

## Q3 2021 Results

**Play to Win** 

October 28, 2021



## Forward looking statements

This document contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forwardlooking 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, risks related to Sanofi's ability to complete the proposed transaction with Kadmon Holdings, Inc. on the proposed terms or on the proposed timeline, including the receipt of required regulatory approvals, the possibility that competing offers will be made, other risks associated with executing business combination transactions, as well as other risks related to Sanofi's business, including the ability to grow sales and revenues from existing products and to develop, commercialize or market new products, competition, 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 fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions 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 and market conditions, cost containment initiatives and subsequent changes thereto, and 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 other previously identified risks. The risks and uncertainties also include the 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, 2020. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.



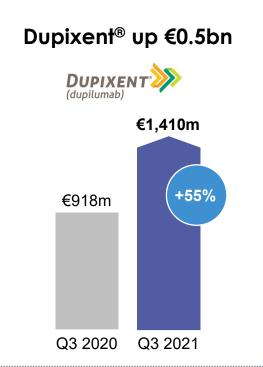
## Agenda

Corporate update	Paul Hudson John Reed	Chief Executive Officer Global Head of R&D
Business update		Specialty Care Vaccines General Medicines Consumer Healthcare
Financial results	Jean-Baptiste de Chatillon	Chief Financial Officer
Q&A session		



## Outstanding quarterly performance drives guidance upgrade





#### Vaccines record sales



Full Year business EPS guidance raised to 14% at CER



## Targeted bolt-ons strengthen Sanofi's key growth areas

#### Rapid acceleration in mRNA



- Pillar to the company's mRNA Center of Excellence
- Developing next-generation mRNA vaccines, including modified mRNA
- Target to have modified quadrivalent flu mRNA vaccine enter the clinic in 2022

#### Opportunity for growth in GenMed



- Adding to the portfolio of core assets of General Medicines, highly complementary of the growing transplant franchise<sup>(1)</sup>
- Expected to be accretive starting 2022
- Adds to the objective of stabilizing General Medicines 2025 sales<sup>(2)</sup> at 2020 level and accretive BOI

Executing on seven value-creating acquisitions since 2019 to add cutting edge technologies and first/best in-class assets



## Delivering R&D milestones and building momentum

#### **Recent R&D progress**

- Four phase 3 readouts for Dupixent<sup>®</sup>
  - ✓ Chronic spontaneous urticaria
  - ✓ Atopic dermatitis 6m to 5yrs
  - ✓ Prurigo nodularis
  - ✓ Eosinophilic esophagitis
- Phase 3 rilzabrutinib (PV)
- ✓ Phase 3 Libtayo® CT combo (1L lung)
- ✓ Nexviazyme® US and Japan approvals
- Sutimlimab and olipudase alfa submissions

#### **Upcoming key milestones**

Product	Target Indication	Milestones	Expected Timeline
Dupixent®	AD 6m-5yrs	Submission in US	Q4 2021
COVID-19 recombinant		Phase 3 read-out (primer and booster)	Q4 2021
Amcenestrant	2/3L BC mono	Phase 2 pivotal read-out	Q4 2021/ Q1 2022
Nirsevimab	RSV	Submission in EU	Q1 2022
Efanesoctocog alfa	Hemophilia A	Phase 3 read-out	Q1 2022
Dupixent®	Prurigo nodularis	Phase 3 read-out (Part B)	H1 2022
Sarclisa	1L MM (IMROZ)	Phase 3 read-out	H1 2022



## Targeting underlying disease mechanisms in Neurology

#### Tolebrutinib (brain-penetrant BTKi)

Phase 2b extension in RRMS showed **98% of patients remained on treatment** after 1 year<sup>(1)</sup>

Low mean MRI lesion activity<sup>(2)</sup>

Annualized relapse rate (ARR) of 0.17 over the 48-week treatment period with majority of patients (89.5%) free of relapses during this period

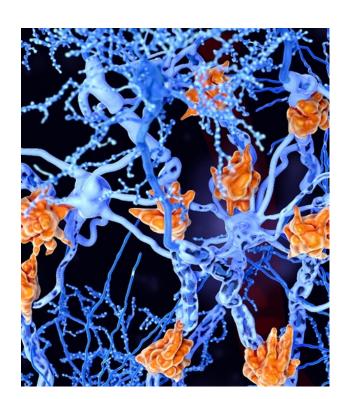
- Continued favorable tolerability of tolebrutinib and no new safety signals
- Data from in vitro studies in human microglia support BTK-dependent inflammatory signal modulation by tolebrutinib

#### SAR'820 (brain-penetrant RIPK1i)<sup>(3)</sup>

Implicated in necroptosis
Potential in PMS

U.S. Fast track designation received for ALS in Q3 2021

Phase 2 start Q1 2022



Pipeline programs represent assets under investigation and are not approved by regulators for the indications being investigated RRMS; relapsing remitting multiple sclerosis; PMS; progressive multiple sclerosis. ALS; amyotrophic lateral sclerosis



<sup>(2)</sup> in patients started on/switched to tolebrutinib 60mg (48wks)



## Dupixent® – quarterly sales nearly tripled in the last 2 years

#### Continued strong performance in Q3

- Worldwide growth of +55% vs Q3 2020
- €1bn sales in US in one quarter
- Ex-US contributing 25% of sales driven by Europe and Japan

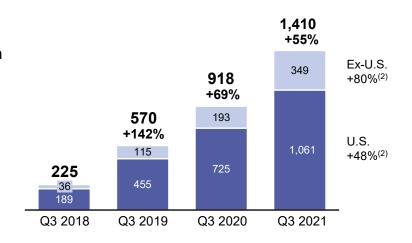
#### In-office patient visits still below pre-COVID levels

• U.S. patient visits at 85%<sup>(1)</sup> of pre-COVID levels

#### Milestones for future growth

- Approval in China for 12-17yrs adolescents with AD in Q3
- Accelerated submissions of AD in <6yrs</li>

#### Global Dupixent® Q3 sales (€m)



Remains on track to achieve >€10bn peak sales target



<sup>(1)</sup> Q3 average of dermatologist, allergist and pulmonologist patient visits (ZoomRx Market Research (Sept '21) (2) Growth Q3 2021 vs Q3 2020

# Dupixent® – accelerating critical milestones in Type 2 inflammatory diseases

Since Q2' 21

2022e

- Chronic spontaneous urticaria
  Pivotal results Part A
- Atopic Dermatitis 12 17 yo Approval in China
- Atopic Dermatitis 6m 5 yo
  Positive pivotal Ph3 readout
- Prurigo nodularis

  1st biologic to show positive Ph3 results
- Eosinophilic esophagitis
  Second positive pivotal Ph3 results Part B
- Asthma
  Asthma 6-11 yo U.S. approval

Asthma

Asthma 6-11 yo EU approval

- Prurigo nodularisSecond study & submission
- Eosinophilic esophagitisSubmission
- Chronic spontaneous urticariaSecond study & submission
  - CindU-ColdPivotal results and submission



## Continued business momentum across Specialty Care

#### Rare Disease strong growth contribution from Pompe

U.S. launch of Nexviazyme<sup>®</sup> in August

#### N&I franchise benefited from Kevzara®

Increased market demand for IL-6 receptor blockers

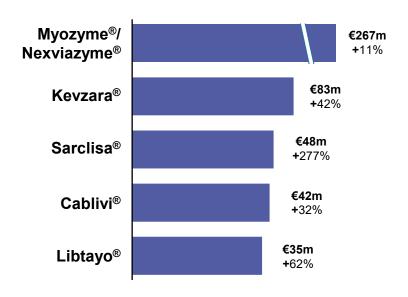
#### Oncology new product portfolio uptake

 Sarclisa® approved and launched in 26 countries (ICARIA) and 8 countries (IKEMA), respectively

#### RBD franchise up 7% ex Sobi<sup>(1)</sup> supply sales

Cablivi® growth driven by Europe in Q3

#### Specialty growth drivers in Q3 2021 (€m)





## Record Q3 sales driven by differentiated Flu vaccines

## Flu sales increased to €1,339m (26%) driven by Fluzone® HD / Efluelda™

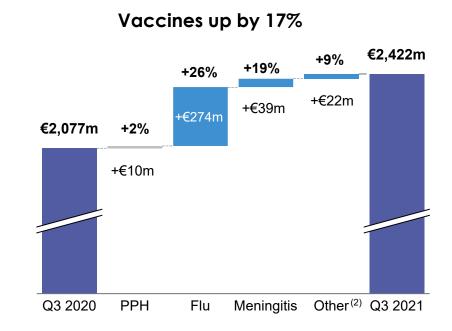
- Europe grew 88% due to successful Efluelda<sup>™</sup> expansion mainly resulting from STIKO recommendation in Germany
- U.S. up 18% due to earlier shipment vs Q3 2020

#### Growth across all other franchises

- Meningitis up 19% compared to prior year's low base
- PPH continued to be impacted by lower birth rates

#### Nirsevimab MELODY data presented at IDWeek<sup>(1)</sup>

MEDLEY results to be shared at ResViNet

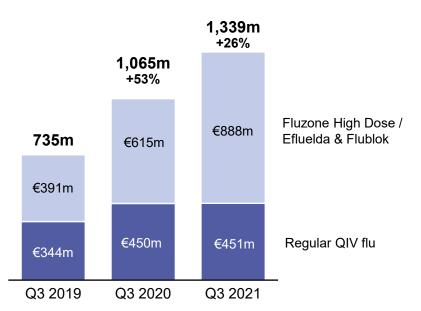




<sup>)</sup> IDWeek, abstract LB13

# Strong market preference for brands recognizing superior protection

## Differentiated flu brands representing 2/3 of Sanofi Flu sales in Q3



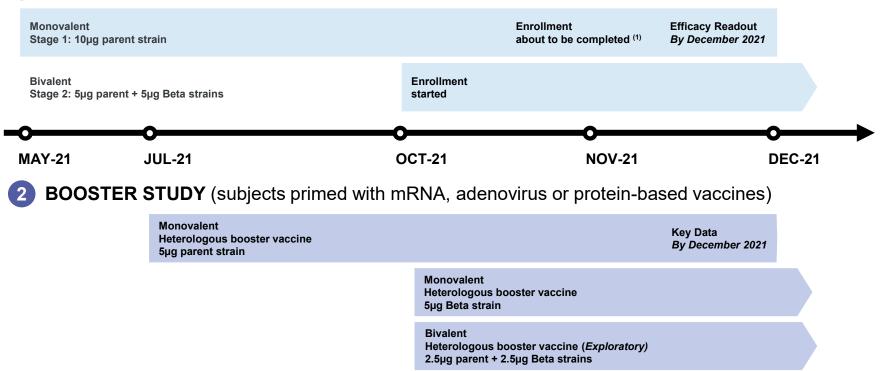
## Value of differentiated product acknowledged by our partners





## COVID-19 recombinant vaccine program

1 PHASE 3 SAFETY & EFFICACY TRIAL - Primary vaccine





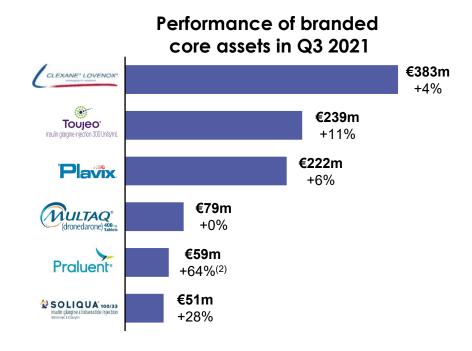
### General Medicines core assets continued to deliver in Q3

General Medicines Q3 sales of €3.6bn (-1.7%)

Core assets growth drivers, €1.4bn (+4.5%<sup>(1)</sup>)

- Demand driven growth of Toujeo<sup>®</sup>, Soliqua<sup>®</sup> and Praluent<sup>®</sup>
- Lovenox® trends stabilizing
- Soliqua® BLA application acceptance in China

Non-core assets of €1.9bn declined 6.3%, including the impact of divestments





## Leveraging Sanofi's experience in transplant

Kadmon acquisition announced in September

- Transaction expected to close in Q4
- Expected to be accretive starting in 2022

Adds Rezurock™ first-in-class treatment for adults and children (12 years old and older) with cGVHD<sup>(1)</sup> launched in U.S. market in August

Rezurock™ addresses significant unmet need

- Treatment failure with steroids as standard of care in ~50% cGVHD patients
- Later lines of therapy offer limited efficacy and tolerability

#### Well-positioned in growing transplant market<sup>(2)</sup>

Sanofi first nine months 2021 transplant sales €433m, +15%





**€263m** +16%



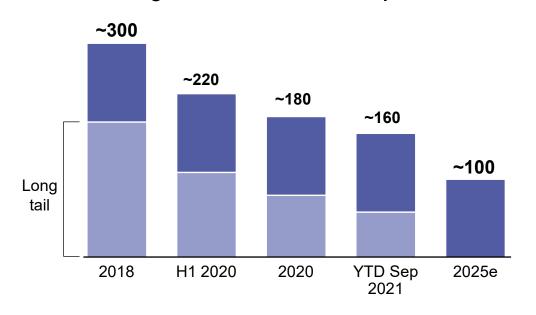


**cGvHD 5,000** patients in U.S. per year<sup>(3)</sup>

- (1) cGVHD chronic graft-vs-host disease
- (2) Sanofi internal analysis
  - www.CIBMTR.com; Steroid-refractory chronic graft-versus-host disease: treatment options and patient management | Bone Marrow Transplantation (nature.com); HCT Trends and Survival Data Bone Marrow Transplantation (2021) 56:2079–2087

# Advancing on simplification and digitalization to create an accretive and resilient GenMed business

#### Streamlining the number of branded product families



- Continuous streamlining of EP portfolio generated ~€0.9bn cash proceeds from divestments 2019 to Q3 2021
- Two exclusive distribution agreements in place covering 41 countries
- Omnichannel HCP digital interactions of ~ 63% reached in 2021



## CHC Q3 sales of €1.2bn with growth across all geographies

#### Progressively closing growth gap to the market

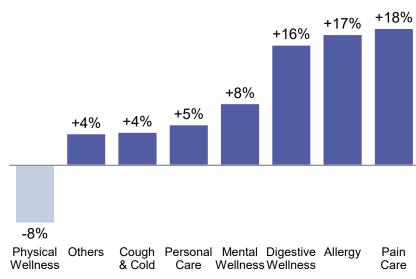
#### Driving growth with key categories

- Pain Care benefited from COVID-19 vaccinations
- Digestive Wellness growth driven by Enterogermina<sup>®</sup>, Buscopan<sup>®</sup>, and Dulcolax<sup>®</sup>
- Allergy category driven by Allegra® growth
- Cough & Cold return to growth

#### Delivering on our strategic roadmap

- A&P reallocated
- Streamlined portfolio: production discontinued or divestitures announced of 111 non-core brands
- Carve-in project progressing as planned

### CHC Q3 2021 sales up 11%





# 19% EPS growth driven by gross margin and continued expense management

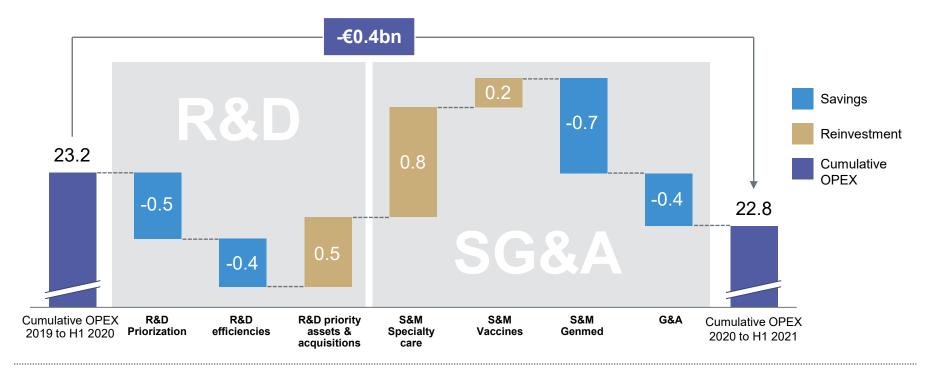
€m	Q3 2021	Q3 2020	% Change
Net Sales	10,432	9,479	+10.1%
Other revenues	397	400	+0.2%
Gross Profit	7,591	6,720	+13.0%
Gross margin %	72.8%	70.9%	
R&D	(1,443)	(1,321)	+9.3%
SG&A	(2,267)	(2,182)	+3.6%
Operating Expenses	(3,710)	(3,503)	+5.7%
Other current operating income & expenses	(289)	(182)	+68.1%
Business Operating Income	3,558	3,027	+17.3%
Business operating margin	34.1%	31.9%	
Effective tax rate	21.0%	22.0%	
Total Business Net Income	2,736	2,299	+18.8%
Average number of shares	1,254.5	1,255.7	
Business EPS	2.18	1.83	+19.1%

#### Q3 earnings drivers

- Double digit top-line growth driven by Dupixent<sup>®</sup>, Vaccines and CHC
- Significant gross margin ratio expansion due to product mix driven by Specialty Care, recovery in Meningitis, and manufacturing efficiencies in Pharma and Vaccines
- R&D spend increased behind priority assets, early pipeline and recent acquisitions
- Commercial investments behind Specialty Care growth drivers and flu vaccines partly offset by continued streamlining of G&A
- BOI margin of 34.1% reflects seasonal contribution from flu sales, gross margin improvement and SG&A phasing



## Reinvesting €1.5bn in growth



€0.4bn benefited BOI margin improvement



## **Expected business dynamics in Q4 2021**

#### **Pharmaceuticals**



Specialty Care expected to grow with Dupixent® as key driver; GenMed core assets expected to grow overall, Lovenox® stable; additional divestitures planned; China VBP Wave 5 implementation and uncertainties around mechanism for insulin class inclusion

#### **Vaccines**



Q4 sales expected in line with previous year, with Flu vaccines sales growth driven by Europe compensating a continued weakness of travel vaccines and lower US PPH sales following Vaxelis™ launch

#### **Consumer Healthcare**



Q4 business growth expected in line with market

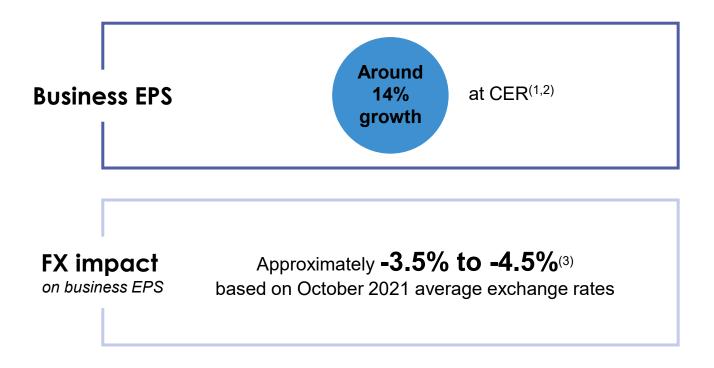
#### Non-sales line items



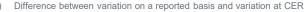
Continued improvement in gross margin; increase in R&D spend due to recent acquisitions



## FY 2021 business EPS guidance raised



<sup>2)</sup> Base for FY 2020 Business EPS growth is €5.86 and excluding the effect of the equity method of accounting for the Regeneron investment in the share of profit/loss of associates and joint ventures line



<sup>(1)</sup> Compared to FY2020 and barring major unforeseen adverse events

## Taking bold action against climate change

#### PRIOR AMBITION

Carbon Neutrality by 2050 (scope 1, 2)

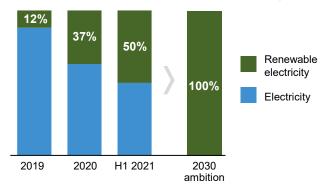
Net Zero: no objective



#### **NEW AMBITION**

Carbon Neutrality by 2030 (scope 1, 2 & 3) Net Zero objective by 2050

#### Switch to renewable electricity



## Other key ESG environment related initiatives

- Eco design of all new products by 2025
- Blister free vaccines by 2027
- 100% Eco car fleet by 2030





In the run-up to the next COP26 in Glasgow, Sanofi has joined the UN's 'Race to Zero' and 'Business Ambition for 1.5°C' initiatives.

Stretching our ambition to reach net zero by 2050



## **Q&A** session



Paul Hudson CEO



Jean Baptiste de Chatillon



Karen Linehan Legal Affairs and General Counsel



John Reed R&D



Olivier Charmeil General Medicine



**Julie van Ongevalle** Consumer Healthcare



**Bill Sibold**Speciality Care



Thomas Triomphe Vaccines



## **R&D** appendices

Q3 2021 results

October 28, 2021



## **Expected 2021 R&D key timelines**

	Product	Milestones	Achieved / Missed <sup>(1)</sup>	Comment
	avalglucosidase alfa	U.S. regulatory decision, PDUFA May 18 (Pompe disease)	×	Achieved, August 6th
	Libtayo®(2)	U.S. regulatory decision, PDUFA Feb 28 (1L NSCLC PD-L1 ≥50%)	✓	Approved
	Libtayo®(2)	U.S. regulatory decision, PDUFA March 3 (advanced BCC)	✓	Approved
H1	Sarclisa <sup>®</sup>	U.S. regulatory decision PDUFA July 18 (RMM-IKEMA)	✓	Approved
2021	amcenestrant	Pivotal data from AMEERA-3 in 2/3L mBC	×	Event-driven, expected in Q4 2021/Q1 2022
	Libtayo <sup>®(2)</sup>	Pivotal data in 1L NSCLC combo with chemotherapy	×	Achieved, August 5th
	Libtayo <sup>®(2)</sup>	Pivotal data in 2L Cervical Cancer	<b>√</b>	Study outcome positive
	amcenestrant	Phase 3 decision for early breast cancer	✓	AMEERA-6 to start H2 2021
	avalglucosidase alfa	EU regulatory decision (Pompe disease)		NAS re-examination requested
	Dupixent®(2)	U.S. regulatory decision (Asthma 6 to 11-year)	✓	Approved
	Sarclisa <sup>®</sup>	EU regulatory decision (Relapsed Multiple Myeloma - IKEMA)	✓	Approved
H2 2021	Dupixent®(2)	Pivotal trial read-out (Chronic Spontaneous Urticaria – CSU)	✓	Study outcome positive
2021	Dupixent®(2)	Pivotal trial read-out (Prurigo Nodularis – PN)	✓	Study outcome positive
	rilzabrutinib	Pivotal trial read-out (Pemphigus)	✓	Study outcome negative
	Sarclisa <sup>®</sup>	Pivotal trial read-out (1L Ti MM– IMROZ)	×	Event-driven, expected in H1 2022
2021	Adding multiple NMEs in I	mmunology, Oncology, and RBD in 2021 to the clinical pipeline		6 NMEs YTD Sept

1L: 1st Line; NSCLC: Non-Small Cell Lung Cancer; PD-L1: Programmed Death-ligand 1; BCC: Basal Cell Carcinoma; RMM: Relapsed or Refractory Multiple Myeloma; 2/3L: 2nd/3rd line; mBC: metastatic Breast Cancer; Ti: Transplant ineligible; NMEs: New Molecular Entities; NAS: new active substance

- (1) Achieved: on-time readout of data, irrespective of trial outcome
- (2) Developed in collaboration with Regeneron

## R&D Pipeline – Phase III & Registration

Phase III		
Name	Description	Indication
amcenestrant	SERD + palbociclib	1L Metastatic breast cancer
Libtayo <sup>®(1)</sup>	Anti-PD-1 mAb + chemotherapy	1L NSCLC
Libtayo <sup>®(1)</sup>	Anti-PD-1 mAb	Adjuvant CSCC
Sarclisa <sup>®</sup>	Anti-CD38 mAb	1L Newly Diag. MM Ti (IMROZ)
Sarclisa <sup>®</sup>	Anti-CD38 mAb	1L Newly Diag. MM Te (GMMG)
Sarclisa <sup>®</sup>	Anti-CD38 mAb	Smoldering MM (ITHACA)
tusamitamab ravtansine	Anti-CEACAM5 ADC	2/3L NSCLC
Dupixent®(1)	Anti-IL4/IL13 mAb	Atopic Dermatitis 6 months - 5 years old
Dupixent <sup>®(1)</sup>	Anti-IL4/IL13 mAb	Prurigo Nodularis
Dupixent <sup>®(1)</sup>	Anti-IL4/IL13 mAb	Eosinophilic Esophagitis
Dupixent <sup>®(1)</sup>	Anti-IL4/IL13 mAb	Bullous Pemphigoid
Dupixent <sup>®(1)</sup>	Anti-IL4/IL13 mAb	Chronic Spontaneous Urticaria
Dupixent®(1)	Anti-IL4/IL13 mAb	Chronic Obstructive Pulmonary Disease
Dupixent <sup>®(1)</sup>	Anti-IL4/IL13 mAb	Chronic Inducible Cold Urticaria
Dupixent <sup>®(1)</sup>	Anti-IL4/IL13 mAb	Chronic Rhinosinusitis without Nasal Polyps
Dupixent®(1)	Anti-IL4/IL13 mAb	Allergic Fungal Rhinosinusitis
itepekimab <sup>(1)</sup>	Anti-IL33 mAb	Chronic Obstructive Pulmonary Disease
venglustat	Oral GCS inhibitor	GM2 Gangliosidosis
Nexviazyme <sup>®</sup>	Enzyme Replacement Therapy GAA	Pompe Disease - Infantile Onset
fitusiran	RNAi targeting anti-thrombin	Hemophilia A and B
fitusiran	RNAi targeting anti-thrombin	Hemophilia A and B pediatric
rilzabrutinib	BTK inhibitor	Immune Thrombocytopenia
efanesoctocog alfa <sup>(2)</sup>	rFVIIIFc – vWF – XTEN <sup>(3)</sup>	Hemophilia A
tolebrutinib	BTK inhibitor	Relapsing Multiple Sclerosis
tolebrutinib	BTK inhibitor	Primary Progressive MS
tolebrutinib	BTK inhibitor	Secondary Progressive MS
nirsevimab <sup>(3)</sup>	Monoclonal Antibody	Respiratory Syncytial Virus (RSV)
SP0253 <sup>(4)</sup>	Recombinant baculovirus vaccine	COVID-19
MenQuadfi™	Meningococcal (A,C,Y,W) conjugate vaccine Meningitis 6w+ (US / EU)	
VerorabVax <sup>®</sup>	VerorabVax® Purified vero rabies vaccine Rabies	

	Registration	
Name	Description	Indication
Libtayo <sup>®(1)</sup>	Anti-PD-1 mAb	2L Cervical Cancer
Dupixent <sup>®(1)</sup>	Anti-IL4/IL13 mAb	Asthma 6-11 years old
olipudase alfa	Enzyme Replacement Therapy ASM	Niemann-Pick Disease - ad+ped
sutimlimab	Anti-complement C1s mAb	Cold Agglutinin Disease
Oncology Immuno-inflammation Rare Diseases	Rare Blood Disorders Neurology Vaccines	R Registrational Study (other than Phase 3)

As of October 28th, 2021

SERD: Selective Estrogen Receptor Degrader; 1L: 1st Line; PD-1: Programmed cell Death protein 1, mAb: monoclonal Antibody; NSCLC: non-small cell lung cancer; CSCC: Cutaneous Squamous Cell Carcinoma; CD: Cluster of Differentiation; MM: Multiple Myeloma; Ti: Transplant ineligible; Te: Transplant eligible; CEACAM5: Carcinoembryonic Antigen Cell Adhesion Molecule 5; ADC: Antibody Drug Conjugate; 2/3L: 2sd/3sd Line; IL: Interleukin; GCS: Glucosylceramide Synthase; RNAi: RNA interference; BTK: Bruton's Tyrosine Kinase; rFVIIIFc – vWF – XTEN: recombinant coagulation Factor VIII Fc – von Willebrand Factor – XTEN Fusion protein; MS: Multiple Sclerosis; rhASM: recombinant human Acid Sphingomyelinase; ASMD: Acid Sphingomyelinase; Deficiency

- Developed in collaboration with Regeneron
- Developed in collaboration with Sobi
- (3) Developed in collaboration with AstraZeneca
- (4) Developed in collaboration with GSK and with funding from Biomedical Advanced Research and Development Authority (BARDA)

## R&D Pipeline – Phase I & II

#### Phase I

Name	Description	Indication
SAR439459	Anti-TGFb mAb	Advanced Solid Tumors
SAR441000 <sup>(4)</sup>	Cytokine mRNA	Solid tumors
SAR442085	Anti-CD38 mAb Fc engineered	Multiple Myeloma
SAR442257	Anti-CD38xCD28xCD3 trispecific mAb	MM / N-H Lymphoma
SAR442720 <sup>(3)</sup>	SHP2 inhibitor mono, combo	Solid tumors
SAR444245 <sup>(15)</sup>	Non-alpha IL-2 mono, combo (PD-1, EGFR)	Solid tumors
SAR444881 <sup>(16)</sup>	Anti-ILT2 mAb	Solid tumors
SAR445419 <sup>(18)</sup>	NK-cell-based immunotherapy	Acute Myeloid Leukemia
SAR443216	Anti-CD3xCD28xHer2 trispecific mAb	Gastric cancer
SAR441566	Oral TNF inhibitor	Inflammatory indications
SAR444656 <sup>(13)</sup>	IRAK4 degrader	Atopic Dermatitis
SAR443726	Anti-IL13/OX40L nanobody	Atopic Dermatitis
SAR442501	Anti-FGFR3 mAb	Achondroplasia
SAR445136(5,14)	Ex Vivo ZFN Gene-Edited Cell Therapy	Sickle Cell Disease
SAR443820 <sup>(6,7)</sup>	RIPK1 inhibitor	Amyotrophic Lateral Sclerosis
SP0148 <sup>(9)</sup>	HSV-2 therapeutic vaccine	Herpes Simplex Virus (HSV) Type
SP0273	mRNA vaccine	Influenza vaccine

Oncology
Immuno-inflammation
Rare Diseases

Rare Blood Disorders
Neurology

Vaccines

Registrational Study (other than Phase 3)

As of October 28th, 2021

TGFb: Transforming Growth Factor beta; mAb: monoclonal Antibody; CD: Cluster of Differentiation; MM: Multiple Myeloma; N-H: Non-Hodgkin; SHP2: Src Homology-2 domain-containing protein tyrosine Phosphatase-2; IL: Interleukin; MK: Natural Killier; TNF: Tumor Necrosis Factor; IRAK4: Interleukin 1 Receptor Associated Kinase 4; FGFR3: Fibroblast Growth Factor Receptor 3; RIPK1: Receptor-Interacting serine/threonine-Protein Kinase 1; SERD: Selective Estrogen Receptor Degrader; 2/3L: 2\*\*/Jo³\* Line; ICOS: Inducible COStimulatory molecule; CEACAMIS: Carcinoembryonic Antigen CBI Adhesion Molecule 5; ADC: Antibody Drug Conjugate; NSCLC: Non-small Cell Lung Gancer; 1L: 1\* line; AML: Acute Myeloid Leukemia; ALL: Acute Lymphoblastic Leukemia; BTK: Bruton's Tyrosine Kinase; IgG: Immunoglobulin G; GCS: Glucosylceramide Synthase; CIDP: Chronic Inflammatory Demyelinating Polyneuropathy

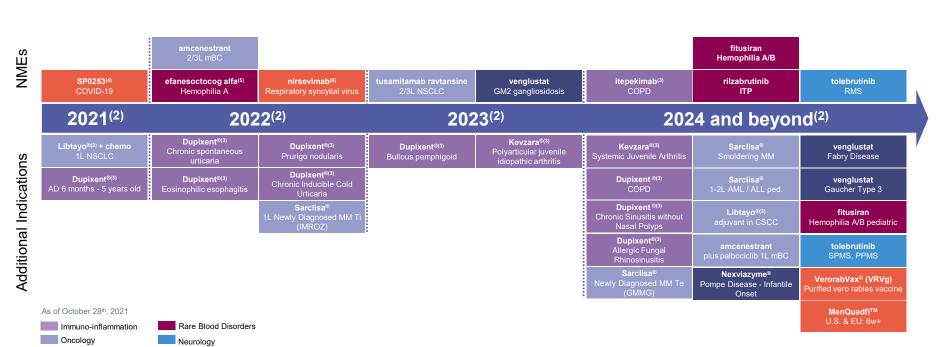
- (1) Formerly known as KY1044/SAR445256
- Developed in collaboration with Immunext
- (3) Developed in collaboration with Revolution Medicines
- (4) Developed in collaboration with BioNTech
- 5) Formerly known as BIVV003
- Developed in collaboration with Denali
- (7) Also known as DNL788
- (8) Also known as DNL758
- (9) Developed in collaboration with Immune Design/Merck
- (10) Developed in collaboration with SK
- (11) Developed in collaboration with Regeneron
- (12) Formerly known as BIVV020
- (13) Developed in collaboration with Kymera (KT474)
- (14) Developed in collaboration with Sangamo
- (15) Formerly known as THOR707
- (16) Developed in collaboration with Biond (17) Formerly known as KY1005/SAR445229
- (18) Formerly known as KDS1001

#### Phase II

		riidse ii	
	Name	Description	Indication
R	amcenestrant	SERD	2/3L Metastatic Breast Cancer
	amcenestrant	SERD	Early Breast Cancer
	alomfilimab <sup>(1)</sup>	Anti-ICOS mAb	Solid tumors
	tusamitamab ravtansine	Anti-CEACAM5 ADC + ramucirumab	2/3L NSCLC
	tusamitamab ravtansine	Anti-CEACAM5 ADC	Exploratory Solid tumors
	tusamitamab ravtansine	Anti-CEACAM5 ADC + pembrolizumab	1L NSCLC
	Sarclisa <sup>®</sup>	Anti-CD38 mAb+ combinations	Relapsed, Refractory Multiple Myeloma
R	Sarclisa <sup>®</sup>	Anti-CD38 mAb	1-2L AML / ALL pediatrics
R	Sarclisa <sup>®</sup>	Anti-CD38 mAb	Patients awaiting kidney transplantation
	SAR444245 <sup>(15)</sup>	Non-alpha IL-2 + cemiplimab	Skin cancers
	SAR443122 <sup>(6,8)</sup>	RIPK1 inhibitor	Cutaneous Lupus Erythematosus
	amlitelimab <sup>(17)</sup>	Anti-OX40L mAb	Atopic Dermatitis
	Dupixent® (11)	Anti-IL4/IL13 mAb	Peanut allergy
R	Kevzara <sup>®(11)</sup>	Anti-IL6 mAb	Polyarticular Juvenile Idiopathic Arthritis
R	Kevzara <sup>®(11)</sup>	Anti-IL6 mAb	Systemic Juvenile Arthritis
	rilzabrutinib	BTK inhibitor	lgG4-related disease
	SAR441344 <sup>(2)</sup>	Anti-CD40L mAb	Sjogren's Syndrome
	SAR444727	BTK inhibitor (topical)	Atopic Dermatitis
	SAR339375	miRNA-21	Alport Syndrome
	venglustat	Oral GCS inhibitor	Fabry Disease
	venglustat	Oral GCS inhibitor	Gaucher Disease Type 3
	Sarclisa <sup>®</sup>	Anti-CD38 mAb	Warm Autoimmune Hemolytic Anemia
	SAR445088 <sup>(12)</sup>	Complement C1s inhibitor	Immune Thrombocytopenia
	SAR445088 <sup>(12)</sup>	Complement C1s inhibitor	Cold Agglutinin Disease
	SAR445088 <sup>(12)</sup>	Complement C1s inhibitor	CIDP
	SAR441344 <sup>(2)</sup>	Anti-CD40L mAb	Multiple Sclerosis
	SP0218	Vero cell	Yellow fever vaccine
	SP0202 <sup>(10)</sup>	Next Generation Conjugate Vaccine	Pneumococcal
	Fluzone® HD (SP0178)	Inactivated influenza Vaccine (IIV)	Pediatric Flu
	SP0125	Vaccine	Respiratory syncytial virus (infants)
	SP0230	Multicomponent vaccine	Meningitis B



## Expected submission timelines<sup>(1)</sup>



1L: 14" line; NSCLC: Non-small Cell Lung Cancer; AD: Atopic Dermatitis; 2/3L: 2nd/3" Line; mBC: metastatic Breast Cancer; MM: Multiple Myeloma; Ti: Transplant ineligible; COPD: Chronic Obstructive Pulmonary Disease; Te: Transplant eligible; ITP: Immune Thrombocytopenia, AML: Acute Myeloid Meukemia; ALL: Acute Lymphoblastic Leukemia; ped: pediatric; CSCC: Cutaneous Squamous Cell Carcinoma; RMS: Relapsing Multiple Sclerosis, SPMS: Secondary-Progressive Multiple Sclerosis; PPMS: Relapsing-Remitting Multiple Sclerosis



Vaccines

Rare Diseases

<sup>(2)</sup> Projects within a specified year are not arranged by submission timing Developed in collaboration with Regeneron

Developed in collaboration with Sobi Developed in collaboration with AstraZeneca



## Financial appendices

Q3 2021 results

October 28, 2021



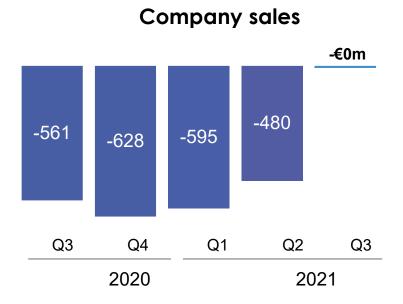
## YTD Sept P&L

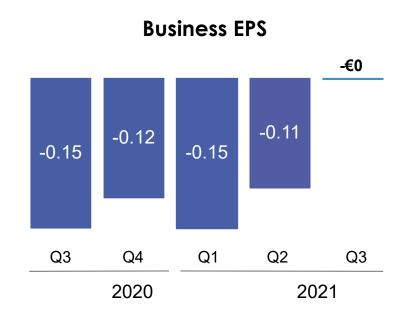
€m	9M 2021	9M 2020	% Change (CER)
Net Sales	27,767	26,659	+8.2%
Other revenues	993	974	+8.1%
Gross Profit	19,981	18,967	+9.6%
Gross margin %	72.0%	71.1%	
R&D	(4,106)	(4,013)	+4.9%
SG&A	(6,797)	(6,789)	+3.6%
Operating Expenses	(10,903)	(10,802)	+4.1%
Other current operating income & expenses	(589)	(437)	+49.0%
Business Operating Income	8,461	7,710	+15.0%
Business operating margin	30.5%	28.9%	
Effective tax rate	21.0%	22.0%	
Total Business Net Income	6,484	5,820	+16.9%
Average number of shares	1,251.7	1,253.0	
Business EPS	5.18	4.64	+17.2%



### Q3 sales and EPS

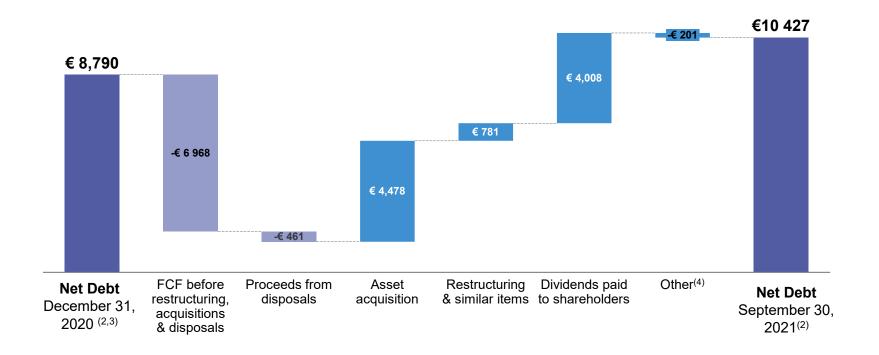
### **Currency impact**







### Net debt evolution in 9M 2021<sup>(1)</sup>





<sup>(2)</sup> Including derivatives used to manage net debt:€193m at December 31, 2020 and -€93m at September 30, 2021

<sup>(3)</sup> Effective January 1, 2019, net debt does not include lease liabilities following the first-time application of IFRS16

Including €140m use of funds from acquisition of treasury shares and €175m of proceeds from issuance of Sanofi shares;

## 2021 currency sensitivity and Q3 2021 currency exposure

2021 Business EPS Currency Sensitivity			
Currency	Variation	Business EPS Sensitivity	
U.S. Dollar	+ 0.05 USD/EUR	- EUR 0.13	
Japanese Yen	+ 5 JPY/EUR	- EUR 0.02	
Chinese Yuan	+ 0.2 CNY/EUR	- EUR 0.02	
Brazilian Real	+ 0.4 BRL/EUR	- EUR 0.01	
Russian Ruble	+ 10 RUB/EUR	- EUR 0.02	



Currency Average Rates			
	Q3 2020	Q3 2021	% change
EUR/USD	1.17	1.18	+0.8%
EUR/JPY	124.05	129.79	+4.6%
EUR/CNY	8.09	7.63	-5.7%
EUR/BRL	6.29	6.16	-2.0%
EUR/RUB	86.28	86.60	+0.4%



# Regeneron Collaboration Accounting Summary

Last Updated: September 2021



# Sanofi accounting of Antibody License and Collaboration Agreement with Regeneron<sup>(1)</sup>

		U.S.	Ex-U.S.
Net sales		Sanofi consolidate	s worldwide net sales
Cost of sales		Sanofi consolidates	worldwide cost of sales
R&D expense		Development costs funded upfront by Sanofi until first positive Phase 3; subsequent costs funded 80% Sanofi / 20% Regeneron  Regeneron 20% reimbursement recorded as a reduction of Sanofi R&D expense	
SG&A expense		Sanofi expenses 100% of its commercial expenses	
1. Regeneron SG&A spend		Sanofi reimburses Regeneron for 100% of Regeneron's commercial expenditures	
Other operating	2. Development balance	_	ulative development costs quarterly <sup>(2)</sup> ; of profit per quarter on all Antibody products combined <sup>(3)</sup>
income and expenses	3. Collaboration profitable	Outflow: Sanofi expenses 50% of profit; paid to Regeneron	Outflow: Sanofi expenses 35% to 45% of profit; paid to Regeneron
	Collaboration in a loss	Inflow: Sanofi recognizes reimbursement of 50% loss from Regeneron	Inflow: Sanofi recognizes reimbursement of 45% loss from Regeneron
Amortization of intangibles (IFRS)	Sales Milestones		Regeneron entitled to receive up to \$250m in milestones starting from \$1bn ex-US sales <sup>(4)</sup>



- (1) Following expiry of the Antibody Discovery Agreement in December 2017, Dupixent®, Kevzara® and itepekimab (SAR440340) continue to be developed and commercialized with Regeneron under the Antibody License and Collaboration Agreement (LCA) signed in November 2007, Amended and Restated November
- 2009, further amended May 2013 and July 2015, restructured in April 2020 and further amended in September 2021
- (2) As of December 31, 2020, such commitments received were \$3.1bn, relative to cumulative development costs of \$8.0bn, of which \$7.2bn were incurred by Sanofi; balance
- includes costs for Dupixent®, Kevzara® and itepekimab as well as Praluent® through March 31, 2020
- (3) Including Dupixent®, Kevzara® and itepekimab
- (4) Praluent® removed from LCA at April 2020 restructuring, but ex-U.S. sales of Praluent® remain included in calculation of sales milestones

# Sanofi Libtayo<sup>®</sup> accounting pursuant to immuno-oncology License and Collaboration Agreement with Regeneron<sup>(1,2)</sup>

		U.S.	Ex-U.S.
Net sales		Consolidated by Regeneron	Consolidated by Sanofi
Cost of sales		Consolidated by Regeneron	Consolidated by Sanofi
R&D expenses		Sanofi reimburses 50% of development expenses incurred during quarter <sup>(3)</sup>	
SG&A expenses		Sanofi expenses 100% of its commercial expenses	
Other operating Income and expenses	1. SG&A reimbursement	Inflow: Regeneron reimburses 100% of Sanofi's U.S. commercial expenses	Outflow: No Regeneron commercial expenses ex-US
	2. Development balance	Regeneron reimburses 50% of pre-POC development costs <sup>(4)</sup> quarterly <sup>(5)</sup>	
	3. Collaboration profitable	Inflow: Sanofi recognizes 50% of collaboration's profits	Outflow: Sanofi expenses 50% of profits; to be paid to Regeneron
	4. Collaboration in a loss	Outflow: Sanofi expenses 50% of losses; to be paid to Regeneron	Inflow: Sanofi recognizes reimbursement of 50% of collaboration's losses
Amortization of intangibles (IFRS)	Sales milestones	Regeneron to receive \$375m milestone when sales of Libtayo® exceed \$2bn over any consecutive 12-month period	

On July 1, 2015, Sanofi and Regeneron entered into an Immuno-Oncology (IO) Discovery and Development Agreement and an IO License and Collaboration Agreement (IO LCA).



(2) Libtayo® collaboration unaffected by the Amended I-O

Discovery and Development Agreement terminated in Q1 2021.

<sup>(3)</sup> The Libtayo® budget is funded equally by the two companies.

<sup>(4)</sup> As of December 31, 2020, amounts to \$104m primarily

for bi-specifics, LAG3 and CTLA-4 development programs conducted in the frame of the IO Discovery Agreement terminated in Q1 2021.

<sup>(5)</sup> Capped at 10% of Regeneron profit share per quarter



## **ESG** appendices

Q3 2021 results

October 28, 2021



## Sanofi ESG ratings

