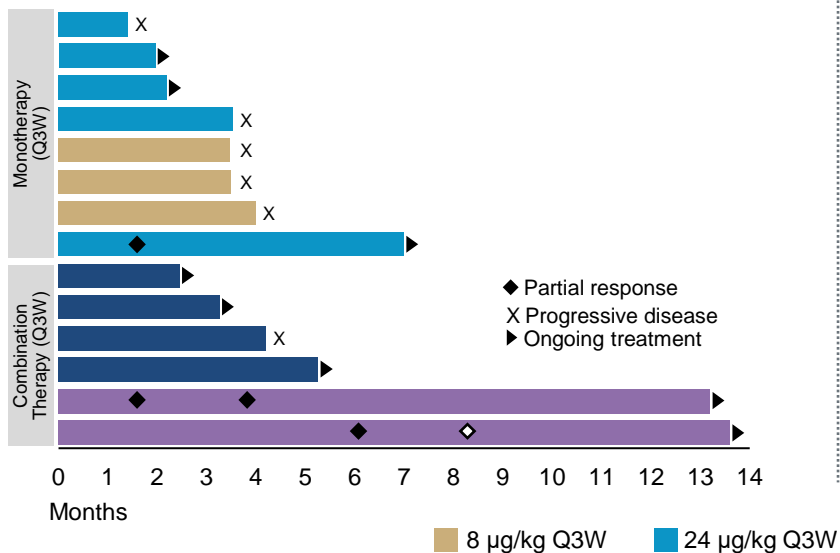
Sanofi and Merck entered into an agreement to conduct a Phase 2 clinical trial to evaluate the safety, pharmacokinetics, and preliminary efficacy of SAR'245, Sanofi will sponsor the clinical trial while Merck (MSD) will provide Keytruda® (pembrolizumab); SAR'245 is an asset under investigation, not approved by regulators, formerly known as THOR707; Q2W: every 2 weeks; Q3W: every 3 weeks

(1) Janku F. et al. Poster presented at AACR Virtual Annual Meeting 2021, April 10-15, 2021. Poster LB041, Q3 week dosing schedule

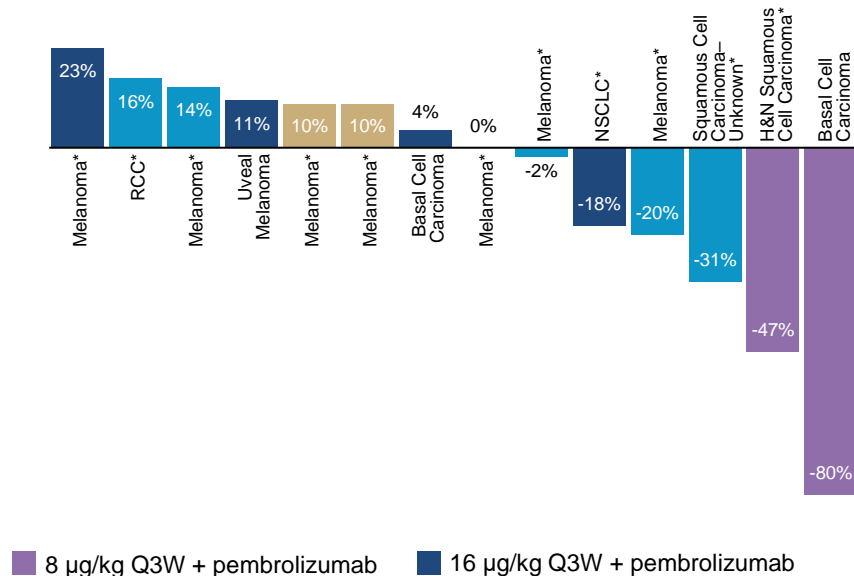
(2) Monotherapy 8 µg/kg and 16 µg/kg Q2W data on file

Early clinical responses as monotherapy and in combination (AACR 2021)

Partial responses in monotherapy and combination (1,2,3)



Three objective responses, two in patients not previously responding to PD-1 (1,2,3)

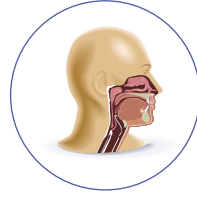
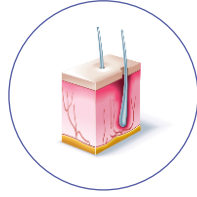


*PD-1 pre-treated patients. SAR'245 is an asset under investigation, not approved by regulators, formerly known as THOR707. Sanofi and Merck entered into an agreement to conduct a Phase 2 clinical trial to evaluate the safety, pharmacokinetics, and preliminary efficacy of SAR'245. Sanofi will sponsor the clinical trial while Merck (MSD) will provide Keytruda® (pembrolizumab);

(1) Janku F. et al. Poster presented at AACR Virtual Annual Meeting 2021, April 10-15, 2021. Poster LB041.

- (2) No response observed in 16 patients with colorectal (n=5), appendiceal, neuroendocrine PDL1-negative cervical, adrenocortical, urachal, and prostate cancers, cholangio-hepatoma, and various sarcomas (n=5)
- (3) No dose-limiting toxicity (DLT), no vascular leak syndrome (VLS) observed

Emerging data further support start of broad Phase 2 program



2 additional basket trials to start by end of 2021

Thoracic

Skin

Head and Neck

- Broad development program planned with monotherapy and combinations
- Combination trials with checkpoint inhibitors, ADCC competent antibodies and other I/O agents

Ambition to extend and strengthen immunotherapy in difficult to treat cancers



Thoracic

Non-small cell lung cancer

Indications

Experimental treatment

1L PD-1 naïve

SAR'245 + pembro

1L PD-1 naïve
(Non-Sq)

SAR'245 + pembro +
carbo-/cis-platin + pemetrexed

2-3L PD-1
Progressors

SAR'245 + pembro w / or w/
out nab-paclitaxel

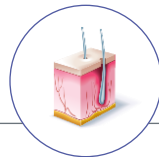
Mesothelioma

Indications

Experimental treatment

2-3L PD-1
naïve

SAR'245 + pembro



Skin

Melanoma

Indications

Experimental treatment

1L PD-1 naïve

SAR'245 + cemiplimab

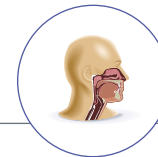
Cutaneous squamous cell carcinoma

Indications

Experimental treatment

1L PD-1 naïve

SAR'245 + cemiplimab



Head and Neck

Head and neck squamous cell carcinoma

Indications

Experimental treatment

1L PD-1 naïve
CPS>1

SAR'245 + pembro

1L PD-1 naïve
CPS>1

SAR'245 + pembro
+ cetuximab

2-3L PD-1
progressors

SAR'245 + pembro

2-3L cetuximab
naïve

SAR'245 + cetuximab



Conclusion

Dietmar Berger

Global Head of Development, CMO



Sanofi's ambition in oncology

1

Building on recent launches



- New indication in 2L MM (IKEMA) in U.S.⁽¹⁾ and EU⁽²⁾



- Approved in locally advanced or metastatic CSCC⁽³⁾, locally advanced BCC⁽⁴⁾ and 1L advanced NSCLC mono (PD-L1 \geq 50%)⁽⁵⁾
- Positive EMA CHMP opinion in 1L advanced NSCLC mono⁽⁶⁾ and 2L locally advanced or metastatic BCC⁽⁷⁾
- Overall survival benefit in 2L cervical cancer⁽⁸⁾

Libtayo® is in collaboration with Regeneron. Amcenestrant, tusamitamib ravtansine, and SAR'245 are assets under investigation, not approved by regulators

- (1) Sarclisa® was FDA approved in combination with carfilzomib and dexamethasone for patients with relapsed or refractory MM who have received 1-3 prior lines of therapy
- (2) Sarclisa® was EC approved in combination with carfilzomib and dexamethasone for the treatment of adult patients with relapsed MM who have received at least one prior therapy
- (3) Libtayo® was FDA approved for the treatment of patients with mCSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation.
- (4) Libtayo® was FDA approved for patients with locally advanced BCC previously treated with a

2

Next generation standard of care backbones

- **Amcenestrant**: potential best-in-class endocrine backbone across all lines of ER+ breast cancer
- **Tusamitamib ravtansine**: first-in-class CEACAM5 ADC
- **Non alpha IL-2 (SAR'245)**: potential best-in-class, future immuno-oncology backbone

3

Innovation driven by novel technologies

- Leveraging **existing platforms** of multi-specifics, nanobodies, ADC's and small molecules
- Expanding into **new platforms** in cell therapy and mRNA
- Exploring first-in-class **checkpoint inhibitors** and novel combinations

- (5) Libtayo® was FDA approved as monotherapy for patients with first-line advanced NSCLC with PD-L1 expression of \geq 50% with no EGFR, ALK, or ROS1 aberrations
- (6) CHMP positive opinion for first-line treatment of adults with metastatic or locally advanced disease that is not a candidate for definitive chemoradiation with PD-L1 expression \geq 50% with no EGFR, ALK or ROS1 aberrations
- (7) CHMP positive opinion for patients who have progressed on or are intolerant to a HHI
- (8) Libtayo® not yet licensed in cervical cancer, pivotal trial stopped early for positive result on overall survival

Q&A



John Reed

EVP, Global Head of R&D



Dietmar Berger

Global Head of Development, CMO



Frank Nestle

Global Head of Research, CSO



Peter Adamson

Global Oncology Development Head



Bill Sibold

EVP, Global Head of Specialty Care



Alexander Zehnder

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Chris Soria

Global Project Head, Amcenestrant