Sanofi oncology pipeline targeting various cancers highlighted at ASCO 2019

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• Pivotal Phase 3 data evaluated isatuximab (anti-CD38) in combination with pomalidomide/dexamethasone in prolonging progression-free survival in relapsed/refractory multiple myeloma

• Longer-term Libtayo® (cemiplimab) data add to growing body of evidence in patients with metastatic or locally advanced CSCC who are not candidates for curative surgery or curative radiation

• Multiple abstracts from Sanofi, including oral SERD in metastatic breast cancer and anti-CEACAM5 in non-squamous non-small cell lung cancer

Sanofi’s oncology franchise and robust pipeline will be featured at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting, delivering against a renewed strategy to address difficult-to-treat and difficult-to-eradicate cancers, including certain types of multiple myeloma, skin cancer, breast cancer, and lung cancer.

Four key molecules in clinical development are the pillars of Sanofi’s late-stage and emerging oncology pipeline: isatuximab, an investigational anti-CD38 monoclonal antibody; Libtayo (cemiplimab), a PD-1 checkpoint inhibitor in development with Regeneron; SAR439859, an investigational oral selective estrogen receptor degrader (SERD); and SAR408701, an investigational anti-CEACAM5 antibody drug conjugate.

“We have a strategic focus to address unmet patient needs across many therapeutic areas at Sanofi, and currently oncology makes up a sizeable portion of our late-stage pipeline,” said John Reed, Head of Research and Development at Sanofi. “Our oncology pipeline is flourishing, offering a progressively expanding diversity of opportunities to help advance the treatment of a variety of cancers. We are excited to showcase this progress at ASCO.”

Positive results in relapsed/refractory multiple myeloma
Reed continued, “We are particularly excited to share the results from our pivotal Phase 3 ICARIA-MM trial of isatuximab in patients with a difficult-to-treat relapse/refractory multiple myeloma. This is the first of multiple Phase 3 trials with isatuximab, our wholly-owned molecule under investigation for the treatment of multiple myeloma. We look forward to the presentation of data at ASCO and believe that the ICARIA-MM data serve as the basis for the first regulatory filings of isatuximab.”

• A phase 3 randomized, open-label, multicenter study comparing isatuximab, pomalidomide, and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone in patients with relapsed/refractory multiple myeloma (RRMM) (Dr. Paul Richardson; Sunday, June 2: Oral Abstract Session, 9:45-12:45 AM, ICARIA presentation, 10:57-11:09 AM)
• Treatment patterns in patients with multiple myeloma (MM): A retrospective study using Medicare data (Dr. Parameswaran Hari; Publication Only)

Growing body of evidence in advanced cutaneous squamous cell carcinoma
Cutaneous squamous cell carcinoma (CSCC) is one of the most commonly diagnosed skin cancers worldwide. Although the majority of patients with CSCC have a good prognosis when the cancer is found early, the cancer can be especially difficult to treat when it progresses to advanced stages. New longer-term data with Libtayo offer updated efficacy and safety outcomes that add to the growing body of evidence for Libtayo in patients with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation. Libtayo is being jointly developed by Regeneron and Sanofi under a global collaboration agreement.
- **Primary analysis of Phase 2 results of cemiplimab, a human monoclonal anti-PD-1, in patients with locally advanced cutaneous squamous cell carcinoma** (Dr. Michael Migden; Saturday, June 1: Poster Display, 1:15-4:15 PM and Poster Discussion, 4:30-6:00 PM)

- **Phase 2 study of cemiplimab, a human monoclonal anti-PD-1, in patients with metastatic cutaneous squamous cell carcinoma (mCSCC ; Group 1): 12 month follow-up** (Dr. Alexander Guminski; Monday, June 3: Poster Display, 1:15-4:15 PM)

- **Treatment patterns and outcomes among patients with advanced cutaneous squamous cell carcinoma in a US community oncology setting** (Dr. C. Lance Cowey; Publication Only)

- **Patterns of major surgeries among patients diagnosed with cutaneous squamous cell carcinoma** (Chieh-I Chen; Publication Only)

### Evolving evidence in breast and lung cancers

Breast cancer is the second most common form of cancer. An estimated 70% of breast cancers are estrogen receptor (ER) positive. SAR439859 is an investigational oral selective estrogen receptor degrader (SERD), a small molecule targeted therapy that binds to estrogen receptors in breast cancer cells to trigger their degradation.

- **Dose-escalation study of SAR439859, an oral selective estrogen receptor (ER) degrader (SERD), in postmenopausal women with ER+/HER2- metastatic breast cancer** (Dr. Aditya Bardia; Poster Display, Sunday, June 2, 8:00-11:00 AM)

- **Phase 1/2 dose-escalation and expansion study investigating SAR439859 +/- palbociclib in postmenopausal women with estrogen receptor-positive (ER+)/HER2- metastatic breast cancer** (Dr. Aditya Bardia; Poster Display, Sunday, June 2, 8:00-11:00 AM)

Carcinoembryonic antigen-related cell adhesion molecule 5 (CEACAM5) is a cell-surface glycoprotein highly expressed in several tumor types, including non-squamous non-small cell lung cancer (NSQ NSCLC). Approximately 20% of lung cancers have a high expression of CEACAMS.

- **First-in-human Phase 1 study of the antibody-drug conjugate (ADC) SAR408701 in advanced solid tumors: dose-expansion cohort of patients (pts) with non-squamous non-small cell lung cancer (NSQ NSCLC)** (Dr. Anas Gazzah; Poster Display, Sunday, June 2, 8:00-11:00 AM)

Additional abstracts supported by Sanofi include:

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<thead>
<tr>
<th>Abstract title</th>
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<tr>
<td>Oral Abstract, Friday, May 31, 2:45-5:45 PM</td>
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<td>Updated results from a randomized phase II study of cabazitaxel (CAB) versus abiraterone (ABI) or enzalutamide (ENZ) in poor prognosis metastatic CRPC</td>
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<td>Poster Session, Saturday, June 1, 1:15-4:15 PM</td>
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<td>Cell-free DNA as a biomarker for taxane treatment in advanced prostate cancer</td>
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<td>Cabazitaxel with Abiraterone Versus Abiraterone Alone Randomized Trial for Extensive Disease Following Docetaxel: the CHAARTED2 Trial: A trial of the ECOG-ACRIN Cancer Research Group (EA8153)</td>
<td>TPS5094</td>
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<td>HSD3B1 and Overall Survival in Men with Low-Volume Metastatic Disease Treated with Androgen Deprivation Therapy or Chemohormonal Therapy in the CHAARTED Randomized Trial</td>
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<td>CALGB 90203 (Alliance): Radical prostatectomy (RP) with or without neoadjuvant chemohormonal therapy (CHT) in men with clinically localized, high-risk prostate cancer (CLHRPC).</td>
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<td>Oral Abstract, Saturday, June 1, 3:00-6:00 PM</td>
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<td>Association of Colon Cancer (CC) Molecular Signatures with Prognosis and Oxaliplatin Prediction-Benefit in the MOSAIC Trial (Multicenter International Study of Oxaliplatin/SFU-LV in the Adjuvant Treatment of Colon Cancer)</td>
<td>3503</td>
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Clinical Science Symposium, Sunday, June 2, 8:00-9:00 AM

Evolutionary action score of TP53 analysis in pathologically high-risk HPV-negative head and neck cancer from a phase II clinical trial: NRG Oncology RTOG 0234

Poster Session, Monday, June 3, 8:00-11:00 AM

Repeated centralized MDT resectability assessment during first-line treatment in 1086 Finnish metastatic colorectal cancer (mCRC) patients nationwide (prospective RAXO study).

Combination of tissues analysis and immune infiltrate in localized colon cancer using Using artificial intelligence in PETACC8 study

Relative Contribution of Clinical and Molecular Features to Outcome Within Low and High Risk T and N Groups in Patients with Stage III Colon Cancers (Alliance)

Is the predictive and prognostic impact of sporadic and familial microsatellite unstable stage III colon cancer different? A pooled analysis of the PETACC8 and NCCTG N0147 (Alliance) trials

About Isatuximab
Isatuximab is an investigational anti-CD38 monoclonal antibody (mAb) for the treatment of patients with relapsed/refractory multiple myeloma. Developed by Sanofi, isatuximab targets a specific epitope of CD38 capable of triggering multiple, distinct mechanisms of action that are believed to promote programmed tumor cell death (apoptosis) and immunomodulatory activity. CD38 is highly and uniformly expressed on multiple myeloma cells and is a cell surface receptor target for antibody-based therapeutics in multiple myeloma and other malignancies. The clinical significance of these findings is under investigation.

Isatuximab is currently being evaluated in multiple ongoing Phase 3 clinical trials in combination with currently available treatments across the multiple myeloma treatment continuum. Isatuximab is also under investigation for the treatment of other hematologic malignancies and solid tumors. Isatuximab is an investigational agent and its safety and efficacy have not been evaluated by the U.S. Food and Drug Administration, the European Medicines Agency, or any other regulatory authority.

About Libtayo
Libtayo is approved in the U.S., Canada and Brazil, and is under review by the European Commission following a positive opinion by the Committee for Medicinal Products for Human Use (CHMP). In the U.S., Libtayo is approved for the treatment of patients with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation.[vi] The generic name for Libtayo in the U.S. is cemiplimab-rwlc, with rwlc as the suffix designated in accordance with Nonproprietary Naming of Biological Products Guidance for Industry issued by the U.S. Food and Drug Administration.

Libtayo is also being investigated in potential registrational trials in non-small cell lung cancer, basal cell carcinoma and cervical cancer, along with additional trials in squamous cell carcinoma of the head and neck, melanoma, colorectal cancer, prostate cancer, multiple myeloma, Hodgkin's lymphoma and non-Hodgkin's lymphoma. These trials are designed to investigate Libtayo as monotherapy; in combination with conventional treatments like chemotherapy; or in combination with other investigational agents, including vaccines, oncolytic viruses and bispecific antibodies, among others. These potential uses are investigational, and their safety and efficacy have not been evaluated by any regulatory authority.

IMPORTANT SAFETY INFORMATION AND INDICATION FOR U.S. PATIENTS

What is the most important information I should know about Libtayo?
Libtayo is a medicine that may treat a type of skin cancer by working with your immune system. Libtayo can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your healthcare provider right away if you develop any symptoms of the following problems or these symptoms get worse:

- **Lung problems (pneumonitis).** Signs and symptoms of pneumonitis may include new or worsening cough, shortness of breath, and chest pain.
- **Intestinal problems (colitis) that can lead to tears or holes in your intestine.** Signs and symptoms of colitis may include diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky or that have blood or mucus; and severe stomach-area (abdomen) pain or tenderness.
- **Liver problems (hepatitis).** Signs and symptoms of hepatitis may include yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), drowsiness, dark urine (tea colored), bleeding or bruising more easily than normal, and feeling less hungry than usual.
- **Hormone gland problems** (especially the adrenal glands, pituitary, thyroid and pancreas). Signs and symptoms that your hormone glands are not working properly may include headaches that will not go away or unusual headaches, rapid heartbeat, increased sweating, extreme tiredness, weight gain or weight loss, dizziness or fainting, feeling more hungry or thirsty than usual, hair loss, feeling cold, constipation, deeper voice, very low blood pressure, urinating more often than usual, nausea or vomiting, stomach-area (abdomen) pain, and changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness.

- **Kidney problems**, including nephritis and kidney failure. Signs of these problems may include decrease in your amount of urine, blood in your urine, swelling in your ankles, and loss of appetite.

- **Skin problems.** Signs of these problems may include rash, itching, skin blistering, and painful sores or ulcers in the mouth, nose, throat, or genital area.

- **Problems in other organs.** Signs of these problems may include headache, tiredness or weakness, sleepiness, changes in heartbeat (such as beating fast, seeming to skip a beat, or a pounding sensation), confusion, fever, muscle weakness, balance problems, nausea, vomiting, stiff neck, memory problems, seizures (encephalitis), swollen lymph nodes, rash or tender lumps on skin, cough, shortness of breath, vision changes, or eye pain (sarcoidosis), seeing or hearing things that are not there (hallucinations), severe muscle weakness, low red blood cells (anemia), bruises on the skin or bleeding, and changes in eyesight.

- **Rejection of a transplanted organ.** Your doctor should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.

- **Infusion (IV) reactions that can sometimes be severe and life-threatening.** Signs of these problems may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, fever, feeling of passing out, back or neck pain, and facial swelling.

Getting medical treatment right away may help keep these problems from becoming more serious.

Your healthcare provider will check you for these problems during your treatment with Libtayo. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may delay or completely stop treatment if you have severe side effects.

**Before you receive Libtayo, tell your healthcare provider about all your medical conditions, including if you:**

- have immune system problems such as Crohn’s disease, ulcerative colitis, or lupus;
- have had an organ transplant;
- have lung or breathing problems;
- have liver or kidney problems;
- have diabetes;
- are pregnant or plan to become pregnant; Libtayo can harm your unborn baby.

**Females who are able to become pregnant:**

- Your healthcare provider will give you a pregnancy test before you start treatment.
- You should use an effective method of birth control during your treatment and for at least 4 months after your last dose of Libtayo. Talk with your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with Libtayo.
  - are breastfeeding or plan to breastfeed. It is not known if Libtayo passes into your breast milk. Do not breastfeed during treatment and for at least 4 months after the last dose of Libtayo.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

The most common side effects of Libtayo include tiredness, rash, and diarrhea. These are not all the possible side effects of Libtayo. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Regeneron Pharmaceuticals and Sanofi at 1-877-542-8296.

**Please see accompanying full Prescribing Information, including Medication Guide.**

**What is Libtayo?**

Libtayo is a prescription medicine used to treat people with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC) that has spread or cannot be cured by surgery or radiation.

It is not known if Libtayo is safe and effective in children.

**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

**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 absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi’s ability to benefit from external growth opportunities 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 conditions, the impact of cost containment initiatives and subsequent changes thereto, the average number of shares outstanding as well as those 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, 2018. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.


[vi] LIBTAYO® (cemiplimab-rwlc) full US Prescribing Information. Regeneron Pharmaceuticals, Inc. / sanofi-aventis U.S. LLC.

Language: English