



# Q1 2021 Results

Play to Win

April 28, 2021



# Forward looking statements

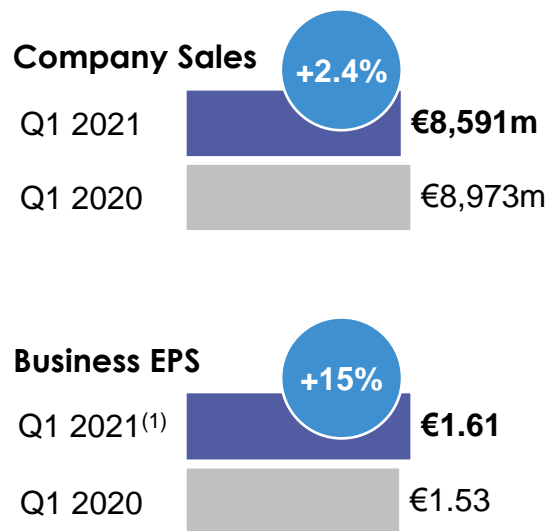
This document contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, 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

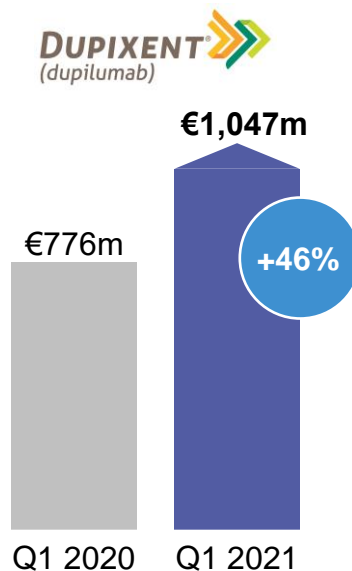
<b>Introduction</b>	<b>Paul Hudson</b>	Chief Executive Officer
<b>Business update</b>	<b>Bill Sibold</b> <b>Thomas Triomphe</b> <b>Olivier Charmeil</b> <b>Julie Van Ongevalle</b>	Specialty Care Vaccines General Medicines Consumer Healthcare
<b>Financial results</b>	<b>Jean-Baptiste de Chatillon</b>	Chief Financial Officer
<b>Q&amp;A session</b>		

# Q1 financial performance fueled by growth drivers

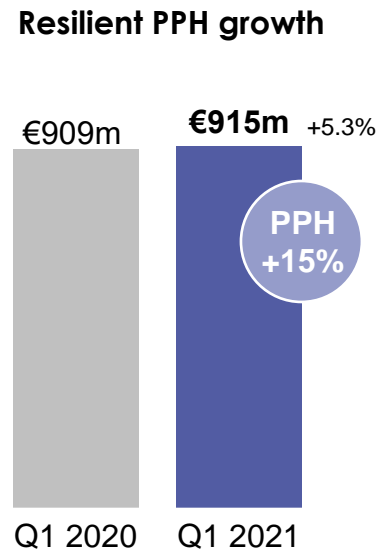
## Sales and EPS growth



## Dupixent® sales strong



## Vaccines delivered

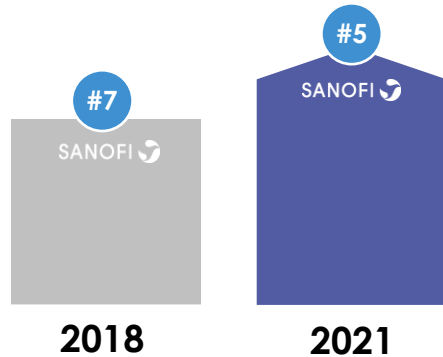


# Expanding affordable access to those most in need



Recognized for making medicines more easily available in low- and middle-income countries<sup>(1)</sup>

Sanofi rankings in **ACCESS TO MEDICINE INDEX**



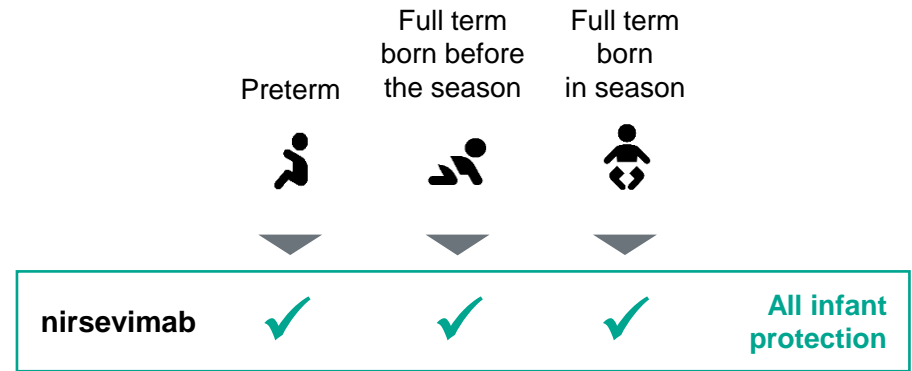
Creation of **SANOFI GLOBAL HEALTH**



# Nirsevimab – all infant protection against RSV

- RSV leading cause of hospitalization in infants
  - 16x more than influenza in infant <1 year<sup>(1)</sup>
- First-in-class single-dose immunization
  - Nirsevimab is designed to provide protection for all infants entering their first RSV season
- **MELODY positive Ph3 topline** results in healthy full-term and late preterm infants  $\geq 35$  wGA
  - Trial continues for safety
  - Data publication expected in scientific journal in 2021
- MEDLEY<sup>(3)</sup> Ph 2/3 data expected H2 2021

## Development program seeks to confirm protection of all infants



50% of infants hospitalized during their first RSV season are born before the start of the season<sup>(2)</sup>

**Regulatory submissions to begin in 2022, one year ahead of schedule**

RSV: respiratory syncytial virus; wGA: weeks gestational age; Nirsevimab under investigation in collaboration with AstraZeneca, not approved by regulators

(1) Zhou H, et al. *Clin Infect Dis*. 2012;54(10):1427–1436

(2) Reeves, et al. *Journal of Infection*. 2019: 468-475.

(3) MEDLEY is an ongoing Ph3 trial studying infants  $\leq 35$  wGA in first RSV season as well as children <24 months with chronic lung disease and congenital heart defect in their second RSV season

# Building our oncology franchise – proof points in H1 2021



Feb 9

FDA approval as first PD-L1 indicated for patients with advanced basal cell carcinoma<sup>(1)</sup>



Feb 22

FDA approval as monotherapy for patients with 1L advanced NSCLC with PD-L1  $\geq 50\%$ <sup>(2)</sup>



Mar 31

FDA approval in combination with carfilzomib and dexamethasone for patients with RMM<sup>(3)</sup>

SAR444245<sup>(4)</sup>

Apr 9

Late-breaking interim clinical data validate not-alpha profile



Apr 19

EC approval in combination with carfilzomib and dexamethasone for patients with RMM<sup>(5)</sup>



June 4, 2021

January

June

Libtayo<sup>®</sup> in collaboration with Regeneron; 1L: first line; NSCLC: non-small cell lung cancer; RMM: relapsed/refractory multiple myeloma; EC: European Commission

(1) Libtayo<sup>®</sup> was FDA approved for patients with locally advanced basal cell carcinoma previously treated with a hedgehog pathway inhibitor (HHI) or for whom a HHI is not appropriate

(2) Libtayo<sup>®</sup> was FDA approved as monotherapy for patients with first-line advanced NSCLC with PD-L1 expression of  $\geq 50\%$  with no EGFR, ALK, or ROS1 aberrations

(3) Sarclisa<sup>®</sup> was FDA approved in combination with carfilzomib and dexamethasone for patients with relapsed or refractory multiple myeloma who have received 1-3 prior lines of therapy

(4) Formerly known as THOR-707

(5) Sarclisa was EC approved in combination with carfilzomib and dexamethasone for the treatment of adult patients with relapsed multiple myeloma who have received at least one prior therapy

# Execution of capital allocation to drive R&D transformation

## Sanofi 2021 YTD transactions focused on priority areas of immunology and oncology

### M&A



Adds proprietary next generation of cell-based cancer immune-therapeutics



Offers access to KY1005, a human mAb targeting key immune system regulator OX40L



Adds novel mRNA-based research platform to reprogram immune cells

### BD



Enhances oncology pipeline with BND-22, a novel immune checkpoint inhibitor targeting ILT2



Broadens gene therapy capabilities with improved tissue-selective AAV vectors



Adds C4XD's oral pre-clinical IL-17A inhibitor program



# Sanofi well positioned for growth in the two largest markets



## U.S. business mix set to drive growth

- Increasing sales shift to Specialty Care, +15% growth in Q1
- ~60% of Specialty Care business in commercial channels
- Diminishing exposure to insulin pricing pressure



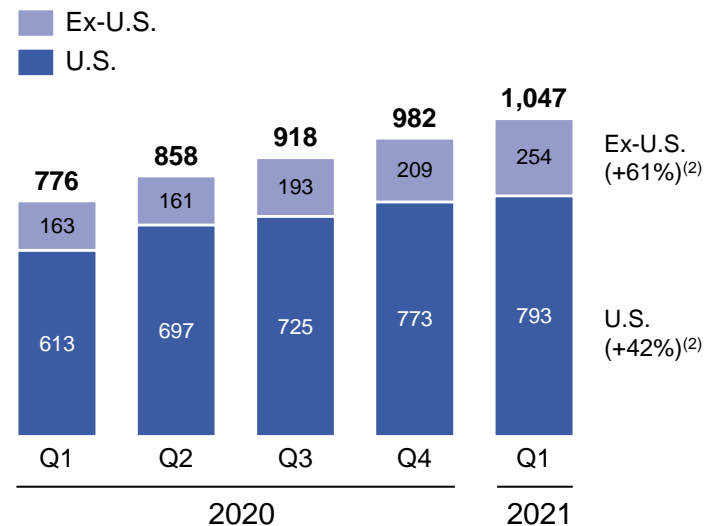
## China positive growth outlook

- Dupixent<sup>®</sup>, Praluent<sup>®</sup> and Toujeo<sup>®</sup> launches to drive 2021 growth, including potential impact from expected VBP in H2
- Dupixent<sup>®</sup> adult AD patient access accelerated by NRDL inclusion
- Digital customer engagement drives agile business model

# Dupixent® – building a worldwide megabrand

- First quarter reaching the €1bn mark
  - Worldwide growth of +46% vs. Q1 2020
  - Ex-U.S. contributed 24% of sales and annualizing €1bn
- In-office patient visits below pre-COVID levels
  - U.S. patient visits continue to be ~80%<sup>(1)</sup> pre-COVID levels
- Upcoming milestones for potential future growth
  - Anticipated FDA and EMA decisions for 6 to 11-year-olds with asthma<sup>(3)</sup>
  - Pivotal data in 6 month to <6-year-olds with AD expected H2
  - Pivotal readouts in PN and CSU expected H2

Global Dupixent® quarterly sales (€m)



*Well on track to achieve >€10bn peak sales target*

AD: moderate to severe atopic dermatitis; PN: prurigo nodularis; CSU: chronic spontaneous urticaria; pipeline programs represent assets under investigation and are not approved by regulators for the uses being investigated.

(1) Q1 average of dermatologist, allergist and pulmonologist patient visits (Spherix COVID-19 Impact, Wave 16 Survey in Mar'21; ZoomRx Market Research (Feb'21))

(2) Represents growth Q1 2020 to Q1 2021

(3) In U.S. seeking an indication for 6 to 11-yr-olds with uncontrolled moderate to severe asthma, and in the EU seeking an indication for 6 to 11-yr-olds with uncontrolled severe asthma

# Dupixent® – executing on worldwide expansion



## European launches set to deliver

- Adult AD reimbursed across EU5
- First and only biologic in AD in EU for children as young as 6 yrs old
- **#1** in asthma new patient share in Germany (32% share)<sup>(1)</sup>
- Pediatric asthma regulatory submission underway



## RoW – driving growth in attractive markets

- Japan AD (15 years and older), asthma and CRSwNP launches
- **#1** in asthma new patient share in Japan (29% share)<sup>(2)</sup>
- **#3** product in Japan in volume growth – up 69%<sup>(3)</sup>
- Australia reimbursement in severe AD and severe Type 2 asthma secured



## China adult AD launch accelerated

- Encouraging start following NRDL inclusion on March 1
- Focused on patient activation and stakeholder engagement
- Hospital listings in major cities
- AD adolescent anticipated decision mid-2021

EU5: France, Germany, Italy, Spain and the United Kingdom; RoW: rest of the world includes countries other than U.S., China, and those in Europe; AD: atopic dermatitis; CRSwNP: chronic rhinosinusitis with nasal polyps; NRDL: national reimbursement drug list

(1) IQVIA LRx-Database, Dupixent®, asthma biologics market (naïve and switches) Source of Business, Observation period 01/2021;

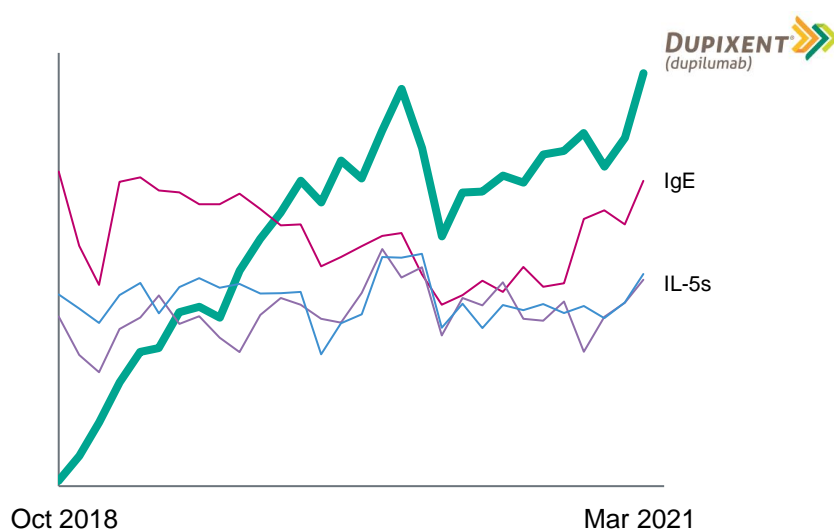
(2) Japan local ATU data W9 Jan 2021; Asthma biologics market (naïve and switches)

(3) IQVIA April 2021 MAT

# Dupixent® leading U.S. respiratory biologic by NBRx

- Type 2 inflammation drives >80% of uncontrolled persistent asthma<sup>(1)</sup>
- Dupixent® inhibits signaling of IL-4 and IL-13 targeting Type 2 inflammation<sup>(2)</sup>
  - Significantly decreases exacerbation rate
  - Rapid and sustained improvement in FEV1
  - Safety and efficacy data out to 3 years<sup>(1)</sup>
- Dupixent® potential in additional respiratory conditions driven by Type 2 inflammation
  - First and only approved biologic therapy to treat CRSwNP
  - Type 2 COPD, CRSsNP, and AFRS development underway

U.S. monthly respiratory NBRx<sup>(3)</sup>



FEV1: forced expiratory volume during first second of the forced breath; CRSwNP: chronic rhinosinusitis with nasal polyps; COPD: chronic obstructive pulmonary disease; CRSsNP: chronic sinusitis without nasal polyps; AFRS: allergic fungal rhinosinusitis; pipeline programs represent assets under investigation and are not approved by regulators for the uses being investigated

(1) LIBERTY ASTHMA TRAVERSE OLE

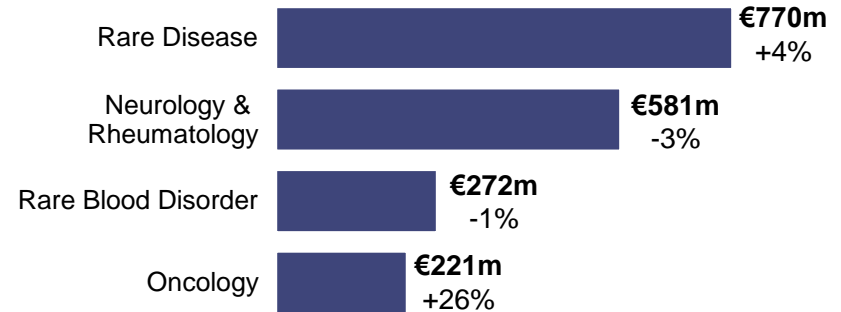
(2) LIBERTY ASTHMA QUEST

(3) IQVIA Source of Business Sanofi adjusted for all channels and by indication (Asthma + Nasal Polyps indications) for dupilumab, benralizumab, mepolizumab, and omalizumab

# Commercial execution continued to deliver across Specialty Care franchises

- Rare Disease franchises grew across geographies
- Neurology & Rheumatology sales supported by resilient Aubagio® performance
  - Lemtrada® and Kevzara® deprioritized
- RBD franchise up 5% ex-Sobi<sup>(1)</sup> supply sales
  - U.S. +3% due to Cablivi® and Alprolix® growth
- Sarclisa® and Libtayo® drove Oncology growth
  - Jevtana® generic entrance in Europe at the end of March

## Q1 2021 sales growth by franchise ex-Dupixent



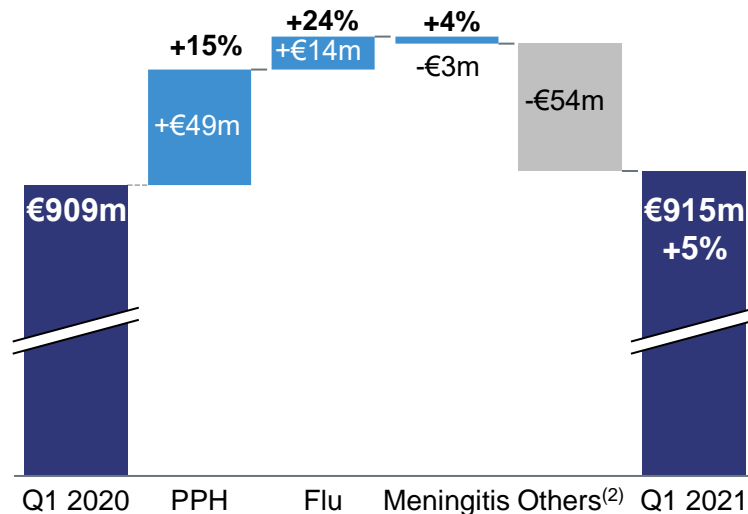
# Making progress in bringing innovation to patients in RBD

Asset	Key progress in Rare Blood Disorders (RBD)	Phase
<b>Sutimlimab</b> CAD	<b>NEJM</b> publication of Phase 3 CARDINAL study results in April; Planning for <b>H2 2021 resubmission</b> with FDA	Registration
<b>Fitusiran</b> Hemophilia A & B	<b>Favorable discussions with FDA</b> in Q1 supporting H2 2022 planned submission	Phase 3
<b>Efanesoctocog alfa<sup>(1,2)</sup></b> Hemophilia A	FDA <b>fast track designation</b> granted in Q1; Phase 3 <b>pediatric study</b> initiated in March	Phase 3
<b>Rilzabrutinib</b> ITP	<b>First patient dosed</b> in Phase 3 trial for patients with persistent or chronic ITP in April	Phase 3
<b>SAR445136<sup>(3,4)</sup></b> Sickle Cell Disease	FDA <b>fast track designation</b> and EMA <b>orphan drug designation</b> granted in Q1; preliminary Phase 1/2 data expected H2 2021	Phase 1/2

# Vaccines – momentum continued in core segments in Q1

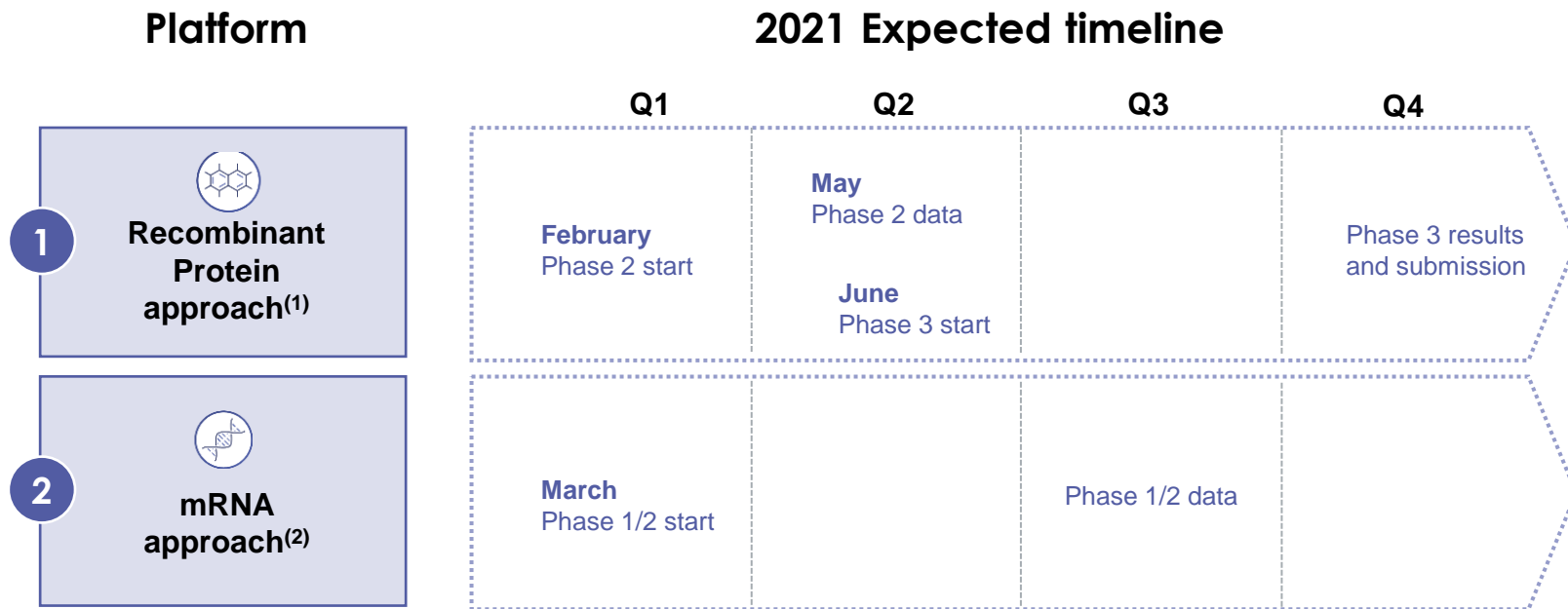
- PPH franchise up double-digits reflecting phasing
  - U.S. up 40% driven by favorable timing of CDC shipment
  - Strong polio sales in Rest of the World
- Flu up due to strong southern hemisphere demand
- Meningitis growth helped by U.S. MenQuadfi™ launch
- Travel (-37%) and Boosters (-9%) due to pandemic
- Upcoming milestones
  - U.S. launch of Vaxelis™<sup>(1)</sup>, first hexavalent vaccine expected in Q2 2021
  - mRNA flu vaccine clinical trial planned to start mid-year

## Vaccines growth by key franchise



*Early pre-orders in northern hemisphere point to another year of strong flu sales*

# Update on COVID-19 vaccine development programs



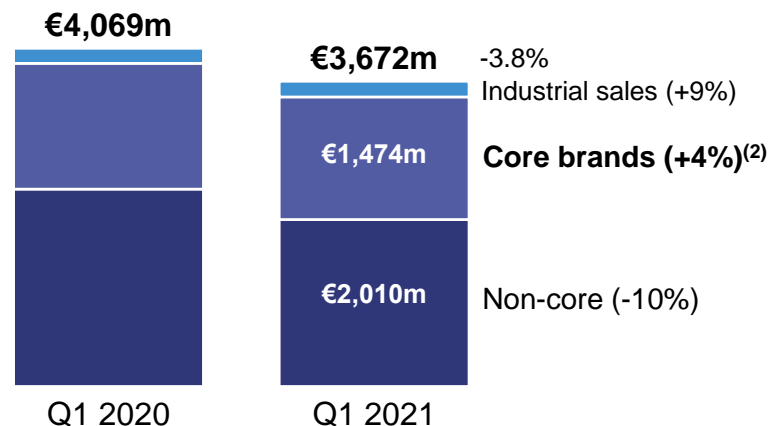
*Preclinical work on variants ongoing*



# General Medicines – core brands grew 4% in Q1

- Performance of core brands driven by demand
  - Lovenox® grew 30%<sup>(1)</sup> benefited from COVID guidelines
  - Toujeo® sales +5% supported by launch in China
  - Plavix® grew in China due to VBP volume growth of 18%
  - Praluent® ex-U.S. up 27% driven by Europe and China
- Non-core portfolio down 10%
  - Portfolio streamlining impact of 3 ppts<sup>(3)</sup>
  - Aproveil® temporary supply constraint impact of ~1 ppts

## Q1 2021 General Medicines Sales

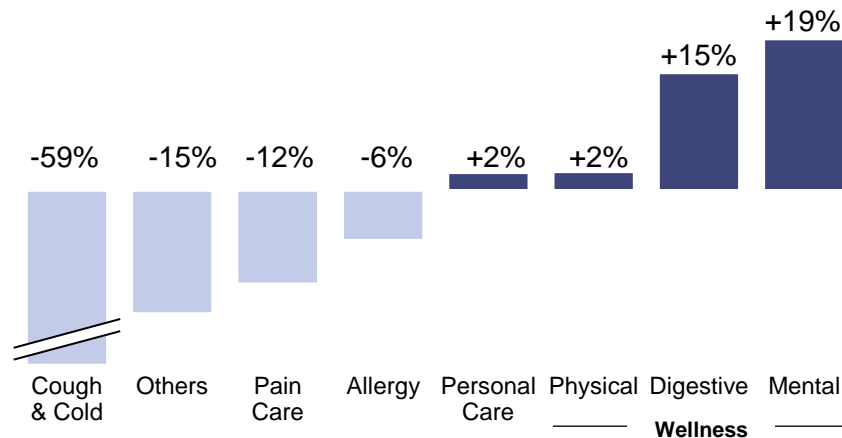


*Simplification and new digital engagement model progressing well*

# Consumer Healthcare – focused on growth franchises

- CHC Q1 sales of €1.1bn, down 7%
  - Cough & Cold in Europe -68% due to social distancing
  - High base for comparison due to Q1 2020 pantry loading
- Wellness brands favored during pandemic
  - Dulcolax<sup>®</sup>, Essentiale<sup>®</sup>, Magne-B6<sup>®</sup>
- U.S. Allergy sales up 4% driven by Xyzal<sup>®</sup>

## Pandemic reflected in category growth in Q1



U.S. omnichannel launch of **Zantac<sup>360</sup>** with famotidine underway

# Q1 double-digit EPS growth driven by leveraged P&L

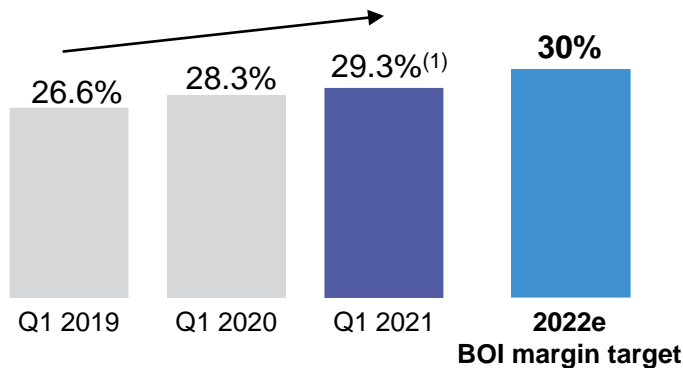
€m	Q1 2021	Q1 2020 <sup>(1)</sup>	% Change (CER)
<b>Net Sales</b>	<b>8,591</b>	<b>8,973</b>	<b>+2.4%</b>
Other revenues	295	343	-6.4%
Gross Profit	6,202	6,469	+2.6%
<i>Gross margin %</i>	72.2%	72.1%	
R&D	(1,266)	(1,340)	-1.7%
SG&A	(2,194)	(2,342)	-0.7%
<b>Operating Expenses</b>	<b>3,460</b>	<b>3,682</b>	<b>-1.1%</b>
Other current operating income & expenses	(101)	(247)	-52.2%
<b>Business Operating Income</b>	<b>2,638</b>	<b>2,537</b>	<b>+13.3%</b>
<i>Business operating margin</i>	30.7%	28.3%	
<i>Effective tax rate</i>	21.0%	22.0%	
<b>Total Business Net Income</b>	<b>2,017</b>	<b>1,920</b>	<b>+14.7%</b>
Average number of shares	1,249.3	1,251.3	
<b>Business EPS</b>	<b>1.61</b>	<b>1.53</b>	<b>+15.0%</b>

## Q1 earnings drivers

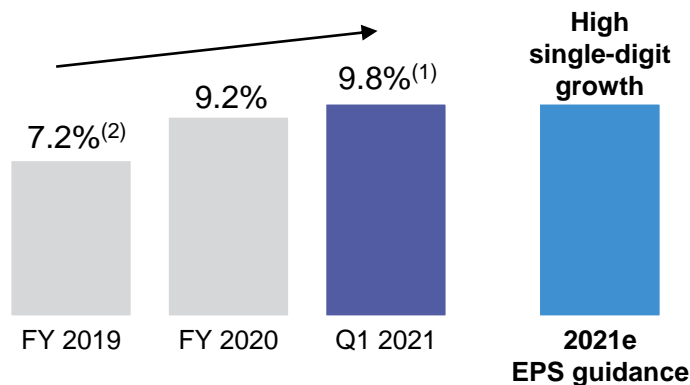
- **Top-line growth** contributed to BOI margin
- Portfolio shift and industrial affairs efficiencies **improved gross margin**
- **R&D spend** increase in key asset development costs offset by operational efficiencies and lower expenses on mature projects
- Ongoing operational efficiencies reflected in **lower SG&A spend**
- **One-time payment** related to a former collaboration<sup>(2)</sup> favorably impacted OOI&E
  - Excluding one-time payment, BOI grew 8.4% with **BOI margin of 29.3%**

# Sanofi on growth trajectory to meet financial targets

## BOI margin



## Business EPS growth



- Dupixent® momentum expected to continue
- Industrial efficiencies

- Higher spend funding growth drivers and pipeline
- Uncertainties from pandemic and pricing environment

# FY 2021 business EPS guidance affirmed

**Business EPS**

High  
single-digit  
growth

at CER<sup>(1,2)</sup>

**FX impact**

*on business EPS*

Approximately **-4% to -5%**<sup>(3)</sup>  
based on April 2021 average exchange rates

(1) Compared to FY2020 and barring major unforeseen adverse events

(2) 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

(3) Difference between variation on a reported basis and variation at CER

# Q&A session



**Paul Hudson**  
CEO



**Olivier Charmeil**  
General Medicines



**Julie van Ongevalle**  
Consumer Healthcare



**Bill Sibold**  
Specialty Care



**Jean-Baptiste de Chatillon**  
CFO



**Karen Linehan**  
Legal Affairs and General Counsel



**John Reed**  
R&D



**Thomas Triomphe**  
Vaccines



# Financial appendices

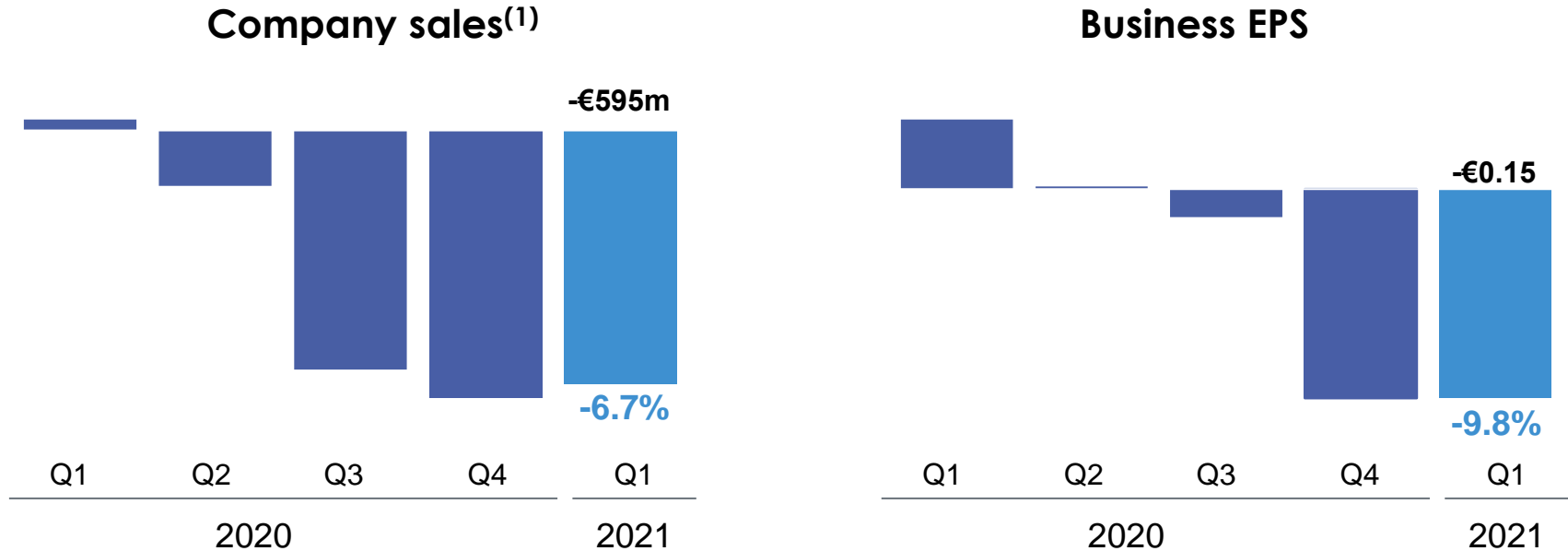
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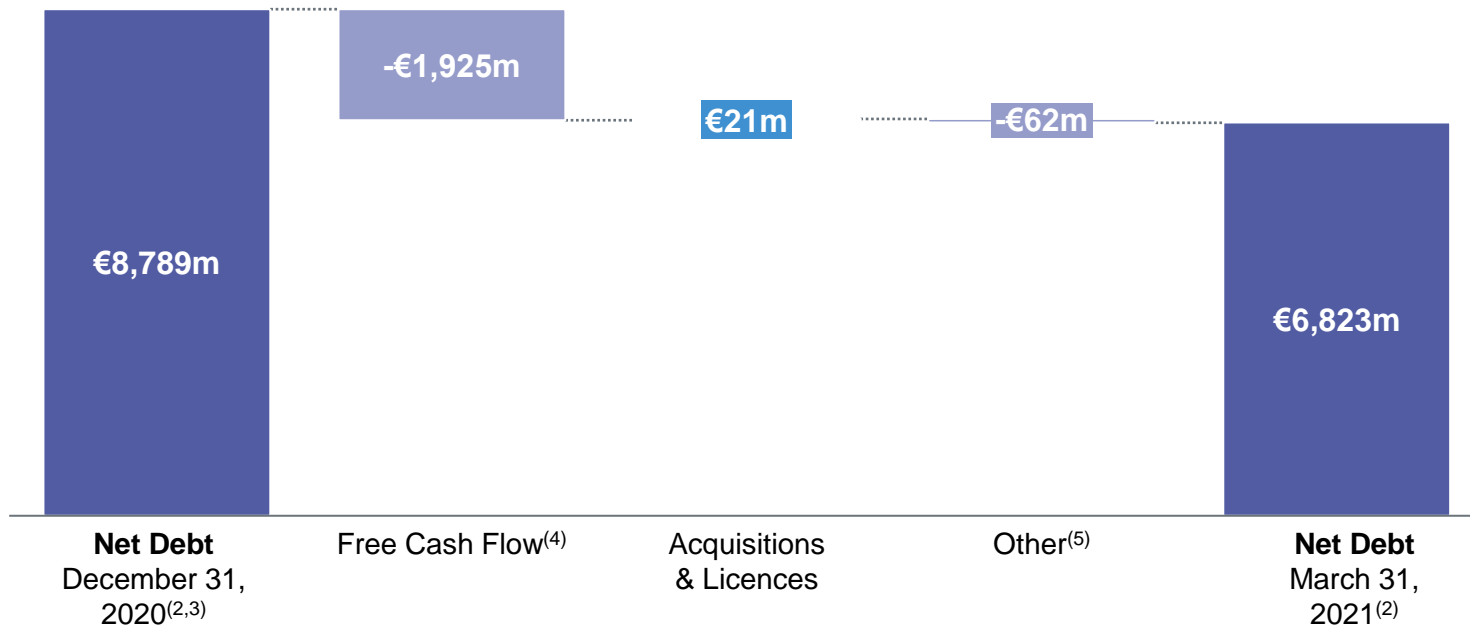
# Q1 sales and EPS impacted by continued weakening of U.S. dollar and Emerging Markets currencies

## Currency impact





# Net debt evolution in Q1 2021<sup>(1)</sup>



(1) Credit ratings reaffirmed: Moody's A1/stable, S&P AA/stable, Scope AA/stable as of March 31, 2021

(2) Including derivatives used to manage net debt: €193m at December 31, 2020 and -€41m at March 31, 2021

(3) Effective January 1, 2019, net debt does not include lease liabilities following the first-time application of IFRS 16

(4) Free Cash Flow (FCF) includes restructuring costs cash-out, investments and divestments not exceeding a cap of €500 million per transaction

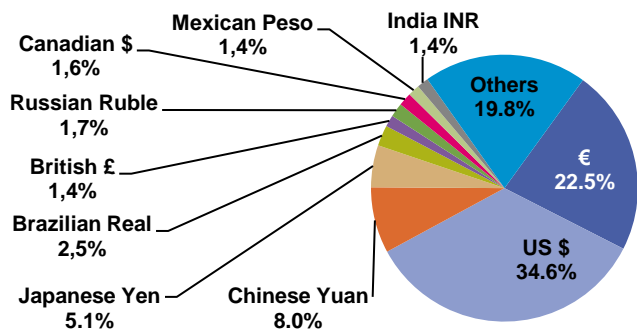
(5) Including €140m use of funds from acquisition of treasury shares and €11m of proceeds from issuance of Sanofi shares

# 2021 currency sensitivity and Q1 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 Exposure on Q1 2021 Sales



## Currency Average Rates

	Q1 2020	Q1 2021	% change
EUR/USD	1.10	1.21	+9.4%
EUR/JPY	120.15	127.69	+6.3%
EUR/CNY	7.71	7.81	+1.3%
EUR/BRL	4.91	6.59	+34.2%
EUR/RUB	73.67	89.72	+21.8%

# Vaxelis™ – Sanofi and Merck JV background

## 1st U.S. pediatric hexavalent combination vaccine

### United States

- First pediatric hexavalent vaccine in the U.S. with launch expected in Q2 2021
- ACIP approval for routine recommendation and inclusion in the VFC program
- Co-promotion by both Sanofi Pasteur and Merck in the U.S.
- Sales & OPEX recorded by the joint venture
  - 50% of the joint venture profits included in “Share of Profit/Loss of Associates and Joint Ventures” P&L line

### Europe

- Vaxelis™ launched in Europe in 2017, currently available in eight countries
- Product sold / distributed by either Sanofi Pasteur or Merck depending on the country
- Profits shared equally by Sanofi Pasteur and Merck
  - Sanofi share of joint venture profits included in “Share of Profit/Loss of Associates and Joint Ventures” P&L line



# R&D appendices

Q1 2021 results

April 28, 2021



# Expected 2021 R&D key timelines

	Product	Milestones	Comment	Achieved / Missed <sup>(1)</sup>
H1 2021	avalglucosidase alfa	U.S. regulatory decision, PDUFA May 18 (Pompe disease)	Fast track designation, BT, Priority review	✗ H2 2021 <sup>(4)</sup>
	Libtayo <sup>®(2)</sup>	U.S. regulatory decision, PDUFA Feb 28 (1L NSCLC PD-L1 $\geq$ 50%)	Priority review	✓
	Libtayo <sup>®(2)</sup>	U.S. regulatory decision, PDUFA March 3 (advanced BCC)	Priority review	✓
	Sarclisa <sup>®</sup>	U.S. regulatory decision PDUFA July 18 (RMM-IKEMA)		✓
	amcenestrant <sup>(3)</sup>	Pivotal data from AMEERA-3 in 2/3L mBC	Fast track designation	
	Libtayo <sup>®(2)</sup>	Pivotal data in 1L NSCLC combo with chemotherapy		✗ H2 2021 <sup>(5)</sup>
	Libtayo <sup>®(2)</sup>	Pivotal data in 2L Cervical Cancer		✓
	amcenestrant <sup>(3)</sup>	Phase 3 decision for early BC	Fast track designation	
H2 2021	avalglucosidase alfa	EU regulatory decision (Pompe disease)		
	Dupixent <sup>®(2)</sup>	U.S. regulatory decision (Asthma 6 to 11-year)		
	Sarclisa <sup>®</sup>	EU regulatory decision (Refractory Multiple Myeloma - IKEMA)		✓
	Dupixent <sup>®(2)</sup>	Pivotal trial read-out (Chronic Spontaneous Urticaria – CSU)		
	Dupixent <sup>®(2)</sup>	Pivotal trial read-out (Prurigo Nodularis – PN)		
	rilzabrutinib	Pivotal trial read-out (Pemphigus)	U.S. and EU orphan designation	
	Sarclisa <sup>®</sup>	Pivotal trial read-out (1L TiMM– IMROZ)		
2021	Adding multiple NMEs in Immunology, Oncology, and RBD in 2021 to the clinical pipeline			

NMEs: new molecular entities; RBD: Rare blood disorder; Ti: transplant ineligible; RMM: relapsing / refractory multiple myeloma; BCC: basal cell carcinoma; BC: breast cancer

- (1) Achieved: on-time readout of data, irrespective of trial outcome
- (2) Developed in collaboration with Regeneron
- (3) Formerly known as SAR439859
- (4) FDA PDUFA 3-month extension to August 18, 2021
- (5) Event driven trial

# R&D Pipeline – Phase III & Registration

## Phase III

Name	Description	Indication
amcnestrant <sup>(7)</sup>	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	2L Cervical Cancer
Libtayo <sup>®(1)</sup>	Anti-PD-1 mAb	adjuvant CSCC
Sarclisa <sup>®</sup>	Anti-CD38 mAb	1L Newly Diag. MM Tt (IMROZ)
Sarclisa <sup>®</sup>	Anti-CD38 mAb	1L Newly Diag. MM Te (GMMG)
Sarclisa <sup>®</sup>	Anti-CD38 mAb	Smoldering Multiple myeloma (ITHACA)
tusamitamab ravtansine <sup>(6)</sup>	Anti-CEACAM5 ADC	NSCLC 2/3L
Dupixent <sup>®(1)</sup>	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 <sup>®(1)</sup>	Anti-IL4/IL13 mAb	Chronic Obstructive Pulmonary Disease
Dupixent <sup>®(1)</sup>	Anti-IL4/IL13 mAb	Cold Urticaria (CIndU-Cold)
Dupixent <sup>®(1)</sup>	Anti-IL4/IL13 mAb	Chronic Sinusitis without nasal polyps
Dupixent <sup>®(1)</sup>	Anti-IL4/IL13 mAb	Allergic Fungal Rhinosinusitis
rilzabrutinib	BTK inhibitor	Pemphigus
itepekimab <sup>(1)</sup>	Anti-IL33 mAb	COPD
venglustat	Oral GCS inhibitor	ADPKD
venglustat	Oral GCS inhibitor	GM2 Gangliosidosis
Cerdelga <sup>®</sup>	Oral GCS inhibitor	Gaucher T1, ERT switch, Pediatric
tolebrutinib <sup>(2)</sup>	BTK inhibitor	Relapsing Multiple Sclerosis (RMS)
tolebrutinib <sup>(2)</sup>	BTK inhibitor	Primary Progressive MS (PPMS)
tolebrutinib <sup>(2)</sup>	BTK inhibitor	Secondary Progressive MS (SPMS)
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 (BIVV001) <sup>(3)</sup>	rFVIII Fc – vWF – XTEN <sup>(4)</sup>	Hemophilia A
nirsevimab <sup>(5)</sup>	Monoclonal Antibody	Respiratory Syncytial Virus
MenQuadfi <sup>TM</sup>	Meningococcal (A,C,Y,W) conjugate vaccine	Meningitis 6w+ (US / EU)
VerorabVax <sup>®</sup> (VRVg)	Purified vero rabies vaccine	Rabies

## Registration

Name	Description	Indication
Dupixent <sup>®(1)</sup>	Anti-IL4/IL13 mAb	Asthma 6-11 years old
sutimlimab	Anti compliment C1s mAb	Cold Agglutinin Disease
avalglucosidase alfa	Enzyme replacement therapy	Pompe Disease
Aubagio <sup>®</sup>	Pyrimidine synthesis inhibitor	Relapsing Multiple Sclerosis – Pediatric
Shan 6 <sup>®</sup>	Pediatric hexavalent vaccine	DTP-HepB-Polio-Hib

<span style="background-color: #8e7cc3; border: 1px solid #000; padding: 2px;"> </span> Immuno-inflammation	<span style="background-color: #8e44ad; border: 1px solid #000; padding: 2px;"> </span> Rare Blood Disorders
<span style="background-color: #3498db; border: 1px solid #000; padding: 2px;"> </span> Oncology	<span style="background-color: #2980b9; border: 1px solid #000; padding: 2px;"> </span> Neurology
<span style="background-color: #2c3e50; border: 1px solid #000; padding: 2px;"> </span> Rare Diseases	<span style="background-color: #e67e22; border: 1px solid #000; padding: 2px;"> </span> Vaccines

- (1) Developed in collaboration with Regeneron
- (2) Proposed international nonproprietary name for SAR442168
- (3) Developed in collaboration with Sobi
- (4) Recombinant Coagulation Factor VIII Fc – von Willebrand Factor – XTEN Fusion protein
- (5) Developed in collaboration with AstraZeneca
- (6) Formerly known as SAR408701
- (7) Formerly known as SAR439859

ADPKD: Autosomal Dominant Polycystic Kidney Disease ; Tt: Transplant ineligible ; Te: Transplant eligible; ADC: Antibody Drug Conjugate; RRMM: Relapsed Refractory Multiple Myeloma ; BTKi: Bruton's Tyrosine Kinase inhibitor ; GCS: Glucosylceramide Synthase ; Hib: Haemophilus influenzae type b; NSCLC: non small cell lung cancer; MM: multiple myeloma; COPD: chronic obstructive pulmonary disease; CSCC: cutaneous squamous cell carcinoma; ERT: enzyme replacement therapy

As of March 31, 2021

# 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>(6)</sup>	SHP2 inhibitor mono, combo	Solid tumors
SAR444245 <sup>(20)</sup>	Non-alpha IL-2 mono, combo (PD-1, EGFR)	Solid tumors
SAR441236	Tri-specific neutralizing mAb	HIV
SAR443122 <sup>(6,7)</sup>	RIPK1 <sup>(11)</sup> inhibitor	Inflammatory indications
SAR444727	BTK inhibitor (topical)	Immune mediated diseases
SAR441566	Oral TNF inhibitor	Inflammatory indications
SAR444656 <sup>(17)</sup>	IRAK4 degrader	Atopic dermatitis
SAR441344 <sup>(2)</sup>	Anti-CD40L mAb	Multiple Sclerosis
SAR443820 <sup>(6,8)</sup>	RIPK1 <sup>(9)</sup> inhibitor	Amyotrophic Lateral Sclerosis
ST400 <sup>(19)</sup>	Ex Vivo ZFN Gene-Edited Cell Therapy	Beta thalassemia
SAR445136 <sup>(5,19)</sup>	Ex Vivo ZFN Gene-Edited Cell Therapy	Sickle Cell Disease
SAR445088 <sup>(16)</sup>	Complement C1s inhibitor	Cold Agglutinin Disease
sutimlimab	Complement C1s inhibitor	Immune Thrombocytopenic Purpura
SP0148 <sup>(10)</sup>	Therapeutic vaccine	Herpes Simplex Virus Type 2
SP0218	Vaccine (Vero cell)	Yellow Fever
SAR442501	FGFR3 antibody	Achondroplasia

Phase II		
Name	Description	Indication
<b>R</b> amcenestrant <sup>(1)</sup>	SERD	Metastatic Breast Cancer 2/3L
amcenestrant <sup>(1)</sup>	SERD	Early Breast Cancer
tusamitamab ravtansine <sup>(13)</sup>	Anti-CEACAM5 ADC + ramucirumab	2/3L NSCLC
tusamitamab ravtansine <sup>(13)</sup>	Anti-CEACAM5 ADC + pembrolizumab	1L NSCLC
Sarclisa®	Anti-CD38 mAb + atezolizumab	Metastatic Colorectal Cancer 1L
<b>R</b> Sarclisa®	Anti-CD38 mAb	1-2L AML / ALL pediatrics
<b>R</b> isatuximab	Anti-CD38 mAb	Patients awaiting kidney transplantation
dupilumab <sup>(15)</sup>	Anti-IL4/IL13 mAb	Peanut allergy
<b>R</b> Kevzara® <sup>(15)</sup>	Anti-IL6 mAb	Polyarticular Juvenile Idiopathic Arthritis
<b>R</b> Kevzara® <sup>(15)</sup>	Anti-IL6 mAb	Systemic Juvenile Arthritis
rilzabrutinib	BTK inhibitor	IgG4-related disease
SAR441344 <sup>(2)</sup>	Anti-CD40L mAb	Sjogren's Syndrome
<b>R</b> SAR445088 <sup>(16)</sup>	Complement C1s inhibitor	Immune Thrombocytopenia
olipudase alfa	rhASM	ASMD ad+ped
SAR339375	miRNA-21	Alport Syndrome
venglustat	Oral GCS inhibitor	Fabry Disease
venglustat	Oral GCS inhibitor	Gaucher Type 3
SP0202 <sup>(12)</sup>	Next Gen Conjugate Vaccine	Pneumococcal
Fluzone® HD	Inactivated influenza Vaccine (IIV)	Pediatric Flu
SP0125	Vaccine	Respiratory syncytial virus (infants)
SP0253 <sup>(21)</sup>	Recombinant baculovirus vaccine	COVID-19
SP0254 <sup>(18)</sup>	mRNA vaccine	COVID-19
SP0230	Multicomponent vaccine	Meningitis B

As of March 31, 2021

MM: Multiple Myeloma ; ALL: Acute Lymphoblastic Leukemia ; NSCLC: Non-Small Cell Lung; FGFR3: Fibroblast Growth Factor Receptor 3; ASMD: Acid sphingomyelinase deficiency

- (1) Formerly known as SAR439859
- (2) Developed in collaboration with Immunex
- (3) Developed in collaboration with Revolution Medicines
- (4) Developed in collaboration with BioNTech
- (5) Formerly known as BIVV003
- (6) Developed in collaboration with Denali
- (7) Also known as DNL788
- (8) Also known as DNL758
- (9) Receptor-Interacting serine/threonine-Protein Kinase 1

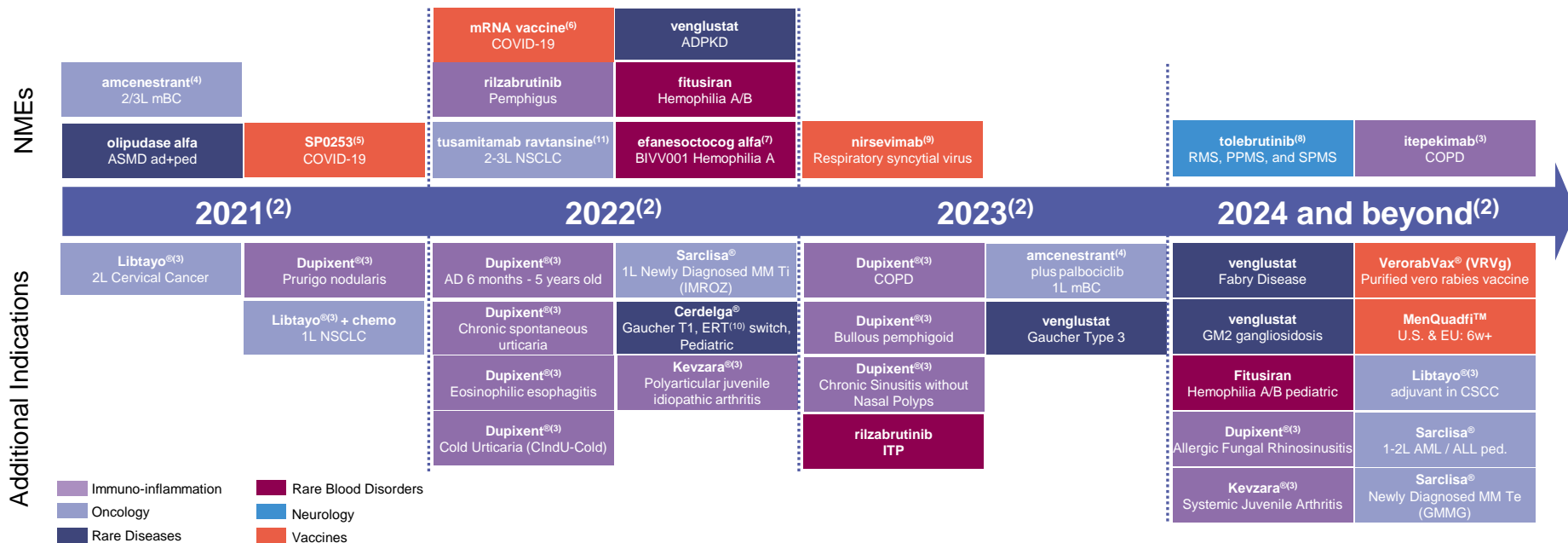
- (10) Developed in collaboration with Immune Design/Merck
- (11) Acid Sphingomyelinase Deficiency also known as Niemann Pick type B
- (12) Developed in collaboration with SK
- (13) Formerly known as SAR408701
- (14) Development discontinued
- (15) Developed in collaboration with Regeneron
- (16) Formerly known as BIVV020
- (17) Developed in collaboration with Kymera (KT474)

- (18) Developed in collaboration with Translate Bio
- (19) Developed in collaboration with Sangamo
- (20) Formerly known as THOR707
- (21) Developed in collaboration with GSK and with funding from Biomedical Advanced Research and Development Authority (BARDA)

- Immuno-inflammation
- Oncology
- Rare Diseases
- Rare Blood Disorders
- Neurology
- Vaccines

**R** Registrational Study (other than Phase 3)

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



As of March 31, 2021, barring unforeseen events

- (1) Excluding Phase 1 (without POC)
- (2) Projects within a specified year are not arranged by submission timing
- (3) Developed in collaboration with Regeneron
- (4) Formerly known as SAR439859
- (5) Developed in collaboration with GSK and with funding from Biomedical Advanced Research and Development Authority (BARDA)
- (6) Developed in collaboration with Translate Bio

- (7) Developed in collaboration with Sobi
- (8) Proposed international nonproprietary name for SAR442168
- (9) Developed in collaboration with AstraZeneca
- (10) Enzyme replacement therapy
- (11) Formerly known as SAR408701

RMS: Relapsing multiple sclerosis, PP: Primary progressive; SP: Secondary progressive; ITP: Immune Thrombocytopenia; MM: Multiple myeloma; CSCC: cutaneous squamous cell carcinoma; AML: acute myeloid leukemia; ALL: acute lymphoblastic leukemia; COPD: chronic obstructive pulmonary disease; Te: transplant eligible; Ti transplant ineligible; ADPKD: Autosomal Dominant Polycystic Kidney Disease; ped: pediatric; NSCLC: non-small cell lung cancer; mBC: metastatic breast cancer; ASMD: acid sphingomyelinase deficiency; mBC: metastatic breast cancer