



# R&D appendices

Q3 2020 Results

October 29, 2020



# R&D Pipeline – Phase III & Registration

## Phase III

Name	Description	Indication
Libtayo <sup>(1)</sup>	Anti-PD-1 mAb monotherapy	1L NSCLC
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 in CSCC
Sarclisa <sup>®</sup>	Anti-CD38 mAb	1L Newly Diag. MM Ti (IMROZ)
Sarclisa <sup>®</sup>	Anti-CD38 mAb	Newly Diag. MM Te (GMMG)
Sarclisa <sup>®</sup>	Anti-CD38 mAb	Smoldering multiple myeloma (ITHACA)
SAR408701	anti-CEACAM5 ADC	NSCLC 2/3L
Dupixent <sup>(1)</sup>	Anti-IL4/IL13 mAb	Asthma 6 - 11 years old
Dupixent <sup>(1)</sup>	Anti-IL4/IL13 mAb	AD 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
rilzabrutinib	BTK inhibitor	Pemphigus
venglustat	Oral GCS inhibitor	ADPKD <sup>(2)</sup>
venglustat	Oral GCS inhibitor	GM2 gangliosidosis
Cerdega <sup>®</sup>	Oral GCS inhibitor	Gaucher T1, ERT switch Pediatric
Tolebrutinib <sup>(3)</sup>	BTK inhibitor	Multiple Sclerosis
fitusiran	RNAi targeting anti-thrombin	Hemophilia A and B
fitusiran	RNAi targeting anti-thrombin	Hemophilia A and B pediatric
BIVV001 <sup>(4)</sup>	rFVIII Fc – vWF – XTEN <sup>(5)</sup>	Hemophilia A
Nirsevimab <sup>(6)</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

As of September 30, 2020

## Registration





Name	Description	Indication
Sarclisa <sup>®</sup>	Anti-CD38 mAb	2L RRM (IKEMA)
Dupixent <sup>(1)</sup>	Anti-IL4/IL13 mAb	AD 6 – 11 years old (EU)
avalglucosidase alfa	Enzyme replacement therapy	Pompe Disease
Aubagio <sup>®</sup>	Pyrimidine synthesis inhibitor	Relapsing Multiple Sclerosis – Pediatric
sutimlimab	Anti Complement C1s mAb	Cold Agglutinin Disease
MenQuadfi <sup>TM</sup>	Meningococcal conjugate vaccine	EU 1y+
Shan 6 <sup>®</sup>	Pediatric hexavalent vaccine	DTP-HepB-Polio-Hib
Supemtek <sup>®</sup>	Recombinant influenza vaccine	EU

 Immuno-inflammation	 Rare Blood Disorders
 Oncology	 Multiple Sclerosis & Neurology
 Rare Diseases	 Vaccines

- (1) Developed in collaboration with Regeneron  
 (2) Autosomal Dominant Polycystic Kidney Disease  
 (3) Proposed international nonproprietary name for SAR442168  
 (4) Developed in collaboration with Sobi  
 (5) Recombinant Coagulation Factor VIII Fc – von Willebrand Factor – XTEN Fusion protein  
 (6) Developed in collaboration with AstraZeneca  
 Ti: transparent inelible; Te: transplant eligible; ADC: antibody drug conjugate; RRM: relapsed refractory multiple myeloma;  
 BTK: Bruton's Tyrosine Kinase inhibitor; GCS: glucosylceramide synthase

# R&D Pipeline – Phase I & II

## Phase I

Name	Description	Indication
SAR439459	anti-TGFb mAb	Advanced Solid Tumors
Amcenenstrant <sup>(1)</sup>	SERD + palbociclib	Metastatic Breast Cancer
SAR440234	T cell engaging multi specific mAb	Leukemia
SAR441000 <sup>(6)</sup>	Cytokine mRNA	Solid tumors
SAR442085	Anti CD38 mAb Fc engineered	Multiple Myeloma
SAR442257	Anti-CD38xCD28xCD3 trispecific mAb	MM / N-H Lymphoma
SAR442720 <sup>(5)</sup>	SHP2 inhibitor + pembrolizumab	Solid tumors
SAR442720 <sup>(5)</sup>	SHP2 inhibitor + cobimetinib	Relapsed Refractory solid tumors
SAR444245 (THOR-707)	Non-alpha IL-2	Solid tumors
 REGN4018 <sup>(4)</sup>	Anti-MUC16xCD3 + cemiplimab	Ovarian Cancer
 REGN5459 <sup>(4)</sup>	Anti-BCMAxCD3 bispecific mAb	Relapsed Refractory MM
 REGN5458 <sup>(4)</sup>	Anti-BCMAxCD3 bispecific mAb	Relapsed Refractory MM
 REGN4018 <sup>(4)</sup>	Anti-MUC16xCD3 bispecific mAb	Ovarian Cancer
SAR441169 <sup>(10)</sup>	RORC (ROR gamma T) antagonist	Psoriasis
SAR441236	Tri-specific neutralizing mAb	HIV
SAR443122 <sup>(9)</sup>	RIPK1 <sup>(9)</sup> inhibitor	Inflammatory indications
PRN473	BTK inhibitor	Immune mediated diseases
SAR441344 <sup>(3)</sup>	Anti-CD40L mAb	Multiple Sclerosis
ST400 <sup>(7)</sup>	Ex Vivo ZFN Gene-Edited Cell Therapy	Beta thalassemia
BIVV003 <sup>(7)</sup>	Ex Vivo ZFN Gene-Edited Cell Therapy	Sickle Cell Disease
BIVV020	Complement C1s inhibitor	Cold Agglutinin Disease
sutimlimab	Complement C1s inhibitor	Immune Thrombocytopenic Purpura
SP0148 <sup>(11)</sup>	Therapeutic vaccine	Herpes Simplex Virus Type 2
SP0218	Vaccine (Vero cell)	Yellow Fever








As of September 30, 2020

- (1) Also known as SAR439859  
 (2) Also known as SAR440340  
 (3) Developed in collaboration with Immunext  
 (4) Regeneron product for which Sanofi has opt-in rights  
 (5) Developed in collaboration with Revolution Medicines  
 (6) Developed in collaboration with BioNTEch

- (7) Developed in collaboration with Sangamo  
 (8) Developed in collaboration with Denali  
 (9) Receptor-interacting serine/threonine-protein kinase 1  
 (10) Developed in collaboration with Lead Pharma  
 (11) Developed in collaboration with Immune Design/Merck  
 (12) Developed in collaboration with Regeneron

- (13) Acid Sphingomyelinase Deficiency also known as Niemann Pick type B  
 (14) Developed in collaboration with SK

## Phase II

Name	Description	Indication
 Amcenenstrant <sup>(1)</sup>	SERD	Metastatic Breast Cancer 2/3L
Amcenenstrant <sup>(1)</sup>	SERD	Early Breast Cancer
SAR408701	Anti-CEACAM5 ADC + ramucirumab	NSCLC 2/3L
 Libtayo <sup>(12)</sup>	Anti-PD-1 mAb	2-L Basal Cell Carcinoma
 Sarclisa <sup>®</sup>	Anti-CD38 mAb	1-2L AML / ALL pediatrics
 isatuximab	Anti-CD38 mAb	patients awaiting kidney transplantation
Sarclisa <sup>®</sup>	Anti-CD38 mAb + cemiplimab	Lymphoma
Sarclisa <sup>®</sup>	Anti-CD38 mAb + atezolizumab	mCRC
Itepekimab <sup>(2)</sup>	Anti-IL33 mAb	COPD
Itepekimab <sup>(2)</sup>	Anti-IL33 mAb	Asthma
romilkimab	Anti-IL4/IL13 bispecific mAb	Systemic Scleroderma
dupilumab <sup>(2)</sup>	Anti-IL4/IL13 mAb	Grass pollen allergy
dupilumab <sup>(2)</sup>	Anti-IL4/IL13 mAb	Peanut allergy
 Kevzara <sup>(2)</sup>	Anti-IL6 mAb	Polyarticular Juvenile Idiopathic Arthritis
 Kevzara <sup>(2)</sup>	Anti-IL6 mAb	Systemic Juvenile Arthritis
rilzabrutinib	BTK inhibitor	Immune Thrombocytopenia
rilzabrutinib	BTK inhibitor	IgG4-related disease
 olipudase alfa <sup>(13)</sup>	rhASM	ASMD ad+ped
SAR339375	miRNA-21	Alport Syndrome
venglustat	Oral GCS inhibitor	Fabry Disease
venglustat	Oral GCS inhibitor	Gaucher Type 3
venglustat	Oral GCS inhibitor	GBA-PD
SP0202 <sup>(14)</sup>	Next Gen Conjugate Vaccine	Pneumococcal
Fluzone <sup>®</sup> HD	Recombinant Vaccine	Pediatric Flu
SP0125	Vaccine	Respiratory syncytial virus (infants)
SP0253	Recombinant baculovirus vaccine	COVID-19

-  Immuno-inflammation  
 Rare Blood Disorders  
 Oncology  
 Multiple Sclerosis  
 Rare Diseases  
 Vaccines

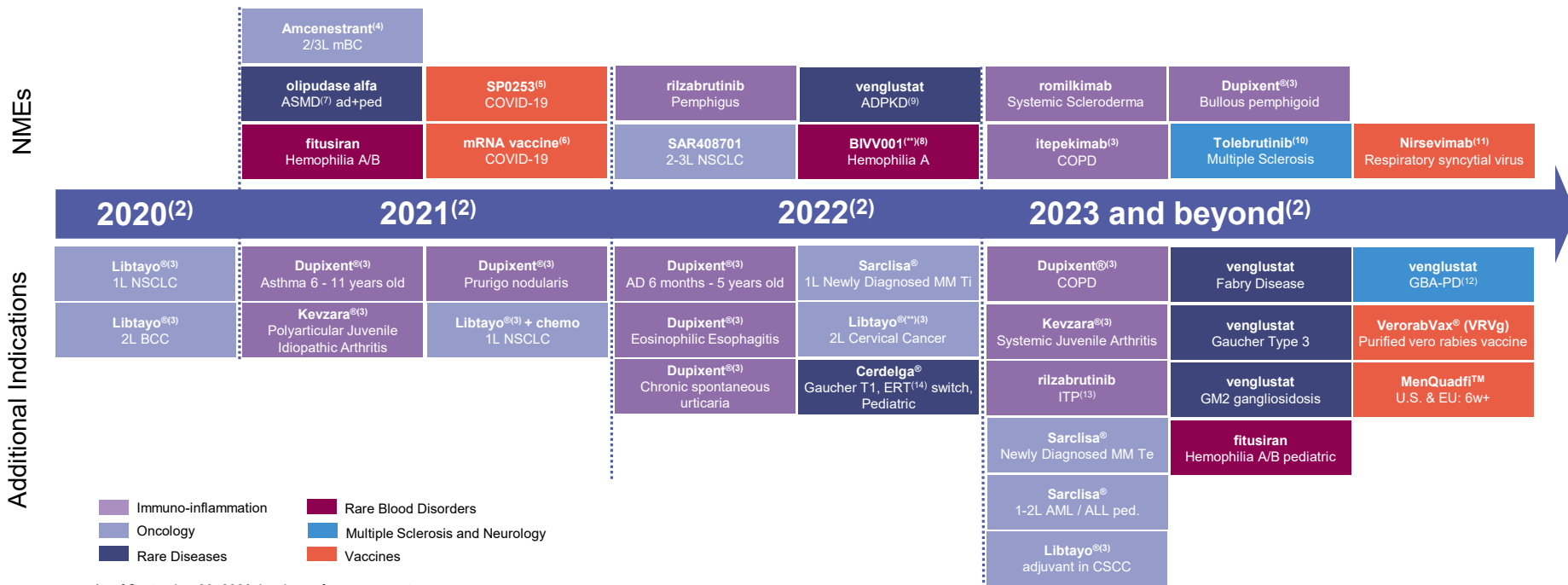
 Registrational Study (other than Phase 3)

 Opt-in rights products for which rights have not been exercised yet



mAb: monoclonal antibody; 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; BCC: basal cell carcinoma; mBC: metastatic breast cancer

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



As of September 30, 2020, 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) Also 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) Acid Sphingomyelinase Deficiency

(8) Developed in collaboration with Sobi  
 (9) Autosomal Dominant Polycystic Kidney Disease  
 (10) Proposed international nonproprietary name for SAR442168  
 (11) Developed in collaboration with AstraZeneca  
 (12) Parkinson's Disease with an associated GBA mutation  
 (13) Immune Thrombocytopenia  
 (14) Enzyme replacement therapy



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; BCC: basal cell carcinoma; mBC: metastatic breast cancer

# 2021 – significant year for Sanofi's pipeline ahead

## Expected pivotal results<sup>(1)</sup>

- Amcenestrant (AMEERA-3) 2L/3L in mBC 
- Fitusiran for Hemophilia A & B 
- BIVV001<sup>(2)</sup> for Hemophilia A 
- Dupixent<sup>®</sup> for CSU & PN 
- Sarclisa<sup>®</sup> 1L Ti MM (IMROZ)
- Libtayo<sup>®</sup> 1L NSCLC with CT
- COVID-19 vaccine candidates
- Rilzabrutinib in Pemphigus **New**

## Expected Phase 2 readouts<sup>(1)</sup>

- Venglustat GBA PD 
- Sarclisa<sup>®</sup> subcutaneous formulation
- Amcenestrant, early BC, AMEERA-4 

 Priority assets

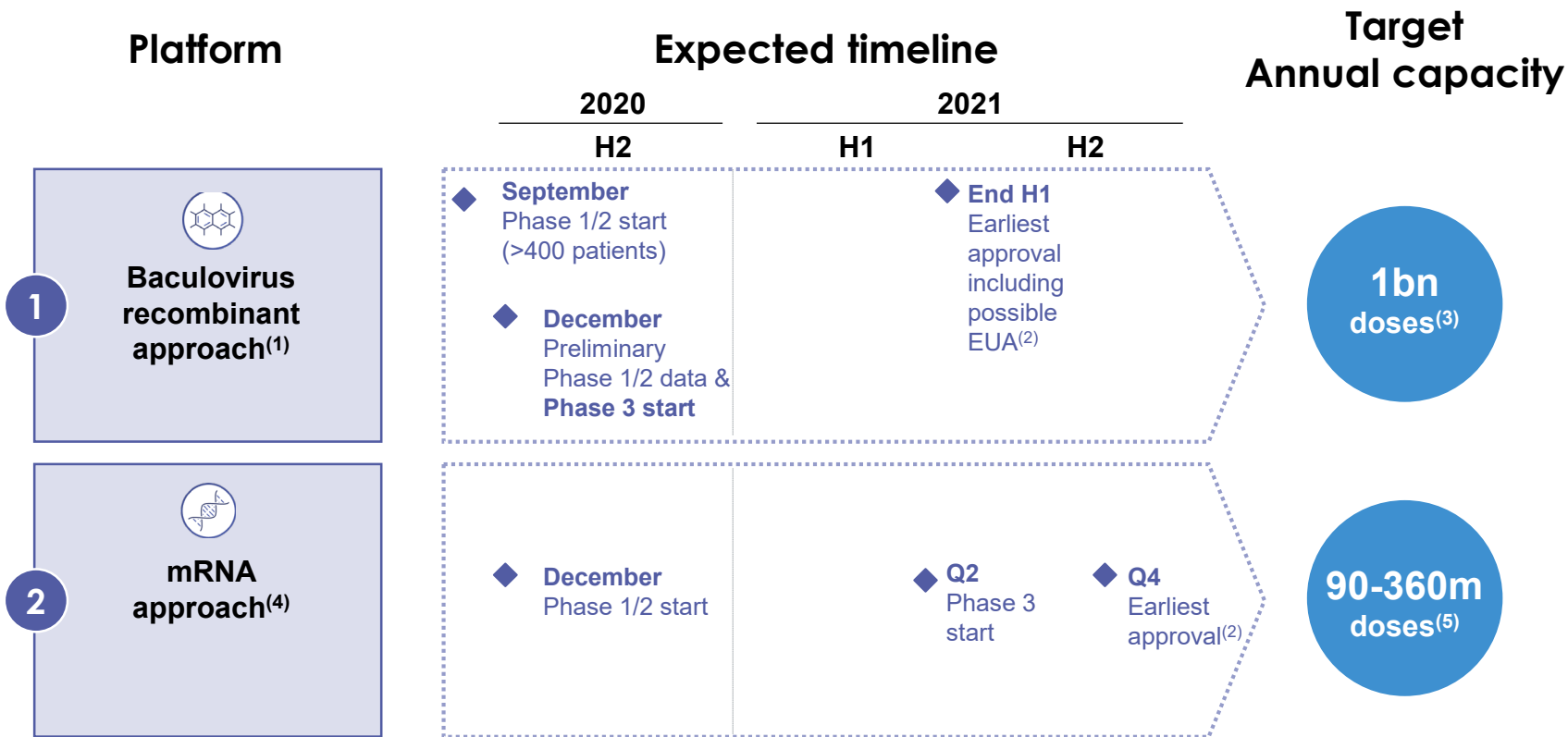
Pipeline programs represent assets under investigation and are not approved by regulators for the uses being investigated.

mBC: metastatic breast cancer; CSU: chronic spontaneous urticaria; PN: prurigo nodularis; 1L Ti MM: first line transplant ineligible multiple myeloma; NSCLC: non-small cell lung cancer; CT: chemotherapy; GBA PD: Parkinson's disease associated with GBA mutation

(1) Represents select molecule highlights; not comprehensive

(2) In collaboration with Sobi

# Accelerating global COVID-19 vaccine availability



(1) In collaboration with GSK

(2) In U.S. and EU; following latest FDA guidance and subject to COVID epidemiology

(3) Estimates pending clinical doses and industrial yields outcome

(4) In collaboration with Translate Bio

(5) Investigating to expand capacity significantly