Dear shareholders,

Day after day, for almost a year, Sanofi has been working to fight the COVID-19 pandemic. Our ability to produce and distribute our medicines and vaccines, which are essential to patients, have been maintained or even increased. We have continued to supply clinical research centers with experimental phase products. From the first days of the crisis, we have collaborated with the authorities on research programs on potential treatments against COVID-19, including the immediate launch of two major research programs on candidate vaccines. We have remained in contact with a large number of doctors and patients to maintain their access to medical information and to ensure continuity of care to the greatest extent possible. More than ever, Sanofi is committed to fulfilling its mission.

Despite an uncertain world, our teams at every level of the company are mobilizing to evolve our ways of working and adapt our organization for new behaviors. This transformation to improve our agility and efficiency will be critical for the success of the ‘Play to Win’ strategy announced by Paul Hudson in December 2019. Third quarter results are solid and on the first nine months of 2020, sales are up 3.0% and business EPS is up 9.3%. We need this growth to finance and accelerate our Research & Development programs: seven new Phase 3 programs to our oncology and immunology pipelines are about to be launched.

Despite this special situation in which we are all living, we can be proud of our mission and our resilience. I would like to thank all Sanofi collaborators again for their exemplary mobilization in the service of patients and caregivers.

I thank you for your trust and continuing loyalty.

"In these uncertain times, we can be proud of our mission and our resilience.”
What can we remember from these Q3 2020 results?

This quarter is another strong proof point that we are delivering on our ‘Play to Win’ strategy relentlessly. Sales and EPS grew by 5.7% and 8.8% respectively in constant currency.

Driving this performance was another outstanding 69% increase in Dupixent® sales, and double-digit growth from our Vaccines business, which set a record for flu vaccine sales in the quarter.

We are clearly accelerating and delivering on transformational science and business execution including launching our key growth driver Dupixent® in China or by making a meaningful acquisition with Principia Biopharma.

Could you tell us more on the new record sales flu vaccines achieved in this quarter?

Sanofi Pasteur achieved record flu vaccine sales in the third quarter, with growth of more than 50% exceeding €1 billion, reflecting strong demand in the northern hemisphere. This is partly due to a favorable mix shift in our portfolio: differentiated vaccines, which pricing is resilient, account for the majority of our global flu sales in the quarter.

Overall, we are confident to maintain our global market leadership with the shipment of approximately 250 million flu vaccine doses worldwide in 2020. Simultaneously, the expansion of our manufacturing capacities is on track to meet the projected increase in worldwide immunization rates.

You celebrated your 1st birthday as Sanofi’s CEO last September. What is your assessment of your time spent since arriving at Sanofi?

I am incredibly proud of the work we do here at Sanofi, the transformation that is underway. It never ceases to amaze me how great our people are and how they continue to deliver on behalf of patients. Our results are strong, but what is really impressive through this part of the year is the fact that we continue to advance our COVID-19 vaccines without a single shortcut, setting the highest bar in safety and efficacy.

At the same time, we continue to advance our broader pipeline with multiple new Phase 3 trials in oncology and immunology, aligned with strategy and looking to change the practice of medicine for patients. Ultimately, we continue to deliver right across the board because of the quality of people and the passion and purpose focus we have in this great company.

“We continue to deliver right across the board because of the quality of people and the passion and purpose focus we have in this great company.”
PREVENTING INFLUENZA IN THE TIME OF COVID-19

The development of vaccines and the fight against the COVID-19 pandemic have been the focus of the world’s attention for most of this year, but the teams at Sanofi Pasteur have also been working to ensure supply of existing vaccines to prevent additional outbreaks of other diseases and spare healthcare systems from preventable hospitalizations.

The COVID-19 pandemic has further boosted demand for influenza vaccines in upcoming seasons to help protect vulnerable people and reduce preventable impact on healthcare systems.

GROWING DEMAND FOR FLU VACCINES

In the context of the COVID-19 pandemic, preventing influenza remains a public health priority. As health authorities worldwide seek to prevent what is preventable: influenza and its potentially severe complications, and the burden this causes on healthcare systems. “Even before the coronavirus pandemic, demand for influenza vaccines was growing,” says Lyn Morgan, Sanofi Pasteur Public Affairs Lead on Influenza and COVID-19. “Vaccination rates in recommended populations typically vary by country: some countries succeed in vaccinating large majorities of their recommended populations while others reach less than half.”

Without consistently high coverage rates, influenza still takes a heavy toll around the world.

AVOIDING AN INFECTION AND ITS COMPLICATIONS

Influenza can trigger severe complications such as pneumonia and more unexpected outcomes such as heart attacks and strokes. Each year, influenza-associated deaths range from 290,000 to 650,000 globally with some 10 million influenza-related hospitalizations. This led many national and international recommending bodies to reinforce the need for influenza vaccination in this season.

A yearly flu shot is considered the most effective way to prevent influenza infection and its complications, which can partially overlap with risk factors from COVID-19. The World Health Organization recommends annual influenza vaccination for people aged 65 and older, pregnant women, people with pre-existing health conditions (such as diabetes, asthma, chronic heart or lung diseases), children aged six months to five years, and healthcare workers. Individual health authority recommendations vary by country.

DIFFERENTIATED VACCINES

Sanofi Pasteur offers several different kinds of influenza vaccines. Its standard-of-care quadrivalent vaccines help protect against all four main virus strain types that circulate each season and are some of the most broadly produced and administered flu vaccines worldwide. In addition, Sanofi has developed high-dose vaccines that are indicated for adults aged 65 and older, as well as a vaccine produced with recombinant protein technology, which ensures an exact match to virus strains recommended by the WHO each season.

1. World Health Organization (WHO).
2. Center for Disease Control and Prevention.
“We have done everything possible to accelerate and optimize our supply of all of our influenza vaccines to help satisfy the additional demand this year around the world,” says Sean Batten, Lead on Global Supply Chain for Influenza Vaccines.

“We sincerely hope that the huge effort that has been made to maximize our ability to meet country requests for vaccines will contribute to less influenza disease this season, and fewer people at risk from its severe effects,” concludes Lyn Morgan.

SUPEMTEK® (INFLUENZA VACCINE) APPROVED BY THE EUROPEAN COMMISSION

On November 18, 2020, the European Commission has granted a marketing authorization for Supemtek®, a quadrivalent (four-strain) recombinant influenza vaccine, for the prevention of influenza in adults aged 18 years and older.

The approval is based on clinical data demonstrating safety and efficacy of Supemtek® demonstrated in two Phase 3 randomized controlled trials involving more than 10,000 patients. In comparison with a standard-dose egg-based quadrivalent influenza vaccine, Supemtek® reduced the risk of influenza by an additional 30% for adults aged 50 years and above.

Supemtek® is the first and only influenza vaccine to rely on recombinant manufacturing technology. This method for producing influenza vaccines differs significantly from the two other production platforms currently in use (egg-based and cell-based). Recombinant technology ensures an exact match of the hemagglutinin protein included in the vaccine to the influenza strains recommended seasonally by the World Health Organization for vaccines, which is an important factor when considering vaccine effectiveness.

This established technology is currently used for the development of one of Sanofi’s vaccines against COVID-19, developed in partnership with GSK and with the support of US Biomedical Advanced Research and Development Authority (BARDA).

The first European launches are expected for the 2022/2023 influenza season, with a possibility of accelerating the availability of doses as early as the 2021/2022 season in certain countries. Outside of the EU, Supemtek® has been available in the US since 2017 – under Flublok® brand name, with over 10 million doses distributed since then.

COVID-19: SANOFI AND GSK TO SUPPORT COVAX

Sanofi and GSK announced on October 28, 2020 they signed a Statement of Intent with Gavi, for making available 200 million doses of their adjuvanted recombinant protein-based COVID-19 vaccine, if approved by regulatory authorities and subject to contract, to the COVAX Facility. Both Companies intend to contribute to COVAX’s ambition to ensure successful COVID-19 vaccines reach those in need, whoever they are and wherever they live, once they obtain appropriate approvals.

NEW “BREAKTHROUGH THERAPY” DESIGNATION FOR DUPIXENT®

The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to Dupixent® (dupilumab) for the treatment of patients 12 years and older with eosinophilic esophagitis (EoE).

There are currently no FDA-approved medicines for EoE, a chronic and progressive type 2 inflammatory disease that damages the esophagus and prevents it from working properly. Over time, excessive type 2 inflammation causes scarring and narrowing of the esophagus, making it difficult to swallow. If left untreated, EoE can affect a patient’s ability to eat and cause food to become stuck after being swallowed (food impaction), which can lead to a medical emergency.

SANOFI INVESTS IN GENE THERAPY IN LYON (FRANCE)

In line with its recent strategic announcements, Sanofi announced on November 5, 2020 a €15 million investment in its Sanofi Genzyme site in Lyon Gerland (France) in order to strengthen its production platform with new cell and viral culture technologies. This investment will enable the platform to accommodate by 2021 the manufacture of clinical batches of gene therapy products currently in development in Boston. The site will thus become for Sanofi the first site in the world for the production of clinical batches of this new therapeutic class.
FOCUS

MULTIPLE SCLEROSIS: CROSSING BARRIERS TO DELIVER NEW MEDICINES

More than 2.3 million people around the world are living with Multiple Sclerosis (MS), a chronic, inflammatory, autimmune, neurodegenerative disease that typically results in accumulation of disability over time.

MS is a chronic disease that affects each person differently, with symptoms ranging from numbness in the limbs or forgetfulness, to paralysis or loss of vision. MS is 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.

As disability increases in MS patients, health status, quality of life, and personal daily activities deteriorate. This can result in loss of ability to work, impair cognition, decrease life expectancy, and increase cost of care.

Despite numerous treatment options for people living with MS, each patient experiences the disease differently and disease progression remains an unaddressed reality for most patients. Throughout the disease, inflammation is present in the brain and spinal cord as well as in the body, leading to a worsening of long-term disability along with accelerated brain volume loss.

Today there are limited ways to effectively address ongoing disease progression in MS. This gap has captured the focus of researchers who are seeking alternate ways to control immune system dysfunction that are thought to be at work in MS disease progression.

As a company that’s been committed to bringing innovative treatments to this community for more than twenty years, Sanofi researchers are among those who continue to explore new mechanisms and approaches to address the challenges that patients continue to confront.

THE IMMUNE SYSTEM’S ROLE IN MS

It is established that T as well as B-cells play a role in MS. The B-cell is one of several types of cells that make up the immune system’s complex network. B-cells are essential to a healthy, functioning immune system, but when B-cells go awry, they are believed to play a major role in activating the cells that attack nerve sheaths in MS patients. That has led researchers to look for ways to control the activity of B-cells.

As part of their effort to identify new approaches to treating this disease, Sanofi scientists are exploring ways to inhibit the activity of an enzyme known as Bruton’s tyrosine kinase (BTK). The enzyme plays an important role in B-cell maturation and function. BTK is an essential component of the B-cell receptor (BCR) signaling pathway, where it regulates B-cell activation and propagation.

Controlling BTK can enable variation of B-cell function, yet without destroying the body’s B-cells entirely. Researchers hope that by inhibiting BTK they may be able to selectively interfere with the activity of B-cells and their effect on microglia (type of neuronal support cell responsible for clearing dead neurons in the central nervous system - CNS), while preserving their beneficial activity. In turn, this could potentially mitigate the neuroinflammation and neurodegeneration in the peripheral nervous system and the CNS.
ADDRESSING DISEASE EFFECTS IN THE BRAIN

While the damage associated with MS occurs in the brain and spinal cord as well as throughout the body, in all forms of MS, and particularly in progressive forms, more damage occurs to nerve sheaths and other cells in the CNS. To truly advance care for patients, scientists knew they would have to target the way B-cells affect microglia in the brain that contribute to neuronal tissue damage and neuroinflammation in MS leading to ongoing disease progressions.

Reaching the brain, however, is a major challenge for research scientists. Humans have evolved a blood-brain barrier that protects the brain by blocking the movement of many harmful substances that may be present in the bloodstream. Unfortunately, the barrier also treats many medicines the same way, thus preventing numerous treatments that work in the rest of the body from getting into the brain. Finding something that has both the potential to be effective and cross into the brain is extremely difficult.

Sanofi’s scientists, in partnership with Principia Biopharma (a Californian Biotech acquired by Sanofi during third quarter 2020, see article below), are now exploring the development of a BTK inhibitor they hope may be able to successfully cross the blood-brain barrier. They hypothesize that, if the substance reaches the brain, it might be possible to modulate B-cells and microglia in the brain and cancel out their damaging effects.

On April 23, 2020, Sanofi announced the investigational BTK (Bruton’s tyrosine kinase) inhibitor, an oral, brain-penetrant, selective small molecule achieved both the primary and secondary endpoints in a Phase 2b trial evaluating efficacy and safety in participants with relapsing forms of multiple sclerosis. The BTK inhibitor (SAR442168, also known as tolebrutinib) significantly reduced disease activity associated with multiple sclerosis (MS) as measured by magnetic resonance imaging.

“We believe that our brain-penetrant BTK inhibitor shows promise for reducing both neuroinflammation and neurodegeneration, markers of disability progression in people living with MS.”

John Reed, MD, PhD, Sanofi’s Global Head of Research & Development

Sanofi has initiated four Phase 3 clinical trials in relapsing and progressive forms of MS. Sanofi’s BTK inhibitor will potentially be first disease-modifying therapy to address sources of multiple sclerosis damage in the brain.

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ACQUISITION OF PRINCIPIA BIOPHARMA

Sanofi announced on September 28, 2020, the successful completion of its acquisition of Principia Biopharma Inc. (“Principia”), for $3.36 billion. Principia is a late-stage biopharmaceutical Californian company dedicated to bringing transformative therapies to patients with significant unmet medical needs in immune-mediated diseases.

The Principia BTK inhibitor franchise is based on its proprietary Tailored Covalency® platform that has generated potential best-in-class clinical candidates. The platform allows the design of both reversible covalent and irreversible covalent small molecule inhibitors that are more selective with less off-target effects.

In 2017, Sanofi had formed a collaboration with Principia under which Principia granted Sanofi an exclusive, worldwide license to develop and commercialize BTK inhibitor ’168 (tolebrutinib) in multiple sclerosis and other central nervous system diseases.

The Principia acquisition:
• further strengthens core R&D areas of autoimmune and allergic diseases;
• provides full control of brain-penetrant BTK inhibitor tolebrutinib in multiple sclerosis, making commercialization more efficient and eliminating future royalty payments;
• allows expansion of tolebrutinib development program into other central nervous system diseases and therapeutic areas;
• adds clinically advanced oral BTK inhibitor rilzabrutinib with potential across a range of immunology and inflammation indications, complementing Sanofi’s existing R&D pipeline.

“The Principia acquisition further strengthens our core areas of autoimmune and allergic diseases, giving us full control of tolebrutinib (SAR442168), as well as additional BTK inhibitors to further develop.”

Paul Hudson, Sanofi Chief Executive Officer
Share performance in Paris

SANOFI SHARE PRICE TREND

Euronext Paris, from January 1, 2019 to November 27, 2020

On November 27, 2020, Sanofi had a market capitalization of around €107bn.

Find out the latest publications online

HALF-YEAR FINANCIAL REPORT 2020

INTEGRATED REPORT 2019
This report provides an overview of how Sanofi’s activities and investments lead to sustainable business performance and provide value for all stakeholders.

Find out all your shareholder and financial publications on our website:

CALENDAR
February 5, 2021
Fourth quarter and full-year 2020 results
April 28, 2021
First quarter 2021 results
April 30, 2021
Annual General Meeting

SANOFI STOCK
\ Euronext Paris, compartment A
Member code: SAN
ISIN code: FR 0000120578
\ Nasdaq
Symbol: SNY
CUSIP number: 80105N1000

SNY
Nasdaq Listed

SHAREHOLDER INFORMATION

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS:
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 the uncertainties inherent in 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 the risks identified 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.

Find out all your shareholder and financial publications on our website:

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