

# LETTER TO SHAREHOLDERS

DECEMBER 2018

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SANOFI

# MESSAGE FROM THE CHAIRMAN



Dear shareholders,

In the third quarter of 2018, Sanofi entered a new phase of growth.

The refocusing of activities and the launch of new products enabled us to strengthen our positions, in particular in Vaccines, Rare Diseases, Multiple Sclerosis, Immunology as well as Consumer Healthcare, and to build new franchises such as Rare Blood Disorders. This step was essential to adapt Sanofi to a fast-evolving environment and also to compensate for the losses of exclusivity, particularly in Diabetes.

Our transformation will continue in 2019 with the creation of two new global business units, the first one dedicated to "Primary Care" in mature markets and the second one "China and Emerging Markets" to leverage the tremendous growth opportunities in these markets.

At the same time, the continued strengthening of our Research & Development pipeline, our financial strength and good cost management give us confidence for the future.

I thank you for your trust and continuing loyalty.

**"The continued strengthening of our R&D pipeline, our financial strength and good cost management give us confidence for the future."**

# THIRD QUARTER 2018 RESULTS



# INTERVIEW WITH THE CHIEF EXECUTIVE OFFICER



### Third-quarter sales growth led by Specialty Care and Vaccines<sup>(3)</sup>

Net sales were €9,392 million, an increase of +3.7% on a reported basis, +6.3% at CER and +3.4% at CER/CS<sup>(4)</sup>.

**Specialty Care** franchise (Sanofi Genzyme) sales were up +34.6% (+16.4% at CER/CS<sup>(4)</sup>) driven by the Immunology and Rare Blood Disorders franchises.

**Vaccines** delivered solid growth with sales up +8.2%, supported by the Polio/ Pertussis/Hib vaccines, which benefited from the Pentaxim<sup>®</sup> supply recovery in China.

**Consumer Healthcare** sales increased +4.1% with growth across all geographies and key categories.

**Diabetes & Cardiovascular** franchise sales were down -6.3%. Global Diabetes franchise sales declined -9.2%, with U.S. sales down -24.3%, and non-U.S. sales up 4.7%.

### Third-quarter business EPS reflects beginning of new growth period

Business EPS<sup>(2)</sup> was up +11.2% at CER to €1.84.

In 2018, business EPS is now expected to grow +4% to +5% at CER<sup>(5)</sup> barring unforeseen major adverse events. The currency impact on 2018 business EPS is estimated to be around -6% applying the average October 2018 exchange rates.

Sales by franchise	Q3 2018	Change at CER
Specialty Care	€2,160M	+34.6%
Diabetes & Cardiovascular	€1,536M	-6.3%
Established Products	€2,131M	-3.2%
Consumer Healthcare	€1,113M	+4.1%
Generics	€383M	-5.6%
Vaccines	€2,069M	+8.2%



### Strong contribution from Emerging Markets<sup>(3)</sup>

Sales: €2,529M, +10.4%

Performance in Emerging Markets was driven in particular by double-digit growth in Diabetes (+13.4%), Rare Diseases (+28.1%), Oncology (+13.9%) and Vaccines (+19.8%).

Also noteworthy is China's contribution, where sales rose +17.7% to €644M.

1 - Growth rates are expressed at constant exchange rates (CER). Growth rates in parentheses are expressed on a reported basis. For definitions of financial indicators, please consult the press release issued on October 31, 2018. 2 - Earnings per share. 3 - Changes in net sales are expressed at constant exchange rates (CER) unless otherwise indicated. 4 - CS: constant structure: adjusted for the Bioverativ acquisition. 5 - 2017 business EPS was €5.52.

### Third quarter 2018 results mark the return to growth that you announced. What were the highlights?

As a result of our strong performance in the third quarter, we are now well positioned to deliver growth. Our main growth drivers, Specialty Care, Vaccines and Consumer Healthcare franchises, as well as our performance in Emerging Markets, more than offset the slowdown in the Diabetes franchise and Established Products.

We also received three regulatory approvals for opportunities that respond to the needs of patients and will help strengthen our Immunology, Oncology and Rare Blood Disorders franchises.

### Could you tell us more about these new products?

The third quarter was full of good news for our Specialty Care business. First, in Immunology, Dupixent<sup>®</sup> was approved in the United States for the treatment of moderate-to-severe asthma. This is the second indication for Dupixent<sup>®</sup> that is already marketed for adults with moderate-to-severe atopic dermatitis and will be evaluated under priority review by the U.S. Food and Drug Administration for the treatment of adolescents with this disease.

In Oncology, we are excited to make Libtayo<sup>®</sup> available to patients in the United States. It is the first and only drug approved for the treatment of metastatic cutaneous squamous cell carcinoma, a potentially fatal skin cancer.

Finally, Cablivi<sup>®</sup>, developed by the recently acquired biotechnology company Ablynx, was approved in Europe for the treatment of a rare blood-clotting disorder and thus expands our new Rare Blood Disorders franchise.

### You have announced a new organization of your global business units in 2019. What are the expected changes?

We want to further refocus our activities in mature markets and across emerging markets. Thus the new Primary Care GBU will combine the Diabetes & Cardiovascular and Established Products businesses for mature markets, notably Europe and North America. The GBU "China and Emerging Markets" will focus on all our businesses, except Vaccines and Consumer Healthcare, in emerging markets to build on their growing importance and accelerate our growth in these countries.

**"We are now well positioned to deliver growth."**

# DUPIXENT® APPROVED FOR TREATMENT OF MODERATE-TO-SEVERE ASTHMA PATIENTS IN THE UNITED STATES



**DUPIXENT®**  
(dupilumab)

**AN INNOVATIVE  
BIOLOGIC DRUG**

Only biologic approved as an add-on maintenance therapy:

- in patients with **moderate-to-severe asthma** with an eosinophilic phenotype or with oral corticosteroid-dependent asthma
- aged **12 years and older**
- offering patients self-administration **at home**

## A NEW TREATMENT OPTION FOR AN IMPORTANT POPULATION OF PATIENTS WITH UNCONTROLLED ASTHMA

The U.S. Food and Drug Administration (FDA) approved Dupixent® (dupilumab) as an add-on maintenance therapy for two important groups of uncontrolled asthma patients: those who are **moderate-to-severe with an eosinophilic phenotype** – an inflammatory subtype frequent in severe asthma – or those with **oral corticosteroid-dependent asthma**.

Dupixent® is indicated for **adults and adolescents** aged 12 years and older who have persistent symptoms despite standard-of-care therapy.

## EFFICACY AND SAFETY OF DUPIXENT® DEMONSTRATED IN CLINICAL TRIALS PROGRAM

Patients with moderate-to-severe asthma often live with **persistent symptoms**, like unpredictable attacks and difficulty breathing, despite being compliant with their current treatment.

In the asthma clinical trials program, Dupixent® **reduced severe exacerbations** (severe asthma attacks) and oral corticosteroid use. It also showed **improvements in lung function** and improved quality of life.

Dupixent® is currently studied in Phase 3 in pediatric asthma.

## SECOND INDICATION FOR DUPIXENT®

This is the second indication for Dupixent® following the product's original approval in March 2017 in the United States for the treatment of **adults with moderate-to-severe atopic dermatitis**.

In both cases, these are **diseases driven by Type 2 inflammation**. Dupixent® inhibits the overactive signaling of interleukin-4 (IL-4) and interleukin-13 (IL-13), two key proteins that contribute to the Type 2 inflammation that may underlie moderate-to-severe asthma and atopic dermatitis.

## POSITIVE PHASE 3 RESULTS IN ADOLESCENT MODERATE-TO-SEVERE ATOPIC DERMATITIS

Detailed results from a pivotal Phase 3 trial for Dupixent® demonstrated a **significant improvement in signs and symptoms of atopic dermatitis in adolescent patients** (12-17 years) with moderate-to-severe atopic dermatitis. Their disease was inadequately controlled with topical therapies or topical treatment was medically inadvisable. Dupixent® not only helped clear the skin and reduce itching, but also improved certain aspects of their quality of life.

Dupixent® has been submitted to U.S. and European health authorities for the treatment of atopic dermatitis in adolescents aged 12 to 17 years. In the U.S., the FDA granted priority review to the submission, with a decision expected in March 2019.



## POSITIVE PHASE 3 TOPLINE RESULTS IN PATIENTS WITH CHRONIC RHINOSINUSITIS WITH NASAL POLYPS

In addition to atopic dermatitis and asthma, Dupixent® demonstrated positive results in a **third Type 2 inflammatory disease: chronic rhinosinusitis with nasal polyps**.

Two pivotal Phase 3 trials evaluating Dupixent® in **adults with inadequately-controlled chronic rhinosinusitis with nasal polyps** met all primary and secondary endpoints: Dupixent® significantly reduced nasal polyp size, nasal congestion severity, and need for systemic corticosteroids and/or surgery.

## R&D ACHIEVEMENTS AND PARTNERSHIPS



### LIBTAYO® APPROVED IN THE UNITED STATES FOR A TYPE OF SKIN CANCER

The U.S. Food and Drug Administration (FDA) approved Libtayo® (cemiplimab-rwlc), a monoclonal antibody co-developed with Regeneron, for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation.

CSCC is **the second most common skin cancer in the United States**.

### PRALUENT® EVALUATED AS POTENTIAL TREATMENT TO REDUCE MAJOR ADVERSE CARDIOVASCULAR EVENTS

The FDA accepted a supplemental Biologics License Application (sBLA) for Praluent® (alirocumab). The sBLA outlines a proposed **update to the Prescribing Information** to include the effect of Praluent® in reducing the overall risk of major adverse cardiovascular events (heart attack, ischemic stroke, death from coronary heart disease and unstable angina requiring hospitalization).

**Praluent® is approved in more than 60 countries**, including the United States, for the treatment of certain patients with hypercholesterolemia.

### APPROVAL OF DENGVAXIA® RECOMMENDED IN EUROPE

The European Medicines Agency's Committee for Medicinal Products for Human Use adopted a positive opinion for the marketing authorization of Sanofi's dengue vaccine Dengvaxia®. The indication for the dengue vaccine recommended by the Committee is for use in prevention of **dengue disease caused by four dengue virus serotypes in individuals 9 to 45 years of age with prior dengue virus infection** and living in endemic areas.

### PARTNERSHIP IN NEUROLOGICAL AND INFLAMMATORY DISEASES

Sanofi plans to **collaborate with Denali Therapeutics** on the development of molecules with the potential to treat a range of neurological diseases, such as multiple sclerosis, amyotrophic lateral sclerosis, and Alzheimer's disease, as well as systemic inflammatory diseases.

# A MORE FOCUSED ORGANIZATION TO SUSTAIN A NEW GROWTH PHASE

Sanofi will change the organizational structure of two of its Global Business Units (GBU) to strengthen its relationship with healthcare professionals and all other stakeholders in mature markets and across emerging markets.

Discover below the new organization to be implemented beginning of 2019, with the launch of the two new GBUs: Primary Care and China & Emerging Markets.

- The new Primary Care GBU will focus on mature markets, which include the United States, Canada, Europe, Japan, South Korea, Australia and New Zealand. It will combine the existing Diabetes & Cardiovascular (DCV) GBU with Established Products, which are currently part of the General Medicines & Emerging Markets GBU.
- The new China & Emerging Markets GBU will focus on Specialty Care, Established Products and Diabetes & Cardiovascular products in these regions.
- Sanofi's other GBUs - Sanofi Genzyme, Sanofi Pasteur and Consumer Healthcare - remain unchanged.

## PRIMARY CARE



The Primary Care GBU will build on the strengths of both our Diabetes and Cardiovascular and Established products franchises in mature markets.

This GBU will be led by Dieter Weinand, who joined Sanofi in November 2018.

## NEW GBU STRUCTURE IN 2019



## CHINA & EMERGING MARKETS



The China & Emerging Markets GBU will focus on the unique characteristics and important growth opportunities in China and other emerging markets.

This GBU will be led by Olivier Charmeil.

## SPECIALTY CARE – SANOFI GENZYME



The Specialty Care GBU comprises our Rare Diseases, Multiple Sclerosis, Oncology and Immunology franchises. Following the acquisitions of Bioverativ and Ablynx, Sanofi has built another new franchise dedicated to Rare Blood Disorders.

This GBU is led by Bill Sibold.

## VACCINES – SANOFI PASTEUR



Sanofi Pasteur, our Vaccines GBU, is a global leader in the vaccine industry, producing each year over one billion doses of vaccines to immunize more than 500 million people around the world.

This GBU is led by David Loew.

## CONSUMER HEALTHCARE



The Consumer Healthcare GBU focuses on four strategic categories - Allergy, Cough & Cold, Pain, Digestive Health and Nutritionals.

This GBU is led by Alan Main.



After 36 years on the Chinese market, with great performance achieved over the past years, China has become our second largest market worldwide. The creation of a new GBU exclusively focused on China & Emerging Markets should allow us to better capture future growth opportunities and address challenges ahead.

### A FORERUNNER PRESENCE

Sanofi opened its first offices in China in 1982. In 2018, China became its second largest market worldwide after the United States. With €2.3 billion of sales generated in the country in 2017, Sanofi became the third largest multinational pharma company in China (and #5, including Chinese pharma companies). The launch of the “Healthy China 2030” initiative by the Chinese government, together with the refocusing of the General Medicines and Emerging Markets GBU on China & Emerging Markets should allow Sanofi to build on the opportunities offered by the Chinese market and tackle the growing competition by local companies.

### OPPORTUNITIES AND CHALLENGES

With the accelerated aging of the Chinese population and the growing prevalence of chronic diseases due to changes in lifestyle and diet, the Chinese government has declared public health as one of its strategic pillars. The implementation of the “Healthy China 2030”

program is expected to make China’s key health indicators reach the same level as in the United States, Europe and Japan. This strategy is based on two main priorities – prevention and treatment. Sanofi is committed to helping realize this ambition, today, with its offer of products adapted to these challenges, and in the future, with upcoming innovations, in terms of treatment solutions, digital technologies and innovative partnerships.

### BUILDING A NEW GBU

With 9,500 employees across the country, three manufacturing sites, a Research & Development hub in Shanghai, a data analytics centre in Chengdu and the future scientific institute in Suzhou, Sanofi is well positioned to respond to local Chinese health needs and play an increasing role globally. Under the leadership of Olivier Charmeil, Executive Vice President, China & Emerging Markets, this new GBU that is expected to be launched at the beginning of 2019, should notably strengthen and grow Sanofi’s position in China.

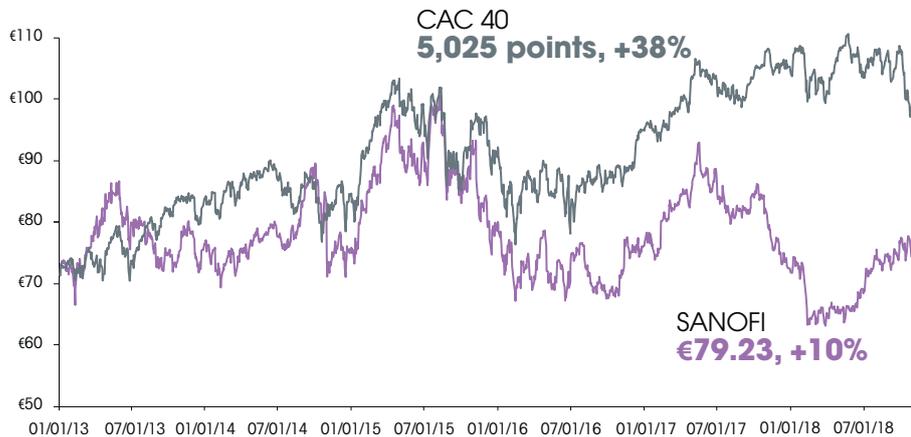


## SHAREHOLDER INFORMATION

# Share performance in Paris

## SANOFI SHARE PRICE TREND

Euronext Paris, from January 1, 2013 to November 16, 2018



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

On November 16, 2018, Sanofi had a market capitalization of over €99bn.

## Salon Actionaria 2018

The Salon Actionaria 2018, Europe's largest exhibition for individual shareholders, was held on November 22 and 23, 2018 in Paris.

The Investor Relations team was on-site to meet current and potential individual shareholders and answer their questions.

During these two days, visitors could listen to educational presentations on Sanofi's strategy and business and discovered the information at their disposal on the Web site and the Sanofi IR mobile application.



## KEY DATES IN 2019

February 7

Full year 2018 results

April 26

First quarter 2019 results

April 30

Annual General Meeting

July 29

Second quarter 2019 results

October 31

Third quarter 2019 results

## SANOFI STOCK

### Euronext Paris, compartiment A

Member code: SAN

ISIN code: FR 0000120578

### New York Stock Exchange

Symbol: SNOY

CUSIP number: 80105N105000

## INVESTOR RELATIONS



### Sanofi – Investor Relations

54 Rue La Boétie – 75008 Paris - France



Tel. Europe: +33 (0) 800 075 876  
Toll-free tel. U.S.: +1 888 516 3002



individualshareholders@sanofi.com



sanofi.com/shareholders



Mobile app: SANOFI IR  
(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.

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