



# Play to Win

Our strategic framework to drive  
innovation and growth

October 2020

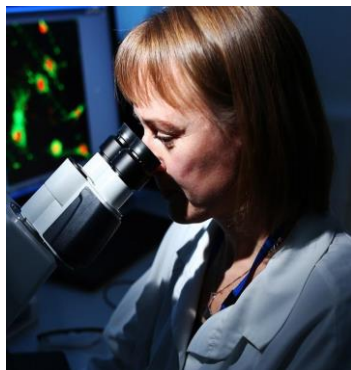


**SANOFI**

# 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

Focus  
on growth



## Dupixent®

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



## Vaccines

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



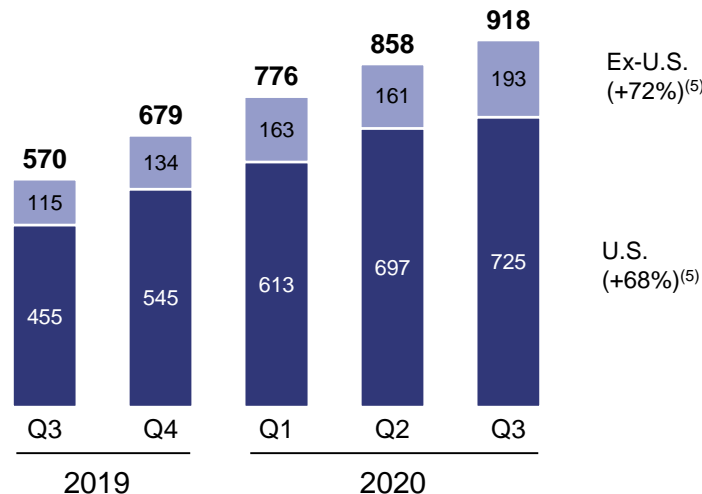
## Pipeline

Prioritize and accelerate portfolio of potentially transformative therapies

# Dupixent® – \$1bn sales in Q3 2020

- >200K 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
- Q3: In the US, NBRx nearing pre-COVID levels<sup>(1)</sup>
  - Strong uptake for AD in ages 6-11 years in the U.S.<sup>(2)</sup>
  - In-office patient visits with dermatologists and allergists remain at ~80%<sup>(3,4)</sup> pre-COVID levels

Global Dupixent® quarterly sales (€m)



*On track to deliver on >€10bn ambition*

AD: moderate to severe atopic dermatitis; EoE eosinophil esophagitis

(1) IQVIA Patient insights; Sep 18, 2020

(2) For the treatment of moderate to severe atopic dermatitis in children ages 6-11 whose disease is not adequately controlled

(3) BrandImpact; Aug 2020

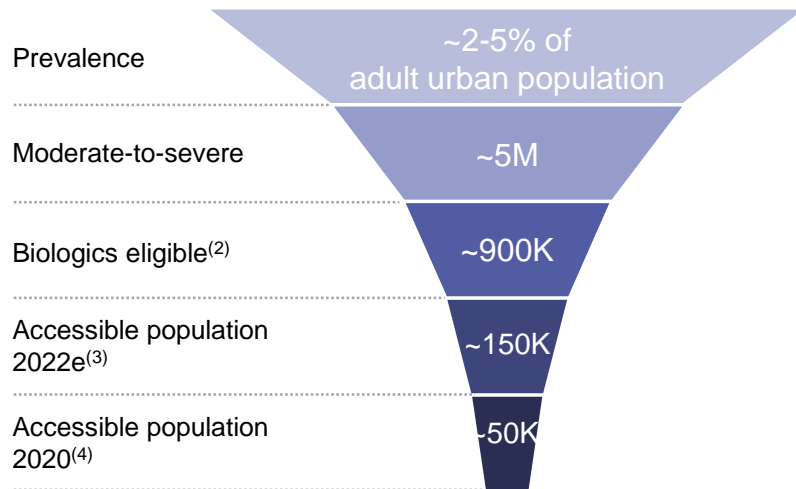
(4) Spherix Global Insights, Wave 10, Dermatology; Sep 23, 2020

(5) Represents Q3 2019 to Q3 2020

# Dupixent® – major growth opportunity in China

- Dupixent® 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
  - >1,100 patients received Dupixent within first 8 weeks
- 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>



AD: atopic dermatitis, NMPA: National Medical Products Administration; NRDL: National Reimbursement Drug List

(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

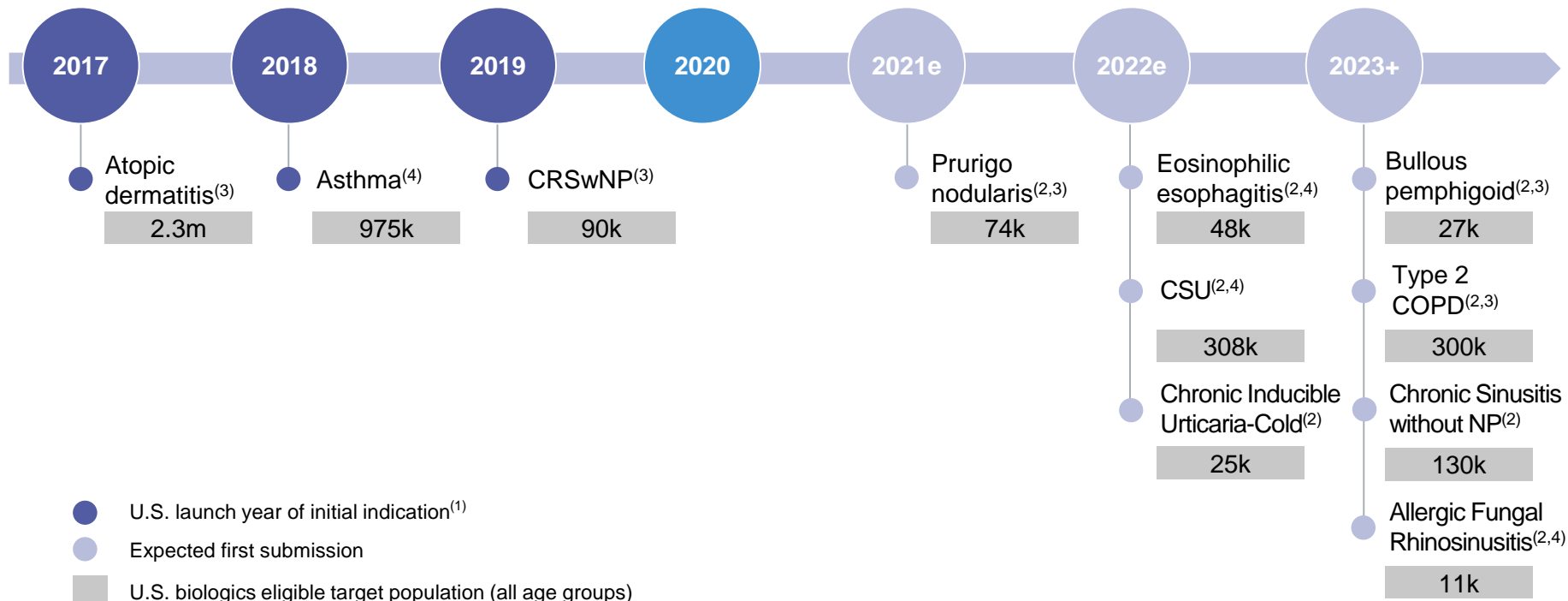
(3) Accessible population considers channel coverage (e.g., hospital listing and provincial inclusion) and affordability (i.e., patient copay which varies by province).

(4) In private pay market only, 2020 estimate

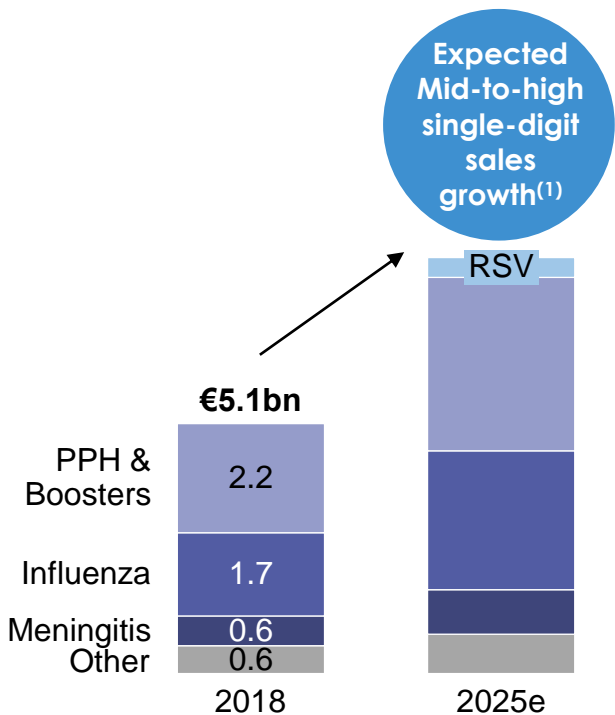
(5) Obtaining IDL (Import Drug License) from NMPA

# Prioritized Type 2 indications for Dupixent®

Focus on growth



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



**RSV<sup>(2)</sup>**

- Launch first prophylaxis against RSV for all infants



**PPH & Boosters**

- Global Hexaxim<sup>®</sup> expansion
- Vaxelis<sup>®</sup> U.S. introduction
- Boosters acceleration



**Influenza**

- Fluzone<sup>®</sup> HD QIV launch
- Flublok<sup>®</sup> expansion
- Increasing VCR

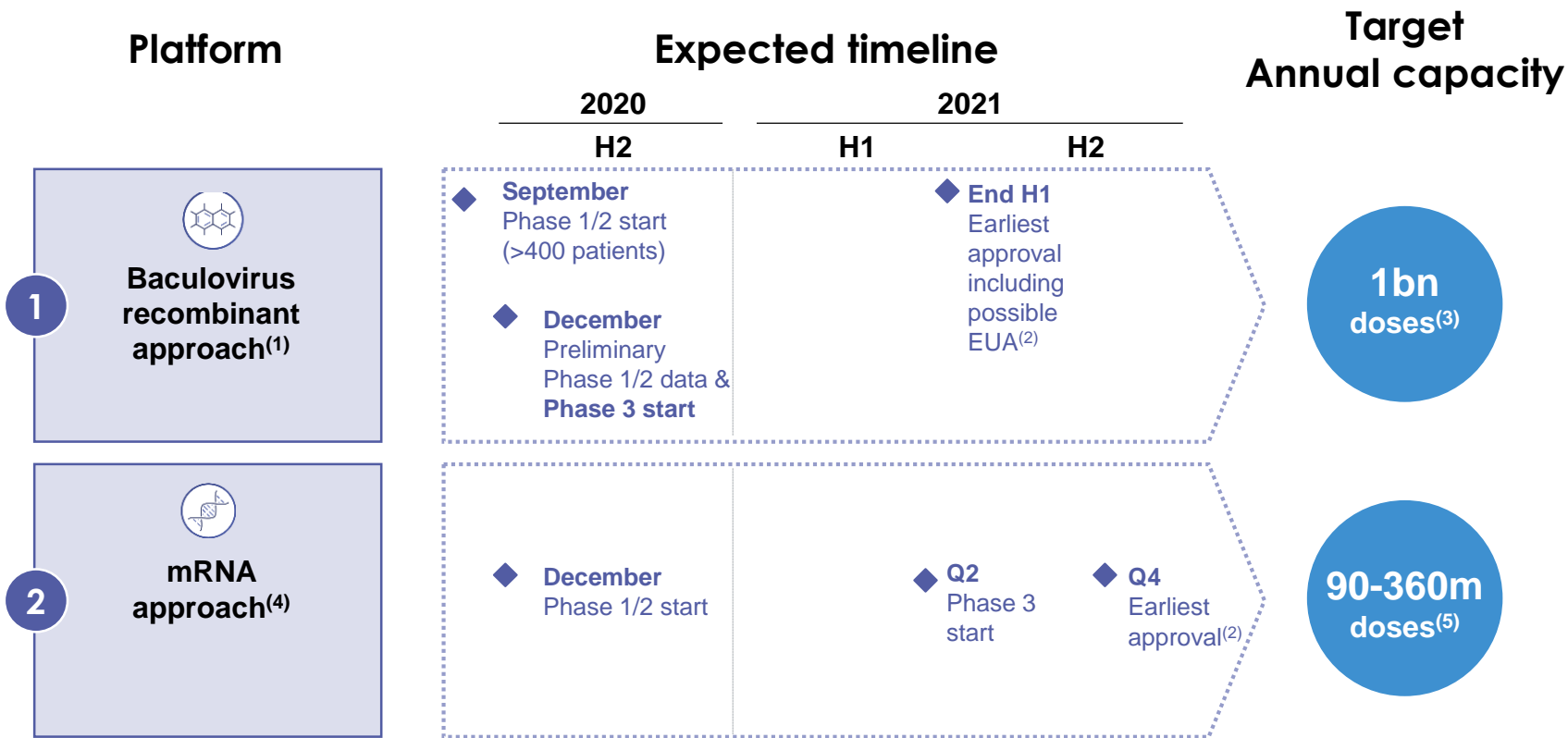


**Meningitis**

- Men ACWY expansion
- MenQuadfi<sup>™</sup> launch in U.S. & Europe



# 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

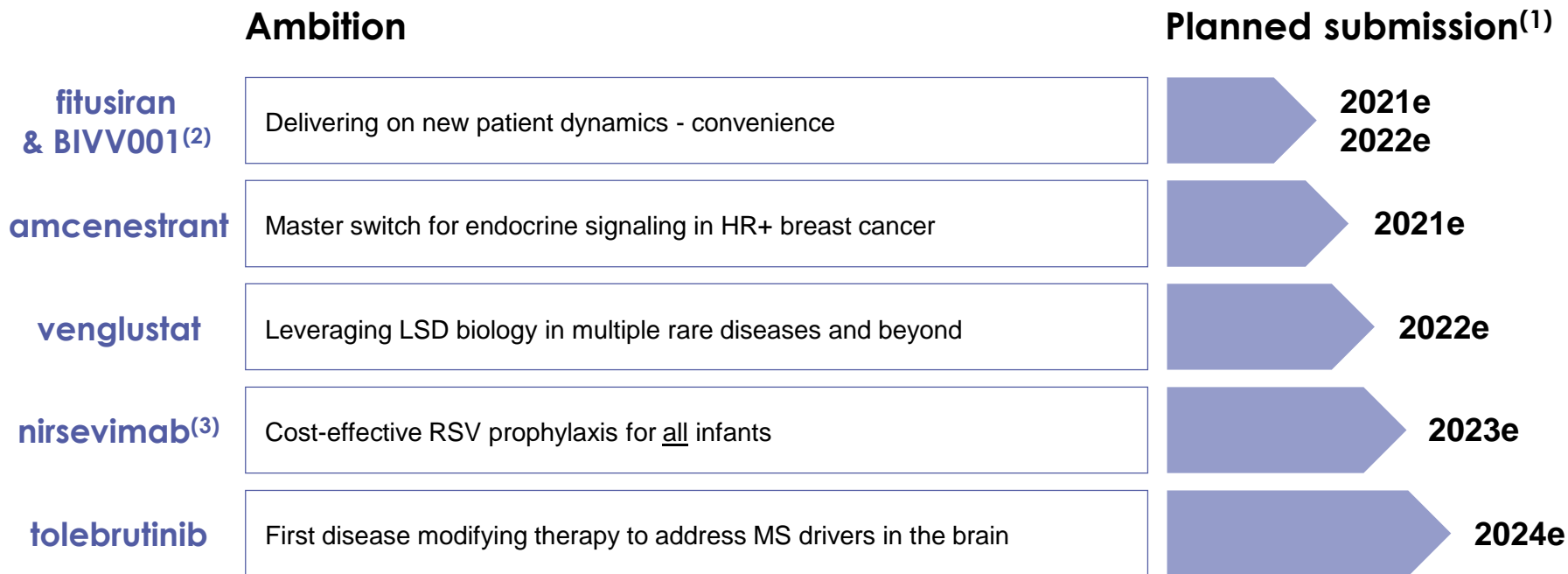
(3) Estimates pending clinical doses and industrial yields outcome

(4) In collaboration with Translate Bio

(5) Investigating to expand capacity significantly

# Accelerate portfolio of potential transformative therapies

Focus  
on growth



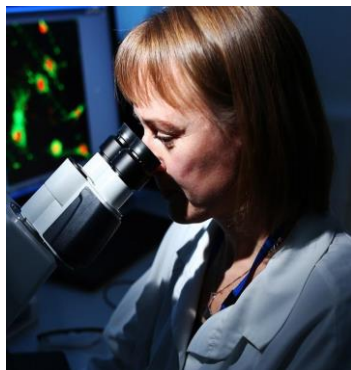
LSD: lysosomal storage disease; MS: multiple sclerosis; RSV: respiratory syncytial virus;  
SERD: selective estrogen receptor degrader; HR+: hormone-receptor positive

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

(2) In collaboration with SOBI

(3) In collaboration with AstraZeneca

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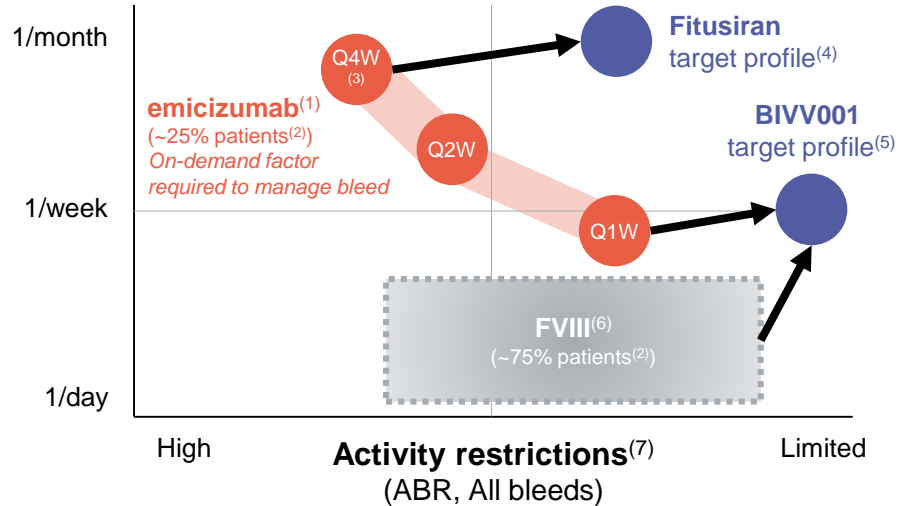
# Hemophilia: Patient experience drives choice

Lead with innovation

## 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

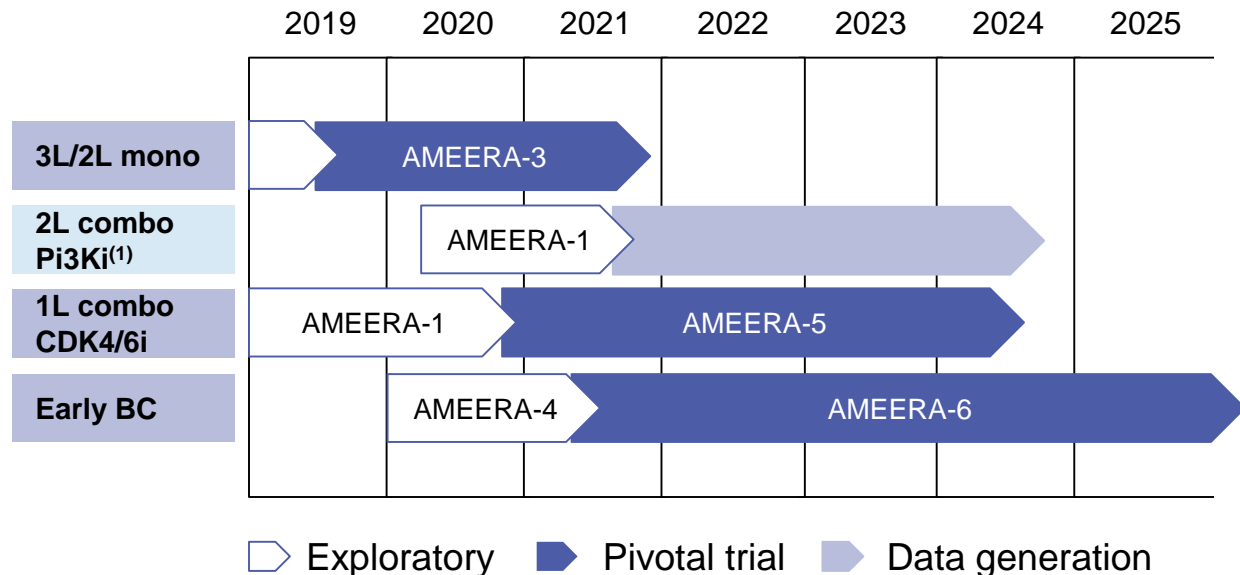
(1) emicizumab: 2.1 ABR with Q4W; 1.6 ABR with Q2W; 0.6 ABR with Q1W (U.S. prescribing information; median ABR (HAVEN-3 for Q1W & Q2W, HAVEN-4 for Q4W))

(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 HTC&s & Direct HTC&s (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

# Amcenestrant: Ambition to be best-in-class endocrine backbone in HR+ breast cancer

Lead with innovation

- 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

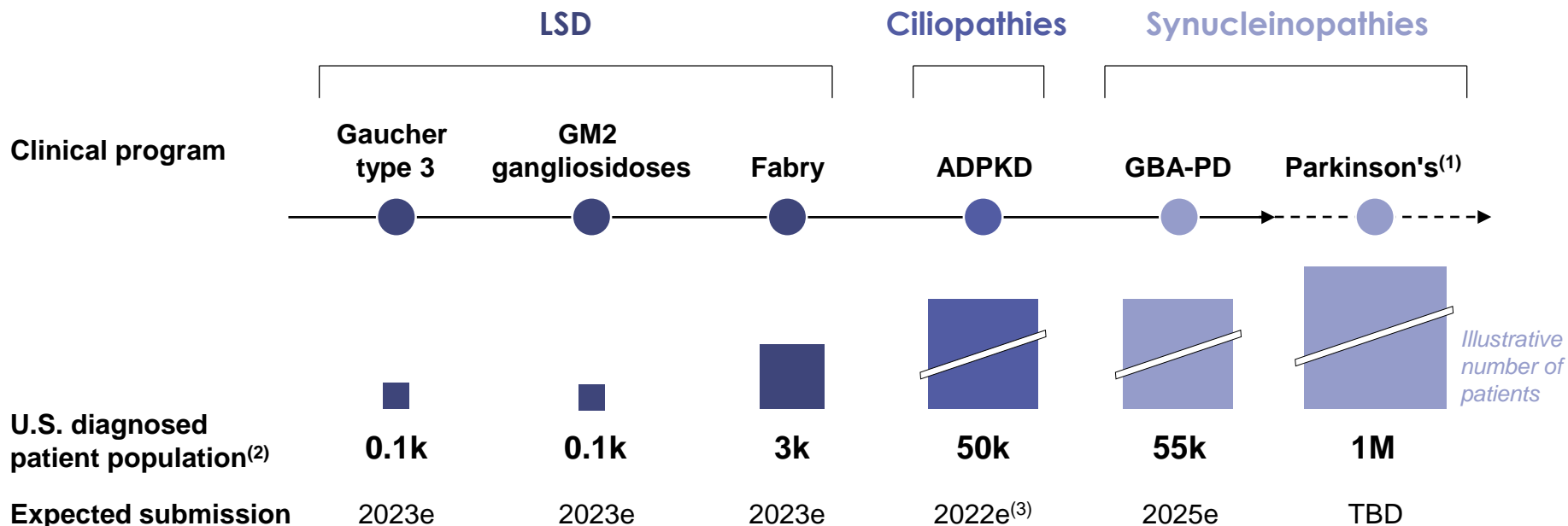


**2L/3L mBC expected to reach market in 2022, ~1 year ahead of other SERDs in development**

# Venglustat: Leveraging LSD biology in multiple rare diseases

Lead with innovation

## GCS inhibition to potentially treat 3 types of disease



LSD: lysosomal storage diseases; GCS: glucosylceramide synthase; ADPKD: autosomal dominant polycystic kidney disease; GBA-PD: Parkinson's disease related to glucocerebrosidase (GBA) gene mutations

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

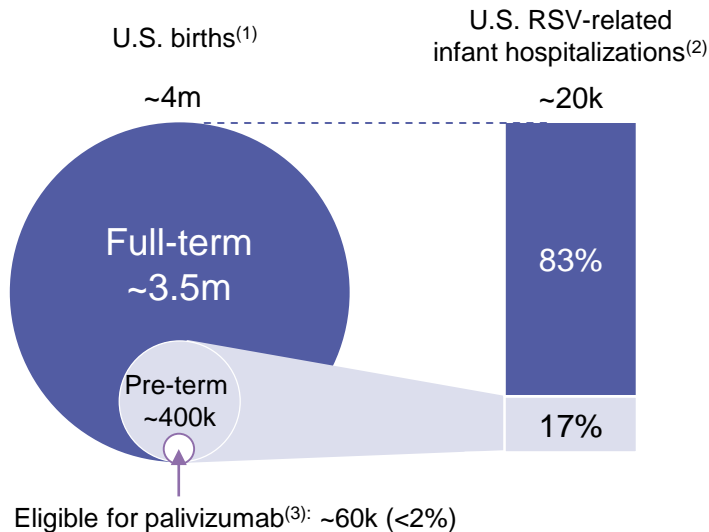
(2) Internal estimates

(3) Potential accelerated submission in the U.S. after Stage 1 of STAGED-PKD  
Note: project under investigation, not approved by regulators

# Nirsevimab: Goal to be cost-effective RSV prophylaxis for all 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**

# Tolebrutinib targets best-in-class profile in multiple sclerosis

Lead with innovation

**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

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*Delivering tolebrutinib target product profile expected to result in leading market position*

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# All tolebrutinib Phase 3 studies in MS initiated and open for enrolment

Lead with innovation

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

*As a fully-owned asset, additional TAs beyond CNS to be evaluated*

DMT: disease modifying therapy; LT: Long-Term; TAs: therapeutic areas; CNS: central nervous system

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

(2) Ocrelizumab: 24% relative reduction of 12-week confirmed disability progression; Montalban X et al, N Engl J Med 2017 Jan 19;376(3):209-220

BTKi (SAR442168) is an asset under investigation and not approved by regulators

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

Lead with innovation

## Platforms

Expanded tools for drug discovery



CD38 knockout NK cells sourced from universal donors



E3 ligase-based protein degradation technology



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

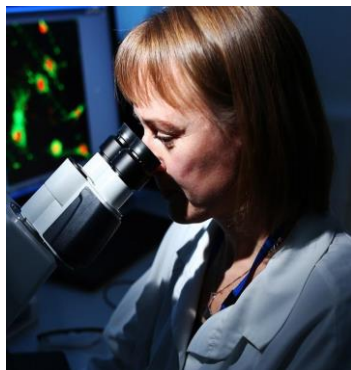
Leveraging expanding capabilities

Building leadership in MM and hematology-oncology

Deepening leadership in immunology

Expanding leadership in differentiated vaccines

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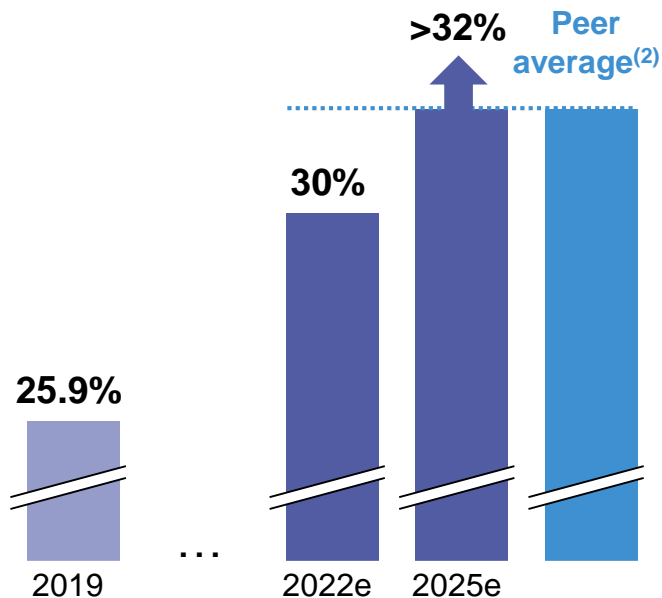


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# Targeting 30% BOI<sup>(1)</sup> margin by 2022

## Sanofi expected BOI margin evolution



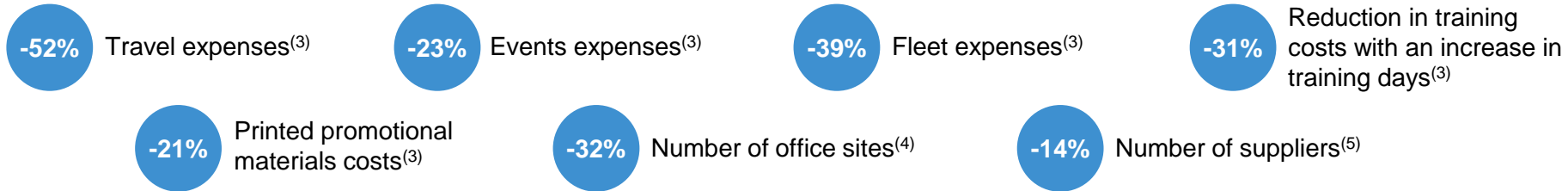
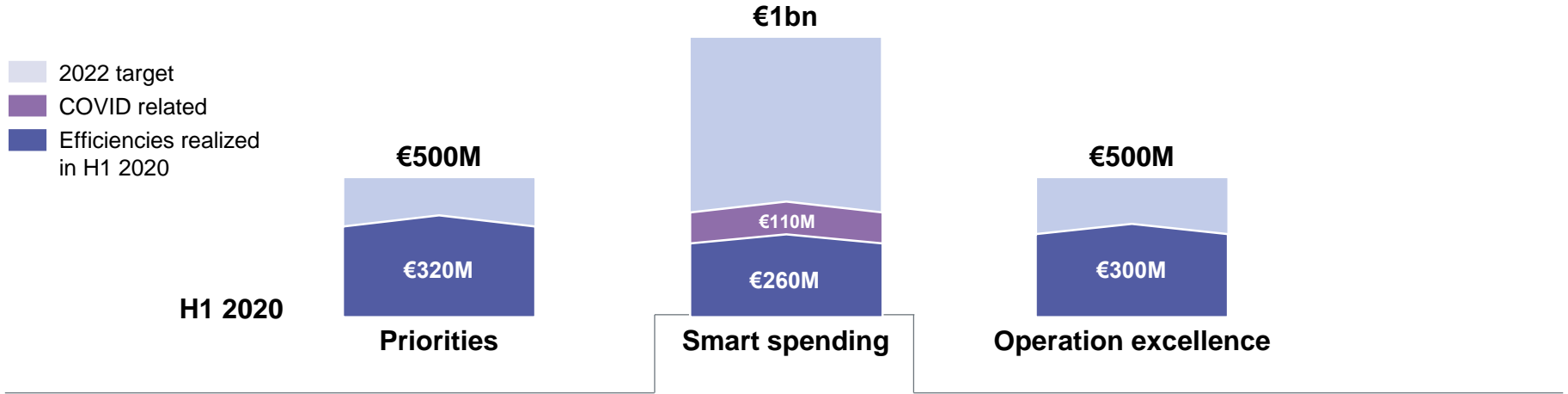
### Expected margin drivers, 2019-2022

- Sales growth
  - Improved mix
  - Smart spending
  - Resource reallocation
  - Operational excellence
- 
- Launch costs
  - Accelerate pipeline

(1) Definition in Q2 2020 earnings [press release](#)

(2) FY 2018 average based on the following peer group: AstraZeneca, Bayer, Bristol-Myers Squibb, Eli Lilly and Company, GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, Novo Nordisk, Pfizer, Roche, Sanofi.

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

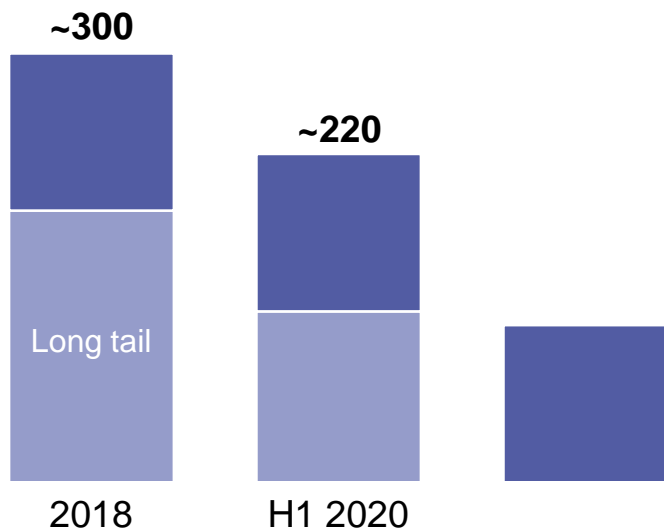


(1) €2bn of savings expected from December 2019 to December 2022  
 (2) Including around €110M related to COVID-19  
 (3) YTD May 2020 vs. YTD May 2019

(4) Excluding R&D and Industrial Affairs, June 2020 vs. June 2019  
 (5) May 2020 vs. December 2019

# Streamlining of Established Products tail underway

## Number of product families



Divestitures include Seprafilm<sup>®</sup> 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 at Q3 results

**Business EPS**

**+7%**

to

**+8%**

at CER<sup>(2,3)</sup>

**FX impact**

*on business EPS*

Approximately **-6% to -7%**<sup>(4)</sup>  
based on October 2020 average exchange rates

(1) Definition in Q3 2020 earnings press release: [https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/2020\\_10\\_29\\_Q3\\_Results\\_PR\\_EN.pdf?la=en&hash=8FAFC6A6DB6E045241FE3E1DEF5410C1](https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/2020_10_29_Q3_Results_PR_EN.pdf?la=en&hash=8FAFC6A6DB6E045241FE3E1DEF5410C1)

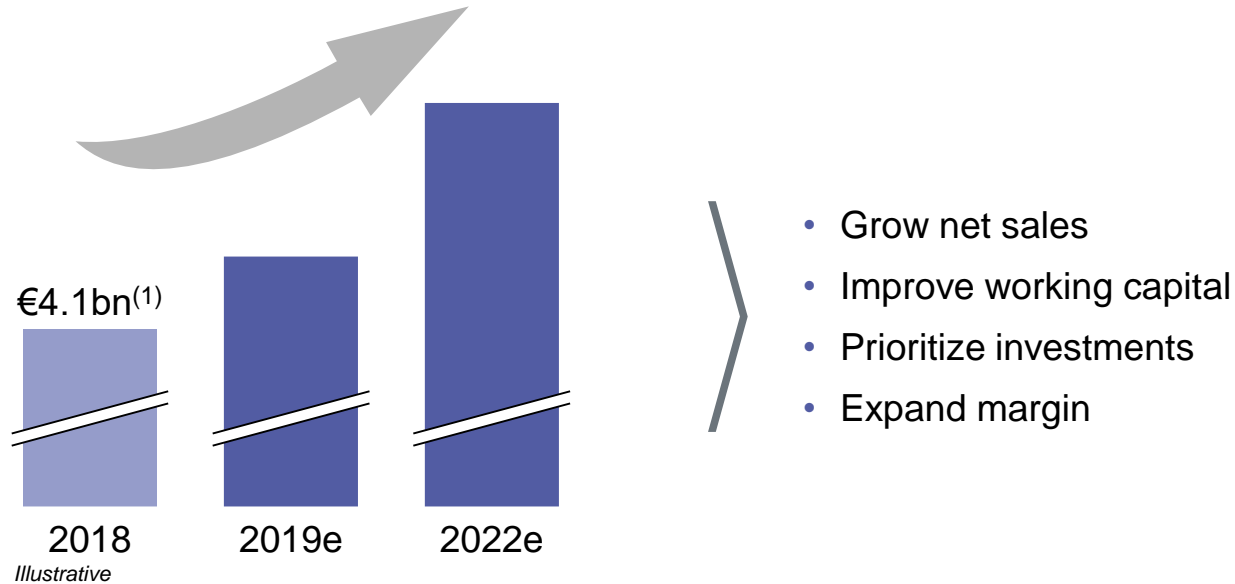
(2) Compared to FY2019 and barring major unforeseen adverse events

(3) 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

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

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

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





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# Empowerment and accountability

Reinvent how we work



## Culture of accountability



Top ~200 leaders to be incentivized on TSR



## Global to local model



Empowering and focusing people locally



## Fully empowered GBUs



End-to-end responsibility from R&D to commercialization



## New ways of working



Allocate time to higher value activities, leveraging digital tools

# New executive team completed with appointments in Q2 2020

Reinvent how we work



# New Global Business Unit organization to support strategy

Reinvent how we work

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

## Standalone<sup>(3)</sup>



### Specialty Care<sup>(1)</sup>



€9.2bn<sup>(2)</sup>  
net sales

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



### Vaccines



€5.7bn<sup>(2)</sup>  
net sales

22.9%



### General Medicines<sup>(1)</sup>



€16.5bn<sup>(2)</sup>  
net sales

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



### Consumer Healthcare



€4.7bn<sup>(2)</sup>  
net sales

33.9%

H1 2020  
BOI  
margin<sup>(4)</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) Pharmaceuticals business operating margin : (Specialty Care + General Medicines)

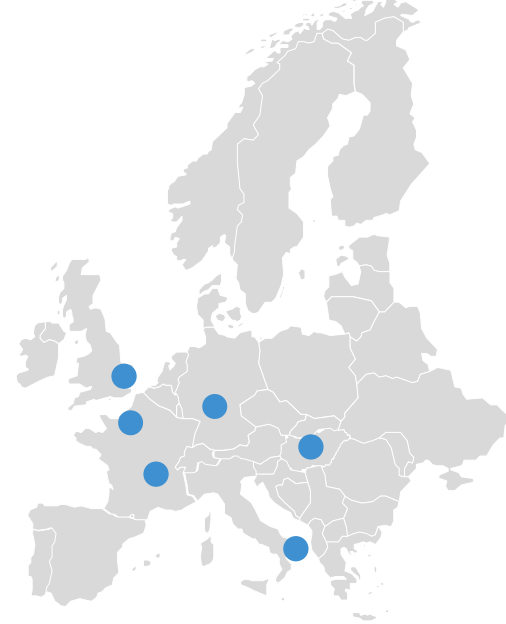
# Ambition to create a leading European company providing active pharmaceutical ingredients

Reinvent how  
we work

## 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



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*Strong European supplier rebalancing industry dependence on Asia*

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# Summary



**Ambition to achieve >€10 billion Dupixent<sup>®</sup> peak sales and mid-to-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**

# 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