SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NYSE: SNY)

Sanofi presents R&D strategy and innovative pipeline

- Robust pipeline expected to support long-term growth
- 9 planned regulatory submissions over next 18 months
- At least 10 pivotal phase 3 studies expected to begin over next 12 months
- R&D model leverages new proprietary technology platforms, multi-targeting molecules and biologics

PARIS, France - 13 December 2017 – Sanofi will host an analyst meeting in Paris today to discuss the company's Research and Development strategy, development pipeline and milestones for 2018. The company will highlight the progress it has made against "Sustaining Innovation", a key pillar of its 2020 strategic roadmap, and advancing a differentiated portfolio addressing unmet needs.

The company's pipeline spans 71 R&D projects, which includes 37 new molecular entities and novel vaccines. At least 10 pivotal phase 3 studies are expected to start over the next 12 months and will evaluate new treatments for:

- chronic obstructive pulmonary disease and eosinophilic esophagitis (dupilumab[1]);
- autosomal dominant polycystic kidney disease (ADPKD), a rare kidney disease (venglustat);
- type 2 diabetes (efpeglenatide, a once-weekly GLP-1 agonist);
- obesity (a GLP-1/GCG dual agonist);
- primary progressive multiple sclerosis (alemtuzumab), and;
- first line NSCLC[2] (cemiplimab).

Regulatory filings expected in the next 12 months include two investigational cancer drugs (cemiplimab and isatuximab), a novel therapy for type 1 diabetes (sotagliflozin) and a potential treatment for uncontrolled, persistent asthma (dupilumab).

[1] Partnered products: cemiplimab, dupilumab, anti-IL33 mAb (Regeneron); sotagliflozin (Lexicon); efpeglenatide (Hanmi); fitusiran, patisiran (Alnylam); mavacamten, MYK-491 (Myokardia).
[2] Non-Small Cell Lung Cancer

"We have seen significant advancement on our ambition to sustain innovation in R&D, with the development of leading technology platforms and proof of concept demonstrated in multiple high-potential projects in late stage trials. We are confident this portfolio will be the foundation for Sanofi's future long-term growth," said Olivier Brandicourt, MD, Chief Executive Officer at Sanofi.

As a key pillar of the 2020 Roadmap, the new Sanofi R&D model is based on three key strategic shifts:

- From small molecules to biologics;
- From mono-targeting to multi-targeting compounds; and
- From licensing to proprietary assets.

The company has continuously adapted its R&D model in recent years to deliver greater efficiency and excellence in development, resulting in a major uplift in productivity. Since 2016, consistent with the three key strategic shifts outlined above, Sanofi has placed increasing emphasis on developing proprietary technology platforms, including multi-specific antibodies (bi- & tri-specific), siRNA, trigonal peptides, dual and triple agonists, and PRR-Antibody conjugates. It has also leveraged external expertise in targeted platforms such as mRNA mixtures and Nanobodies®.

"We aim to advance multi-targeting therapeutic approaches for core disease pathways that have the potential to attack more than one disease at a time or bring improved risk benefit in the treatment of a single disease," said Elias Zerhouni, MD, Global Head of R&D at Sanofi. "2018 will be an important year as we expect multiple milestones for Sanofi's late-stage pipeline, made possible through the prioritization principles we have consistently applied to our early-stage research programs."

Building a competitive position in Specialty Care

Immunology

Sanofi is strengthening its specialty care portfolio and has executed launches in its fast-growing immunology franchise. Dupilumab, which we are developing in collaboration with Regeneron, has potential across multiple indications. Phase 3 trials for uncontrolled, persistent asthma recently demonstrated a potentially clinically important profile among biologic treatments. Submission in this important indication is expected before the end of 2017. Clinical development is underway in nasal polyposis, eosinophilic esophagitis, food allergies and in pediatric populations in most of these indications. Additionally, phase 3 development for dupilumab is now planned in chronic obstructive pulmonary disease (COPD). Sanofi, in collaboration with Regeneron, also

expects to bring SAR440340, an anti-IL-33 antibody, which has the potential for a broader spectrum of immune modulation, into phase 2 in atopic dermatitis, asthma and COPD in 2018, alone or in combination with dupilumab.

Oncology

Sanofi is committed to re-building its position in oncology and has made major progress in the past two years. This strategy is starting to deliver and we anticipate 14 new proof-of-concept studies to be initiated, four potential proof-of-concept readouts, six phase one starts and three BLA/ MAA submissions in 2018. Cemiplimab is an investigational PD-1 checkpoint inhibitor and the backbone of our checkpoint immuno-oncology strategy with our partner Regeneron. It is being studied in cutaneous squamous cell carcinoma (CSCC), for which it was granted "Breakthrough Therapy" designation by the U.S. Food and Drug Administration (FDA), with an expected regulatory submission in Q1 2018. The development program also includes large or untapped opportunities in immuno-oncology, such as basal cell carcinoma, cervical cancer, and first line lung cancer.

Isatuximab is a Sanofi investigational antiCD38 monoclonal antibody with a first regulatory submission expected in 2018 for relapsed refractory multiple myeloma (RRMM). Beyond multiple myeloma, and building on the emerging evidence that CD38 inhibition may reverse resistance to PD-L1, isatuximab will be studied in combination with cemiplimab or other immuno-oncology agents. Sanofi will also present early research programs for its Selective Estrogen Receptor Degrader (SERD) and TGF-beta program to overcome PD-1 resistance.

Multiple Sclerosis

In multiple sclerosis (MS), Sanofi plans to build on the proven long-term clinical profile of Lemtrada® (alemtuzumab) by initiating a Phase 3 study in 2018 for alemtuzumab in patients with primary progressive multiple sclerosis (PPMS). Consistent with Sanofi's rigorous prioritization methodology, the company will deprioritize GLD-52 in this indication in favor of alemtuzumab. In addition, Sanofi, in collaboration with Principia, will be developing a novel Bruton's tyrosine kinase (BTK) inhibitor, designed to access the brain and spinal cord by crossing the blood-brain barrier and impact immune cell and brain cell signaling. It is currently being studied in MS with potential applications in other central nervous system diseases[3].

Sustaining leadership in Rare Disease, Diabetes & Cardiovascular and Vaccines

[3] The Principia transaction remains subject to customary regulatory approvals and has not yet closed.

Rare Disease

Sanofi's Rare Disease pipeline is structured with the goal of sustaining innovation in lysosomal storage disorders, while also expanding strategically into related conditions. Clinical development programs include venglustat, an oral inhibitor of glucosylceramide synthase, in Fabry Disease, Gaucher Disease Type 3, GBA Parkinson's Disease and autosomal dominant polycystic kidney disease (ADKPD). Late-stage/pivotal programs include olipudase, a first-in-class enzyme replacement therapy (ERT) for the non-neurological manifestations of acid sphingomyelinase deficiency (ASMD), and avalglucosidase alfa, a novel ERT for Pompe disease. Finally, through a strategic collaboration with Alnylam, we are advancing the development of patisiran for hATTR[4] amyloidosis and fitusiran for hemophilia A and B, with and without inhibitors.

Diabetes & Cardiovascular

Sanofi is committed to sustaining a leadership position in diabetes and expanding into adjacent co-morbidities. Its late-stage diabetes pipeline includes sotagliflozin, an investigational SGLT-1/2 inhibitor being developed in collaboration with Lexicon, and efpeglenatide, a once-weekly GLP-1 being developed in collaboration with Hanmi. Both of which potentially offer unique patient advantages. Additionally, Sanofi is leveraging its novel peptide incretin platform to develop breakthrough assets for diabetes, obesity and non-alcoholic steatohepatitis (NASH). The lead compound is an oral dual agonist of GLP-1/GCG which has shown highly competitive weight loss in the clinic and is expected to enter phase 3 in obesity in 2018. A phase 2 study in NASH is also due to start in 2018.

In cardiovascular, Sanofi continues to work in collaboration with Myokardia on therapeutic options for genetic forms of cardiomyopathy. The lead compound is mavacamten, an oral modulator of cardiac myosin, which is in phase 2 for HCM[5] and is expected to start a registrational phase 2b/3 study in 2018.

Vaccines

Sanofi has six key vaccine projects currently in development, and priority disease areas include influenza, meningitis and respiratory syncytial virus (RSV). RSV is the leading cause of infant viral mortality and represents a new potential category for Sanofi. The company is taking a complementary dual approach to RSV with a monoclonal antibody in phase 2, in collaboration with MedImmune, and a vaccine in phase 1.

Webcast details

The event will be webcast live on Sanofi's website at 8:30 am CET/2:30

[4] hATTR = Hereditary Transthyretin-Mediated Amyloidosis
[5] HCM= Hypertrophic cardiomyopathy

am EST. The webcast details and full presentation will be made available on Sanofi's Investor Relations webpage and an Appendix compiling all Sanofi studies registered on clinicaltrials.gov will also be published.

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 of new products, including future clinical trial results and analysis of clinical data (including post-marketing data), 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. There are additional risks that may cause actual results to differ materially from those contemplated by the forward-looking statements, such as the lack of commercial success of certain product candidates once approved, pricing pressures, both in the United States and abroad, including pharmaceutical reimbursement and pricing, the future approval and commercial success of therapeutic alternatives, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, changes in applicable laws or regulations, the impact of cost containment initiatives and subsequent changes thereto, as well as those risks and 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, 2016. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Appendix 1: R&D Pipeline – New Molecular Entities [(*)]

R : Registration Study (other than Phase 3)
O : Opt-in rights products for which rights have not been exercised yet

- Immuno-inflammation
- MS, Neuro, Ophthalmology
- Oncology
- Rare Disease
- Diabetes Solutions
- Cardiovascular & metabolism
- Infectious Disease
- Vaccines

Phase 3

R **isatuximab** Anti-CD38 mAb +pomalidomide/dexamethasone Relapsed Refractory Multiple Myeloma	**patisiran** [(**)] siRNA inhibitor targeting TTR Hereditary ATTR amyloidosis
GZ402666 avalglucosidase alfa Pompe Disease	**fitusiran**[(9)(**)] siRNA targeting Anti-Thrombin Hemophilia
sotagliflozin [(**)] Oral SGLT-1&2 inhibitor Type 1 Diabetes	**SAR341402** Rapid acting insulin Type 1 & Type 2 Diabetes
efpeglenatide[(**)] Long-acting GLP-1 receptor agonist Type 2 Diabetes	

Phase 2

SAR156597 IL4/IL13 Bi-specific mAb Systemic Scleroderma	**SAR425899** GLP-1R/GCG dual agonist Obesity/Overweight in T2D	**GZ389988** TRKA antagonist Osteoarthritis
mavacamten[(7)(**)] Myosin inhibitor Obstructive Hypertrophic Cardiomyopathy	R **cemiplimab**[(4)(**)] PD-1 inhibitor mAb Advanced CSCC (Skin cancer)	**SAR407899** rho kinase Microvascular Angina
R **SAR566658** Maytansin-loaded anti-CA6 mAb Triple Negative Breast Cancer	Combination **ferroquine / OZ439**[(**)] Antimalarial	R **olipudase alfa** rhASM Deficiency Acid Sphingomyelinase Deficiency[(6)]
Tuberculosis Recombinant subunit vaccine	O **SAR339375**[(6)] miRNA-21 Alport Syndrome	**HIV** Viral vector prime & rgp120 boost vaccine

venglustat Oral GCS inhibitor Gaucher related Parkinson's Disease	**SP0232[8] mAb[**]** Respiratory syncytial virus Monoclonal antibody	**SAR422459** ABCA4 gene therapy Stargardt Disease

Phase 1

SAR440340[**] Anti-IL33 mAb Asthma	**UshStat®** Myosin 7A gene therapy Usher Syndrome 1B	**SAR439794** TLR4 agonist Peanut Allergy
SAR228810 Anti-protofibrillar AB mAb Alzheimer's Disease	**SAR408701** Maytansin-loaded anti-CEACAM5 mAb Solid Tumors	**SAR438335** GLP-1/GIP dual agonist Type 2 Diabetes
SAR439459 anti-TGFβ mAb Advanced Solid Tumors	**SAR440181[3][**]** Myosin activation Dilated Cardiomyopathy	**O** **REGN3767[1]** Anti LAG-3 mAb Advanced Cancers
SAR439859 SERD Metastatic Breast Cancer	**Herpes Simplex Virus Type 2** HSV-2 vaccine	**O** **ALN-TTRsc02[2]** Sub-cutaneous siRNA inhibitor targeting TTR Hereditary ATTR Amyloidosis
Respiratory syncytial virus Infants Vaccines	**O** **ALN-GO1[2]** Investigational RNAi therapeutic Primary Hyperoxaluria Type 1 (PH1)	

(1) Regeneron product for which Sanofi has opt-in right
(2) Alnylam product for which Sanofi has opt-in right
(3) Also known as MYK491
(4) Also known as SAR439684 and REGN2810
(5) Also known as Niemann Pick type B
(6) Regulus product for which Sanofi has opt-in right

(7) Also known as SAR439152 and as MYK461
(8) Also known as MEDI8897
(9) Currently on clinical hold pending outcome of FDA discussion – Expected to resume around year-end

(*) data related to all studies published in clinicaltrials.gov
(**) Partnered and/or in collaboration – Sanofi may have limited or shared rights on some of these products

Appendix 2: R&D Pipeline – Additional Indications (*)

R : Registration Study (other than Phase 3)
O : Opt-in rights products for which rights have not been exercised yet

- Immuno-inflammation
- MS, Neuro, Ophthalmology
- Oncology
- Rare Disease
- Diabetes Solutions
- Cardiovascular & metabolism
- Infectious Disease
- Vaccines

Registration

VaxiGrip® QIV IM Quadrivalent inactivated influenza vaccine (6-35 months)
PR5i DTP-HepB-Polio-Hib Pediatric hexavalent vaccines, U.S.

Phase 3

dupilumab(**) Anti-IL4Rα mAb Asthma 6 – 11 years old	R **isatuximab** Anti-CD38 mAb 1st line Ti (IMROZ)	**dupilumab(**)** Anti-IL4Rα mAb Asthma 12y+
R **isatuximab** Anti-CD38 mAb Relapsing Refractory Multiple Myeloma (IKEMA)	**dupilumab(**)** Anti-IL4Rα mAb Nasal Polyposis	**Aubagio®** teriflunomide Relapsing Multiple Sclerosis - Pediatrics
Dupixent®(**) Anti-IL4Rα mAb Atopic Dermatitis 12 – 17 years old	**Sotagliflozin(**)** Oral SGLT-1&2 inhibitor Type 2 Diabetes	**Dupixent®(**)** Anti-IL4Rα mAb Atopic Dermatitis 6 – 11 years old
Praluent®(**) Anti-PCSK9 mAb CV events reduction	**Dupixent®(**)** Anti-IL4Rα mAb Atopic Dermatitis 6 months – 5 years old	**Fluzone® QIV HD** Quadrivalent inactivated Influenza vaccine - High dose
R **cemiplimab(1)(**)** PD-1 inhibitor 2nd line Cervical Cancer	**Men Quad TT** Advanced meningococcal ACYW conjugate vaccine	R **cemiplimab(1)(**)** PD-1 inhibitor 1st line NSCLC
Pediatric pentavalent vaccine DTP-Polio-Hib Japan		

Phase 2

dupilumab[(**)] Anti-IL4Rα mAb Eosinophilic Esophagitis	**sotaglifozin**[(**)] (SAR439954) SGLT 1 & 2 inhibitor – Worsening Heart Failure	**sarilumab(**)** Anti-IL6R mAb Polyarticular Juvenile Idiopathic Arthritis
mavacamten[(4)(**)] Myosin inhibitor Non-Obstructive Hypertrophic Cardiomyopathy	**sarilumab(**)** Anti-IL6R mAb Systemic Juvenile Arthritis	**Rabies VRVg** Purified vero rabies vaccine
R **cemiplimab**[(1)(**)] PD-1 inhibitor mAb Advanced Basal Cell Carcinoma	**Adacel+** Tdap booster	**venglustat** Oral GCS inhibitor Gaucher Disease Type 3
Shan 6 DTP-HepB-Polio-Hib Pediatric hexavalent vaccine	**venglustat** Oral GCS inhibitor Fabry Disease	

Phase 1

isatuximab + cemiplimab[(1)(**)] Anti-CD38 mAb + PD1 inhibitor mAb Relapsing Refractory Multiple Myeloma
isatuximab Anti-CD38 mAb + CyBord[(2)] Newly Diagnosed Multiple Myeloma
SAR439459 + cemiplimab[(1)(**)] Anti-TGFβ mAb + PD1 inhibitor mAb Advanced Solid Tumors
SAR439859 SERD + Palbociclib Metastatic Breast Cancer
O **cemiplimab**[(1)(**)] **+ REGN3767**[(3)] PD1 inhibitor mAb + anti LAG-3 mAb Advanced Cancers

(1) Also known as SAR439684 and REGN2810
(2) Cyclophosmamide + bortezomib (Velcade) + dexamethasone
(3) Regeneron product for which Sanofi has opt-in right
(4) Also known as SAR439152 and as MYK461

(*) data related to all studies published in clinicaltrials.gov
(**) Partnered and/or in collaboration – Sanofi may have limited or shared rights on some of these products