

Oncology Strategy and ASCO R&D event

We are just getting started

June 2, 2020



Forward looking statements

This presentation contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi's annual report on Form 20-F for the year ended December 31, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Agenda

Introduction	Paul Hudson	Chief Executive Officer	
Sanofi in Oncology	John Reed	Executive Vice President, Global Head of Research & Development	
Sarclisa®	Dietmar Berger	Senior Vice President, Global Head of Development, Chief Medical Officer	
Libtayo®	Alexander Zehnder	Global Franchise Head, Oncology	
Anti-CEACAM5 '701	Peter Adamson	Global Oncology Development Head	
SERD '859	Peter Adamson	Global Oncology Development Head	
Conclusion	John Reed	Executive Vice President, Global Head of Research & Development	
Q&A session			







Introduction

Paul Hudson

Chief Executive Officer



Our ambition in Oncology

-  Transform **strong science** into **commercial leadership**
-  Focus on **4 core areas** with ambition to shape **4 anchor assets into blockbusters**
-  Develop **novel combinations** to improve patients' outcomes
-  Position Sanofi as **partner of choice in selected areas** based on best-in-class backbones and leading platforms to generate first-in-class medicines

Ambition to shape 4 anchor assets into blockbusters

	Ambition	Current status	Blockbuster potential
Sarclisa®⁽¹⁾	Best-in-class profile in multiple myeloma	Approved with Pd for RRMM ⁽³⁾	Positive pivotal data with Kd in 2L+ RMM P3 (IKEMA) P3 in 1L Ti/Te MM ongoing SMM to be initiated ⁽⁴⁾
Libtayo®⁽²⁾	Serving larger patient populations with competitive profile	Approved in metastatic/locally advanced CSCC	Positive pivotal data in 1L NSCLC Positive pivotal data in 2L BCC Adjuvant CSCC P3 ongoing Backbone for novel combinations
Anti-CEACAM5 '701^(1,5)	First-in-class CEACAM5-targeting ADC for lung cancer	PoC data in CEACAM5+ 2L nsq NSCLC (single agent)	Pivotal P3 (fast-to-market) 2L CEACAM5+ NSCLC ongoing, PoC in earlier NSCLC lines and further CEACAM5+ tumors initiating
SERD '859^(1,5)	Best-in-class endocrine backbone for HR+ breast cancer	PoC data in 3L+ HR+ BC (single agent)	Pivotal P2b (fast-to-market) in 2L+ HR+ BC PoC combo and studies in earlier lines ongoing

 **SERD '859^(1,5)**
Priority asset

MM: multiple myeloma; RRMM: Relapsed/refractory multiple myeloma; TI: Transplant ineligible; Te: Transplant eligible; HR+: Hormone Receptor positive; CSCC: Cutaneous Squamous Cell Carcinoma; BCC: Basal Cell Carcinoma; NSCLC: Non-Small Cell Lung Cancer; SMM: Smoldering multiple myeloma; ADC: Antibody Drug Conjugate; BC: breast cancer; nsq: non-squamous; PoC: Proof of Concept, clinical and commercial evidence to initiate pivotal study

(1) Wholly owned assets (2) Libtayo® in collaboration with Regeneron - Sales are consolidated by Regeneron in the U.S and Sanofi ex U.S. (3) and ≥2 prior therapies, including lenalidomide and a proteasome inhibitor. Approved in the U.S., EU, Canada, Australia and Switzerland, indication in certain non-U.S. countries also includes disease progression on last therapy (4) These uses of isatuximab are investigational and have not been evaluated by any regulatory authority. (5) Anti-CEACAM5 '701 and SERD '859 not approved by the regulators

Momentum is building in Sanofi Oncology

March 2, 2020: Sarclisa® FDA Approval

FDA approves Sarclisa® (isatuximab-ctc) for patients with relapsed refractory multiple myeloma

- Sarclisa in combination with pomalidomide and dexamethasone (pom-dex) significantly reduced the risk of disease progression or death by 40% compared to pom-dex alone in a pivotal trial
- FDA approval based on data from the only randomized Phase 3 trial (ICARIA-MM) to evaluate an anti-CD38 in combination with pom-dex that has provided results to date
- Multiple myeloma is the second most common blood cancer affecting more than 100,000 patients in the U.S. approximately 32,000 Americans are diagnosed with multiple myeloma each year

PARIS – March 2, 2020 – The U.S. Food and Drug Administration (FDA) has approved Sarclisa® (isatuximab-ctc) in combination with pomalidomide and dexamethasone (pom-dex) for the treatment of adults with relapsed refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor. Sarclisa is expected to be available to patients in the U.S. shortly.

Sarclisa is a monoclonal antibody that binds to the CD38 receptor on multiple myeloma cells.

"Today's FDA approval of Sarclisa provides a new treatment option for patients with difficult-to-treat multiple myeloma. These are patients whose disease has returned or become refractory to their prior treatments," said Paul Hudson, Chief Executive Officer, Sanofi. "At Sanofi, we are focused on discovering and developing medicines that may change the prognosis of patients, and Sarclisa offers a potential new standard of care in the United States. We continue to invest in medicine, Sarclisa is a comprehensive disease program in multiple myeloma, as well as in other blood cancers and solid tumors."

Sarclisa Safety Profile and Efficacy in Difficult-to-Treat Patients

In the ICARIA-MM study, Sarclisa added to pom-dex (Sarclisa combination therapy) demonstrated a statistically significant improvement in progression-free survival (PFS) with a median PFS of 11.53 months compared to 8.47 months with pom-dex alone (OR 0.58; 95% CI: 0.44-0.81, p<0.001). In addition, Sarclisa combination therapy also demonstrated a significantly greater overall response rate compared to pom-dex alone (80.4% vs. 35.3%, p<0.001).

April 27, 2020: Libtayo® NSCLC 1624 Early Stop

Phase 3 trial of Libtayo® (cemiplimab) as monotherapy for first-line advanced non-small cell lung cancer stopped early due to high percentage improvement in overall survival

- Libtayo demonstrated the rate of death by 32.4% compared to chemotherapy
- Sanofi and Regeneron plan regulatory submissions in 2020

Paris and Tarrytown, NY – April 27, 2020 – Sanofi and Regeneron Pharmaceuticals, Inc. (NASDAQ:REGN) today announced the primary endpoint of overall survival (OS) was met in a Phase 3 trial comparing the PD-1 inhibitor Libtayo® (cemiplimab) to platinum doublet chemotherapy in patients with first-line locally advanced or metastatic non-small cell lung cancer (NSCLC) that tested positive for PD-L1 in ≥25% of tumor cells. Based on a recommendation by the Independent Data Monitoring Committee to stop the trial early, the trial will be modified to allow all patients to receive Libtayo for this investigational use.

The data will form the basis of regulatory submissions in the U.S. and European Union (EU) in 2020.

"While demonstrating a survival benefit in first-line NSCLC has been challenging for immunotherapies, the now FDA-approved anti-PD-1 monotherapy has changed the therapeutic paradigm," said George D. Yancopoulos, M.D., Ph.D., Co-Founder, President and Chief Scientific Officer of Regeneron. "We are pleased with the results of this trial that demonstrate the survival benefit of Libtayo in these patients and hope they become a potential alternative for physicians and patients."

A pre-specified interim analysis conducted by the IMDC demonstrated that patients treated with Libtayo monotherapy had a significant increase in OS. Libtayo doubled the rate of death by 32.4% (HR:0.67; 95% CI:0.52-0.87), p<0.001, compared to platinum doublet chemotherapy, despite a higher rate of patients dying the trial within the past six months and all chemotherapy patients being able to crossover to Libtayo if their disease progressed. No new Libtayo safety signals were identified. Detailed trial data will be presented at a future medical meeting.

"This is the largest clinical trial evaluating a PD-1 inhibitor as a first-line monotherapy in patients with advanced non-small cell lung cancer with high PD-L1 expression. The positive results are extremely encouraging, and we look forward to advancing a potential new standard of care for these patients," said David M. Golden, M.D., Ph.D., Chief Medical Officer of Regeneron.

May 5, 2020: Libtayo® BCC Pivotal Trial

Libtayo® (cemiplimab) shows clinically meaningful and durable responses in second-line advanced basal cell carcinoma

- Objective responses seen in 29% of patients with locally advanced basal cell carcinoma (BCC)
- In a preliminary analysis, objective responses seen in 21% of patients with metastatic BCC
- An estimated 85% of patients who responded to Libtayo maintained their response for at least one year
- Sanofi and Regeneron plan regulatory submissions in 2020

Paris and Tarrytown, NY – May 5, 2020 – Today's data for a pivotal, single-arm, open-label for Sanofi and Regeneron's PD-1 inhibitor Libtayo® (cemiplimab) in patients with first-line basal cell carcinoma (BCC) who had progressed on or were intolerant to prior genotoxic therapy (GTT) therapy were announced today. Libtayo demonstrated statistically meaningful and durable responses in this population of patients for whom there are no treatment options. Sanofi and Regeneron plan regulatory submissions in 2020.

"BCC is a skin cancer and is the most common cancer worldwide, with approximately two new skin cancers diagnosed in the U.S. alone every year. While the vast majority of BCCs are caught early and cured with surgery or radiation, a small proportion of tumors can be advanced and sometimes become life-threatening lesions locally advanced, which are difficult to treat. Approximately 20,000 U.S. patients have advanced BCC and it is believed that about 3,000 die each year. BCC makes the second non-melanoma skin cancer for which Libtayo has demonstrated first-in-class data and follows the initial U.S. trial in advanced cutaneous squamous cell carcinoma (cSCC) in 2018.

In this trial, the objective response rate (ORR) for patients (n=64) with locally advanced BCC was 29% (95% CI: 19%-40%), with an estimated duration of response (DOR) being one year in 85% of responders. The durable disease control rate (DCR – time or stable disease lasting at least 6 months) was 60% (95% CI: 48%-70%). In a primary analysis of patients (n=98) with metastatic disease, the ORR was 21% (95% CI: 13%-30%), with an estimated DOR exceeding one year in 65% of responders. The DCR was 48% (95% CI: 28%-68%). All data were assessed by an independent trial review. Data are expected to continue to evolve with further follow-up against both endpoints.

"This is the largest clinical trial evaluating a PD-1 inhibitor as a first-line monotherapy in patients with advanced non-small cell lung cancer with high PD-L1 expression. The positive results are extremely encouraging, and we look forward to advancing a potential new standard of care for these patients," said David M. Golden, M.D., Ph.D., Chief Medical Officer of Regeneron.

May 12, 2020: Sarclisa® IKEMA Early Achievement of Primary Endpoint

Sarclisa® (isatuximab) Phase 3 IKEMA trial meets primary endpoint early in patients with relapsed multiple myeloma

- IKEMA trial results released early based on recommendation of an Independent Data Monitoring Committee
- Addition of Sarclisa significantly reduced the risk of disease progression or death compared to carfilzomib and dexamethasone alone
- Results will be submitted to an upcoming medical meeting and on the basis for regulatory submissions later this year

IRIS – May 12, 2020 – The Phase 3 IKEMA clinical trial evaluating Sarclisa® (isatuximab) added to carfilzomib and dexamethasone met the primary endpoint of its first interim analysis, demonstrating significantly prolonged progression-free survival (PFS) compared to standard of care carfilzomib and dexamethasone alone in patients with relapsed multiple myeloma. There were no new safety signals identified in this study.

"When Sarclisa was added to standard-of-care treatment carfilzomib and dexamethasone in this phase 3 trial, results clearly demonstrated a significant reduction in risk of disease progression or death," said John Reed, M.D., Ph.D., Global Head of Research and Development at Sanofi. "This is the second positive phase 3 trial for Sarclisa, further supporting the potential our medicine has to improve outcomes for patients struggling with relapsed multiple myeloma."

Results will be submitted to an upcoming medical meeting and are anticipated to form the basis of regulatory submissions planned for later this year.

In this randomized, multi-center, open label Phase 3 IKEMA clinical trial enrolled 302 patients with relapsed multiple myeloma across 68 centers spanning 15 countries. All 68 participants received one to three prior anti-myeloma therapies. During the trial, 65% was administered (through an intravenous infusion at a dose of 10mg/kg) on

June 2, 2020: Sarclisa® IKEMA EHA Late Breaker

Sarclisa® (isatuximab) combination therapy demonstrated superior progression free survival and clinically meaningful depth of response in patients with relapsed multiple myeloma

- Sarclisa added to carfilzomib and dexamethasone (Sarclisa combination) reduced risk of disease progression or death by 47% versus standard of care carfilzomib and dexamethasone (po-dex) alone
- Sarclisa combination therapy delivered considerable depth of response, with undetectable levels of multiple myeloma (MM) in nearly 30% of patients with relapsed MM (MPO-negative 19th sensitivity)
- Results from first planned interim analysis of the Phase 3 IKEMA trial selected as late-breaking presentation at EHA25 Virtual Congress

June 2, 2020 – Sarclisa® (isatuximab) added to carfilzomib and dexamethasone (Sarclisa combination therapy) reduced the risk of disease progression or death by 47% (p<0.001) compared to standard of care carfilzomib and dexamethasone (po-dex) in patients (n=320) with relapsed multiple myeloma (MM). Sarclisa combination therapy compared to po-dex alone showed a treatment benefit in terms across multiple subgroups.

Results from the Phase 3 IKEMA trial follow the topline announcement on May 12, that Sarclisa combination therapy met the trial primary endpoint at the pre-planned interim analysis. Interim results will be presented during the late-breaking session of the 25th European Hematology Association (EHA) Virtual Congress (EHA25) on June 14, 2020 on the basis for global regulatory submissions later this year.

In the Phase 3 IKEMA trial, the addition of Sarclisa to carfilzomib and dexamethasone reduced the risk of disease progression or death by 47% compared to treatment with carfilzomib and dexamethasone alone, said Philippe Moreau, M.D., Department of Hematology, Université Hospital of Nantes, France. "These results suggest the potential of Sarclisa to become a new standard of care in relapsed multiple myeloma."

A median progression free survival (PFS), defined as time to disease progression or death, for KD was 19.15 months, the median PFS for patients receiving Sarclisa combination therapy had not been reached at the time of the pre-planned interim analysis. Safety and tolerability of Sarclisa observed in this trial was consistent with the need safety profile of Sarclisa in other clinical trials, with no new safety signals

June 2, 2020: Sarclisa® EU Approval

European Commission approves Sarclisa® (isatuximab) for adults with relapsed and refractory multiple myeloma

EC approval based on data from first randomized Phase 3 trial (ICARIA-MM) to report results evaluating an anti-CD38 monoclonal antibody combined with pomalidomide and dexamethasone (pom-dex) Sarclisa in combination with pom-dex significantly reduced the risk of progression or death by 40% versus pom-dex alone Multiple myeloma is the second most common blood cancer, with approximately 40,000 new cases per year in Europe

June 2, 2020 – The European Commission (EC) has approved Sarclisa® (isatuximab-ctc) in combination with pomalidomide and dexamethasone (pom-dex) for the treatment of adults with relapsed and refractory multiple myeloma (MM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor demonstrated disease progression on the last therapy.

Sarclisa is a monoclonal antibody (mAb) that binds to a specific epitope on the CD38 (CD38) cells.

"EC approval of Sarclisa represents an important additional therapeutic option (may set a new standard of care for myeloma patients in Europe who are in line of new effective treatments because their disease has returned or they have time refractory to their previous treatment," said John Reed, M.D., Ph.D., Global Head of Research and Development at Sanofi. "Sarclisa in combination with pom-dex demonstrated median progression-free survival of nearly one year, a 47% improvement over pom-dex alone, in patients who had already failed at prior therapies."

Efficacy and Safety Profile in Difficult-to-Treat Patients

In the ICARIA-MM study, Sarclisa added to pom-dex (Sarclisa combination therapy) demonstrated a statistically significant improvement of progression-free survival (PFS) with a median PFS of 11.53 months compared to 8.47 months with pom-dex alone (OR 0.58; 95% CI: 0.44-0.81, p<0.001). Sarclisa combination therapy demonstrated a significantly greater overall response rate compared to pom-dex (80.4% vs. 35.3%, p<0.001). In additional analyses, Sarclisa combination therapy to pom-dex alone showed a treatment benefit consistent across select reflective of real-world practice, including patients with high risk cytogenetics.



Sanofi in Oncology

John Reed

**Executive Vice President, Global Head of
Research & Development**



Strengthening our organization with world-class talents



Yong-Jun Liu

**Global Research
Head**

Founder of MDACC
Cancer Immunology
Research Institute,
Research Head at
Medimmune

Started in **2016**



Alexander Zehnder

**Global Franchise
Head, Oncology**

Former Head of
Avastin franchise at
Roche/Genentech,
Head of Sanofi Italy

Started in **2018**



Nahid Latif

**Oncology
Regulatory Head**

Former Executive
Director, Oncology
Regulatory Affairs at
Merck & Co, Sr.
Director Regulatory
Affairs at AbbVie

Started in **2018**



Dietmar Berger

**Global
Development Head**

Former Global Clinical
Development Head,
Hematology/Oncology,
at Roche/Genentech

Started in **2019**



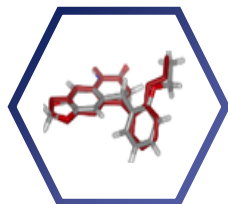
Peter Adamson

**Global Oncology
Development Head**

Member of U.S.
National Cancer
Advisory Board, former
Chair of Children's
Oncology Group

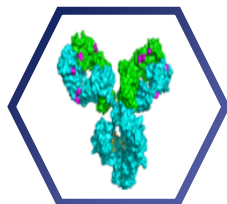
Started in **2020**

Sanofi platforms for Oncology drug discovery



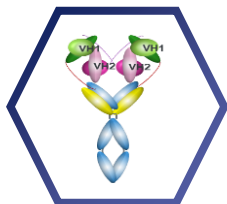
Small molecules

▼
SERD '859
SHP2i⁽¹⁾
...



Monoclonal antibodies

▼
Sarclisa®
Libtayo®⁽²⁾
Anti-TGFb
...

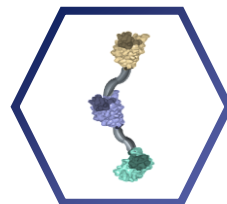


Bi-specific antibodies

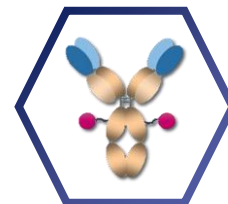


Tri-specific antibodies

▼
T-cells engagers
NK-cells engagers
...

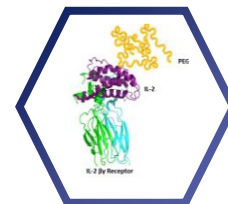


Nanobodies



Antibody Drug Conjugates

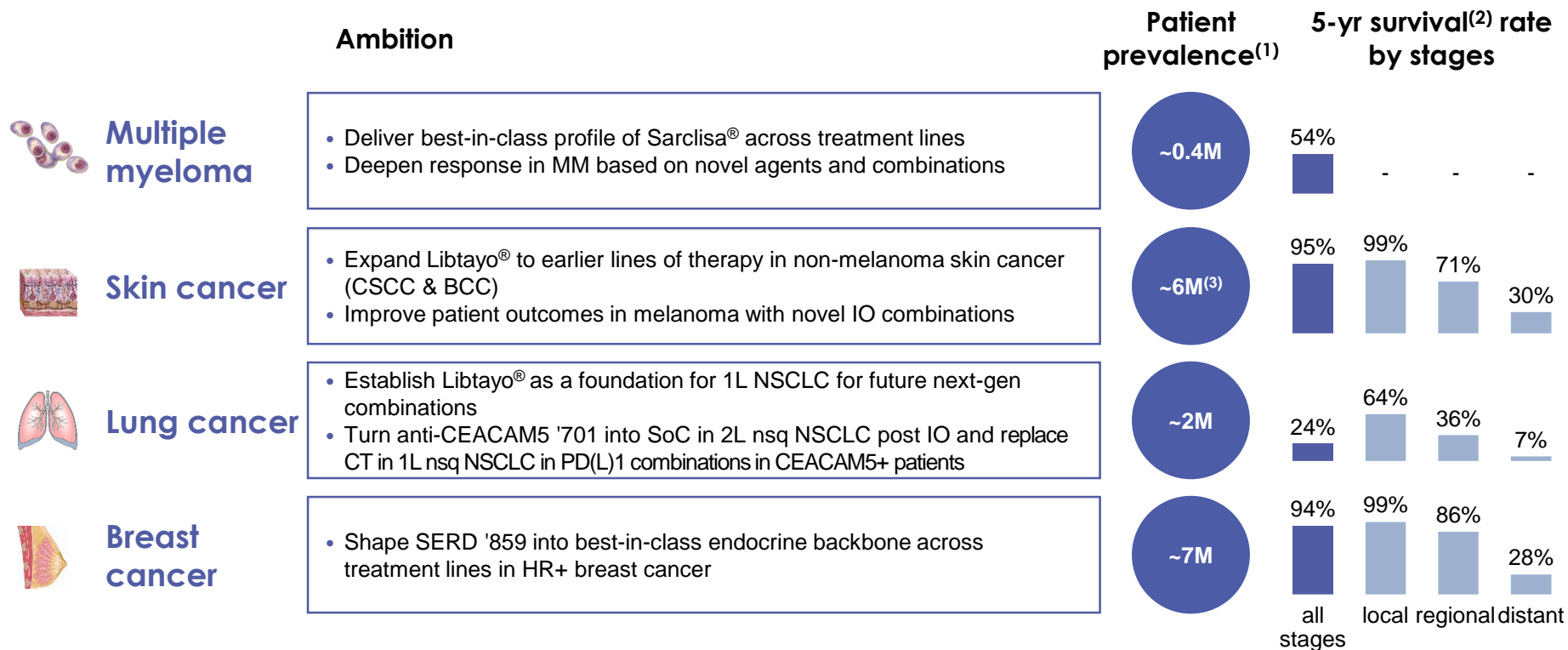
▼
Anti-CEACAM5
'701
...



Synthorins

▼
THOR707
...

Step #1: Lay a foundation with anchor assets in 4 oncology disease indications

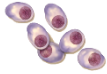
















MM: multiple myeloma; IO: Immuno-Oncology; CT: Chemotherapy; CSCC: Cutaneous Squamous Cell Carcinoma; BCC: Basal Cell Carcinoma; NSCLC: Non-Small Cell Lung Cancer; HR+:

Hormone Receptor positive; SoC: Standard of Care

(1) 5-year prevalence, worldwide, 2018. Source: International agency for research on cancer (2) Surveillance, Epidemiology, and End Results (SEER) Program (3) Prevalence of ~1M for melanoma, ~5M for non-melanoma

Step #2: Build on the foundational assets with potential best-in-disease combinations

	Marketed (€1.7bn sales in '19)	Late stage	Early stage	Pre-clinical
 <p>Multiple myeloma & other blood cancers</p>	 <p>SARCLISA (isatuximab-irfc)</p>		<ul style="list-style-type: none"> • TGFb 	<p>~15 NMEs with first-in-class or best-in-class potential poised to enter clinical development in the next two years</p>
 <p>Skin cancer</p>	 <p>LIBTAYO⁽¹⁾ (cemiplimab-rwic) Regeneron</p>		<ul style="list-style-type: none"> • CD123-CD3 • SHP2i⁽²⁾ 	
 <p>Lung cancer</p>	 <p>AXOTERE (docetaxel)</p>	<ul style="list-style-type: none"> • Libtayo[®]⁽¹⁾ • Anti-CEACAM5 '701 	<ul style="list-style-type: none"> • THOR-707 	
 <p>Breast cancer & other hormone positive cancers</p>	 <p>AXOTERE (docetaxel)</p>	<ul style="list-style-type: none"> • SERD '859 	<ul style="list-style-type: none"> • Cytokine mRNA⁽³⁾ • CD38-CD28-CD3 	
<p>Other</p>	  		<ul style="list-style-type: none"> • CD38 ADCC 	 Anchor program
	  			

Sanofi Oncology portfolio: selected studies

Asset	Mechanism of Action	PoP		PoC	
		First in Human	Post Proof of Principle trial	Pivotal study	
Sarclisa®	Anti-CD38 mAb	ICARIA: multiple myeloma – 3L+ RRMM			
		IKEMA: multiple myeloma – 2L+ RMM			
		GMMG - multiple myeloma - 1L NDMM Te - Induction & Maintenance			
		IMROZ - multiple myeloma - 1L NDMM Ti			
		ITHACA - Smoldering multiple myeloma - High-Risk			
		Acute Myelogenous Leukemia/Acute Lymphoblastic Leukemia (T&B) - 1-2L Monotherapy			
		SC administration			
Libtayo®(1)	Anti-PD-1	2L BCC - locally advanced			
		2L BCC - metastatic			
		1L NSCLC - monotherapy			
		1L NSCLC - chemotherapy combo			
		2L Cervical Cancer			
		CSCC Adjuvant			
		CSCC Neo-Adjuvant(2)			
Anti-CEACAM5 '701	Maytansin loaded anti-CEACAM5 mAb	CARMEN-LC03 - NSCLC - monotherapy 2/3L			
		CARMEN-LC04 - NSCLC - ramucirumab combination 2/3L			
		CARMEN-LC05 - NSCLC - pembrolizumab combination 1L			
		mBC & Pancreatic cancer - basket study			
SERD '859	SERD	AMEERA-3 - HR+ mBC 2/3L monotherapy			
		AMEERA-1 - CDK4/6i and Pi3Ki combos			
		AMEERA-5 - 1L HR+ mBC combo with CDK4/6			
		AMEERA-4 - Early HR+ BC			
SAR439459	TGFb inhibition mAb	Advanced Solid Tumors (monotherapy & combo)			
SAR440234	T-cell engaging bispecific (CD3/CD123) Ab	Leukemia			
SAR441000	Cytokine mRNA(1)	Solid Tumors (monotherapy & combo)			
SAR442257	Anti-CD3/CD28/CD38 Trispecific mAb	Multiple myeloma			Study completed or primary endpoint achieved
SAR442085	Anti-CD38 mAb Fc engineered	Multiple myeloma			Study in progress
SAR442720	SHP2 inhibitor(1)	Solid Tumors (monotherapy & combo)			Study planned
SAR444245/THOR707	Not-alpha IL-2	Solid Tumors (monotherapy & combo)			

PoP: Proof of Principle, early clinical evidence; PoC: Proof of Concept, clinical and commercial evidence to initiate pivotal study; BC: breast cancer; RRMM: Relapsed/Refractory multiple myeloma; NDMM: Newly Diagnosed multiple myeloma; SC: Sub-cutaneous; CSCC: Squamous cell skin cancer; BCC: Basal Cell Carcinoma; NSCLC: Non-small-cell lung carcinoma; mBC: metastatic Breast cancer; HR+: hormone receptor positive; CDK: cyclin-dependent kinases; Pi3Ki: phosphoinositide 3-kinase inhibitor. Other than the approved Sarclisa® + Pd indications listed on slide 6 in certain countries, these uses of isatuximab, including any SC use of isatuximab, are investigational and have not been evaluated by any regulatory authority

(1) In collaboration with external partners (2) Pilot study – Non registration



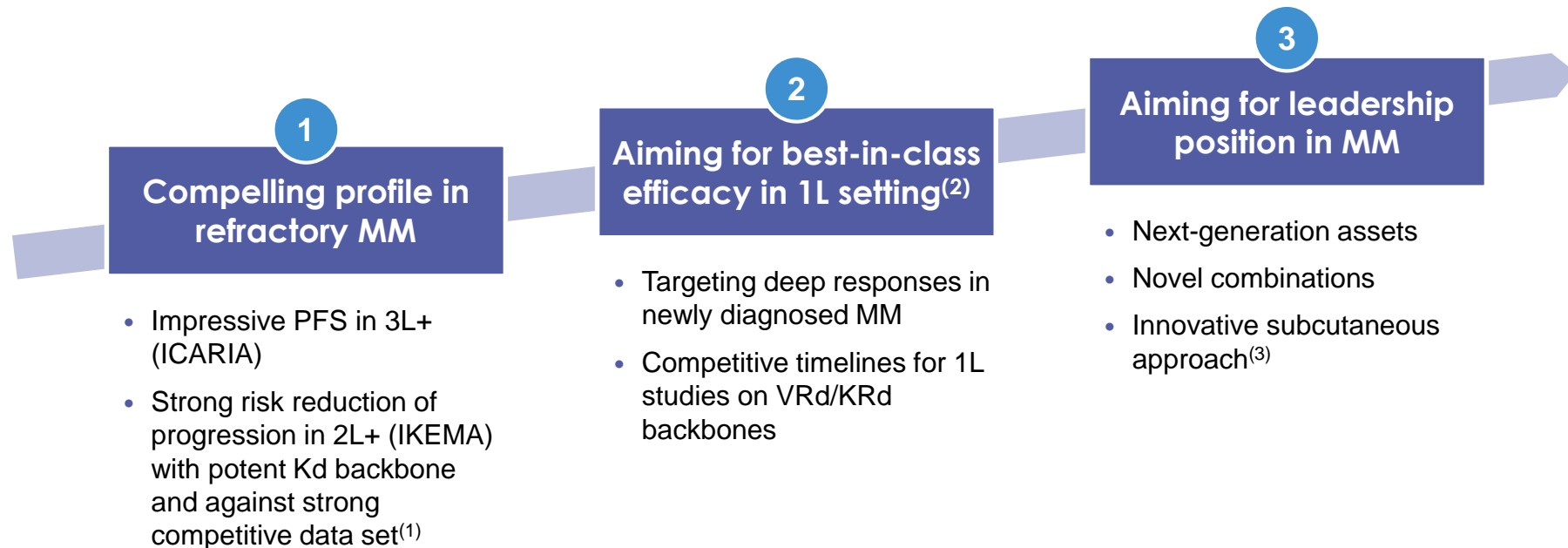
Sarclisa[®]
**Ambition: Best-in-class profile in
multiple myeloma**

Dietmar Berger

Senior Vice President, Global Head of
Development, Chief Medical Officer



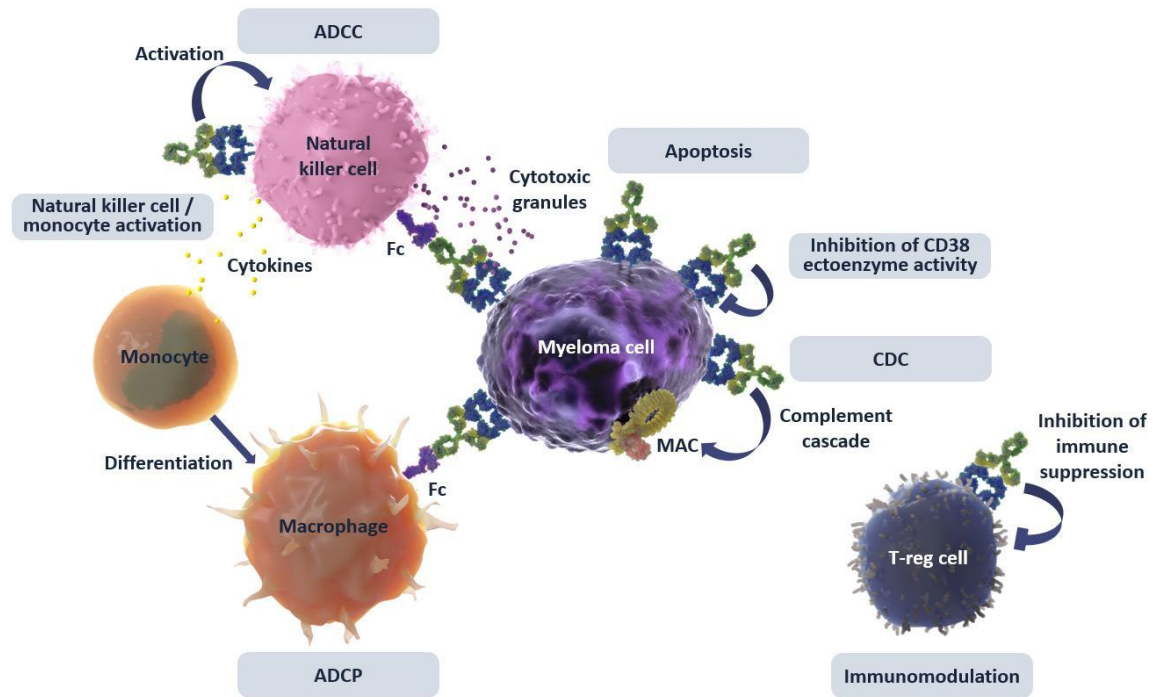
Sarclisa[®]: Emerging best-in-class profile



PFS: Progression-Free Survival; MM: multiple myeloma; Kd: carfilzomib and dexamethasone; VRd: bortezomib, lenalidomide and dexamethasone; KRd: carfilzomib, lenalidomide and dexamethasone

(1) Use of isatuximab with Kd is investigational and has not been evaluated by any regulatory authority; no cross trial comparisons of efficacy should be made; statement expresses Sanofi's expectation that if approved for use in combination with Kd, Sarclisa will be competitive in the market. (2) Uses of isatuximab 1L is investigational and has not been evaluated by any regulatory authority (3) Subcutaneous use of isatuximab is investigational and has not been evaluated by any regulatory authority

Sarclisa®: Anti-CD38 mAb with differentiated profile⁽¹⁾

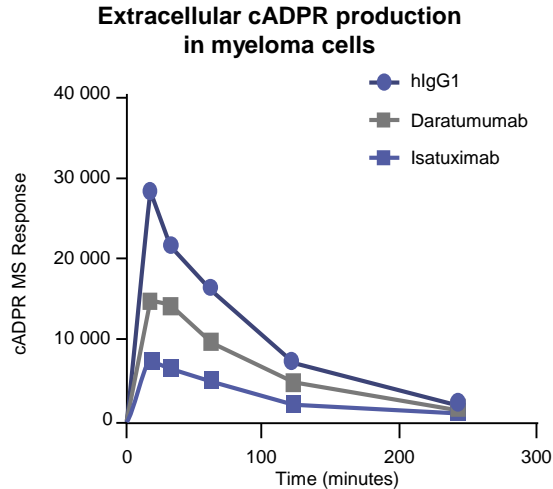


Sarclisa® targets a different epitope than daratumumab and has demonstrated **multiple mechanisms of actions**^(1,2,3)

- ADCC, CDC and ADPC
- Inhibition of CD38 ectoenzyme activity
- Immunomodulation
- Direct apoptosis

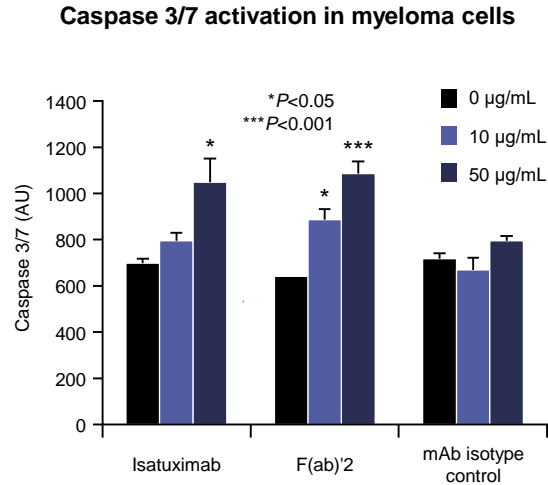
Preclinical data support differentiated profile

Significant inhibition of CD38 ectoenzyme activity⁽¹⁾



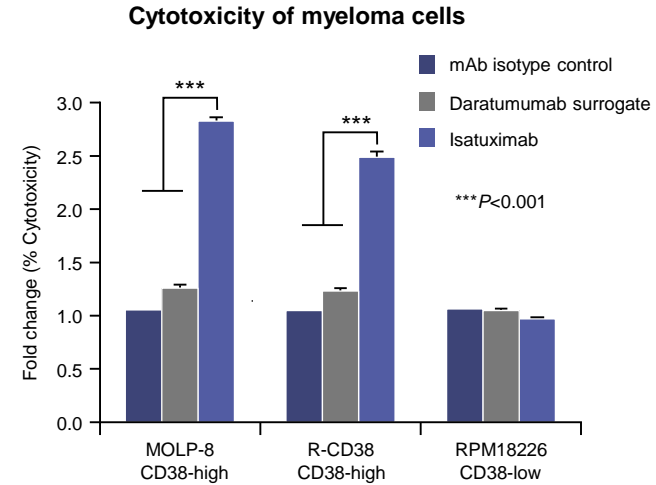
CD38 thought to be dominant enzyme for the generation of adenosine (immuno-suppressive in bone marrow of MM patients)

Apoptotic activity in the absence of cross-linking^(2,3)



Isatuximab directly inducing apoptosis of MM cells without requiring Fc-cross-linking agents

Cytotoxicity in the absence of effector cells⁽²⁾



Isatuximab inducing direct cytotoxicity against CD38+ myeloma cell lines in the absence of effector cells

AU, arbitrary units; (c)ADPR, (cyclic) adenosine diphosphoribose
mAb, monoclonal antibody; MM, multiple myeloma; MS, mass spectrometer; NAD nicotinamide adenine dinucleotide

(1) Zhang B, et al. Presented at: AACR; April 5–9, 2014; San Diego, CA (2) Jiang H, et al. Leukemia. 2016;30:399–408 (3) Overdijk MB, et al. J Immunol. 2016;197:807–13

Note: the information on this slide is for the purpose of illustrating Sarclisa®'s differentiated MOAs. No conclusions should be drawn regarding the clinical efficacy of Sarclisa® alone or in comparison to any other product. No head to head studies have been conducted comparing the clinical efficacy Sarclisa® with any of the products listed on this slide

ICARIA displayed 11.5 months PFS for Sarclisa® in RRMM with at least 2 prior lines of treatment

	ICARIA		EQUULEUS ^(2,5)	ELOQUENT-3 ⁽³⁾	
	Isa-Pd	Pd	Dara-Pd	Elo-Pd	Pd
Design & patient characteristics					
Phase	3	3	1b	2	2
Patients in trial	N=154	N=153	N=103	N=60	N=57
Prior lines of therapy (Line: n%)	2-3: 66%; 4+: 34%	2-3: 66%; 4+: 34%	1-3: 48%; 4+: 52%	2-3: 60%; 4+: 40%	2-3: 63%; 4+: 37%
Efficacy⁽¹⁾					
Median PFS, mo (95% CI)	11.5 (8.9-13.9)	6.5 (3.6-4.7)	8.8 (4.6-15.4)	10.3 (5.6-NR)	4.7 (2.8-7.2)
Hazard Ratio (95% CI)	0.596 (0.436-0.814)		-	0.54 (0.34-0.86)	
Safety					
TEAE Gr 3-4	85%	71%	99%	57%	60%
Discontinuation Rate due to AEs	7%	9%	13% ⁽⁴⁾	18%	24%

RRMM: Relapsed/refractory multiple myeloma; Pd: pomalidomide and dexamethasone; PFS: Progression Free Survival; AE: Adverse event; TEAE: Treatment Emergent Adverse Event
 (1) Overall Response Rate: Isa-Pd (60.4%), Pd (35.3%), Dara-Pd (60%), Elo-Pd (53.3%) (2) Chari A, et al. Blood. 2017;130:974-981 (3) Dimopoulos MA, et al. N Engl J Med. 2018;379:1811-22 (4) U.S. Prescribing Information (5) EQUULEUS was a single arm study. The primary endpoint was safety. ORR and MRD were secondary endpoints. The PFS of daratumumab has been studied in phase 3 trials with other backbone combinations.

Note: No head to head studies have been conducted comparing the safety or efficacy of Sarclisa® with daratumumab or elotuzumab. The information on this slide is for the purpose of illustrating Sanofi's expectation that Sarclisa® will be competitive in the market. The studies listed on this slide involve different study designs, endpoints and patient populations, and no inferences of clinical superiority should be made.

IKEMA met primary endpoint early

Patient characteristics

- **N = 302**
 - Isa-Kd: N=179
Median age 65 (37–86)
 - Kd: N=123
Median age 63 (33-90)
- **Number of prior lines:**
 - 1: 44% Isa-Kd; 45% Kd
 - 2+: 56% Isa-Kd; 55% Kd

	Results	Isa-Kd	Kd
	PFS HR	0.53 (0.32-0.89, p=0.0007)	
	mPFS	Not reached	19.15m
Efficacy	ORR	87%	83%
	≥ VGPR	73%	56%
	≥ CR	40%	28%
	MRD-Neg (10⁻⁵, ITT)	30%	13%
Safety profile ⁽¹⁾	Median exposure	80w	61w
	Grade ≥3 TEAEs	77%	67%
	Fatal TEAEs	3%	3%
	Discont. due to TEAEs	9%	14%

Full results to be presented at EHA

ITT: intention-to-treat; Kd: carfilzomib and dexamethasone; HR: Hazard Ratio; PFS: Progression Free Survival; TEAE: Treatment Emergent Adverse Event; ORR: Overall Response Rate; CR: Complete Response; VGPR: Very good partial response

(1) Median duration of follow up: 20.7 months

Note: Use of isatuximab with Kd is investigational and has not been evaluated by any regulatory authority.

Reminder of CANDOR⁽¹⁾ results

Patient characteristics

- **N = 466**
 - Dara-Kd: N=312
Median age 64 (29–84)
 - Kd: N=154
Median age 65 (35-84)
- **Number of prior lines:**
 - 1: 46%
 - 2+: 54%

	Results	Dara-Kd	Kd
	PFS HR	0.63 (0.45-0.86, p=0.0014)	
	mPFS	Not reached	15,8m
Efficacy	ORR	84%	75%
	≥ VGPR	69%	49%
	≥ CR	29%	10%
	MRD-Neg (10⁻⁵, ITT)	18%	4%
Safety profile ⁽²⁾	Median exposure	68w	40w
	Grade ≥3 TEAEs	82%	74%
	Fatal TEAEs	10%	5%
	Discont. due to TEAEs	22%	25%

Dara: daratumumab; ITT: intention-to-treat; Kd: carfilzomib and dexamethasone; HR: Hazard Ratio; PFS: Progression Free Survival; TEAE: Treatment Emergent Adverse Event; ORR: Overall Response Rate; CR: Complete Response; VGPR: Very good partial response

(1) CANDOR (NCT03158688) is a randomized phase III study comparing the combination of daratumumab + Kd to Kd alone in patients with RRMM

(2) Median duration of follow up: 17.1m-17.2 months

Note: no head to head studies have been conducted comparing the safety and efficacy of Sarclisa® plus Kd against daratumumab plus Kd. The information on this slide is for the purpose of illustrating Sanofi's expectation that Sarclisa® will be competitive in the market if approved for use with Kd. CANDOR and IKEMA involve different study designs and patient populations, and no implications of clinical superiority should be made from this slide period.

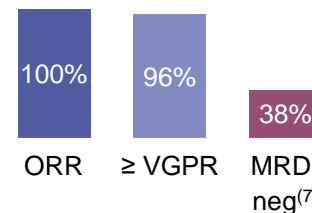
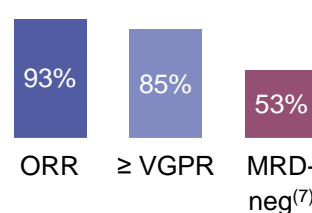
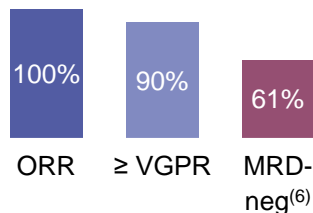
Sarclisa® in newly diagnosed MM: early promising results for Isa-KRd and Isa-VCd/VRd quadruplets

Isa-KRd regimen⁽¹⁾ (CONCEPT-GMMG)

Isa-VCd regimen^(3,4)

Isa-VRd regimen^(3,5)

★ Selected for the "Highlights of the day" session at ASCO



N = 153 adult patients with newly diagnosed MM and high-risk disease⁽²⁾

- N = 117 transplant-eligible (Te)
- N = 36 transplant-ineligible (Ti)

Interim analysis on induction (6 cycles) reporting on N = 50 patients

- N = 46 Te patients
- N = 4 Ti patients



EMN ph3 study: Isa-KRd in 1L Te

N = 44 adult patients with newly diagnosed MM and transplant-ineligible (Ti)

- N = 17 on Isa-VCd
- N = 27 on Isa-VRd

Expansion cohort of 46 patients with no intent for immediate ASCT (not included in analysis below)



IMROZ ph3 study: Isa-VRd in 1L Ti
GMMG ph3 study: Isa-VRd in 1L Te

ORR: Overall Response Rate; MRD: Minimal Residual Disease, at sensitivity level of 10⁻⁵; VGPR: Very good partial response; VRd: bortezomib, lenalidomide and dexamethasone; KRd: carfilzomib, lenalidomide and dexamethasone; VCd: bortezomib, cyclophosphamide, and dexamethasone

(1) ASCO abstract number 8508 (2) Defined as ISS stage 2 or 3 and [Del (17p) or t(4;14) or t(14;16) or > 3 copies 1q21] (3) ASCO abstract number 8529 (4) Results of 15 efficacy-evaluable patients (5) Results of 26 efficacy-evaluable patients (6) MRD evaluable (7) Intention-to-treat analysis.

Note: use of isatuximab in these studies are investigational and has not been evaluated by any regulatory authority

Expanding Sarclisa® to early lines with competitive timelines

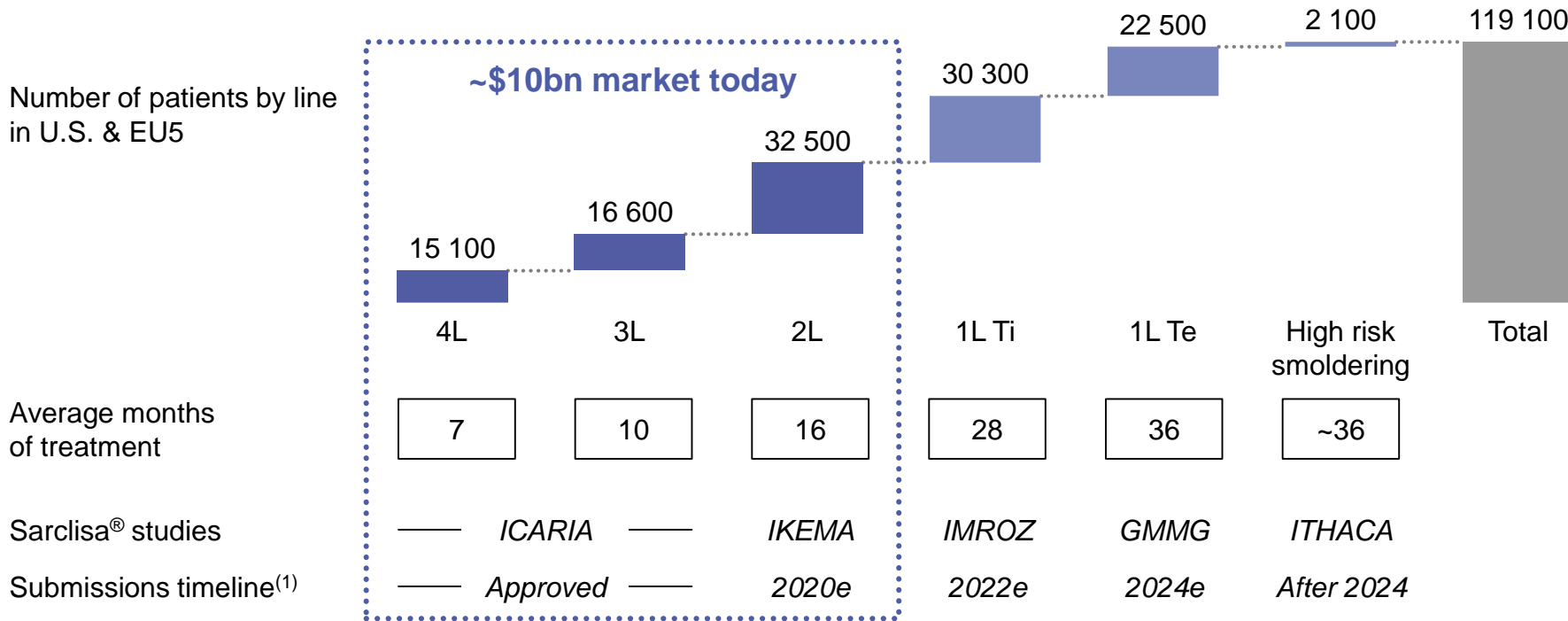
Study	Arm	Line	Study initiation	Headline results/ primary completion
ICARIA	Isa-Pd vs. Pd	3L+	H2 2016	H1 2019
IKEMA	Isa-Kd vs. Kd	2L+	H2 2017	H1 2020
IMROZ	Isa-VRd vs. VRd	1L Ti	H2 2017	2022e
GMMG	Isa-VRd vs. VRd	1L Te	H2 2018	2024e
EMN	Isa-KRd vs. KRd	1L Te	H2 2020	-
ITHACA	Isa-Rd vs Rd	High risk smoldering	Q2 2020	After 2024

*Potential
future SoC
backbone*

No CD38 VRd or KRd-based quadruplets approved for newly diagnosed multiple myeloma

Pd: pomalidomide and dexamethasone; Kd: carfilzomib and dexamethasone; VRd: bortezomib, lenalidomide and dexamethasone; KRd: carfilzomib, lenalidomide and dexamethasone; Rd: lenalidomide and dexamethasone; SoC: Standard of Care
Other than the approved Sarclisa® + Pd indications listed on slide 6 in certain countries, these uses of isatuximab, including any SC use of isatuximab, are investigational and have not been evaluated by any regulatory authority

Sarclisa®: Attractive 2L+ opportunity with the ambition to compete in the significantly larger 1L setting



(1) Based on PFS

Other than the approved Sarclisa® + Pd indications listed on slide 6 in certain countries, these uses of isatuximab, including any SC use of isatuximab, are investigational and have not been evaluated by any regulatory authority

Source: Decision Resources Group, 2019; Sanofi data

Sarclisa[®]: Building leadership position in multiple myeloma

Exploring novel combinations

- Bi-specifics
- TGFb
- THOR707



Subcutaneous
patient-centric delivery⁽¹⁾

Next-generation assets

- **Enhanced antibody-dependent cellular cytotoxicity:**
Fc engineered anti CD38
- **First-in-class tri-specific:**
Anti CD38-CD28-CD3

Sarclisa®: Summary

Ambition: Best-in-class profile

- > Differentiated Mechanism of Action
- > 11.5m PFS in 3L+ patients (ICARIA)
- > Strong risk reduction of progression in 2L setting (47%), on top of Kd standard of care backbone (IKEMA)
- > Promising early results in newly diagnosed MM with gold standard of care (KRd, VRd, VCd); competitive timelines in 1L Ti & 1L Te in VRd combos; initiating phase 3 in high-risk smoldering multiple myeloma
- > Aspiring for leadership position in multiple myeloma with next generation molecules and novel combinations

PFS: Progression free survival; MRD: Minimal Residual Disease; VRd: bortezomib, lenalidomide and dexamethasone; Kd: carfilzomib dexamethasone, KRd: carfilzomib, lenalidomide and dexamethasone; VCd: bortezomib, cyclophosphamide, and dexamethasone; SoC: Standard of Care

Other than the approved Sarclisa® + Pd indications listed on slide 6 in certain countries, these uses of isatuximab, including any SC use of isatuximab, are investigational and have not been evaluated by any regulatory authority



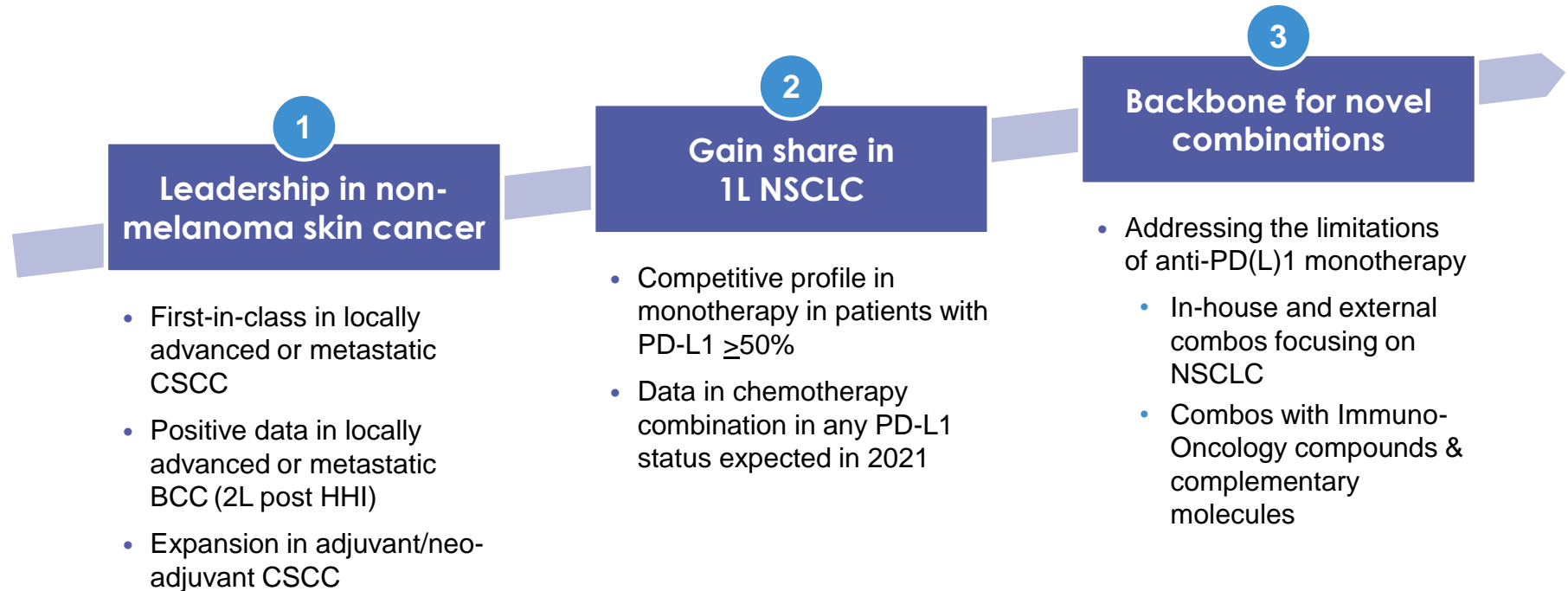
Libtayo®
**Ambition: Serving larger
patient populations with
competitive profile**

Alexander Zehnder

Global Franchise Head, Oncology



Libtayo[®]: Serving larger patient populations with competitive profile



Libtayo® to be first in 3 significant market segments in non-melanoma skin cancer

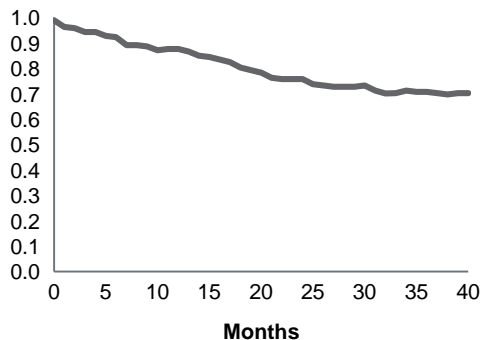
Locally advanced or metastatic CSCC

Launched in 2018 in U.S. and 2019 in Europe

~15,000 eligible patients⁽¹⁾

OS at 24 months = 73.3%
(95% CI: 66.1-79.2)⁽²⁾

Probability of survival (N=193)

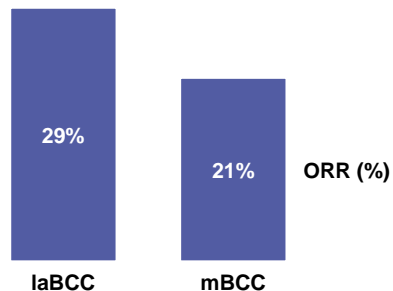


Locally advanced or metastatic BCC (2L)

Positive data announced on May 5, 2020, expected launch in 2021

2,000-4,000 eligible patients⁽¹⁾

Meaningful and durable responses in 2L BCC⁽³⁾: ~85% of responses maintained for at least 1 year

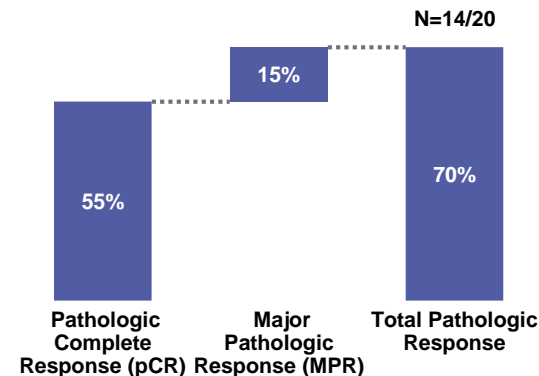


Neo-/Adjuvant CSCC

Phase 3 results expected in 2024 + neo-adjuvant in 2023⁽⁵⁾, expected launch in 2024

~60,000 eligible patients⁽¹⁾

Pathologic response to Neo-adjuvant Libtayo^(4,5)

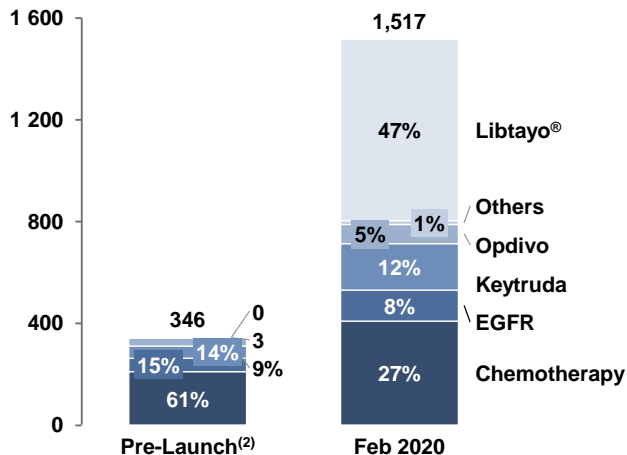


Fast uptake in advanced CSCC secures market leadership in 2nd year post launch

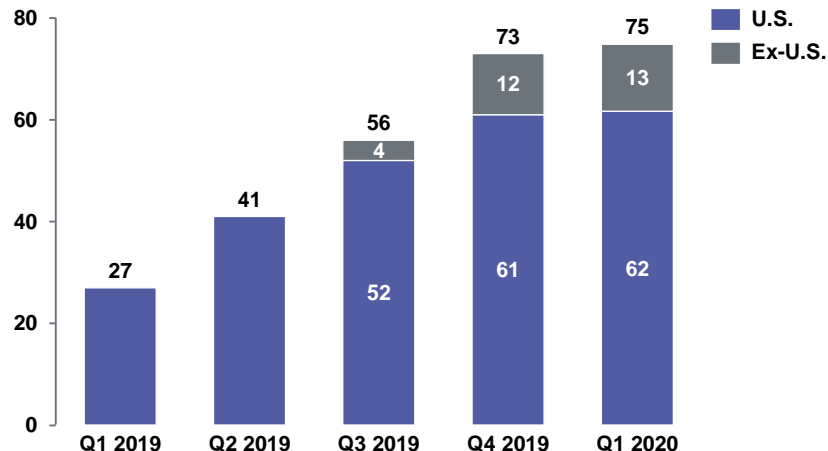
Libtayo® share in advanced CSCC reached 47%
 Claims increased 4-fold since launch

Sales momentum
 Libtayo® annualized sales of ~\$300m

Monthly number of claims⁽¹⁾



Sales⁽³⁾ (\$m)



Worldwide annualized sales of \$300m with room to grow in la/m CSCC

Significant commercial opportunity in 1L NSCLC

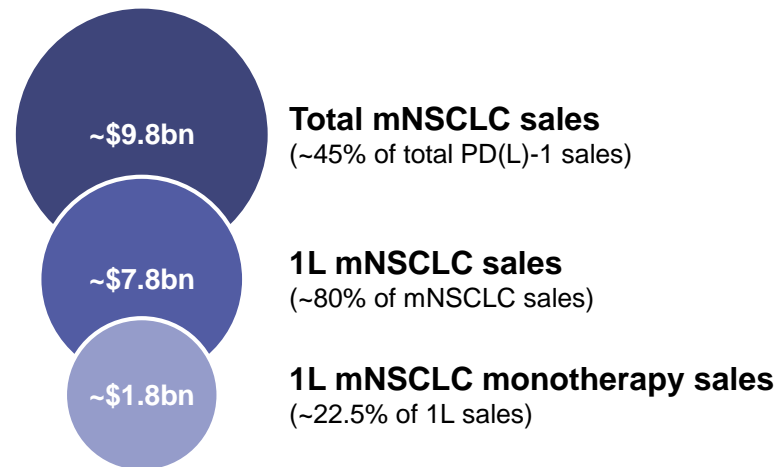
U.S. eligible patient population for initial lung cancer approval

Population, 2019

1L mNSCLC	~120k
Biomarker free (Non -ALK, -EGFR, -ROS)	~80%
PD-L1 high ($\geq 50\%$)	~30%
PD-L1 class share	~60%
Eligible population for PD-L1 High approval	~17k

Significant opportunity in largest PD(L)-1 indication

Worldwide PD(L)-1 sales in mNSCLC, \$bn, 2019



Competitive profile in PD-L1 \geq 50%, second Libtayo[®] 1L study (any PD-L1 status) to read out in 2021

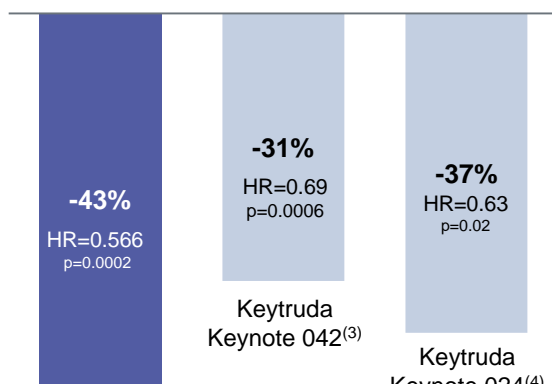
Overall OS risk reduction



Libtayo
1624⁽¹⁾

patients 710

OS risk reduction in PD-L1 \geq 50%



Libtayo
1624⁽²⁾

563

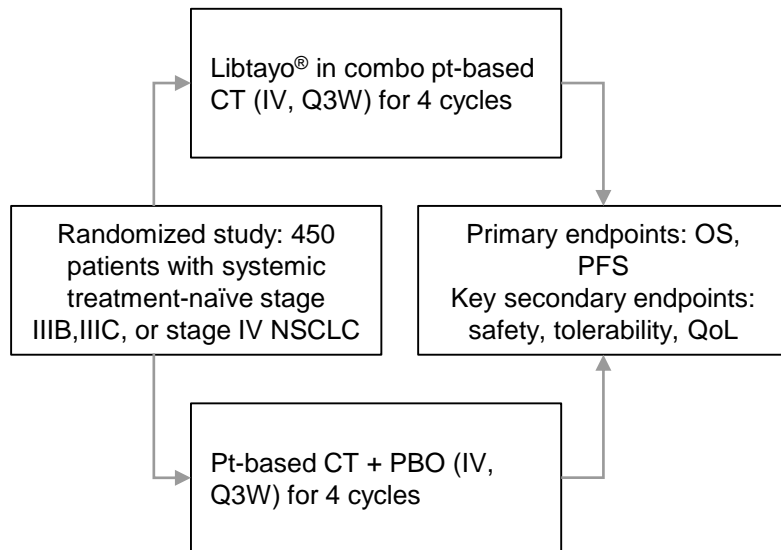
Keytruda
Keynote 042⁽³⁾

599

Keytruda
Keynote 024⁽⁴⁾

305

Libtayo[®] with chemotherapy (study 16113)



1L NSCLC Libtayo plus chemotherapy, independent of PD-L1 expression, data expected in 2021

OS: Overall survival, PFS: Progression Free survival, QoL: Quality of life; CT: Chemotherapy; PBO: Placebo; Pt: Platinum; NSCLC: non-small cell lung cancer

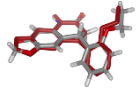
For illustrative purposes only. Not based on head to head data. Limited conclusions should be derived from this indirect comparison of efficacy given that the variability of trial designs

(1) Overall ITT Analysis, Sanofi Press Release April 27 (2) Modified ITT: patients with \geq 50% PD-L1 expression in tumor in whom PD-L1 assay was performed according to FDA-labeling (3)

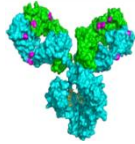
Mok et al., Lancet 2019 4) Reck et al., JCO 2020

Libtayo[®]: Potential backbone for novel combinations⁽¹⁾

Small Molecules



Monoclonal antibodies



Immuno ADCs and conventional ADCs



Multi-specific Antibodies



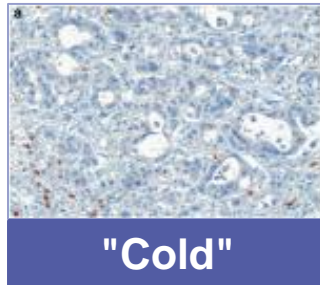
Synthetic biology (Synthorins)



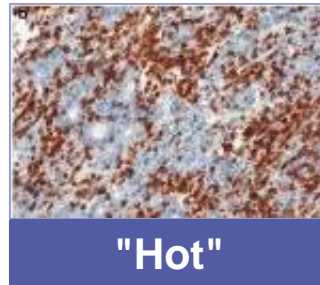
T- and NK cell engagers



Synthetic mRNA⁽²⁾



Non-immunogenic tumor with low immune infiltrate



Immunogenic tumor with significant immune infiltrate



Checkpoint inhibitors and other immunomodulators

Libtayo[®]: Summary

Ambition: Serving larger patient populations with competitive profile

- Leadership in non-melanoma skin cancer, with opportunity to be first across locally advanced/metastatic CSCC & BCC and adjuvant CSCC
- Competitive profile in 1L NSCLC in PD-L1 \geq 50%; data expected in 2021 in combination with CT for broad 1L population irrespective of PD-L1 status
- Potential backbone for novel combinations to improve patient outcomes vs. current Immuno-Oncology regimens



Anti-CEACAM5 '701

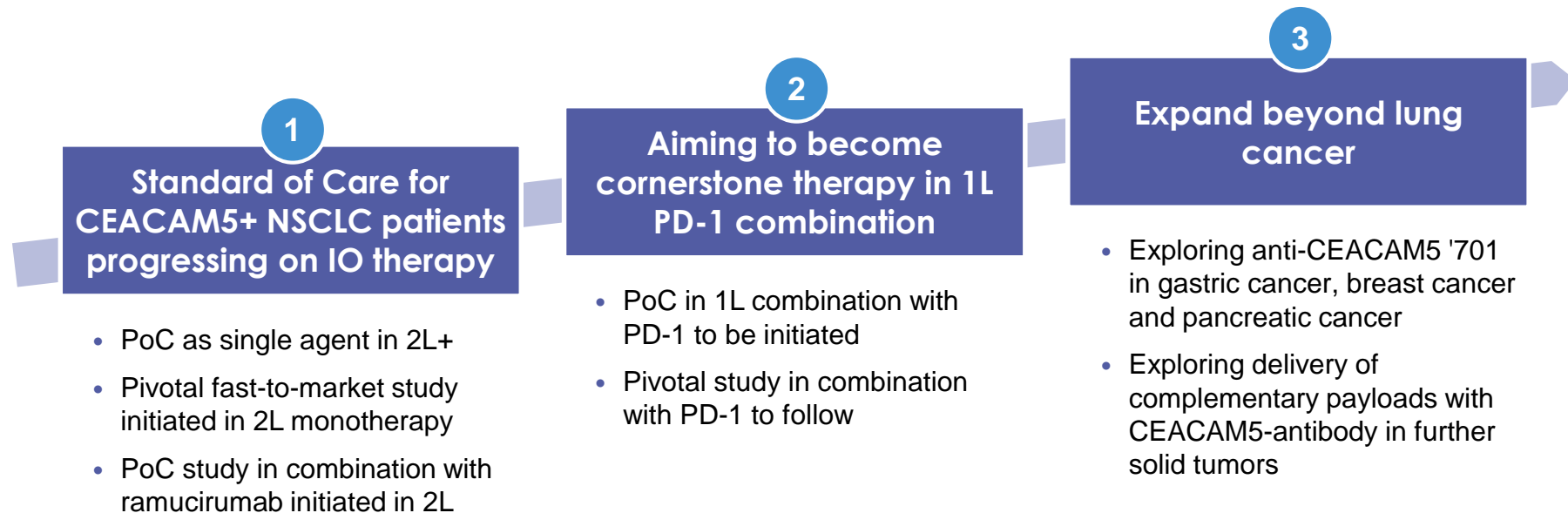
Ambition: First-in-class CEACAM5-targeting ADC

Peter Adamson

Global Oncology Development Head



Anti-CEACAM5 '701: First-in-class CEACAM5-targeted ADC



Anti-CEACAM5 '701 is a highly specific antibody designed to deliver payload specifically to tumor cell

Tumor selective profile

CEACAM5:

- Highly expressed on tumor cells, limited expression in healthy cells

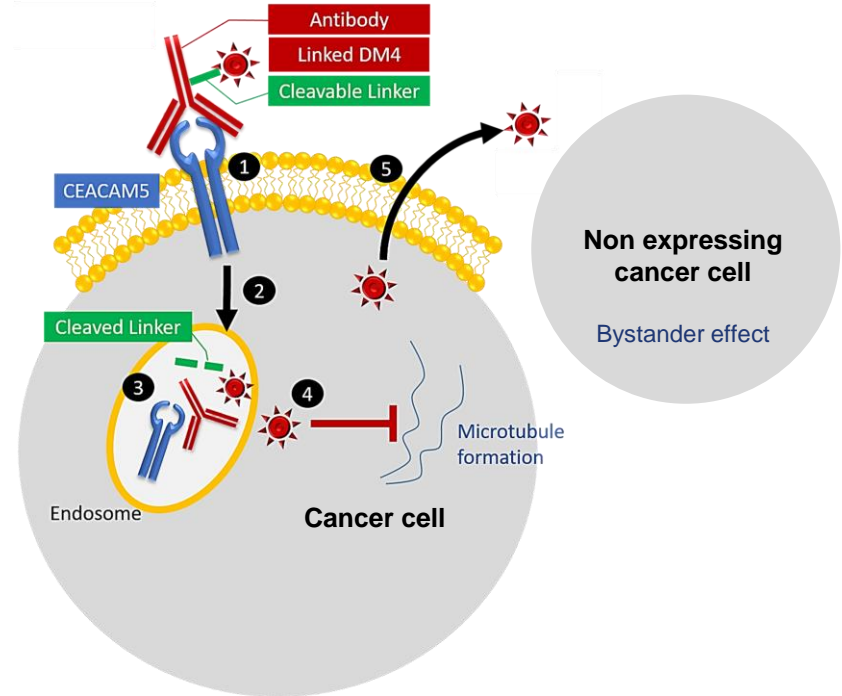
Anti-CEACAM5 '701:

- Humanized antibody with high selectivity for CEACAM5

Payload:

- DM4/Maytansinoid
- Anti-tubulin, 100-times more potent than docetaxel

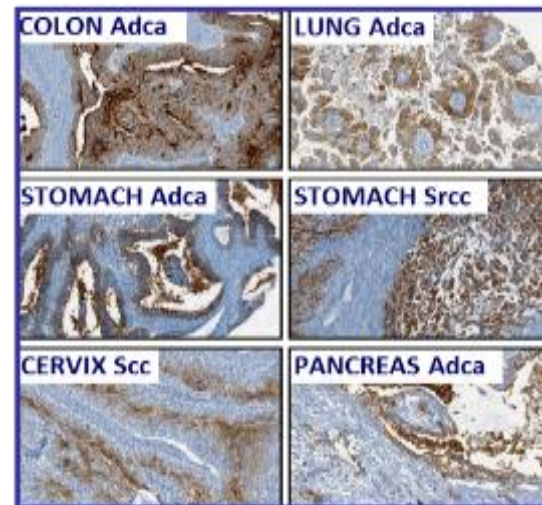
Linker stable in plasma



Anti-CEACAM5 '701 being developed for anti-tubulin sensitive tumors with high CEACAM5 expression

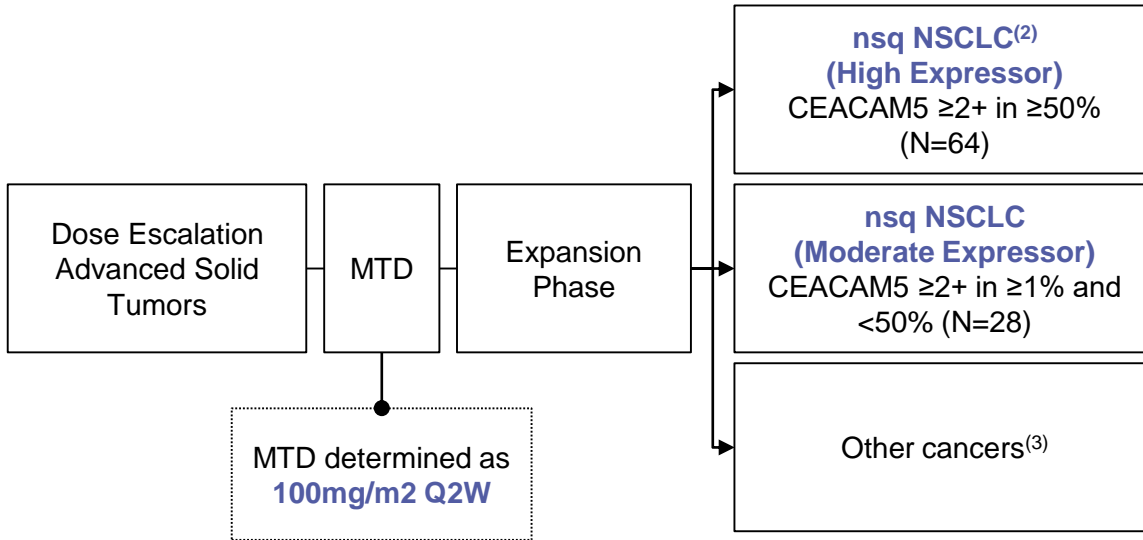
High prevalence in several cancer types

Cancer Type	Population with high CEACAM5 expression ⁽¹⁾	1L metastatic incidence (thousands, U.S.)	Anti-tubulin-sensitive
Gastric Adenocarcinoma	25-30%	12	Yes
NSCL Adenocarcinoma	20-30%	74	Yes
Pancreas adenocarcinoma	10-20%	27	Yes
Metastatic breast cancer	5-15%	39	Yes
Colorectal Adenocarcinoma	80-90%	44	No



CEACAM5 is expressed with significant frequency and intensity in several cancer types

First-in-human anti-CEACAM5 '701 phase 1/2 study design⁽¹⁾



Primary endpoints:

- Dose-limiting toxicity (DLT; escalation phase)
- Overall response rate (ORR; expansion phase)

Secondary endpoints:

- Safety
- Recommended Phase 2 dose identification
- Duration of response (DOR)

MTD: Maximum Tolerated Dose, nsq: non-squamous; DLT: dose limiting toxicity

(1) A first-in-human study for the evaluation of the safety, PK and antitumor activity of anti-CEACAM5 '701 in patients with advanced solid tumors (NCT02187848)

(2) High Expressor NSCLC – 2 interim analyses (at first 15 treated patients and at first 30 treated patients)

(3) Small Cell Lung Cancer, Gastric and Colorectal

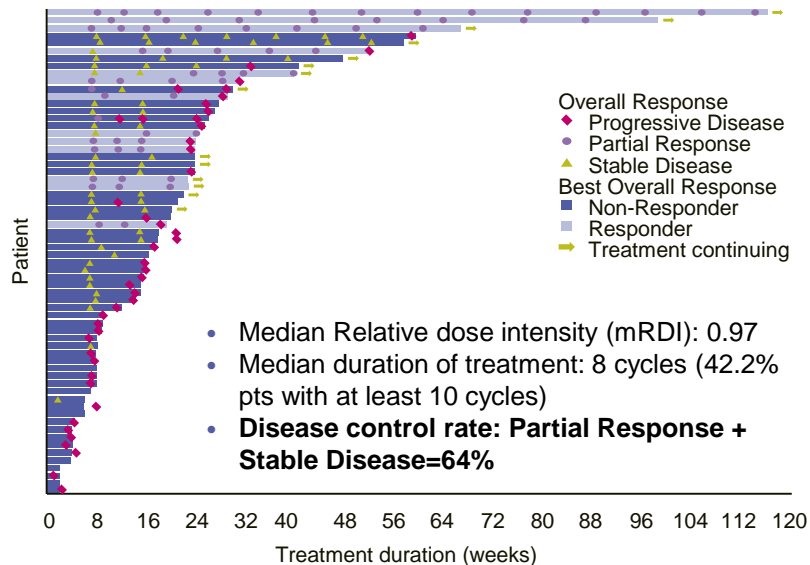
Note: SAR408701 is an asset under investigation, not approved by regulators

First-in-human anti-CEACAM5 '701 phase 1/2: baseline patient characteristics (nsq NSCLC cohorts)

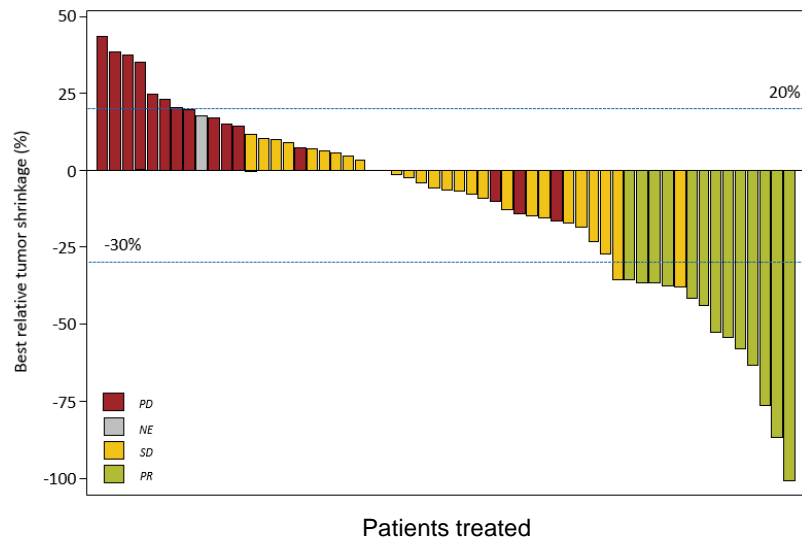
Characteristic	High expressors (n = 64)	Moderate expressors (n = 28)	Total (n = 92)
Age, years			
• Median (range)	61.5 (41-91)	64.5 (31-73)	62.5 (31-91)
Race, n (%)			
• White	52 (81.3%)	25 (89.3%)	77 (83.7%)
• Asian	12 (18.8%)	3 (10.7%)	15 (16.3%)
Sex, n (%)			
• Male	37 (57.8%)	10 (35.7%)	47 (51.1%)
• Female	27 (42.2%)	18 (64.3%)	45 (48.9%)
ECOG PS, n (%)*			
• 0	19 (29.7%)	7 (25.0%)	26 (28.3%)
• 1	45 (70.3%)	20 (71.4%)	65 (70.7%)
Number of organs involved, n (%)			
• ≥3	38 (59.4%)	14 (50%)	52 (56.5%)
Number of prior regimens for advanced disease			
• Median (range)	3.0 (1-10)	3.0 (1-7)	3.0 (1-10)
Prior treatment, n (%)			
• Anti-tubulin	39 (60.9%)	17 (60.7%)	56 (60.9%)
• Anti-PD-1/PD-L1	45 (70.3%)	24 (85.7%)	69 (75.0%)

Anti-CEACAM5 '701: Tumor size reduction & treatment duration in high expressors

Outcome & Duration of Treatment



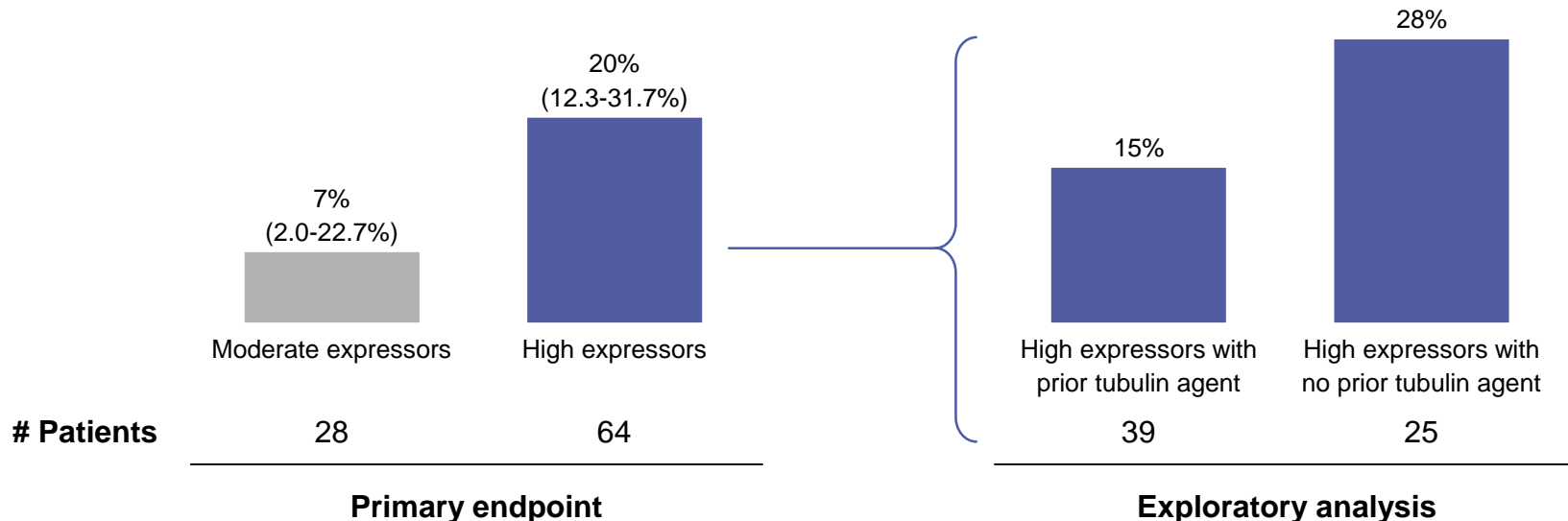
Best Relative Tumor size reduction



Median Duration of Response was 5.6 months (range: 2.0 – 24.6 months)

Results support use of anti-CEACAM5 '701 in nsq NSCLC CEACAM5 high expressors

Overall Response Rate (%)



Anti-CEACAM5 '701: Favorable safety profile demonstrated to date

Pooled safety analysis, moderate & high expressors cohorts

Anti-CEACAM5 '701 100 mg/m² Q2W (n=92)

	All Grades, n (%)	Grade ≥3, n (%)
Any class, clinical treatment emergent adverse events ≥ 10%	92 (100%)	47 (51.1%)
Corneal Adverse Events (incl. Keratopathy/Keratitis)	35 (38.0%)	10 (10.9%)
• Of which leading to dose modification	25 (27.2%)	7 (7.6%)
Asthenia	34 (37.0%)	4 (4.3%)
Peripheral neuropathy (SMQ ⁽¹⁾)	25 (27.2%)	1 (1.1%)
Diarrhea	21 (22.8%)	1 (1.1%)
Dyspnea	20 (21.7%)	10 (10.9%)
Decreased appetite	19 (20.7%)	0
Cough	14 (15.2%)	0
Nausea	12 (13.0%)	1 (1.1%)
Arthralgia	10 (10.9%)	0
Constipation	10 (10.9%)	0
Hematological toxicity		
Neutropenia	4 (4.4%)	0
Anemia	69 (75.8%)	2 (2.2%)
Thrombocytopenia	11 (12.2%)	0

Ocular events most frequent clinical adverse event, **manageable with dose delay and/or dose reduction**

Dyspnea most frequent serious adverse event, reported in 5 (5.4%) patients, all as a **symptom of progressive disease**

Much improved hematologic and GI toxicity profile compared to conventional therapy (docetaxel boxed warning for neutropenia and hepatic effects)

Potential strongly differentiating value proposition for target patients

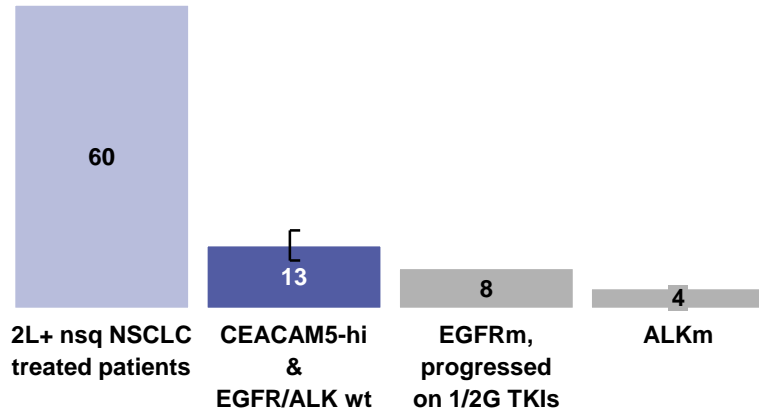
Taking anti-CEACAM5 '701 across all lines of treatments in nsq NSCLC

Line of treatment	Ambition	Target population ⁽¹⁾	Study name	Regimen	Size	Primary endpoints	Initiation	Read-out
2L+	Become SoC for 2L+ patients who have progressed following immune oncology or chemotherapy	~10-15k	CARMEN-LC03	Monotherapy	554	PFS and OS	Q1 2020	2022e
			CARMEN-LC04	Combo with ramucirumab	30	ORR	Q2 2020	2021e
1L	Become cornerstone therapy in 1L PD-1 combination	~12-18k	CARMEN-LC05	Combo with PD-1	45	ORR	Q3 2020	2022e

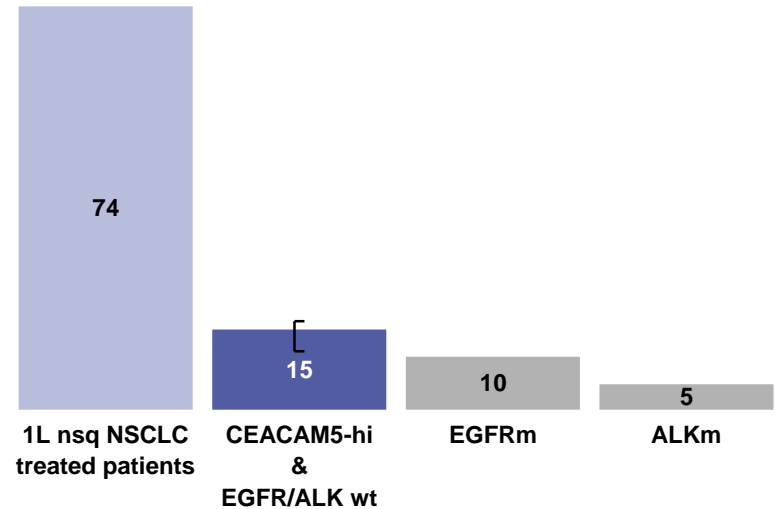
Companion diagnostic (CDx) being developed to identify CEACAM5+ patients

Anti-CEACAM5 '701: focused on a significant subpopulation in nsq NSCLC

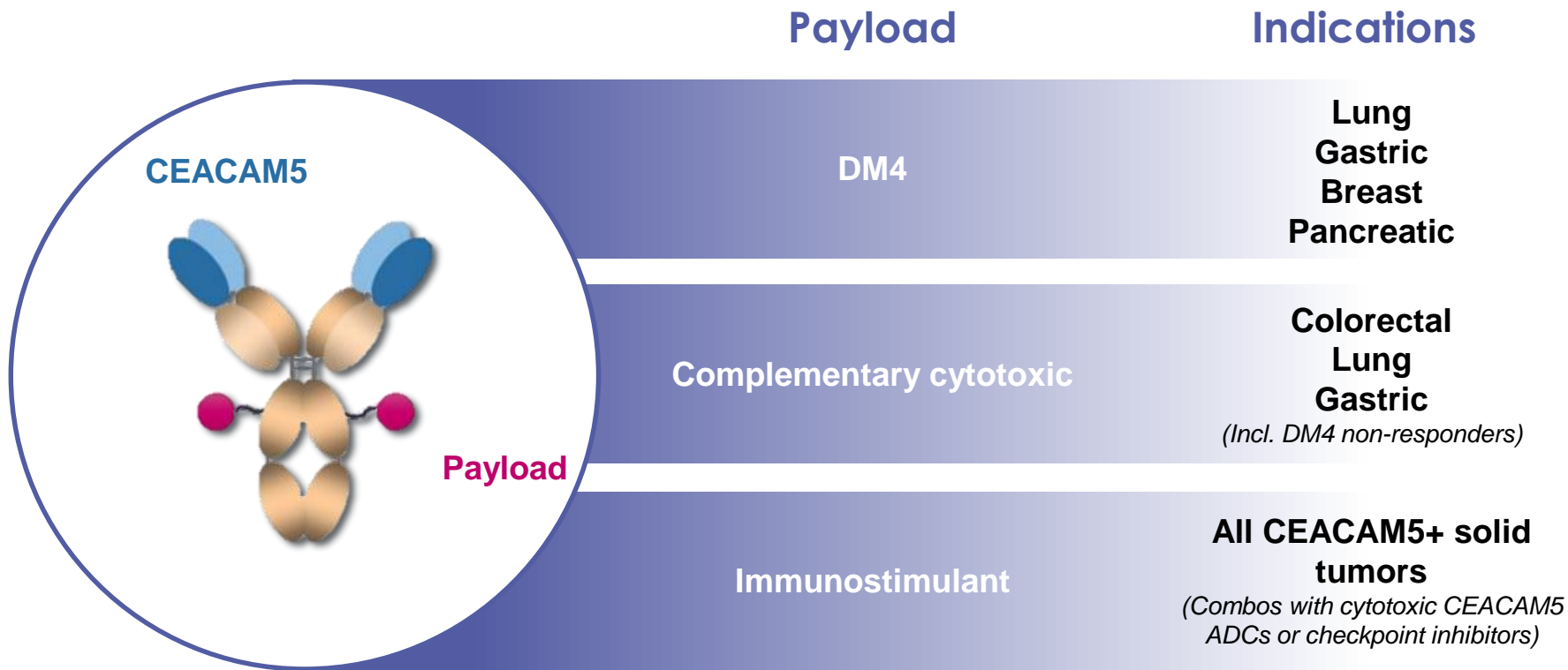
Eligible patients in 2L+ nsq NSCLC
(U.S.), in thousands



Eligible patients in 1L nsq NSCLC
(U.S.), in thousands



Anti-CEACAM5 '701: Novel CEACAM5 ADCs with different payloads expands opportunity across many tumor types



Anti-CEACAM5 '701: Summary

Ambition: First-in-class CEACAM5-targeting ADC



Efficacy and favorable safety profile demonstrated in patients with CEACAM5 high expressing 2L+ nsq NSCLC



Aiming to offer new treatment options for patients with CEACAM5 high expressing nsq NSCLC across all lines (~25% of patients)


- SoC for patients progressing on Immuno-Oncology therapy
- Aiming to become cornerstone therapy with PD-1 inhibitor in 1L



Taking CEACAM5 Antibody Drug Conjugates beyond lung cancer

- Exploring anti-CEACAM5 '701 in gastric, breast and pancreatic cancer
- Exploring different payloads in multiple solid tumor types



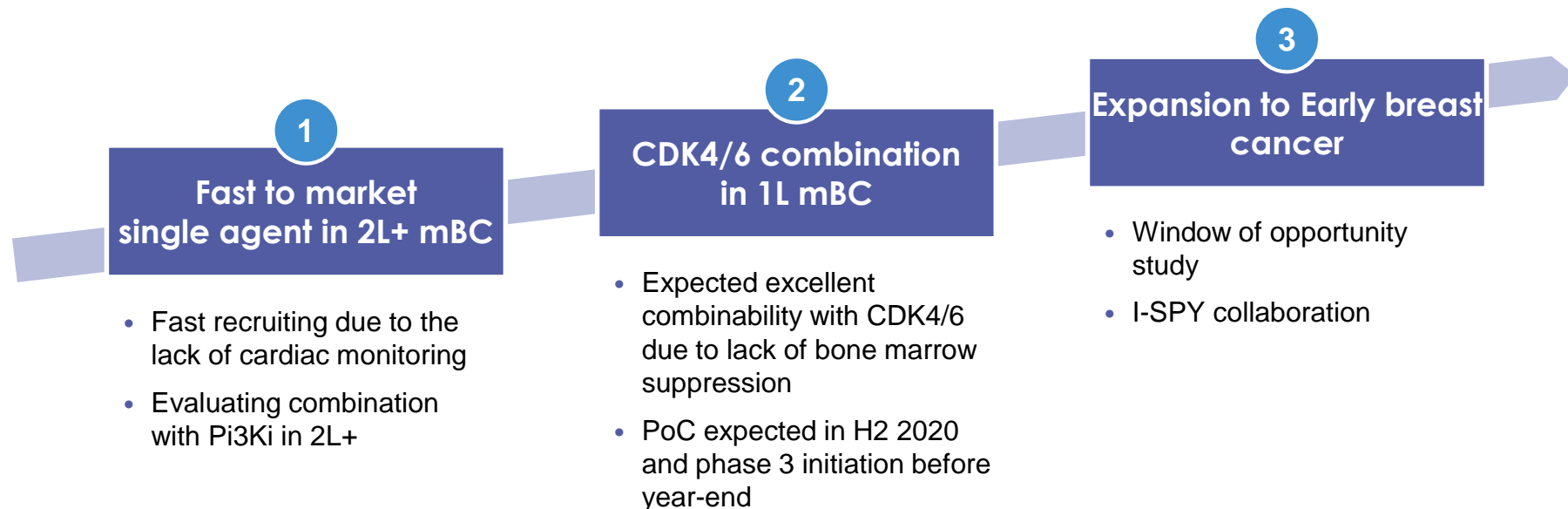
 **SERD '859**
**Ambition: best-in-class endocrine
backbone in HR+ BC**

Peter Adamson

Global Oncology Development Head



SERD '859: Potential best-in-class endocrine backbone in HR+ breast cancer

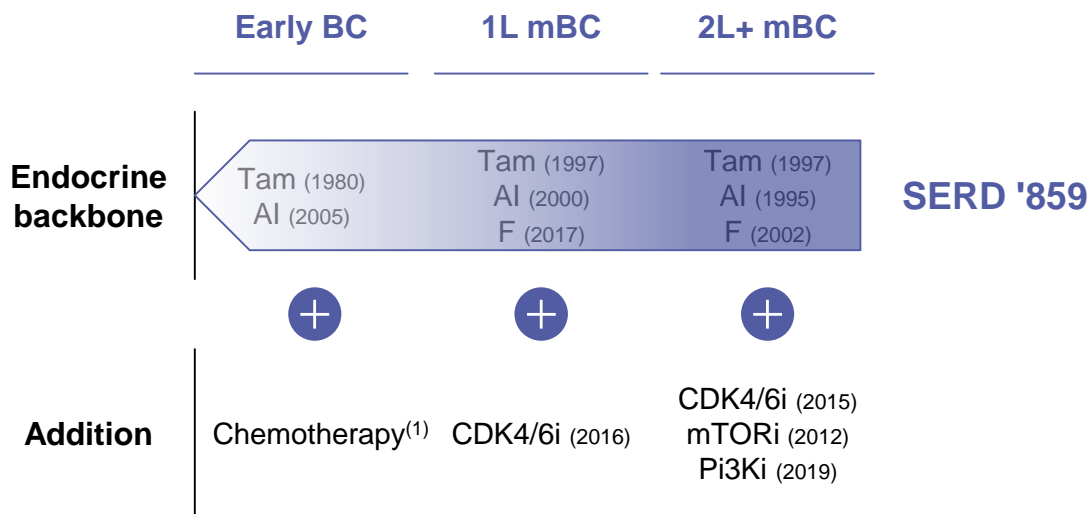


SERD '859 target profile provides potential to become the new standard endocrine backbone for HR+ breast cancer

SERD '859 target profile

- ✓ **Efficacy:** potent broad ER degrader irrespective of ESR1 mutation status
- ✓ **Safety:** no cardiotoxicity, no liver toxicity signals to date
- ✓ **Tolerability:** no grade 3 event, good GI profile, QoL and no vision impact
- ✓ **Combinability:** Clean hematological toxicity profile
- ✓ **Treatment burden:** Oral

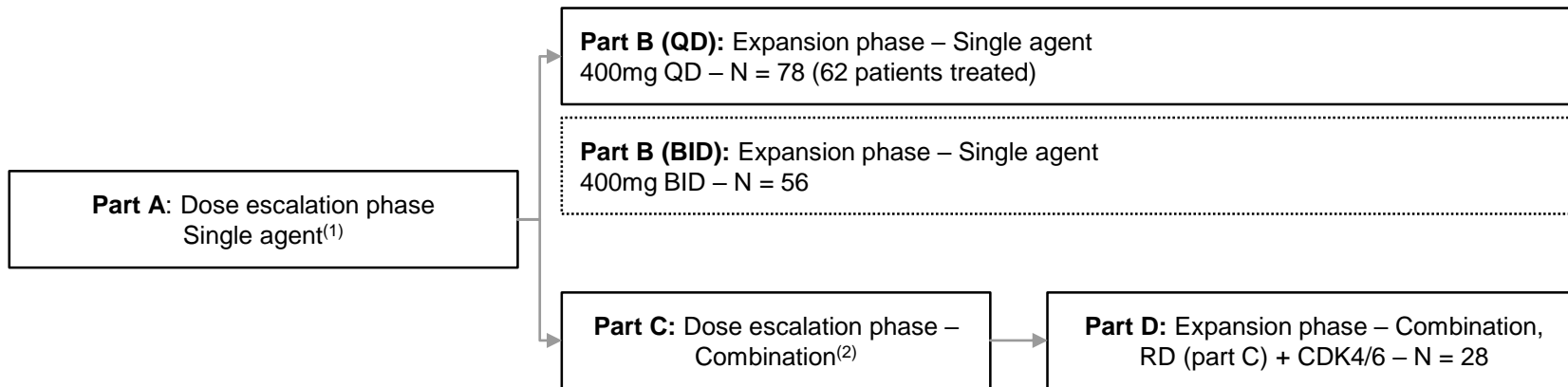
Evolution of SoC in HR+ breast cancer



HR+: hormone-receptor positive; ER: Estrogen Receptor; ESR1: Estrogen Receptor 1; QoL: Quality of life; GI: Gastrointestinal; DDI: drug interaction, CT: chemotherapy; Tam: tamoxifen; AI: aromatase inhibitor; F: fulvestrant; CDK: cyclin-dependent kinases; QTc: QT corrected; Pi3Ki: phosphoinositide 3-kinase inhibitor; mTORi: mammalian target of rapamycin inhibitors; SoC: Standard of Care

(1) Some patients only receive endocrine therapy, depending on disease staging
SAR439859 is an asset under investigation, not approved by regulators

AMEERA-1 design: Single-Agent and Combinations



30 among the 62 treated patients (48.4%) had ≥ 3 prior lines of therapy in the advanced setting

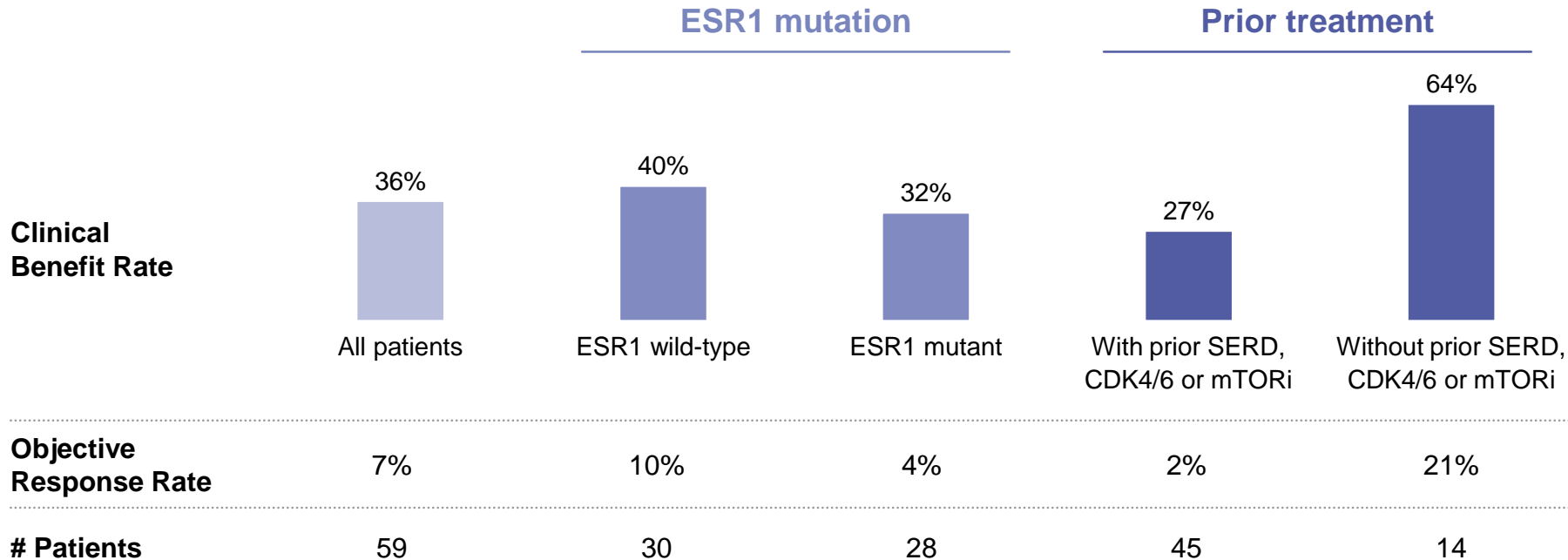
Note: Doses explored (mg): Daily: 20, 100, 200, 400, 600; Twice daily: 2*200, 2*300; RD: recommended dose

(1) Based on occurrence of dose limiting toxicity at cycle 1, (N=31-42 patients) together with target saturation (FES PET scans) and pharmacokinetics parameters

(2) Based on occurrence of dose limiting toxicity at cycle1 (N=12 patients) and pharmacokinetics parameters, up to 2 recommended doses can be selected

SAR439859 is an asset under investigation, not approved by regulators

SERD '859: Clinically meaningful treatment effect in heavily pre-treated population



Backbone landscape in 2L+ setting

	Trial	Study regimen	N	SERD '859 / Fulvestrant alone results		Prior CDK4/6, mTOR, Fulvestrant
				ORR	CBR	
2L+ setting	AMEERA-1	SERD '859	59	6.8%	35.6%	Permitted
	AMEERA-1	SERD '859	14⁽¹⁾	21.4%	64.3%	No
	SANDPIPER	Fulvestrant (+/- taselisib)	134	11.9%	37.3%	No
	PALOMA-3	Fulvestrant (+/- palbociclib)	138	11%	36%	No
	SoFEA	Fulvestrant (+/- anastrozole)	178	8%	31%	No
	EFFECT	Fulvestrant (+/- exemestane)	270	7.4%	32.2%	No

ORR: objective response rate; CBR: clinical benefit rate; CDK: cyclin-dependent kinases; mTORi: mammalian target of rapamycin inhibitor

Source: data on file

SAR439859 is an asset under investigation, not approved by regulators

(1) subpopulation appropriate to compare directly to fulvestrant literature and relevant to performance in earlier lines

Clean safety profile will be required to become backbone

SERD '859 ≥ 150 mg QD⁽¹⁾ – All patients (N=62)

Safety observations

TRAEs, n(%)	Grade 1-2	Grade ≥ 3
Any class	38 (61.3)	-
Hot flush	10 (16.1)	-
Constipation	6 (9.7)	-
Arthralgia	6 (9.7)	-
Decreased appetite	5 (8.1)	-
Vomiting	5 (8.1)	-
Diarrhea	5 (8.1)	-
Nausea	5 (8.1)	-
Fatigue	4 (6.5)	-

Other SERD development programs

GDC9545⁽²⁾ - 40 patients in cohort A (monotherapy)

- **3 Grade 3 events:** fatigue, transaminase increase, diarrhea
- 3 patients (7,5%) with asymptomatic bradycardia (all grade 1)

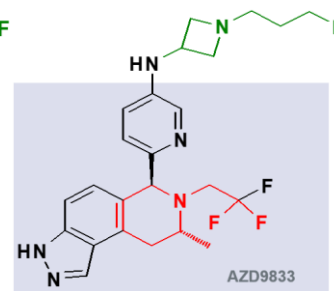
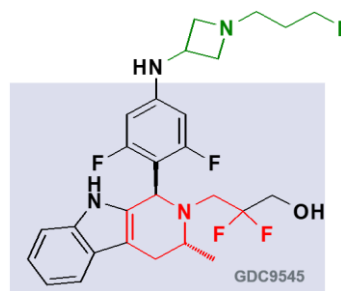
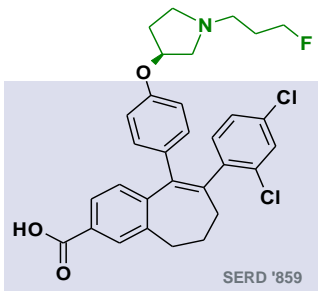
AZD9833⁽³⁾ - 60 patients

- **3 Grade 3 events:** visual disturbance, dizziness, vomiting
- 45% sinus bradycardia, including 2 patients with grade 2

Molecular structure

Degrader chain

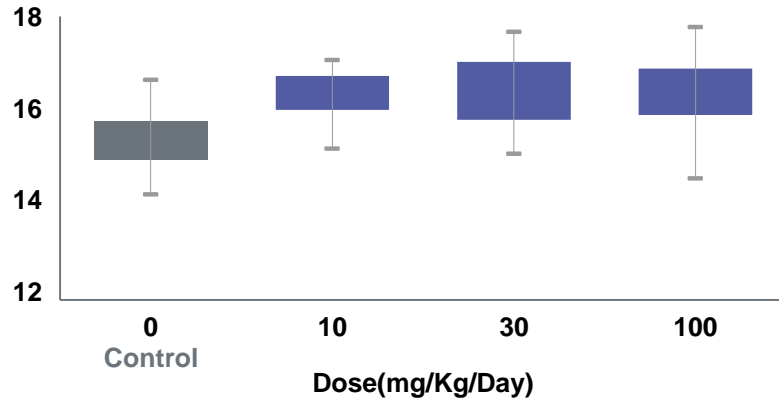
Scaffold



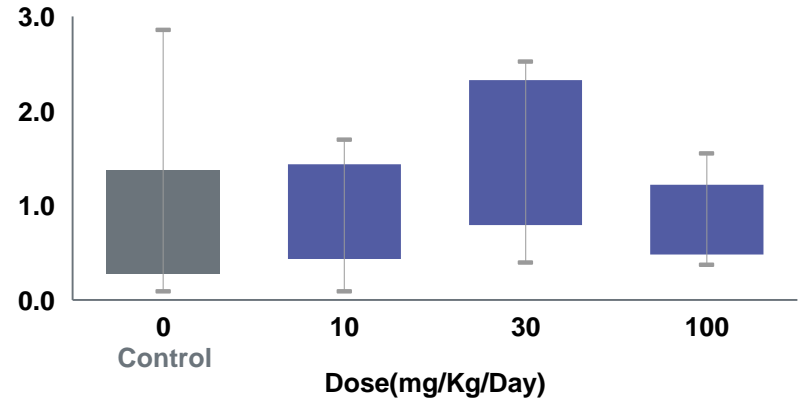
SERD '859: No significant bone marrow suppression observed, supporting combinability potential

3-months repeat-dose Toxicity Study in Rats

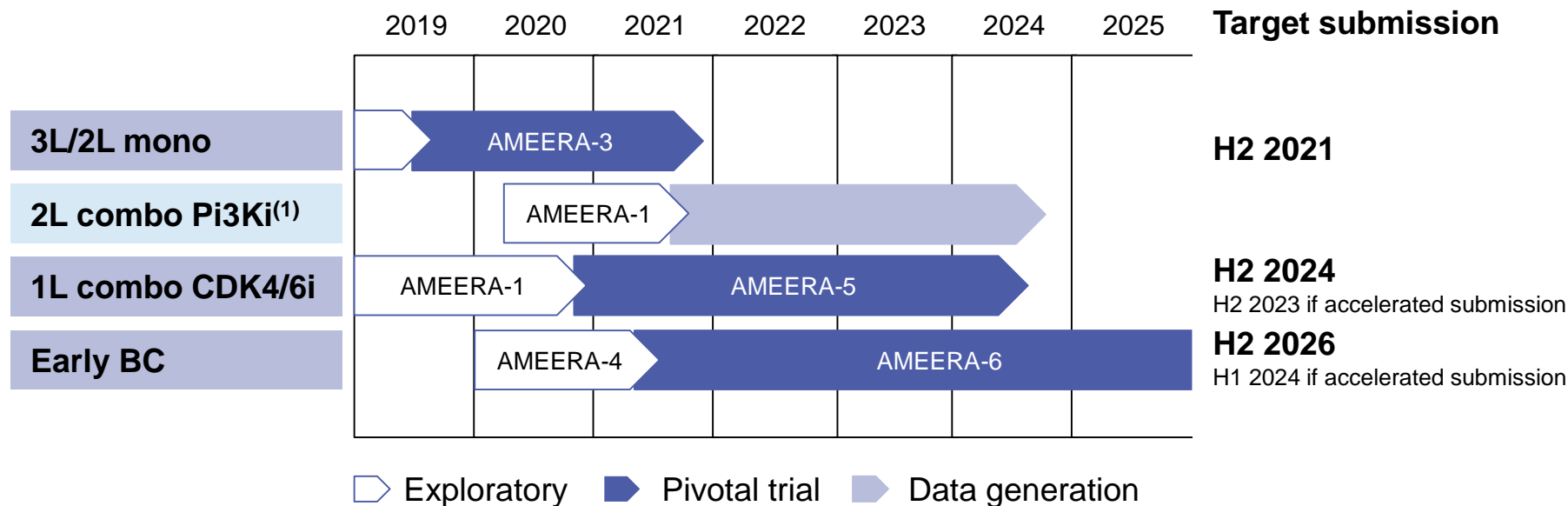
Hemoglobin g/dL



Neutrophils 10e9/L



Ambition to establish SERD '859 as best-in-class endocrine backbone in HR+ breast cancer

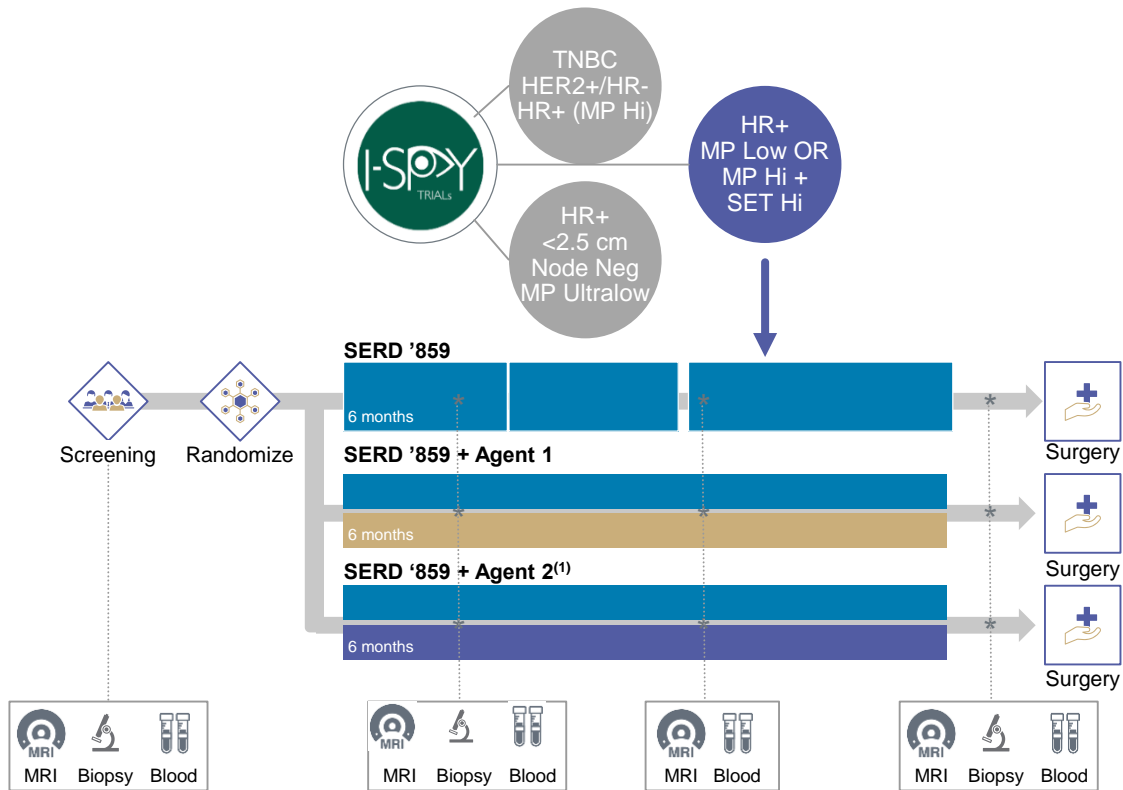


2L/3L mBC expected to reach market in 2022, >1 year ahead of other SERDs in development

SERD '859: Announcing the I-SPY 2 Endocrine Optimization Protocol (EOP) pilot study to establish new platform

For patients with high risk early stage breast cancer who may not benefit from neoadjuvant chemotherapy

- Feasibility endpoint
- Informative MRIs & biomarkers
- **Position SERD '859 to become the endocrine backbone** for future I-SPY 2 adaptive neoadjuvant combinations



SERD '859 data supports ambition to become BiC endocrine backbone in HR+ BC across treatment lines

	Target profile	SERD '859 phase 1 data
Efficacy	100% receptor degradation: potent broad ER degrader irrespective of ESR1 mutation status	Competitive ORR and CBR
Safety	No cardiotoxicity No liver toxicity	No bradycardia signals No QTc prolongation signals No liver enzyme elevation signals
Tolerability	Favorable GI profile Favorable Quality of Life No vision impact	No grade 3 TRAEs, incl. nausea, vomiting, dizziness No visual disturbances signals
Combinability	Benign hematologic toxicity profile	Clean hematological profile with no significant myelosuppression

SERD '859: Summary

Ambition: Best-in-class endocrine backbone in HR+ breast cancer



Compelling efficacy with CBR of 36% (all-comers) and 64% (in patients without prior SERD, mTORi, CDK4/6)



Demonstrated safety and tolerability required to become best-in-class backbone



Aiming for initial approval in 2022, >1 year before other SERDs in development



Lack of bone marrow suppression should result in excellent combinability



Conclusions

John Reed

**Executive Vice President, Global Head of
Research & Development**



Ambition to shape 4 anchor assets into blockbusters

	Ambition	Current status	Blockbuster potential
Sarclisa®⁽¹⁾	Best-in-class profile in multiple myeloma	Approved with Pd for RRMM ⁽³⁾	Positive pivotal data with Kd in 2L+ RMM P3 (IKEMA) P3 in 1L Ti/Te MM ongoing SMM to be initiated ⁽⁴⁾
Libtayo®⁽²⁾	Serving larger patient populations with competitive profile	Approved in metastatic/locally advanced CSCC	Positive pivotal data in 1L NSCLC Positive pivotal data in 2L BCC Adjuvant CSCC P3 ongoing Backbone for novel combinations
Anti-CEACAM5 '701^(1,5)	First-in-class CEACAM5-targeting ADC for lung cancer	PoC data in CEACAM5+ 2L nsq NSCLC (single agent)	Pivotal P3 (fast-to-market) 2L CEACAM5+ NSCLC ongoing, PoC in earlier NSCLC lines and further CEACAM5+ tumors initiating
SERD '859^(1,5)	Best-in-class endocrine backbone for HR+ breast cancer	PoC data in 3L+ HR+ BC (single agent)	Pivotal P2b (fast-to-market) in 2L+ HR+ BC PoC combo and studies in earlier lines ongoing

 **SERD '859^(1,5)**

Priority asset

MM: multiple myeloma; RRMM: Relapsed/refractory multiple myeloma; TI: Transplant ineligible; Te: Transplant eligible; HR+: Hormone Receptor positive; CSCC: Cutaneous Squamous Cell Carcinoma; BCC: Basal Cell Carcinoma; NSCLC: Non-Small Cell Lung Cancer; SMM: Smoldering multiple myeloma; ADC: Antibody Drug Conjugate; BC: breast cancer; nsq: non-squamous; PoC: Proof of Concept, clinical and commercial evidence to initiate pivotal study

(1) Wholly owned assets (2) Libtayo® in collaboration with Regeneron - Sales are consolidated by Regeneron in the U.S and Sanofi ex U.S. (3) and ≥2 prior therapies, including lenalidomide and a proteasome inhibitor. Approved in the U.S., EU, Canada, Australia and Switzerland, indication in certain non-U.S. countries also includes disease progression on last therapy (4) These uses of isatuximab are investigational and have not been evaluated by any regulatory authority. (5) Anti-CEACAM5 '701 and SERD '859 not approved by the regulators

Significant news flow expected in the next 18 months

H2
2020

Sarclisa®

Filing (IKEMA) RMM

Libtayo®(1)

Filing BCC 2L

Libtayo®(1)

Presentation of NSCLC PD-L1 $\geq 50\%$ results at medical conference

Libtayo®(1)

Filing 1L NSCLC monotherapy

SERD '859

PoC in combination with CDK4/6i & adjuvant BC

H1
2021

SERD '859

Pivotal results 2L-3L BC monotherapy

SHP2i(1)

PoC in combination with cobimetinib

H2
2021

Libtayo®(1)

Pivotal results 1L NSCLC CT combination

Sarclisa®

Pivotal results (IMROZ) 1L NDMM Ti

TGFb

PoC in NSCLC, MM², CRC, MuC

T-cell engaging CD3/CD123

PoC in AML (monotherapy)

Sarclisa®

PoC in Lymphomas (PTCL)

Sarclisa®

PoC for SC formulation

SERD '859

PoC in mBC combination with Pi3Ki





SHP2i(1)

PoP in combination with pembrolizumab

THOR707

PoP in NSCLC

Our ambition in Oncology

-  Transform **strong science** into **commercial leadership**
-  Focus on **4 core areas** with ambition to shape **4 anchor assets into blockbusters**
-  Develop **novel combinations** to improve patients' outcomes
-  Position Sanofi as **partner of choice in selected areas** based on best-in-class backbones and leading platforms to generate first-in-class medicines

Q&A session



Paul Hudson
Chief Executive Officer



Bill Sibold
Executive Vice President, Sanofi
Genzyme



Peter Adamson
Global Oncology Development Head



Dmitri Wiederschain
Global Immuno-Oncology Research Head



John Reed
Executive Vice President, Global
Head of Research & Development



Dietmar Berger
Senior Vice President, Global Head of
Development, Chief Medical Officer



Laurent Debussche
Global Molecular Oncology Research Head



Alexander Zehnder
Global Franchise Head, Oncology