

# LETTER TO SHAREHOLDERS

#47

DECEMBER 2016



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**SANOFI**

# MESSAGE FROM THE CHAIRMAN



SERGE WEINBERG, CHAIRMAN OF THE BOARD OF DIRECTORS

## DEAR SHAREHOLDERS,

As we approach the end of the year, we can be satisfied with the progress we have made in terms of financial results, innovation for patients and the implementation of our strategy.

We achieved better than expected results in the first nine months of the year, largely due to the diversity of our businesses. We have demonstrated again this quarter that we can count on dynamic franchises such as Rare Diseases, Multiple Sclerosis, Vaccines and on our performance in Emerging Markets to offset the slowdown of our Diabetes business in the United States. Pricing pressure by payers, and especially on the prices of our insulins, are a reality. They have an undeniable impact on our sales but we are adapting.

Our ability to innovate is the best way to ensure our growth. This innovation is not limited to the discovery of new treatments; it also encompasses our initiatives in favor of a complete management of patients by giving them the tools to more effectively monitor their disease or to improve compliance. It is in this spirit that we have created Onduo, a joint venture with Verily, in charge of developing a comprehensive platform for the management of diabetes.

We decided to initiate a process to carve out and divest the Generics business in Europe, which is expected to take place over the next 12 to 24 months. This is in line with our strategy to continue investing in businesses where we can be among the world leaders.

I thank you for your trust and continuing loyalty.



OUR ABILITY TO INNOVATE  
IS THE BEST WAY TO ENSURE  
OUR GROWTH. ”

# STRONG THIRD QUARTER 2016 RESULTS



## INTERVIEW WITH THE CHIEF EXECUTIVE OFFICER



OLIVIER BRANDICOURT, CHIEF EXECUTIVE OFFICER

## ■ 2016 GUIDANCE RAISED ON STRONG THIRD-QUARTER RESULTS

In Q3 2016, Sanofi recorded a strong financial performance, with aggregate company sales up 3.0% and business EPS<sup>3</sup> up 12.4% at CER. Exchange rate movements had a limited negative impact in Q3: 0.9 percentage points on sales and 1.2 points on business EPS.

Given the performance in the first nine months of the year, Sanofi now expects 2016 business EPS to grow between 3% and 5% at CER, barring unforeseen major adverse events.<sup>5</sup>

## ■ SPECIALTY CARE AND VACCINES CONTINUE TO SUPPORT SOLID SALES PERFORMANCE

The Specialty Care business continues to be an important growth driver for Sanofi. The **Multiple Sclerosis** franchise is up 54.3% at CER. It now has annualized sales of €1.8 billion. The **Rare Diseases** franchise increased by 14.3% at CER, notably due to the continuous increase in the number of new patients treated, in particular with Fabrazyme<sup>®</sup> (for Fabry disease) and Myozyme<sup>®</sup> / Lumizyme<sup>®</sup> (for Pompe disease).

**Sanofi Pasteur** recorded a 14.4% sales increase at CER, supported by early delivery of influenza vaccines in the United States.

Global sales of the **Diabetes & Cardiovascular** franchise are nearly stable. Sales of the Diabetes franchise were slightly down by 1.5% at CER, with the U.S. decline partially offset by strong sales in Emerging Markets (+13.6% at CER) and stable sales in Europe (-0.6% at CER).

Sales by franchise	Q3 2016	Change at CER
Specialty Care	€1,517M	+18.5%
Diabetes & Cardiovascular	€1,929M	+0.3%
Established Products	€2,535M	-7.4%
Consumer Healthcare	€791M	-1.2%
Generics	€453M	+1.3%
Vaccines	€1,803M	+14.4%
Animal Health	€624M	+4.0%



### Strong growth in Emerging Markets

In Q3 2016, aggregate sales in Emerging Markets increased by 5.6% to €2,548M.

In **Brazil**, a public immunization program against dengue was launched in the state of Paraná.

1 - Growth rates are expressed at constant exchange rates (CER). Growth rates in brackets are expressed on a reported basis. For definitions of financial indicators, please consult the press release issued on October 28, 2016.

2 - Including Animal Health Business which is reported on a single line in the consolidated income statements in accordance with IFRS 5 (Non-current held for sale and discontinued operations).

3 - Earnings per share 4 - Business EPS 2015: €5.64 5 - See forward looking statement in the press release issued on October 28, 2016.

## ■ WHAT ARE THE HIGHLIGHTS OF THE 3<sup>RD</sup> QUARTER 2016?

Sanofi reported a solid financial performance this quarter. The implementation of a more focused organization has allowed us to become more efficient and to generate savings that have contributed to this performance.

Of note, our Specialty Care and Vaccines franchises remain key growth drivers, while the Diabetes & Cardiovascular and the General Medicine & Emerging Markets franchises have shown considerable improvement compared to the previous quarter. As a result, we are able to increase our full-year 2016 Business EPS guidance.

## ■ WHAT WAS THE CONTRIBUTION OF NEWLY LAUNCHED PRODUCTS?

Major launches of new products are progressing. Toujeo<sup>®</sup>, our new generation insulin, generated global sales of €167M and continues to perform well in our main markets. Praluent<sup>®</sup> is approved in 41 countries for hypercholesterolemic patients and its sales, €35M in the third quarter, continue to progress globally, although they still reflect significant payer utilization management restrictions in the U.S. and limited market access in Europe. As for the Dengvaxia<sup>®</sup> vaccine, it generated sales of €30M in the third quarter and is now registered in 13 countries where dengue fever is endemic.

## ■ WHAT ABOUT THE PRODUCTS CURRENTLY UNDER REVIEW BY HEALTH AUTHORITIES?

The U.S. Food and Drug Administration (FDA) accepted the Biologics License Application of Dupixent<sup>®</sup> (dupilumab) for priority review in patients with moderate-to-severe atopic dermatitis after granting Breakthrough Therapy designation in 2014.

Concerning sarilumab, for the treatment of rheumatoid arthritis, we have received a complete response letter from the FDA regarding our Biologics License Application. This letter outlines certain deficiencies identified during a routine good manufacturing practice inspection of the Sanofi facility where sarilumab is filled and finished. We work closely with the FDA towards a timely resolution that addresses these concerns, to allow the potential approval of the product. The letter does not identify any concerns relating to the safety or efficacy of sarilumab.

In the Diabetes area, the U.S. FDA approved once-daily Soliqua<sup>™</sup> 100/33, the fixed-ratio combination of insulin glargine and lixisenatide, for the treatment of adults with inadequately controlled type 2 diabetes. In Europe, the Committee for Medicinal Products for Human Use of the European Medicines Agency has recommended the approval of the product under the brand name Suliqua<sup>™</sup>. The European Commission is expected to make a final decision on marketing authorization for Suliqua<sup>™</sup> in the coming months.

# DUPIXENT®: NEW HOPE FOR ADULT PATIENTS WITH MODERATE-TO-SEVERE ATOPIC DERMATITIS



Nancy, Atopic Dermatitis, United States

**1-3%**  
OF ADULTS<sup>1</sup> WITH

**ATOPIC DERMATITIS**

**WORLDWIDE**

Strong medical need for a  
**safe and effective  
long-term treatment  
in moderate-to-severe AD**

1- Nutten S. Atopic Dermatitis: Global Epidemiology and Risk Factors. *Ann Nutr Metab.* 2015;66(suppl 1): 8-16

2- Dupixent® is currently under clinical development by Sanofi and Regeneron and its safety and efficacy have not been fully evaluated by any regulatory authority.

## VERY ENCOURAGING PHASE III RESULTS

On October 1<sup>st</sup> 2016, Sanofi and Regeneron announced detailed results from two Phase III studies evaluating Dupixent® (dupilumab), injected subcutaneously once per week, or every two weeks, in adults with inadequately-controlled moderate-to-severe atopic dermatitis. The studies evaluated extent and severity of the disease. They met primary endpoints, in particular those concerning **clearing or near-clearing of skin lesions**. They also met key secondary endpoints, including **reduction in itch, improvement in patient-reported anxiety and depression symptoms, and certain quality of life measures**.

## FAST TRACK PRODECURE IN THE U.S.

The Biologics License Application for Dupixent® was accepted for **priority review** by the U.S. Food and Drug Administration (FDA). Its decision is expected on March 29, 2017. In 2014, the FDA granted Dupixent® **Breakthrough Therapy designation** in adults with uncontrolled moderate-to-severe atopic dermatitis, recognizing its **potential to**

**demonstrate a substantial improvement over available therapies**. The UK health authority awarded the product a **Promising Innovative Medicine** status. European and U.S. health authorities have conditionally accepted Dupixent® as the trade name for dupilumab.

## CLINICAL STUDIES IN MULTIPLE INDICATIONS

Dupilumab is also being evaluated in other immune-mediated diseases:

- **Asthma:** Phase III ongoing
- **Nasal polyposis:** Phase III to start in Q1 2017
- **Eosinophilic esophagitis:** Phase II ongoing

## MODERATE-TO-SEVERE ATOPIC DERMATITIS (AD)

- Serious, chronic form of eczema
- Skin rashes
- Intense itching
- Skin dryness and lesions

> SERIOUS INCIDENCE ON THE QUALITY OF LIFE

## LAUNCH OF ONDUO, A JOINT-VENTURE CREATED THROUGH SANOFI AND VERILY'S DIABETES-FOCUSED COLLABORATION

On September 12, 2016, Sanofi and Verily Life Sciences LLC (former Google Life Sciences), subsidiary of Alphabet, announced the creation of Onduo, a joint-venture to develop a comprehensive diabetes management platform. Onduo's mission is to help people with diabetes live full, healthy lives by developing comprehensive solutions that combine devices, software, medicine, and professional care.

Under the leadership of Dr. Joshua Riff, Onduo will leverage Verily's experience in miniaturized electronics, analytics, and consumer software development, and Sanofi's clinical expertise and experience in bringing innovative treatments to people living with diabetes.

Onduo is a digital healthcare company that uses data to help people with diabetes live their best life. Our name comes from our belief that progress is possible when we work in partnership and move forward, together. Join us!

Get in Touch

Onduo is a digital healthcare company that uses data to help people with diabetes live their best life. The name Onduo comes from the belief that progress is possible when different players work in partnership and move forward together.

## DEVELOPMENT OF A VACCINE AGAINST ZIKA VIRUS

Sanofi Pasteur, Fiocruz (Immuno-biological Technology Institute of the Brazilian Oswaldo Cruz Foundation) and WRAIR (Walter Reed Army Institute of Research - United States Department of Defense Laboratory) agreed on October 27, 2016 to collaborate on research for a vaccine against the Zika virus.

In September 2016, the BARDA (Biomedical Advanced Research and Development Authority) within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services agreed to fund Sanofi's manufacture of the inactivated Zika vaccine for Phase II development.

Fiocruz, whose activities will complement WRAIR and Sanofi Pasteur's activities, will provide additional expertise, thus increasing the likelihood of successfully developing and licensing a safe and effective Zika vaccine as quickly as possible.

## CORPORATE GOVERNANCE

### SANOFI APPOINTS ALAN MAIN TO EXECUTIVE COMMITTEE AND EXECUTIVE VICE PRESIDENT, CONSUMER HEALTHCARE



Alan Main was appointed Executive Vice President Consumer Healthcare, effective October 1<sup>st</sup>, 2016. He will be a member of the Executive Committee and lead the newly created Consumer Healthcare global business unit. Alan Main will be responsible for building and maintaining Sanofi's leading position in Consumer Healthcare. This includes the expected integration of Boehringer Ingelheim business into Sanofi.

### BONNIE L. BASSLER LEAVES SANOFI'S BOARD OF DIRECTORS

Bonnie L. Bassler resigned as Director of Sanofi on September 6, 2016, due to a potential conflict of interest related to her impending membership on another board.

## INDIVIDUAL SHAREHOLDERS COMMITTEE



### MEETING WITH PHILIPPE LUSCAN, EXECUTIVE VICE PRESIDENT, GLOBAL INDUSTRIAL AFFAIRS

On September 23, 2016, the Shareholders Committee gathered at Sanofi's headquarters in Paris and met with Philippe Luscan, Executive Vice-President Global Industrial Affairs and President, Sanofi France. He outlined the company's ambition to make Sanofi Industrial Affairs the gold standard in the pharmaceutical industry, noting that Sanofi's annual investments in the industrial sites network were as high as €1 billion, worldwide.

He also explained the challenges in terms of performance and evolution of the industrial network, in particular the evolution towards biotechnologies in Sanofi's key French, German and U.S. sites.

# SANOFI GENZYME

## THE FAST-GROWING SPECIALTY CARE BUSINESS UNIT

In 2016, Sanofi implemented a new organization based on five Global Business Units (GBUs) to refocus on its key activities. Sanofi Genzyme, the Specialty Care GBU, focuses on rare diseases, multiple sclerosis, oncology and immunology. While Sanofi Genzyme has expanded our expertise from rare diseases to new therapeutic areas, we remain unified by the same ambitious principles: addressing unmet medical needs, exploring innovative technologies and treatment approaches and improving the lives of patients worldwide.

### RARE DISEASES

Sanofi Genzyme is committed to bettering the lives of patients with rare diseases by offering sustainable, transformative healthcare options.

We have long been a leader in the development and delivery of targeted therapies for patients with rare genetic diseases, including lysosomal storage disorders, a group of more than 40 serious and progressive diseases caused by enzyme deficiencies.

Our rare diseases portfolio includes therapies for **Gaucher disease** (Cerezyme®, Cerdelga®); **Pompe disease** (Myozyme®/Lumizyme®), **Fabry disease** (Fabrazyme®) and **Mucopolysaccharidosis I** (Aldurazyme®) and certain types of **thyroid cancer** (Caprelsa®, Thyrogen®).

We are committed to addressing a significant unmet need that still exists for patients with rare diseases: **lack of access to an early diagnosis**. We work to improve the diagnosis of rare diseases through physician education, awareness programs and support of testing and screening initiatives.

### RESEARCH AREAS

Our research portfolio includes **next generation therapies** for Pompe disease and Fabry disease as well as investigational therapies for patients with Type 3 Gaucher disease and Acid Sphingomyelinase Deficiency, which currently have no treatments available.

In addition to internal research and development, we have formed several partnerships to help develop new treatment options for rare diseases including an alliance with Alnylam Pharmaceuticals. We are working with Alnylam on investigational products in the areas of

Approximately  
**7,000**  
identified rare diseases

**80%**  
are genetic

Less than  
**100**  
have an approved treatment

[www.alliance-maladies-rares.org](http://www.alliance-maladies-rares.org)



Ailin, Gaucher Disease, Cuba

**hemophilia** (fitusiran) and **familial amyloidotic polyneuropathy** (patisiran).

### MULTIPLE SCLEROSIS

Multiple sclerosis (MS) is an **autoimmune disorder** caused when the body's immune system attacks the central nervous system, damaging the myelin sheath - the protective layer covering the nerves that carry signals between the brain and spinal cord and the rest of the body - ultimately destroying the nerves and causing irreversible damage.

Sanofi Genzyme's MS franchise consists of **Aubagio®**, a once-daily oral therapy, and **Lemtrada®**, an intravenous infusion therapy administered in two treatment courses, 12 months apart. Both products have been developed for patients with relapsing forms of MS.

### RESEARCH AREAS

Our research efforts are focused on investigational treatments to **address unmet**

**needs for relapsing and progressive forms of MS**, and to potentially protect and repair the brain. We are committed to further advancing the treatment of MS and improving outcomes for individuals living with this disease.

**2.5 million**  
people live with MS worldwide

Dr. N. Danziger, Neurology, Med-Line Editions, 2011



Dave, Multiple Sclerosis, UK

## IMMUNOLOGY

Sanofi Genzyme holds the cornerstone of a **major new franchise in Immunology**, an area in which we hope to make a difference in patients' lives. In collaboration with Regeneron Pharmaceuticals, we are developing two monoclonal antibodies.

The first, **sarilumab**, an investigational interleukin-6 receptor (IL-6R) antibody, is under



Tanya, Atopic Dermatitis, Canada

**70 million**  
people with rheumatoid arthritis in the world<sup>1</sup>

**1 - 3%**  
adults with atopic dermatitis in the world<sup>2</sup>

**235 million**  
people with asthma in the world<sup>1</sup>

<sup>1</sup> - World Health Organization  
<sup>2</sup> - Nulten S. Atopic Dermatitis: Global Epidemiology and Risk Factors. Ann Nutr Metab. 2015;66(suppl 1):8-16

development for the treatment of moderate-to-severe rheumatoid arthritis, a chronic and painful inflammatory disease that damages the joints.

The second, **Dupixent**<sup>®</sup> (dupilumab), an investigational anti-IL-4/IL-13, is under review by health authorities in the United States for moderate-to-severe **atopic dermatitis**, a serious, chronic form of eczema. Dupilumab is also under development for **asthma, nasal polyposis** and **eosinophilic esophagitis**.

## ONCOLOGY

Sanofi has a strong heritage in oncology, notably in **chemotherapy** with Taxotere<sup>®</sup>, Jevtana<sup>®</sup> and Eloxatine<sup>®</sup>. We have diversified our presence in this area with Thymoglobulin<sup>®</sup>, an immuno-suppressive and immuno-modulating agent especially indicated in cases of rejection in organ transplantation, Mozobil<sup>®</sup> for hematological malignancies (cancers affecting the bone marrow or blood) and Zaltrap<sup>®</sup>, an angiogenesis inhibitor.

Now as part of the Specialty Care GBU, Sanofi Genzyme's ambition is to **rebuild the oncology portfolio** and fight cancer in all its different forms by carrying out research on the different pathways involved in the development, growth and propagation of cancer cells.

### RESEARCH AREAS

Our oncology research portfolio currently includes five projects, in particular isatuximab,



James, Prostate Cancer, United States

**14 million**  
new cancer cases and

**8.2 million**  
cancer-related deaths worldwide  
in 2012

World Cancer Report 2014

an anti-CD38 monoclonal antibody for **multiple myeloma**.

We are also working in partnership with Evotec, Apeiron Biologics and Regeneron Pharmaceuticals to **develop an innovative portfolio in immuno-oncology**, a promising area that directly targets the immune system checkpoints. As part of our alliance with Regeneron, we are jointly developing an inhibitor of programmed cell death protein 1 (PD-1) for **squamous cell carcinoma**, which is the first indication in Phase II.

## 3 QUESTIONS TO...



**DAVID MEEKE,**  
EXECUTIVE VICE PRESIDENT,  
HEAD OF SANOFI GENZYME

### THE NEW SPECIALTY CARE GBU WAS CREATED AT THE BEGINNING OF THE YEAR. WHAT DOES THIS MEAN FOR SANOFI GENZYME?

The new global business unit structure and our new name, Sanofi Genzyme, represent a closer integration within Sanofi while recognizing the experience Genzyme has developing highly specialized treatments and forging close relationships with physician and patient communities over the last 30 years.

This started with our focus in rare diseases and expanded to include multiple sclerosis in 2011 and immunology and oncology in 2016. Across these franchises, the patients we serve have debilitating and complex conditions that are often

difficult to diagnose and treat. We customize and refine our efforts according to the unique characteristics of each disease, but our constant guiding factor is a science-driven, patient-focused specialty care approach.

### WHAT ARE THE NEXT MOST IMPORTANT MILESTONES FOR SANOFI GENZYME?

We have two promising new therapies in development with Regeneron: Sarilumab for the treatment of adult patients with moderately to severely active rheumatoid arthritis, and Dupixent<sup>®</sup> under review with the U.S. FDA for treatment of adult patients with inadequately controlled moderate-to-severe atopic dermatitis. We expect an FDA decision at the end of March regarding potential approval of Dupixent<sup>®</sup>. For sarilumab, we are addressing deficiencies that the U.S. FDA identified during an inspection of the facility where sarilumab is filled and finished. We have begun to implement corrective measures so that the FDA can reassess the approval of the product as soon as possible.

### HOW DO YOU SEE THE FUTURE?

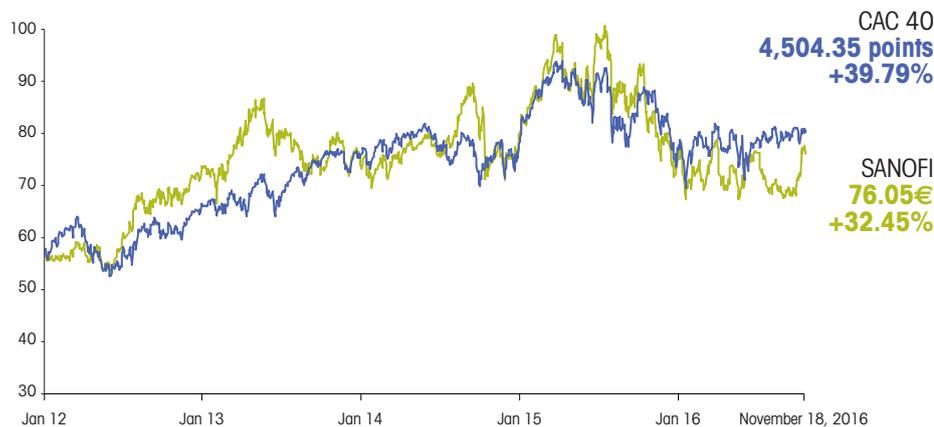
We have an unwavering commitment to supporting programs that best meet patient needs. This comes in many forms ranging from our focus on helping patients gain access to an early diagnosis to providing humanitarian support in areas where access to treatment is limited to advancing new investigational therapies. Beyond sarilumab and Dupixent<sup>®</sup> we have a robust pipeline with clinical programs in rare diseases, MS and oncology. We are excited for the opportunities that the future holds for patients and their families.

# SHARE PERFORMANCE

## IN PARIS

### SANOFI SHARE PRICE TREND OVER 5 YEARS

Euronext Paris, from January 1, 2012 to November 18, 2016



CAC 40 rebased on the Sanofi share price – Source: vwdgroup

On November 18, 2016, Sanofi had a market capitalization of more than €98bn.

## SALON ACTIONARIA

### 2016

The 19<sup>th</sup> edition of Salon Actionaria, European's largest exhibition dedicated to individual shareholders, was held on November 18<sup>th</sup> and 19<sup>th</sup>, 2016, at the Palais des Congrès in Paris.

#### MORE THAN 25,000 VISITORS ATTENDED THE EXHIBITION

The Investor Relations team, alongside the individual shareholders committee, were on-site to represent the company during the two days.

Once again, Salon Actionaria was the opportunity for Sanofi's Investor Relations team to meet current and potential individual shareholders, and to answer their questions about Sanofi's perspectives.

During these two days, the discussions on the booth and the quiz on Sanofi's business helped visitors better understand one of the world's healthcare leaders.

The Investor Relations team also gave an overview of the company's innovations. For the first time this year, a wide selection of medicines and vaccines distributed throughout the world were presented in a showcase. Visitors could also try out the SANOFI IR mobile app on tablets available on the booth.



### CALENDAR

- **February 8, 2017:** Full-year results 2016
- **April 28, 2017:** First quarter results 2017
- **May 10, 2017:** Annual general meeting, Palais des Congrès, Paris

### SANOFI STOCK

- **Euronext Paris, compartment A**  
Member code: SAN  
ISIN code: FR 0000120578
- **New York Stock Exchange**  
Symbol: SNY  
CUSIP number: 80105N105000

### SHAREHOLDER RELATIONS

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(available in the App Store and Google Play)

#### Forward-looking statement:

This letter contains projections and other forward-looking statements that are not historical facts. Although the management of Sanofi believes that these projections and forward-looking statements, and their underlying assumptions, are reasonable as of the date of this letter, investors are cautioned that such projections, assumptions, intentions and forward-looking 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 or implied. These risks and uncertainties include those discussed elsewhere in this letter, as well as in the filings of Sanofi with the U.S. Securities and Exchange Commission (SEC) and the French Autorité des marchés financiers (AMF), notably under the caption "Risk Factors" in the company's annual report on Form 20-F. Other than as required by applicable law, Sanofi does not undertake any obligation to update any statement that is not a historical fact.

The Letter to Shareholders is published by Sanofi Investor Relations / Shareholder Relations.

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