

## Sanofi to showcase data from its transformative oncology pipeline at 2021 ASCO Meeting

- \* Early clinical data for investigational oral selective estrogen receptor (SERD), amcnenestrant, show potential to become a new endocrine backbone therapy in ER+ HER2- breast cancer
- \* Data that reinforce Libtayo<sup>®</sup> (cemiplimab-rwlc) as a standard of care in advanced non-melanoma skin cancer and advanced non-small cell lung cancer, including new data in historically underrepresented patients with brain metastases
- \* Longer term data and new analyses for Sarclisa<sup>®</sup> (isatuximab-irfc) further strengthen efficacy profile, including for elderly patients and patients with high-risk cytogenetic abnormalities

**PARIS – May 19, 2021** – New research being presented at the upcoming virtual American Society of Clinical Oncology (ASCO) Annual Meeting from June 4-8 highlights Sanofi’s transformative science and commitment to patient care across difficult-to-treat cancers, including multiple myeloma, skin, lung and breast cancers.

*“Our pipeline of innovative investigational medicines continues to expand, supporting our goal to address critical gaps in treatment options for patients with cancers of high unmet need,” says Peter C. Adamson, Global Development Head, Oncology at Sanofi. “We look forward to presenting the latest data across our oncology portfolio and pipeline in four key areas – multiple myeloma, skin cancers, lung cancers and breast cancer, including data supporting the potential for amcnenestrant to become a best-in-class oral endocrine backbone therapy.”*

### Early clinical data for amcnenestrant, our investigational oral selective estrogen receptor degrader (SERD), show potential to become a new endocrine backbone therapy in ER+ HER2- breast cancer\*

- Abstract 1058: AMEERA 1: Phase 1/2 study of amcnenestrant (SAR439859), an oral selective estrogen receptor (ER) degrader (SERD), with palbociclib (palbo) in postmenopausal women with ER+/human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer (MBC)
- Abstract TPS1104: AMEERA-5: A randomized, double-blind phase 3 study of amcnenestrant (SAR439859) + palbociclib versus letrozole + palbociclib for previously untreated ER+/HER2- advanced breast cancer (*Trial in Progress*)

Click [here](#) to read the full amcnenestrant data press release issued by Sanofi.

## Data analyses reinforce Libtayo® (cemiplimab-rwlc) as a standard of care in advanced non-melanoma skin cancer indications and in advanced non-small cell lung cancer, including new data in historically underrepresented patients with brain metastases

### Libtayo in Non-melanoma Skin Cancer

- Abstract 9547: Checkpoint inhibition in immunosuppressed or immunocompromised patients with advanced cutaneous squamous cell carcinoma (CSCC): Data from prospective CemiplimAb-rwlc Survivorship and Epidemiology (C.A.S.E.) study
- Abstract 9566: Health-related quality of life (HRQoL) in patients (pts) with locally advanced basal cell carcinoma (laBCC) treated with cemiplimab: analysis of a phase II, open-label clinical trial
- Abstract e18830: Budget impact (BI) analysis of cemiplimab-rwlc for advanced basal cell carcinoma (BCC) after hedgehog inhibitor (HHI) therapy in the United States

### *Other Sanofi studies in Non-Melanoma Skin Cancer*

- Abstract e18740: Frequency, characteristics, and subsequent treatment (Tx) of real-world patients (pts) who discontinue hedgehog inhibitors (HHI) as first-line (1L) systemic Tx for advanced basal cell carcinoma (aBCC)
- Abstract e18742: Outcomes in patients (pts) with advanced basal cell carcinoma (aBCC) who discontinued hedgehog inhibitors (HHI) as first-line (1L) systemic treatment (Tx) in a US community oncology setting: A retrospective observational study

### Libtayo in Non-small Cell Lung Cancer

- Abstract 9085: Cemiplimab monotherapy as first-line (1L) treatment of patients with brain metastases from advanced non-small cell lung cancer (NSCLC) with programmed cell death-ligand 1 (PD-L1)  $\geq 50\%$ ; EMPOWER-Lung 1 subgroup analysis
- Abstract 9078: Patient-reported symptoms, functioning, and quality of life (QoL) in patients treated with cemiplimab monotherapy for first-line treatment of advanced NSCLC with PD-L1  $\geq 50\%$ : Results from EMPOWER-Lung 1 study
- Abstract e18817: Budget impact (BI) analysis of cemiplimab for first-line (1L) advanced non-small cell lung cancer (NSCLC) with programmed cell death-ligand 1 (PD-L1)  $\geq 50\%$  in the United States
- Abstract e21091: Network meta-analysis (NMA) of immuno-oncology (IO) monotherapy (mono) as first-line (1L) treatments (txs) for advanced non-small cell lung cancer (NSCLC) with PD-L1 expression  $\geq 50\%$

Libtayo is being jointly developed by Sanofi and Regeneron under a global collaboration agreement.

### **Longer term data and new analyses for Sarclisa® (isatuximab-irfc) further strengthen its efficacy profile, including for elderly patients and patients with high-risk cytogenetic abnormalities**

- Abstract 8017: Updates from ICARIA-MM, a Phase 3 study of isatuximab (Isa) plus pomalidomide and low-dose dexamethasone (Pd) versus Pd in relapsed and refractory multiple myeloma (RRMM)
- Abstract 8042: Isatuximab plus carfilzomib and dexamethasone in relapsed multiple myeloma patients with high-risk cytogenetics: IKEMA subgroup analysis
- Abstract 8026: Isatuximab plus carfilzomib and dexamethasone versus carfilzomib and dexamethasone in elderly patients with relapsed multiple myeloma: IKEMA subgroup analysis
- Abstract e20015: Isatuximab plus carfilzomib and dexamethasone in East Asian patients with relapsed multiple myeloma: IKEMA subgroup analysis
- Abstract 8034: Isatuximab plus carfilzomib and dexamethasone in patients with relapsed multiple myeloma according to prior lines of treatment and refractory status: IKEMA subgroup analysis

### **Biomarker research for tusamitamab ravtansine, an early-stage, potential first-in-class investigational anti-CEACAM5 antibody drug conjugate for advanced non-small cell lung cancer\***

- Abstract e21030: Validation of an immunohistochemical assay, CEACAM5 IHC 769, under development for use with the antibody-drug conjugate tusamitamab ravtansine (SAR408701)

### **Safety, pharmacokinetic and pharmacodynamic data with our investigational transforming growth factor beta (TGF-β)\***

- Abstract 2510: Safety, pharmacokinetic and pharmacodynamic results from dose escalation of SAR439459, a TGFβ inhibitor, as monotherapy or in combination with cemiplimab in a phase 1/1b study

### **Early data with investigational anti-ICOS antibody, KY1044, submitted by Kymab, a Sanofi company\***

- Abstract 2624: A phase 1/2 open-label study of KY1044, an anti-ICOS antibody with dual mechanism of action, as single agent and in combination with atezolizumab, in adult patients with advanced malignancies
- Abstract 2626: KY1044 to target the ICOS pathways inducing intratumoral Treg depletion and agonism of effector T cells: Preliminary pharmacodynamic markers from a phase 1/2 multicenter trial

## Independent research supported by Sanofi

<b>Jevtana (Cabazitaxel)</b>	
Abstract 5059	First results from a randomized Phase II study of cabazitaxel (CBZ) versus an androgen receptor targeted agent (ARTA) in patients with poor-prognosis castration-resistant prostate cancer (mCRPC)
Abstract 1008	Randomised multicentre trial of 3 weekly Cabazitaxel versus weekly Paclitaxel chemotherapy in the first line treatment of HER2 negative metastatic breast cancer (MBC)
Abstract e17027	Prostate cancer intensive, non-cross reactive therapy (PRINT) for CRPC: interim analysis of efficacy endpoints

Click [here](#) to view these abstracts along with the full digital program located in the ASCO Meeting Library.

\*These assets are currently under investigation and their safety and efficacy has not been fully evaluated by any health authority.

### About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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#### Sanofi Forward-Looking Statements

*This press release 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, 2020. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.