

# Play to Win

# Our strategic framework to drive innovation and growth

September 2020

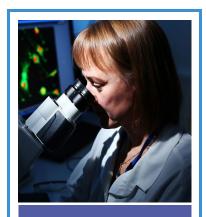


## Forward looking statements

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## Play to win



Focus on growth

Portfolio prioritization to strengthen profile



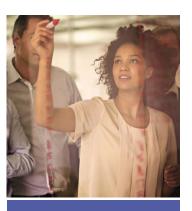
Lead with innovation

Bring transformative therapies to patients



Accelerate efficiency

Decisive actions to expand margins



Reinvent how we work

Empowerment and accountability



## Our key growth drivers





### **Dupixent®**

Maximize patient benefits with ambition to achieve >€10 billion peak sales across type 2 inflammatory diseases



### **Vaccines**

Expected mid-to-high singledigit growth<sup>(1)</sup>, through differentiated products, market expansion, launches



### **Pipeline**

Prioritize and accelerate portfolio of potentially transformative therapies



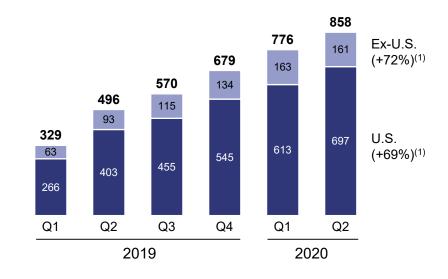
## Dupixent® – on track to deliver on >€10bn ambition



#### >170K patients on Dupixent® worldwide

- Expect strong continued momentum fueled by:
  - Deeper penetration in AD and asthma
  - Expansion into younger populations
  - Continued global rollout across indications
  - Expansion into additional Type 2 inflammatory diseases
- Dupixent<sup>®</sup> launched in 44 countries in adult AD
  - 54 additional launches in 2020 as planned

#### Global Dupixent® quarterly sales (€m)



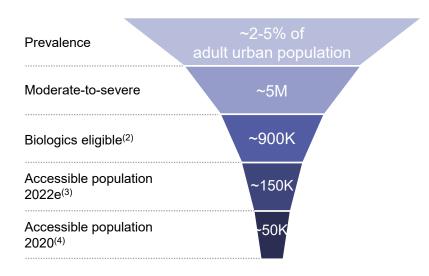


## Dupixent® – major growth opportunity in China



- Dupixent<sup>®</sup> launched 25 days after NMPA approval<sup>(5)</sup>
  - First biologic approved for adult with moderate to severe atopic dermatitis
- Targeting large number of major hospitals at launch
- Expected NRDL submission in 2021
- Expanding across age groups and indications
  - Potential for 5 plus additional launches by 2025

# High unmet need in first approved type 2 indication, adult AD<sup>(1)</sup>



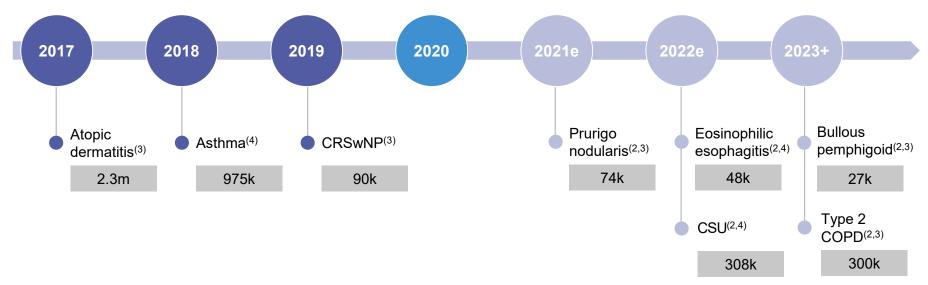


- (1) Based on China KOL estimates and publications as well as internal analysis
- (2) Diagnosed moderate-to-severe uncontrolled patients- Diagnosis rate assumed as of 2020
- (3) Accessible population considers channel coverage (e.g., hospital listing and provincial inclusion) and affordability (i.e., patient copay which varies by province).
- (4) In private pay market only, 2020 estimate
- (5) Obtaining IDL (Import Drug License) from NMPA



## Prioritized Type 2 indications for Dupixent®







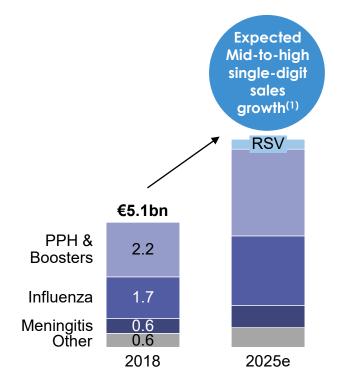
Expected first submission

U.S. biologics eligible target population (all age groups)



# Vaccines: Strong growth driven by 3 core franchises & RSV







RSV<sup>(2)</sup>



**PPH & Boosters** 



Influenza



**Meningitis** 

- Launch first prophylaxis against RSV for all infants
- Global Hexaxim<sup>®</sup> expansion
- Vaxelis® U.S. introduction
- Boosters acceleration
- Fluzone<sup>®</sup> HD QIV launch
- Flublok<sup>®</sup> expansion
- Increasing VCR
- Men ACWY expansion
- MenQuadfi™ launch in U.S. & Europe



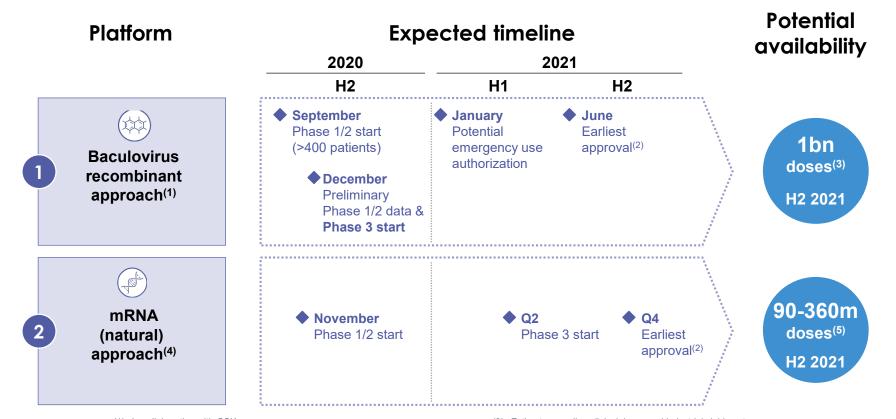
PPH: Polio Pertussis Hib combination vaccines; RSV: Respiratory Syncytial Virus; HD QIV: High-Dose Quadrivalent Influenza Vaccine; VCR: Vaccination Coverage Rate

1) Sales CAGR from 2018 base to 2025

(2) Expected submission in 2023

## Accelerating global COVID-19 vaccine availability







<sup>(1)</sup> In collaboration with GSK

<sup>(2)</sup> In U.S. and EU; development plans and registration pathway being consolidated with rest of the world

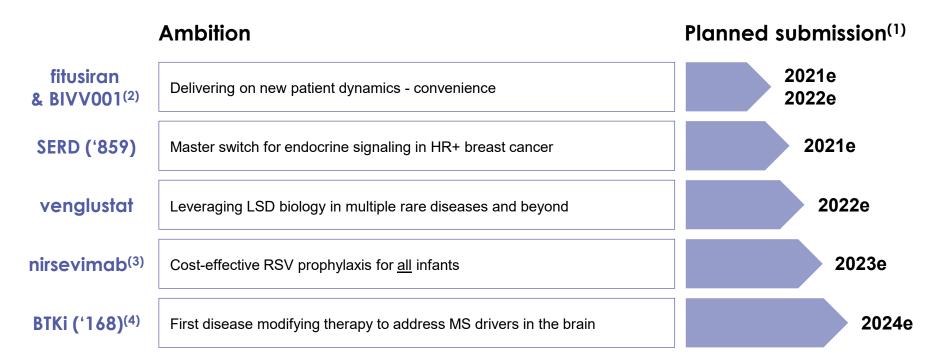
<sup>(3)</sup> Estimates pending clinical doses and industrial yields outcome

<sup>(4)</sup> In collaboration with Translate Bio

<sup>(5)</sup> Investigating to extend capacity significantly

# Accelerate portfolio of potential transformative therapies







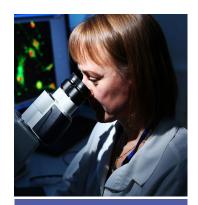
BTKi: bruton tyrosine kinase inhibitor; LSD: lysosomal storage disease; MS: multiple sclerosis; RSV: respiratory syncytial virus; SERD: selective estrogen receptor degrader; HR+: hormone-receptor positive

<sup>(2)</sup> In collaboration with SOBI(3) In collaboration with Astrair

In collaboration with AstraZeneca
In collaboration with Principia

First submission for products with multiple potential indications, investigational program not yet reviewed by any regulatory authority

## Play to win



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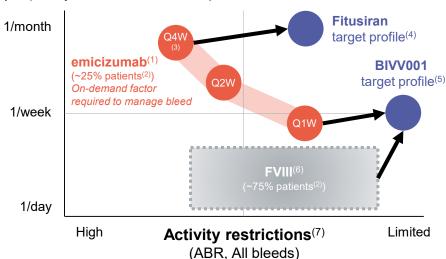
## Hemophilia: Patient experience drives choice



### Target profiles vs. marketed products

#### Treatment burden

(frequency & number of needles)



#### Different patients, different needs



#### Fitusiran – high-efficacy monthly therapy

- Aiming for 15-20% FVIII equivalent level<sup>(4)</sup>, allowing strenuous activity level
- First real once-monthly Hemophilia treatment



#### BIVV001 – higher for longer

- One week of protection, including ~3.5 days at normal activity level and ~6 days at strenuous activity level
- Increased joint protection



Q4W: once every four weeks; Q2W: once every two weeks; Q1W: once per week; ABR: annualized bleed rate

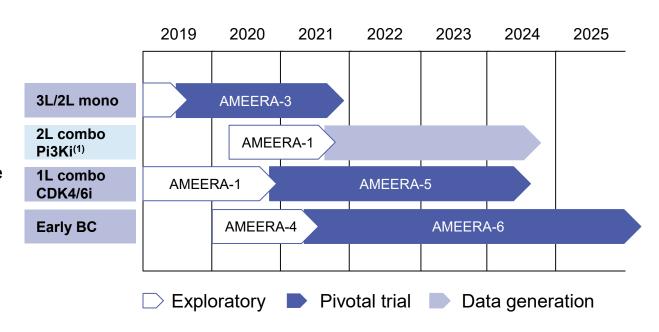
(1) emicizumab: 2.1 ABR with Q4W; 1.6 ABR with Q2W; 0.6 ABR with Q1W (U.S. prescribing information; median ABR (HAVEN-3 for Q1W & Q2W, HAVEN-4 for Q4W)

(2) Based on Evaluate Pharma 2020, U.S. patients (3) 7% of emicizumab patients on monthly dosing – 2019 Specialty Pharmacy data obtained through Specialty Pharmacy Distributors, Hemophilia Alliance HTCs & Direct HTCs (4) fitusiran: 0.84 ABR with Q4W (Phase 2 OLE Interim Results) (5) BIVV001: Target Product Profile aiming for weekly dose, no bleed reported in Phase 1 repeat dose study (6) Individualized prophylaxis varies from daily to every 4 days and between <1 and >1 ABR (7) No head-to-head studies comparing the efficacy of emicizumab and fitusiran or BIVV001 have been conducted Fitusiran and BIVV001 are assets under investigation and are not approved by any regulators – BIVV001 in collaboration with Sobi

# SERD '859: Ambition to be best-in-class endocrine backbone in HR+ breast cancer



- Compelling efficacy with CBR of 36% (all-comers) and 64% (in patients without prior SERD, mTORi, CDK4/6)
- Demonstrated safety and tolerability required to become best-in-class backbone
- Lack of bone marrow suppression should result in excellent combinability



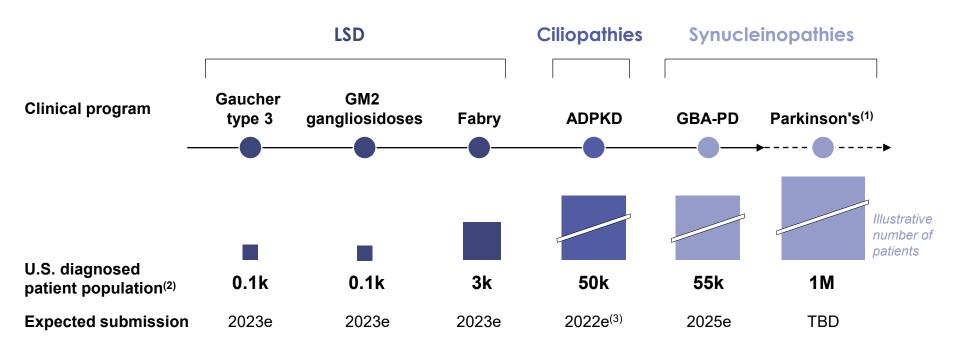
2L/3L mBC expected to reach market in 2022, >1 year ahead of other SERDs in development



## Venglustat: Leveraging LSD biology in multiple rare diseases



## GCS inhibition to potentially treat 3 types of disease



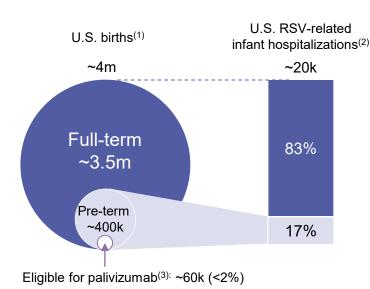


(1) Subset of patients being studied in GBA-PD development program

# Nirsevimab: Goal to be cost-effective RSV prophylaxis for <u>all</u> infants



#### 98% of infants still at risk



### High disease burden

- High medical care costs from RSV-related LRTI (\$4.2bn<sup>(4)</sup>)
- Congested ER / ICU during RSV seasons
- Risk of long-term sequelae

#### Nirsevimab has potential to cover all infants through single injection



- (1) Estimates based on birth cohort projected in 2024: Lancet Global Health Vol 7 Jan 2019
- (2) U.S. RSV-related infant hospitalizations; Hall, NEJM 2009 Feb 5;360(6):588-98
- (3) Palivizumab eligible population: CHD/CLD & ≤28wGA
- (4) Estimated global costs of in-patient and out-patient management in children <5 years in 2017, unpublished data from Respiratory Syncytial Virus Consortium in Europe Note: asset under investigation in collaboration with AstraZeneca, not approved by regulators

# BTKi ('168) targets best-in-class profile in multiple sclerosis



Safety



Similar to placebo

Low treatment burden



Oral once-daily, no monitoring

Relapse rate reduction



In line with anti-CD20

Slowing disability in RMS



Only BTKi with demonstrated CNS penetration and engagement of potential markers of disability progression

Efficacy in progressive disease



Accelerated development across full MS spectrum: RMS, PPMS and NR-SPMS, with first target submission in H1 2024

Delivering BTKi ('168) target product profile expected to result in leading market position



# First patients enrolled in BTKi Phase 3 study program in Q2



	Phase 3 program			
	Relapsing (RMS)	Primary Progressive (PPMS)	Non Relapsing Secondary Progressive (NR-SPMS)	Long Term Study Relapsing (RMS)
Comparator	vs. Aubagio®	vs. Placebo	vs. Placebo	-
Opportunity	~900K diagnosed <sup>(1)</sup>	~120K diagnosed <sup>(1)</sup>	~172K diagnosed <sup>(1)</sup>	Confirmation of LT efficacy and safety profile
	Disability accumulates despite treatment	Only one approved DMT with modest efficacy <sup>(2)</sup>	No approved DMTs for SPMS without relapses	
Target #of patients	N = 900 + 900	N = 990	N = 1290	N = 126
Submission	H1 2024e	H1 2025e	H1 2025e	Not applicable



<sup>(1)</sup> Source: Sanofi analysis of U.S. and EU5 (UK, France, Germany, Italy, Spain)

# Recent deals aligned with Sanofi's new approach to R&D



#### **Platforms**

**Expanded tools for drug discovery** 



CD38 knockout NK cells sourced from universal donors



E3 ligase-based protein degradation technology

**Translate**BIO

Novel mRNA vaccines platform

## **Pathways**

Deep understanding of disease pathways

Leveraging innate immune system by enhancing ADCC

Complete IRAK4 knockdown rather than simple kinase inhibition at a critical node of innate immunity

Targeting viral proteins as vaccine antigens

### **Patients**

Relentless patient focus

Improving patient outcomes by increasing response rates and survival

Potentially highly efficacious, oral treatment for dermatology & rheumatology indications

Rapid generation of vaccine candidates for emerging (viral) pathogens

## **Capabilities**

Leveraging expanding capabilities

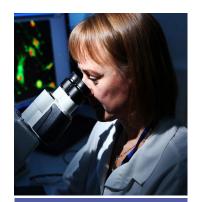
Building leadership in MM and hematology-oncology

Deepening leadership in immunology

Expanding leadership in differentiated vaccines



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Reinvent how we work

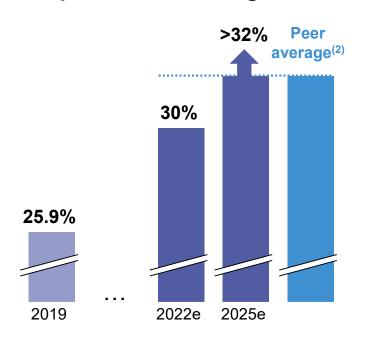
Empowerment and accountability



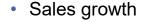
## Targeting 30% BOI<sup>(1)</sup> margin by 2022

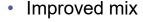


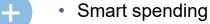
### Sanofi expected BOI margin evolution



## Expected margin drivers, 2019-2022









Operational excellence



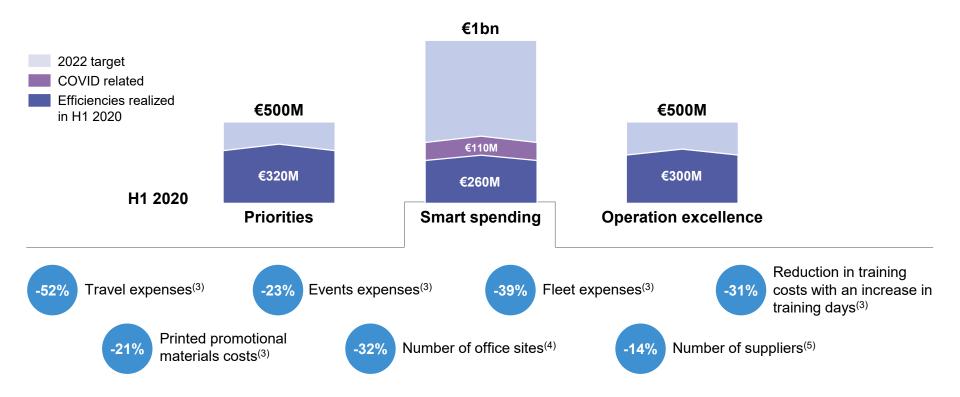
- Launch costs
- Accelerate pipeline



<sup>(1)</sup> Definition in Q2 2020 earnings <u>press release</u>

# €2bn savings expected by 2022<sup>(1)</sup> €990M<sup>(2)</sup> already achieved in H1 2020







<sup>(1) €2</sup>bn of savings expected from December 2019 to December 2022

(5) May 2020 vs. December 2019

<sup>(2)</sup> Including around €110M related to COVID-19

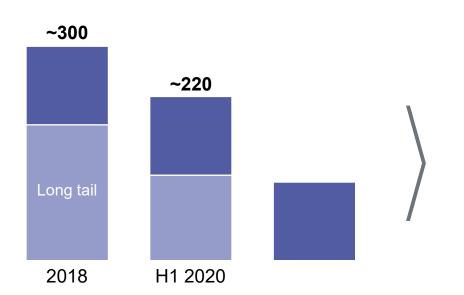
<sup>(3)</sup> YTD May 2020 vs. YTD May 2019

<sup>(4)</sup> Excluding R&D and Industrial Affairs, June 2020 vs. June 2019

## Streamlining of Established Products tail underway



### Number of product families

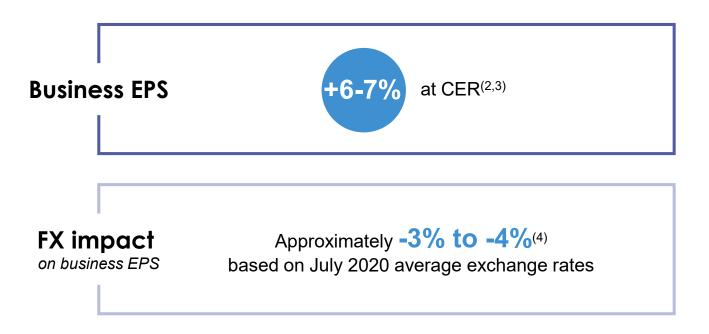


Divestitures include Seprafilm® and a portfolio of EP tail products

Total of ~€680 million cash proceeds during H1 2020

Objective to reduce to ~100 product families by 2025

# FY 2020 business EPS<sup>(1)</sup> guidance raised to 6-7% at Q2 results





<sup>(2)</sup> Compared to FY 2019 and barring major unforeseen adverse events

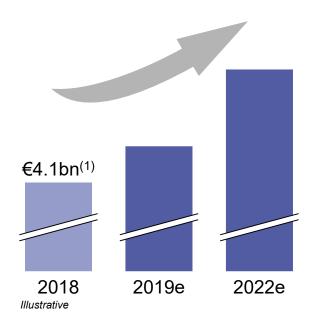
<sup>(3)</sup> Base for FY 2019 Business EPS growth is €5.64 reflecting 2 cents of impact from IFRS 16 and excluding the effect of the equity method of accounting for the Regeneron investment in the share of profit/loss of associates and joint ventures line





## Objective to increase Free Cash Flow<sup>(1)</sup> by ~50% by 2022<sup>(2)</sup>

#### Free Cash Flow<sup>(1)</sup> evolution



- Grow net sales
- Improve working capital
- Prioritize investments
- Expand margin



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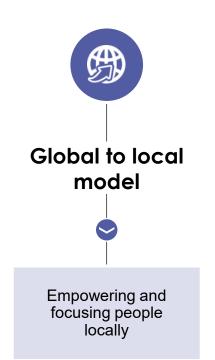
## **Empowerment and accountability**

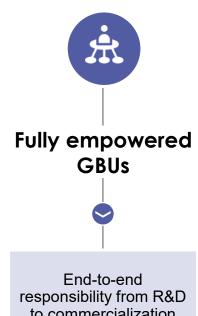




to be incentivized

on TSR







**New ways** of working

to commercialization



# New executive team completed with appointments in Q2





# New Global Business Unit organization to support strategy



### 3 core GBUs<sup>(3)</sup> with focus on prioritized portfolio









33.9%

H1 2020 BOI margin<sup>(4)</sup>

37.5%<sup>(5)</sup>

22.9%

37.5%<sup>(5)</sup>

GBU: Global Business Unit; RBD: Rare Blood Disorder; RD: Rare Disease; PPH: Polio, Pertussis & Hib; IA: Industrial Affairs

- (1) Global Business Unit will now include emerging markets sales contributions
- (2) 2019 sales
- (3) Subject to consultation with social partners and works councils
- 4) BOI margin: Business Operating margin
- (5) Phamaceuticals business operating margin : (Specialty Care + General Medicines)

# Ambition to create a leading European company providing active pharmaceutical ingredients



### New industry champion

- Expected sales of €1 bn by 2022, rank world #2
- Headquartered in France
- Potential IPO on Euronext Paris in 2022
- Sanofi to hold minority stake of ~30%

### Six European manufacturing sites



Strong European supplier rebalancing industry dependence on Asia



## Summary



Ambition to achieve >€10 billion Dupixent® peak sales and midto-high single-digit Vaccines sales growth<sup>(1)</sup>



Six late-stage R&D priority assets in focused areas (Immunology, Oncology, Rare Diseases and Vaccines)



Margin expansion and resources allocation to priority areas



New team and an empowered organization focused on delivering results



## H2 2020-2021 – significant year for Sanofi's pipeline ahead

#### Pivotal results(1)

- Dupixent <sup>®(2)</sup> in Asthma for 6 to 11-year old <sup>®</sup>
- SERD '859 2L/3L monotherapy in mBC <sup>1</sup>
- 🔹 Fitusiran for Hemophilia A & B 🔯
- BIVV001 for Hemophilia A <sup>®</sup>
- Dupixent® for CSU & PN
- Sarclisa<sup>®</sup> 1L Ti MM (IMROZ)
- Libtayo<sup>®</sup> 1L NSCLC with CT



### Proof of concept readouts<sup>(1)</sup>

- SERD '859 combination, adjuvant in mBC
- Venglustat GBA PD
- SHP2<sup>(3)</sup> for solid tumors in combination
- Sarclisa® subcutaneous formulation

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; PD: Parkinson's disease



- 2) Developed in collaboration with Regeneron
- (3) In collaboration with Revolution Medicines

