











## Clinical Trials Appendices

# R&D Pipeline – New Molecular Entities(\*)

Phase 1 (Total:17)		Phase 2 (Total:7)		Phase 3 (Total:7)	Registration (Total:2)
<b>SAR441344</b> Anti-CD40L mAb Multiple Sclerosis	<b>BIVV001</b> <sup>(4)</sup> rFVIII Fc – vWF – XTEN <sup>(5)</sup> Hemophilia A	<b>SAR440340</b> <sup>(**)</sup> Anti-IL33 mAb Atopic Dermatitis	<b>SAR422459</b> <sup>(**)(12)</sup> ABCA4 gene therapy Stargardt Disease	<b>isatuximab</b> Anti-CD38 mAb 3L Relapsing Refractory MM (ICARIA)	<b>cemiplimab</b> <sup>(**)</sup> PD-1 inhibitor mAb Advanced CSCC (EU)
<b>REGN5458</b> <sup>(1)</sup> Anti BCMA-CD3 bispecific mAb RRMM	<b>ST400</b> <sup>(6)</sup> ZFN Gene Editing Technology Beta thalassemia	<b>SAR156597</b> IL4/IL13 bi-specific mAb Systemic Sclerosis	<b>HIV</b> Viral vector prime & rgp120 boost vaccine	<b>avalglucosidase alfa</b> Neo GAA Pompe Disease	<b>Zynquista</b> <sup>TM(**)</sup> Oral SGLT-1&2 inhibitor Type 1 Diabetes (U.S./EU)
<b>REGN4018</b> <sup>(1)</sup> Anti MUC16-CD3 bispecific mAb Ovarian Cancer	<b>BIVV003</b> <sup>(6)</sup> ZFN Gene Editing Technology Sickle Cell Disease	<b>olipudase alfa</b> rhASM Acid Sphingomyelinase Deficiency <sup>(10)</sup>	<b>SP0232</b> <sup>(13)(**)</sup> Respiratory syncytial virus Monoclonal Antibody	<b>venglustat</b> Oral GCS inhibitor ADPKD <sup>(14)</sup>	
<b>SAR408701</b> Maytansin-loaded anti-CEACAM5 mAb Solid Tumors	<b>SAR443060</b> <sup>(7)</sup> RIPK1 inh <sup>(8)</sup> Amyotrophic Lateral Sclerosis	<b>SAR339375</b> <sup>(11)</sup> miRNA-21 Alport Syndrome		<b>fitusiran</b> RNAi therapeutic targeting anti-thrombin Hemophilia A and B	
<b>SAR439459</b> anti-TGFβ mAb Advanced Solid Tumors	<b>SAR442168</b> <sup>(9)(**)</sup> BTK inhibitor Multiple Sclerosis			<b>sutimlimab</b> <sup>(15)</sup> Anti Complement C1s mAb Cold Agglutinin Disease	
<b>SAR439859</b> SERD Metastatic Breast Cancer	<b>Herpes Simplex Virus Type 2</b> HSV-2 vaccine			<b>SAR341402</b> Rapid acting insulin Type 1/2 Diabetes	
<b>SAR442720</b> <sup>(2)</sup> SHP2 inhibitor Solid Tumors	<b>Respiratory syncytial virus</b> Infants Vaccines			<b>efpeglenatide</b> <sup>(**)</sup> Long-acting GLP-1 agonist Type 2 Diabetes	
<b>SAR440234</b> T cell engaging multi spe mAb Leukemia	<b>Next Gen PCV</b> Pneumococcal Conjugate Vaccines				
<b>SAR441000</b> <sup>(3)</sup> Cytokine mRNA Melanoma					

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

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

 Immuno-inflammation	 MS & Neuro
 Oncology	 Diabetes
 Rare Diseases	 Cardiovascular & metabolism
 Rare Blood Disorders	 Vaccines

(1) Regeneron product for which Sanofi has opt-in rights  
 (2) Developed in collaboration with REVOLUTION Medicines; also known as RMC-4630  
 (3) Developed in collaboration with BioNtech  
 (4) Sanofi Product for which Sobi has opt-in rights  
 (5) Recombinant Coagulation Factor VIII Fc – von Willebrand Factor – XTEN Fusion protein  
 (6) Developed in collaboration with Sangamo  
 (7) Also known as DNL747  
 (8) Receptor-interacting serine/threonine-protein kinase 1  
 (9) Also known as PRN2246

(10) Also known as Niemann Pick type B  
 (11) Regulus product for which Sanofi has decided to opt-in  
 (12) Identification of out-licensing partner ongoing  
 (13) Also known as MEDI8897  
 (14) Autosomal Dominant Polycystic Kidney Disease  
 (15) Also Known as BIVV009  
 (\*) Phase of projects determined by clinicaltrials.gov disclosure timing  
 (\*\*) Partnered and/or in collaboration – Sanofi may have limited or shared rights on some of these products

# Additional Indications(\*)

Phase 1 (Total:5)	Phase 2 (Total:17)	Phase 3 (Total:23)	Registration (Total:3)
<b>O</b> <b>cemiplimab<sup>(*)</sup> + REGN4018<sup>(1)</sup></b> PD-1 inhibitor mAb + Anti-MUC16-CD3 bispecific mAb - Ovarian Cancer	<b>dupilumab<sup>(**)</sup></b> Anti-IL4Rα mAb Grass Immunotherapy	<b>isatuximab + cemiplimab<sup>(**)</sup></b> Anti-CD38 mAb + PD-1 inhibitor mAb Advanced Malignancies	<b>dupilumab<sup>(**)</sup></b> Anti-IL4Rα mAb Asthma 12y+ (EU)
<b>SAR439859</b> SERD + Palbociclib Metastatic Breast Cancer	<b>R</b> <b>sarilumab<sup>(**)</sup></b> Anti-IL6R mAb Polyarticular Juvenile Idiopathic Arthritis	<b>isatuximab + cemiplimab<sup>(**)</sup></b> Anti-CD38 mAb + PD-1 inhibitor mAb Lymphoma	<b>Dupixent<sup>®(**) </sup></b> Anti-CD38 mAb Atopic Dermatitis 12 – 17 years old (U.S./EU)
<b>SAR439459 + cemiplimab<sup>(**)</sup></b> Anti-TGFβ mAb + PD-1 inhibitor mAb Advanced Solid Tumors	<b>sarilumab<sup>(**)</sup></b> Anti-IL6R mAb Systemic Juvenile Arthritis	<b>isatuximab + atezolizumab<sup>(**)</sup></b> Anti-CD38 mAb + PD-L1 inhibitor mAb Advanced Malignancies	<b>Cerdelga<sup>®</sup></b> eliglustat Gaucher Type 1, switch from ERT - Pediatric
<b>sutimlimab<sup>(2)</sup></b> Anti Complement C1s mAb Idiopathic Thrombocytopenic Purpura	<b>SAR440340<sup>(**)</sup></b> Anti-IL33 mAb COPD	<b>isatuximab + atezolizumab<sup>(**)</sup></b> Anti-CD38 mAb + PD-L1 inhibitor mAb Solid Tumors	<b>Aubagio<sup>®</sup></b> teriflunomide Relapsing Multiple Sclerosis - Pediatric
<b>SAR443060<sup>(3)</sup></b> RIPK1 inh <sup>(4)</sup> Alzheimer's Disease	<b>SAR440340<sup>(**)</sup></b> Anti-IL33 mAb Asthma	<b>venglustat</b> Oral GCS inhibitor Fabry Disease	<b>Lemtrada<sup>®</sup></b> alemtuzumab Relapsing Remitting Multiple Sclerosis - Pediatric
	<b>dupilumab<sup>(**)</sup> + AR101</b> Anti-IL4Rα mAb Peanut Allergy - Pediatric	<b>venglustat</b> Oral GCS inhibitor Gaucher Type 3	<b>Zynquista<sup>TM(**) </sup></b> Oral SGLT-1&2 inhibitor Type 2 Diabetes
	<b>R</b> <b>cemiplimab<sup>(**)</sup></b> PD-1 inhibitor mAb Advanced Basal Cell Carcinoma	<b>venglustat</b> Oral GCS inhibitor Gaucher related Parkinson's Disease	<b>Zynquista<sup>TM(**) </sup></b> Oral SGLT-1&2 inhibitor Worsening Heart Failure in Diabetes
	<b>isatuximab + cemiplimab<sup>(**)</sup></b> Anti-CD38 mAb + PD-1 inhibitor mAb Relapsing Refractory MM	<b>Rabies VRVg</b> Purified vero rabies vaccine	<b>Praluent<sup>®(**) </sup></b> alirocumab LDL-C reduction - Pediatric
	<b>SP0173 Tdap booster US</b> Tdap booster	<b>cemiplimab<sup>(**)</sup> + chemotherapy</b> PD-1 inhibitor mAb 1L NSCLC	<b>Fluzone<sup>®</sup> QIV HD</b> Quadrivalent inactivated Influenza vaccine - High dose
		<b>cemiplimab<sup>(**)</sup></b> PD-1 inhibitor mAb 2L Cervical Cancer	<b>Men Quad TT</b> Advanced generation meningococcal ACYW conjugate vaccine
		<b>isatuximab</b> Anti-CD38 mAb 1-3L Relapsing Refractory MM (IKEMA)	<b>Pediatric pentavalent vaccine</b> DTP-Polio-Hib Japan
			<b>Shan 6</b> DTP-HepB-Polio-Hib Pediatric hexavalent vaccine

- Immuno-inflammation
- Oncology
- Rare Diseases
- Rare Blood Disorders
- MS & Neuro
- Diabetes
- Cardiovascular & metabolism
- Vaccines

- R** Registrational study (other than Phase 3)
- O** Opt-in rights products for which rights have not been exercised yet

- (1) Regeneron product for which Sanofi has opt-in rights
- (2) Also known as BIVV009
- (3) Also known as DNL747
- (4) Receptor-interacting serine/threonine-protein kinase 1
- (5) Transplant eligible
- (6) Transplant ineligible
- (\*) Phase of projects determined by clinicaltrials.gov disclosure timing
- (\*\*) Partnered and/or in collaboration - Sanofi may have limited or shared rights on some of these products

# Expected Submission Timeline<sup>(1)</sup>

NIMES

<b>isatuximab</b> anti-CD38 mAb 3L RRM (ICARIA)	<b>fitusiran</b> RNAi therapeutic targeting anti-thrombin Hemophilia A/B	<b>avalglucosidase alfa</b> Neo GAA Pompe Disease	<b>venglustat</b> Oral GCS inhibitor ADPKD <sup>(6)</sup>			<b>SAR156597</b> IL4/IL13 bi-specific mAb Systemic Scleroderma	<b>SAR422459<sup>(**)</sup></b> ABCA4 gene therapy Stargardt Disease
<b>SAR341402</b> Rapid acting insulin Type 1/2 Diabetes - EU <sup>(3)</sup>	<b>sutimlimab<sup>(4)</sup></b> Anti Complement C1s mAb Cold Agglutinin Disease	<b>olipudase alfa</b> rhASM ASD <sup>(5)</sup>	<b>efpeglenatide<sup>(**)</sup></b> Long acting GLP1-R agonist Type 2 Diabetes		<b>SP0232 mAbs<sup>(7)(**)</sup></b> Respiratory syncytial virus	<b>SAR440340<sup>(**)</sup></b> Anti-IL33 mAb Atopic dermatitis	<b>HIV</b> Viral vector prime & rgp120 boost vaccine

2019<sup>(2)</sup>

2020<sup>(2)</sup>

2021<sup>(2)</sup>

2022<sup>(2)</sup>

2023 and beyond<sup>(2)</sup>

Additional Indications

<b>dupilumab<sup>(**)</sup></b> Anti-IL4Rα mAb Nasal Polyposis Adult	<b>sarilumab<sup>(**)</sup></b> Anti-IL6R mAb Polyarticular Juvenile Idiopathic Arthritis	<b>Aubagio<sup>®</sup></b> teriflunomide Relapsing MS – Ped.	<b>isatuximab</b> Anti-CD38 mAb (IMROZ) 1L Newly Diagnosed MM T1	<b>Dupilixent<sup>®(**)</sup></b> dupilumab AD 6 months - 5 years old	<b>sarilumab<sup>(**)</sup></b> Anti-IL6R mAb Giant Cell Arteritis	<b>SAR440340<sup>(**)</sup></b> Anti-IL33 mAb COPD	<b>isatuximab</b> Anti-CD38 mAb Newly Diagnosed MM Tε (GMMG)
<b>Fluzone<sup>®</sup> QIV HD</b> Quadrivalent inactivated Influenza vaccine - High dose	<b>Dupilixent<sup>®(**)</sup></b> dupilumab AD 6 - 11 years old -	<b>Zynquista<sup>TM(**)</sup></b> Oral SGLT-1&2 inhibitor Type 2 Diabetes	<b>cemiplimab<sup>(**)</sup></b> PD-1 inhibitor mAb 2L Cervical Cancer	<b>dupilumab<sup>(**)</sup></b> Anti-IL4Rα mAb Eosinophilic Esophagitis	<b>sarilumab<sup>(**)</sup></b> Anti-IL6R mAb Polymyalgia Rheumatica	<b>SAR440340<sup>(**)</sup></b> Anti-IL33 mAb Asthma	<b>venglustat</b> Oral GCS inhibitor GrPD <sup>(6)</sup>
<b>Men Quad TT</b> Adv. generation meningococcal U.S.: 2y+ & EU: Toddlers+	<b>isatuximab</b> Anti-CD38 mAb 1-3L RRM (IKEMA)	<b>Shan 6</b> DTP-HepB-Polio-Hib Pediatric hexavalent vaccine	<b>cemiplimab<sup>(**)</sup></b> PD-1 inhibitor mAb 1L NSCLC	<b>dupilumab<sup>(**)</sup></b> Anti-IL4Rα mAb Asthma 6 - 11 years old	<b>sarilumab<sup>(**)</sup></b> Anti-IL6R mAb Systemic Juvenile Arthritis	<b>dupilumab<sup>(**)</sup>+ AR101</b> Anti-IL4Rα mAb Peanut Allergy - Pediatric	<b>venglustat</b> Oral GCS inhibitor Fabry Disease
<b>Pentacel<sup>®</sup> vIPV</b> DTaP-IPV/Hib	<b>cemiplimab<sup>(**)</sup></b> PD-1 inhibitor mAb Advanced BCC		<b>Zynquista<sup>TM(**)</sup></b> Oral SGLT-1&2 inhibitor Worsening Heart Failure in Diabetes	<b>venglustat</b> Oral GCS inhibitor Gaucher Type 3	<b>Cerdelga<sup>®</sup></b> eliglustat Gaucher Type 1, switch from ERT – Pediatric	<b>Pediatric pentavalent vaccine</b> DTP-Polio-Hib (Japan)	<b>Rabies VRVg</b> Purified vero rabies vaccine
				<b>SP0173 Tdap booster US</b> Tdap booster	<b>Praluent<sup>®(**)</sup></b> alirocumab LDL-C reduction - Pediatric		

- (1) Excluding Phase 1  
 (2) Projects within a specified year are not arranged by submission timing  
 (3) Submission strategy for the U.S. under evaluation  
 (4) Also known as BIVV009  
 (5) Acid Sphingomyelinase Deficiency  
 (6) Autosomal Dominant Polycystic Kidney Disease

- (7) Also known as MEDI8897  
 (8) Gaucher Related Parkinson's Disease  
 (\*\*\*) Partnered and/or in collaboration – Sanofi may have limited or shared rights on some of these products

- |  |   |
|--|---|
| <span style="display: inline-block; width: 15px; height: 15px; background-color: #800080; border: 1px solid black;"></span> Immuno-inflammation  | <span style="display: inline-block; width: 15px; height: 15px; background-color: #4169E1; border: 1px solid black;"></span> MS & Neuro                  |
| <span style="display: inline-block; width: 15px; height: 15px; background-color: #FFD700; border: 1px solid black;"></span> Oncology             | <span style="display: inline-block; width: 15px; height: 15px; background-color: #ADD8E6; border: 1px solid black;"></span> Diabetes                    |
| <span style="display: inline-block; width: 15px; height: 15px; background-color: #E6E6FA; border: 1px solid black;"></span> Rare Diseases        | <span style="display: inline-block; width: 15px; height: 15px; background-color: #90EE90; border: 1px solid black;"></span> Cardiovascular & metabolism |
| <span style="display: inline-block; width: 15px; height: 15px; background-color: #FFFF00; border: 1px solid black;"></span> Rare Blood Disorders | <span style="display: inline-block; width: 15px; height: 15px; background-color: #D2B48C; border: 1px solid black;"></span> Vaccines                    |

# Pipeline Movements Since Q3 2018

## Additions

### Registration

### Phase 3

**Shan 6**  
DTP-HepB-Polio-Hib  
Pediatric hexavalent vaccine

### Phase 2

**SAR440340<sup>(\*\*)</sup>**  
Anti-IL33 mAb  
Atopic Dermatitis

**isatuximab + cemiplimab<sup>(\*\*)</sup>**  
Anti-CD38 mAb + PD-1 inhibitor mAb  
Lymphoma

**isatuximab + atezolizumab<sup>(\*\*)</sup>**  
Anti-CD38 mAb + PD-L1 inhibitor mAb  
Solid Tumors

### Phase 1

**SAR441344**  
Anti-CD40L mAb  
Multiple Sclerosis

**SAR443060**  
RIPK1 inhibitor  
Amyotrophic Lateral Sclerosis

**SAR443060**  
RIPK1 inhibitor  
Alzheimer's Disease

**SAR441000**  
Cytokine mRNA  
Melanoma



**REGN5458**  
Anti BCMA-CD3 bispecific mAb  
RRMM

**BIVV003**  
ZFN Gene Editing Technology  
Sickle Cell Disease

**Next Gen PCV**  
Pneumococcal Conjugate  
Vaccines

# Pipeline Movements Since Q3 2018

## Removals

### Registration

### Phase 3

**cemiplimab<sup>(\*\*)</sup> + ipilimumab**  
 PD-1 inhibitor mAb + CTLA4 mAb  
 1L NSCLC ≥ 50% PDL1+

**mavacamten<sup>(\*\*)</sup>**  
 Myosin inhibitor  
 Obstructive Hypertrophic Cardiomyopathy

### Phase 2

**GZ389988**

TRKA antagonist  
 Osteoarthritis

Combination  
**ferroquine / OZ439<sup>(\*\*)</sup>**  
 Antimalarial

**ALX0171**

Anti RSV Nanobody  
 Respiratory Syncytial Virus

**SAR425899**

GLP-1/GCG dual agonist  
 Obesity/Overweight In T2D

**mavacamten<sup>(\*\*)</sup>**

Myosin inhibitor  
 Non-Obstructive Hypertrophic Cardiomyopathy

**SAR407899**

rho kinase  
 Microvascular Angina

### Phase 1

**SAR439794<sup>(\*\*)</sup>**

TLR4 agonist  
 Peanut Allergy

**SAR438335**

GLP-1/GIP dual agonist  
 Type 2 Diabetes



**REGN3767**

Anti LAG-3 mAb  
 Advanced Cancers



**REGN4659**

Anti-CTLA-4 mAb  
 Cancer

**SAR228810<sup>(\*\*)</sup>**

Anti-protofibrillar AB mAb  
 Alzheimer's Disease

**SAR440181<sup>(\*\*)</sup>**

Myosin activation  
 Dilated Cardiomyopathy

**SAR247799**

S1P1 agonist  
 Cardiovascular indication



**cemiplimab<sup>(\*\*)</sup> + REGN4659**  
 PD-1 inhibitor mAb + Anti-CTLA-4 mAb  
 NSCLC



**cemiplimab<sup>(\*\*)</sup> + REGN3767**  
 PD-1 inhibitor mAb + anti LAG-3 mAb  
 Advanced Cancers

**UshStat<sup>®(1)</sup>**

Myosin 7A gene therapy  
 Usher Syndrome 1B

# R&D Pipeline Summary – Total Projects<sup>(1)</sup>

	Phase 1	Phase 2	Phase 3	Registration	TOTAL
Immuno-inflammation	1	8	7	2	18
Oncology	11	6	7	1	25
Rare Diseases	0	4	3	0	7
Rare Blood Disorders	4	0	2	0	6
Multiple Sclerosis and Neurology	3	2	2	0	7
Diabetes	0	0	4	1	5
Cardiovascular Disease	0	0	1	1	2
Vaccines	3	4	4	0	11
<b>TOTAL</b>	<b>22</b>	<b>24</b>	<b>30</b>	<b>5</b>	

46
35

81

Total Projects

# Expected R&D Milestones

Products	Expected milestones	Timing
Dupixent®	U.S. regulatory decision in Atopic Dermatitis in Adolescent patients	Q1 2019
Zynquista™ (sotagliflozin)	U.S. regulatory decision expected in Type 1 Diabetes	Q1 2019
dupilumab	U.S. sBLA filing in Nasal Polyposis	Q1 2019
Dupixent®	EU regulatory decision in Asthma in Adult/Adolescent patients	Q2 2019
Zynquista™ (sotagliflozin)	EU regulatory decision expected in Type 1 Diabetes	Q2 2019
Praluent®	EU regulatory decision in CV events reduction ODYSSEY OUTCOMES	Q2 2019
Praluent®	U.S. regulatory decision in CV events reduction ODYSSEY OUTCOMES	Q2 2019
cemiplimab	EU regulatory decision expected in Advanced Cutaneous Squamous Cell Carcinoma	Q2 2019
dupilumab	Start of Phase 2b/3 trial in Chronic Obstructive Pulmonary Disease	H1 2019
Dupixent®	EU regulatory decision in Atopic Dermatitis in Adolescent patients	Q3 2019
sutimlimab	Expected pivotal trial read-out in Cold Agglutinin Disease	Q4 2019
Zynquista™ (sotagliflozin)	Expected pivotal trial read-out in Type 2 Diabetes	Q4 2019
Dupixent®	Expected pivotal trial read-out in Atopic Dermatitis in 6-11 years	Q4 2019
Olipudase	Expected pivotal trial read-out in Niemann Pick Type B	Q4 2019
Isatuximab	Expected pivotal trial read-out in 1-3L RRMM (IKEMA)	Q1 2020