



**SANOFI** 

# JP Morgan Healthcare Conference

Olivier Brandicourt, Chief Executive Officer

San Francisco, January 9, 2018

# Forward Looking Statements

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# Agenda

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Executing on Sanofi's 2020 Strategic Roadmap



Sustaining Innovation in R&D to support long term growth



Building leadership in Specialty Care



Strengthening the portfolio in Diabetes



Conclusion



# Significant Progress on our Strategic Roadmap in 2017

## 4 Key Pillars of Sanofi's 2020 Strategic Roadmap

### 1 Reshaping the portfolio

- ✓ Asset swap in CHC and integration completed
- ✓ Obtained full control of EU vaccines business
- ✓ Strengthened vaccines portfolio with Flublok<sup>®(1)</sup> and the RSV vaccine<sup>(2)</sup>
- ✓ Announcement of EU generics divestiture expected by end of 2018

### 2 Delivering outstanding launches

- ✓ Dupixent<sup>®</sup> exceeding launch expectations
- ✓ Steady share gains for Kevzara<sup>®</sup> in U.S. market
- Praluent<sup>®</sup>, Soliqua<sup>®</sup> and Dengvaxia<sup>®</sup> launches meet expectations

### 3 Simplifying the organization

- ✓ Increased accountability through GBU structure
- ✓ Focused organization driving performance
- ✓ Cost savings expected to reach €1.5bn in 2017

### 4 Sustaining innovation in R&D

- ✓ Important advances in a differentiated pipeline
- ✓ Disciplined investments in high value projects
- ✓ Driving long term growth based on proprietary technology platforms

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# Sanofi Research and Development

71

projects in development for NMEs  
or additional indications<sup>(1)</sup>

9

potential submissions in  
next 18 months

7

NME and Vaccine  
approvals since 2015<sup>(2)</sup>

>10

pivotal study starts in  
next 12 months

# Sanofi's R&D Hub Model to Capture Innovation Through Cutting Edge Platform Technologies and Capabilities

## North America Hub

- Multi-Specifics
- PRR Antibody Conjugates

## French Hub

- Multi-Specifics
- PRR Antibody Conjugates

## German Hub

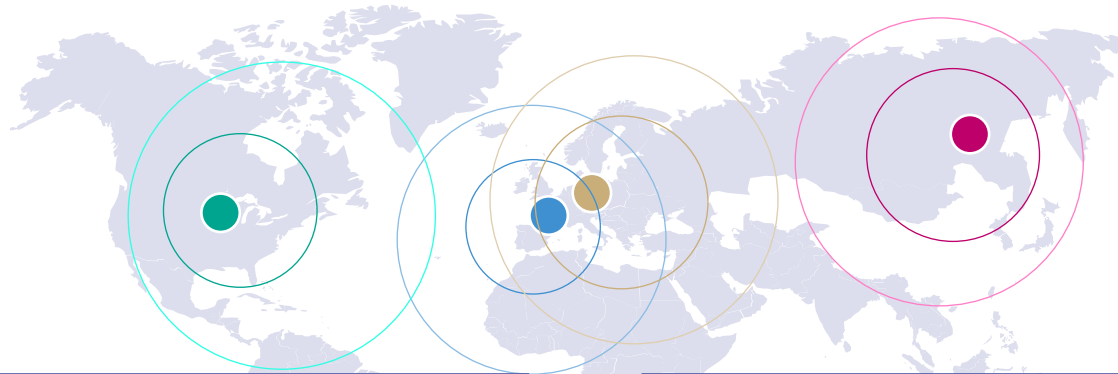
- Multi-Specifics
- Peptides
- siRNA

## Asia-Pacific Hub

- Digital Hub

## Partnered Tech

- BioNTech mRNA Mixture
- Ablynx Nanobodies



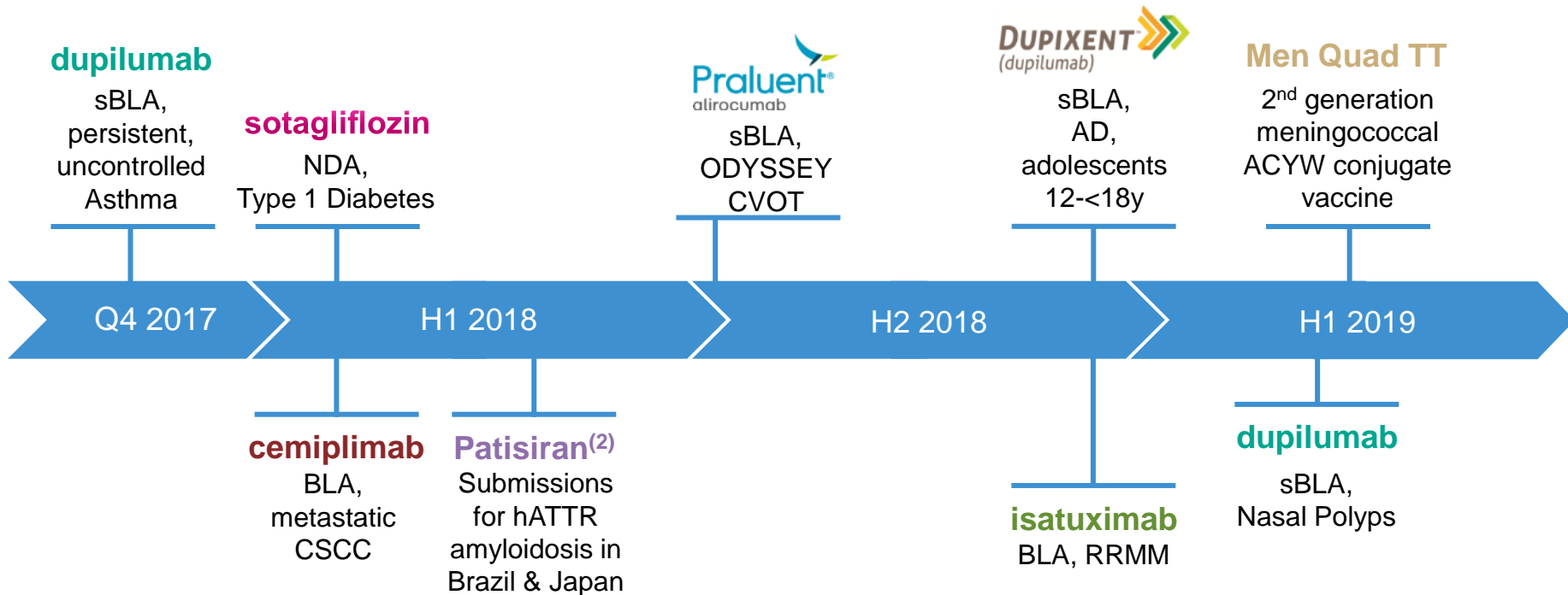
Working across geographies, organizations and disciplines around the Hub model



Connecting with our biomedical ecosystem to generate value through networks

# 9 Potential Submissions<sup>(1)</sup> for New Products or Additional Indications Over Next 18 Months

## Planned Submissions





# New Wave of Pivotal Study Starts Expected Over the Next 12 Months

**dupilumab<sup>(1)</sup>**

Anti-IL4R $\alpha$  mAb

- COPD
- Eosinophilic Esophagitis

**isatuximab**

Anti-CD38 mAb

- 1L MM SCT eligible
- 1L MM SCT ineligible

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

Oral GCS inhibitor

- Autosomal dominant polycystic kidney disease (ADPKD)

**alemtuzumab**

- Primary Progressive MS

**SAR425899**

GLP-1/GCR dual agonist

- Obesity

**cemiplimab<sup>(1)</sup>**

- 1<sup>st</sup> line NSCLC

**efpeglenatide<sup>(3)</sup>**

Once-weekly GLP-1RA

- Type 2 Diabetes

**mavacamten<sup>(4)</sup>**

- Obstructive Hypertrophic Cardiomyopathy

# Sanofi R&D Key Strategies

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**Therapeutic  
Modalities**

small molecules



biologics

**Mode  
of Action**

mono-targeting



multi-targeting

**Technology  
Platforms**

licensing



proprietary

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# Dupilumab Being Evaluated as First-in-Class Dual Inhibitor of IL4/IL13 in Key Type 2 Conditions

## Atopic Dermatitis



- ✓ Breakthrough therapy in moderate-to-severe AD
- ✓ First-in-class biologic treatment

## Asthma



- ✓ Efficacy in 3 pivotal trials
- ✓ Largest Phase 3 program of a biologic therapy in asthma

## Nasal Polyposis



- ✓ Positive Proof of Concept data
- ✓ No currently approved biologic
- ✓ Phase 3 fully enrolled

## Eosinophilic Esophagitis



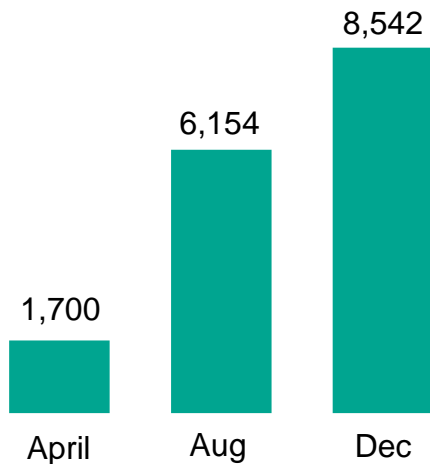
- ✓ Positive Proof of Concept data
- ✓ No currently approved biologic

**dupilumab**

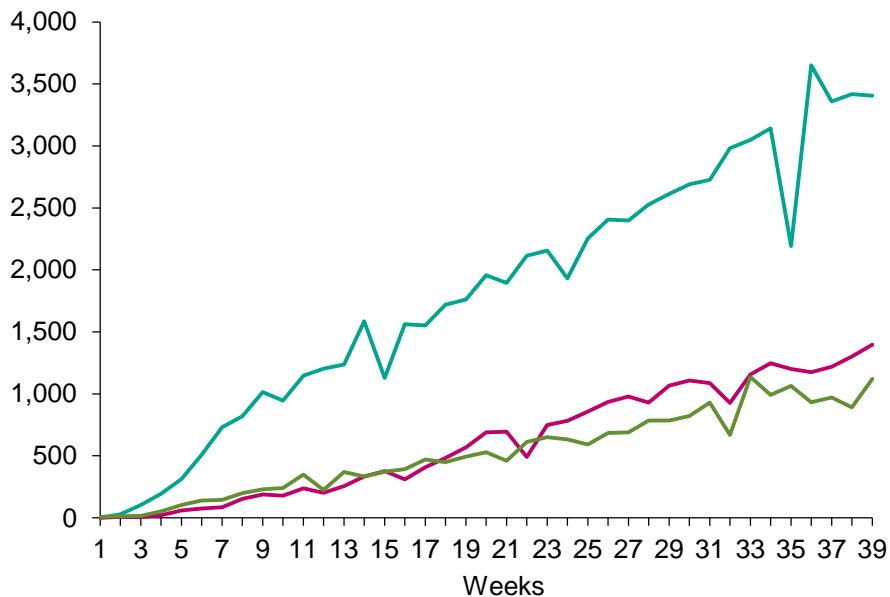
# Strong U.S. Dupixent® Launch Outperforming Analogs

## Total Dupixent® Prescribers

Growing prescriber breadth



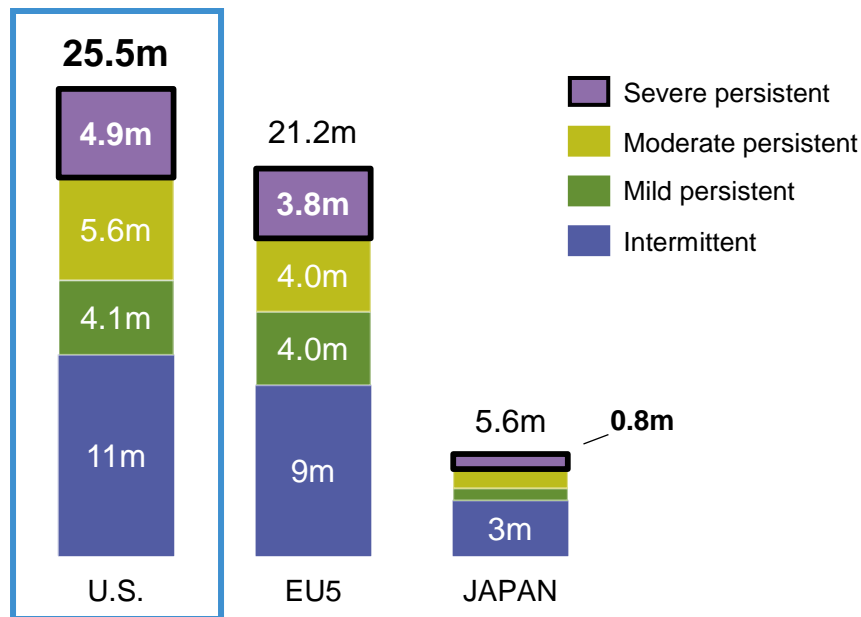
## Weekly TRx Since Launch<sup>(1)</sup>



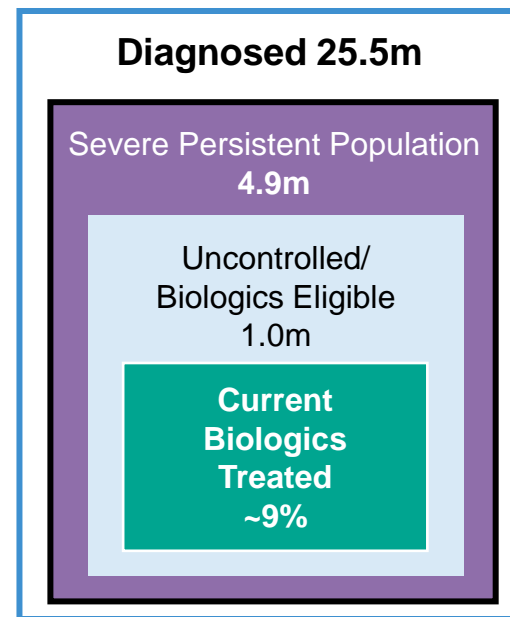
# Dupilumab Clinical Program Focused on Population with Uncontrolled Persistent Asthma

Nearly 20% of diagnosed asthma patients have severe persistent disease

Asthma patients by disease severity 2016 (all ages)

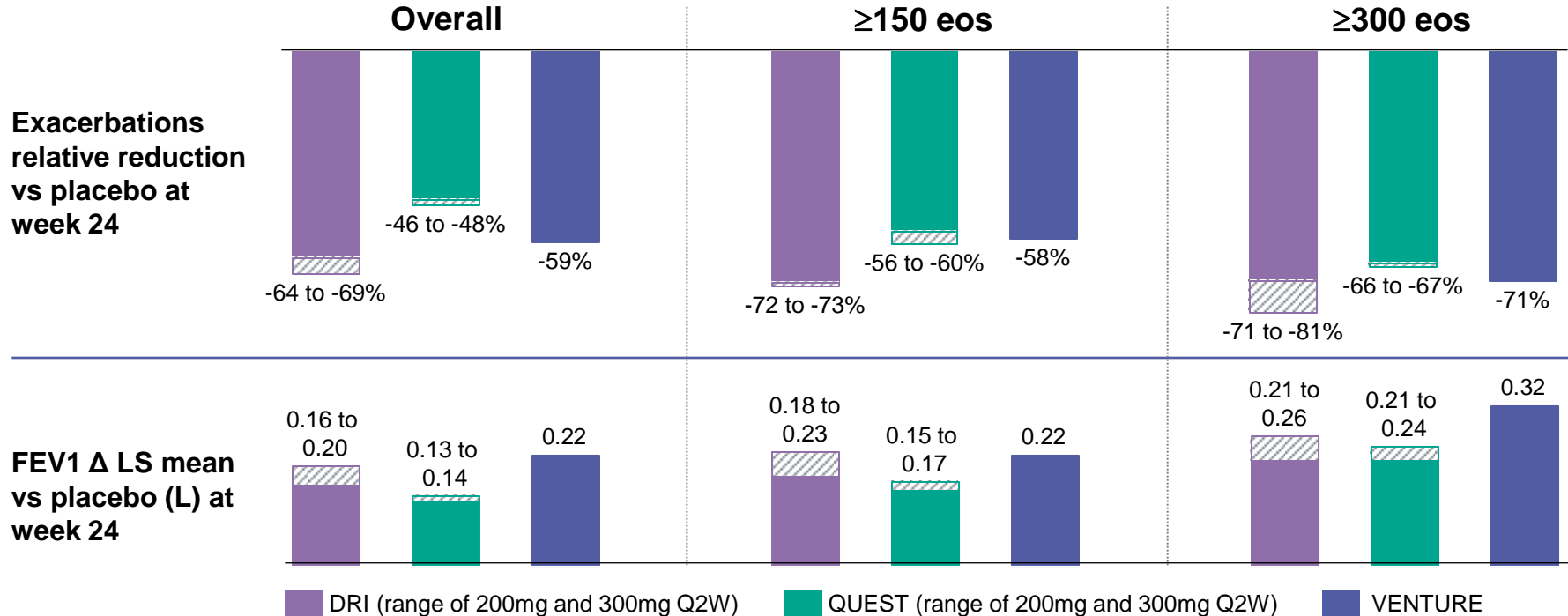


U.S. Patient Population



# Dupilumab Demonstrated Efficacy Across Broad Population and Independent of Eosinophilic Phenotype

## Consistent Reduction in Risk of Exacerbation and Improvement in Lung Function

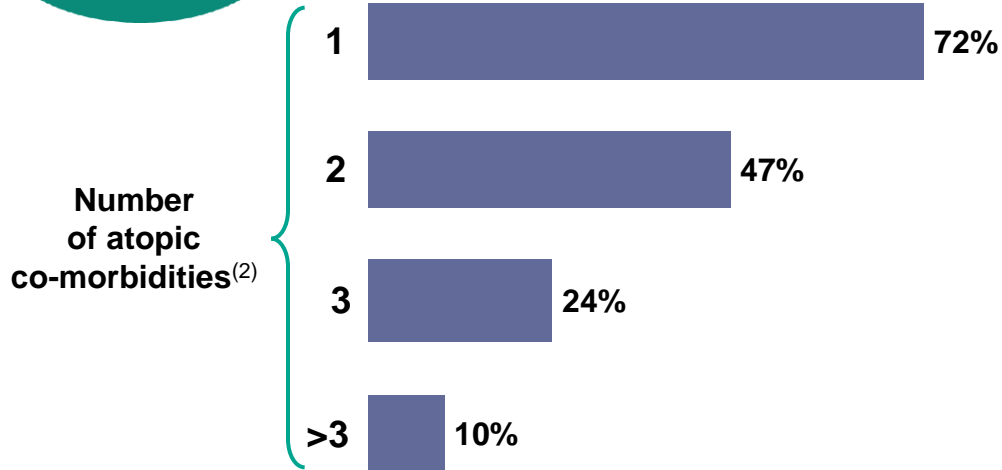


# The Role of Blocking the IL4/IL13 Pathway on the Burden of Certain Co-Morbidities is Being Evaluated

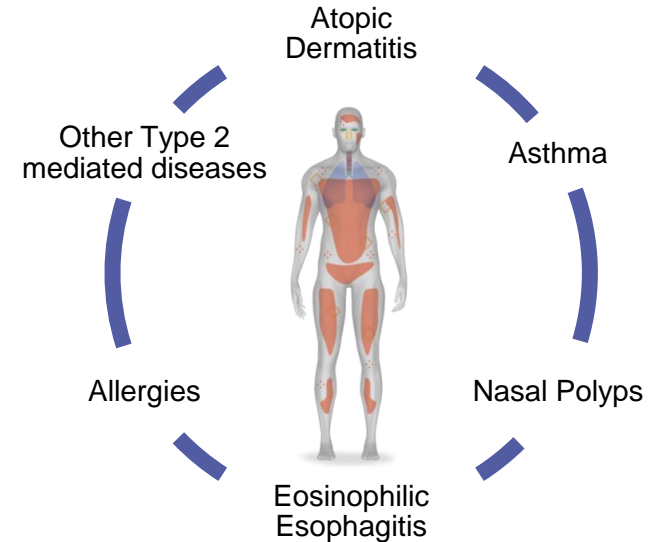
Example:  
**Atopic Dermatitis**



Percentage of Patients with 1 or Multiple Co-Morbidities<sup>(1)</sup>



Co-Morbid Type 2 Immune Diseases<sup>(2)</sup>



Start of clinical program evaluating co-morbidities planned for 2018

(1) SOLO1, SOLO2, CHRONOS

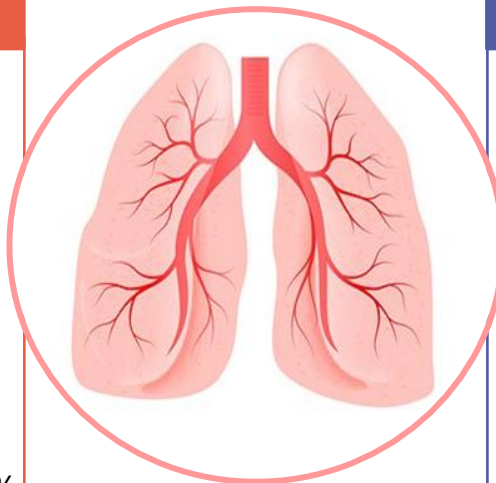
(2) Defined as one or more of: Atopic Dermatitis, Asthma, Nasal Polyposis, Eosinophilic Esophagitis, Food Allergy, Allergic Rhinitis, Chronic Rhinosinusitis, Allergic Conjunctivitis, Hives. The safety and efficacy of dupilumab on Asthma, Nasal Polyps, Eosinophilic Esophagitis, Allergies and other Type 2 mediated diseases is either under clinical investigation (or being considered for clinical investigation) and has not been evaluated by any Regulatory Authority



# Dupilumab to Start Phase 3 Program in COPD in 2018

## Large unmet need for new treatment options in COPD

- Estimated market of ~€16bn in 2025<sup>(1)</sup>
- Despite existing therapies a large subset of patients still experience severe exacerbations
- Significant need for a new MoA
  - Approximately 2m patients in the U.S. at risk despite inhaled triple therapy<sup>(2)</sup>
  - Penetration of biologics by 2025 ~10-15%



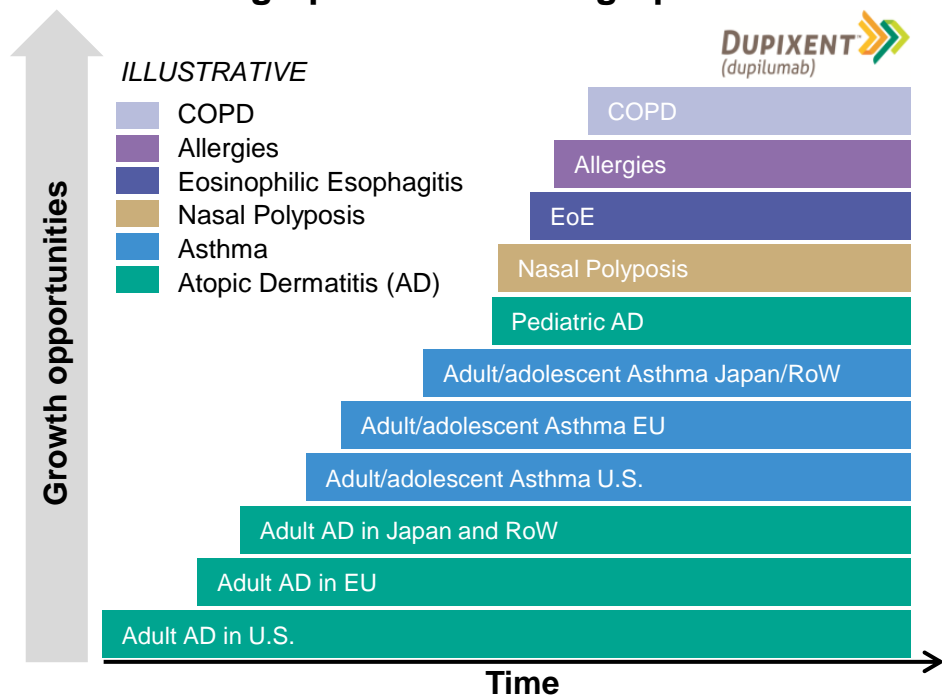
## Compelling rationale for dupilumab development program in COPD

- Unmet need to prevent exacerbation and to improve pulmonary function
  - No approved biologics to date
- Type 2 inflammation plays a key role in a group of COPD patients and is associated with decreased lung function<sup>(3)</sup>
- Leverage robust efficacy and safety data to build COPD development program for dupilumab

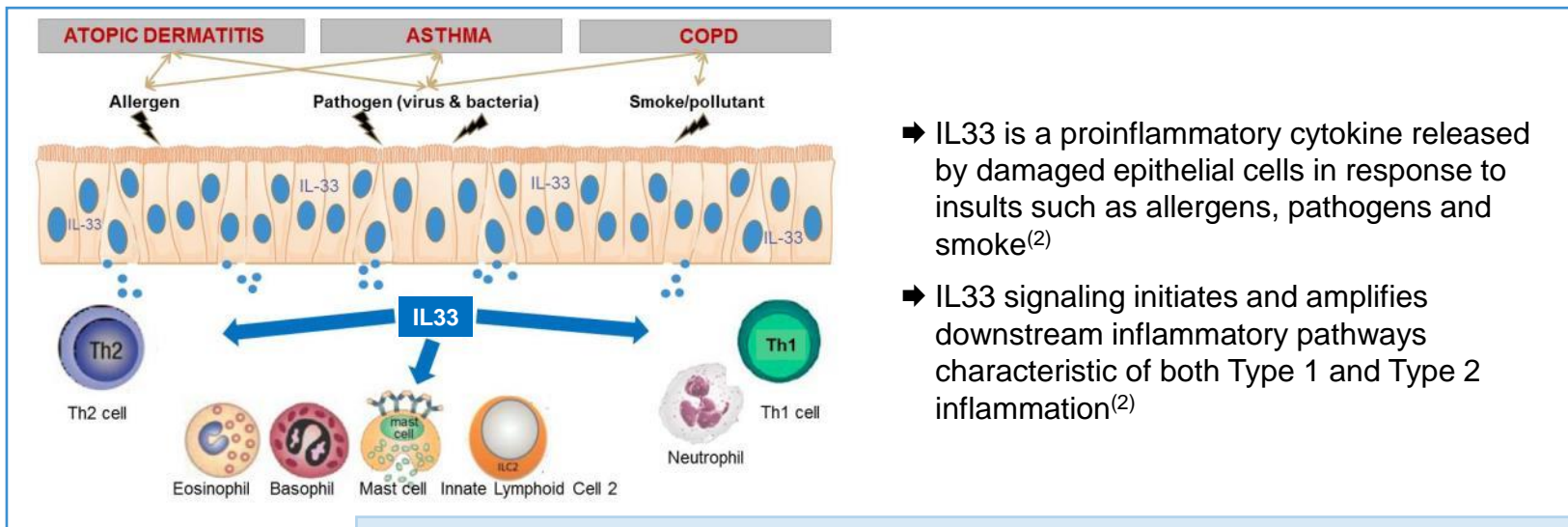
# Global Launch Opportunities in Multiple Diseases to Realize the Full Potential of a 'Pipeline in a Product'

- Dupilumab expected to be a key growth driver with significant commercial potential in multiple diseases
- Building a portfolio of opportunities around one compound
  - Launch of new indications over time
  - Geographic roll-out in global markets
  - Penetration into adult, adolescent and pediatric populations
  - Expansion in combination use

## Growth Opportunities across Diseases, Geographies and Demographics<sup>(1)</sup>



# IL33 mAb<sup>(1)</sup>: Potential for Broader Spectrum of Immune Modulation in Atopic Dermatitis, Asthma and COPD



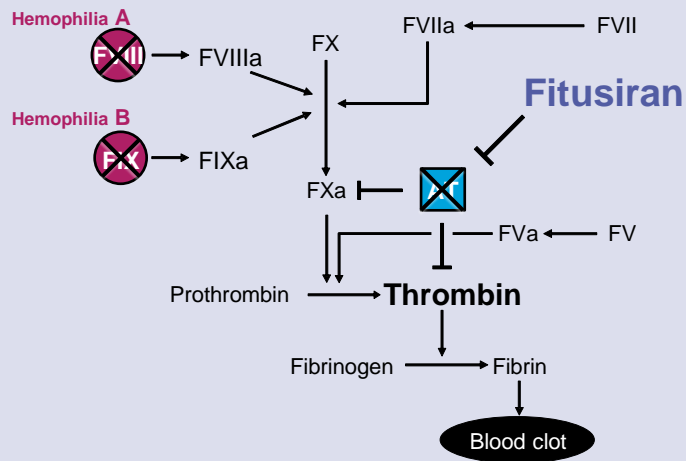
➔ IL33 is a proinflammatory cytokine released by damaged epithelial cells in response to insults such as allergens, pathogens and smoke<sup>(2)</sup>

➔ IL33 signaling initiates and amplifies downstream inflammatory pathways characteristic of both Type 1 and Type 2 inflammation<sup>(2)</sup>

- Target identified and validated by human genetics<sup>(3)</sup>
- Major opportunity in monotherapy and in combination
  - Building on the benefit of dupilumab in AD, as well as potentially asthma and COPD

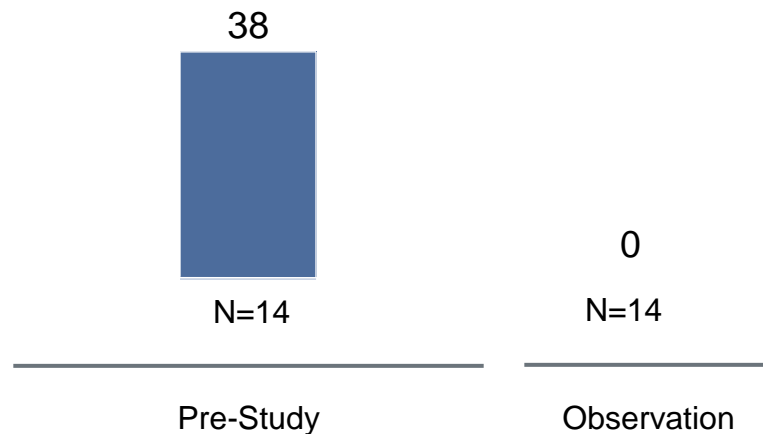
# Fitusiran<sup>(1,2)</sup>: RNAi Therapeutic for Hemophilia Demonstrated Encouraging Efficacy in Phase 1/2 Study

## Fitusiran Mechanism of Action



## Fitusiran Phase 1/2 Study in Patients with Inhibitors

Primary endpoint Annualized Bleeding Rate (ABR)



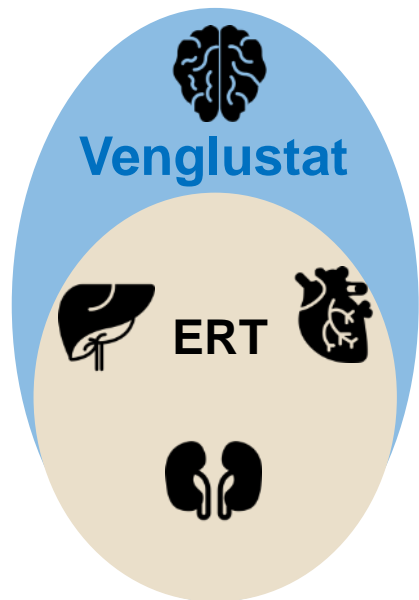
Fitusiran is an investigational agent and has not been evaluated by any regulatory authority

Safety/tolerability profile includes increased AST/ALT in HCV Ab positive patients and one case of thrombosis, possibly drug-related

(1) As per press release from December 15, 2017, Sanofi and Alnylam announced that the U.S. FDA has lifted the hold on clinical studies with fitusiran

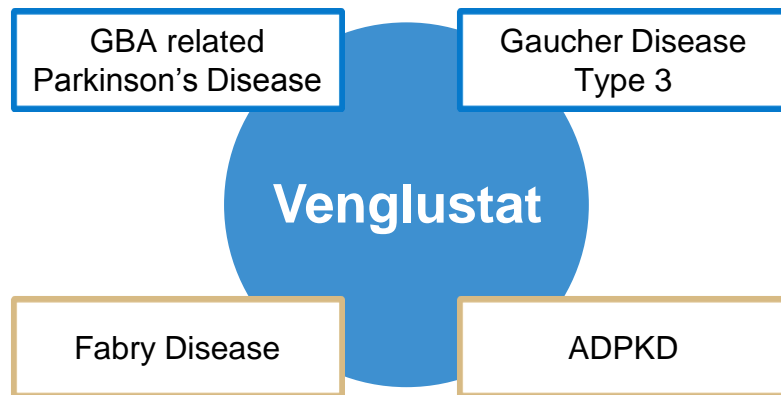
(2) As per press release from January 7, 2018, Sanofi and Alnylam entered into strategic restructuring of RNAi therapeutics rare disease alliance

# Venglustat<sup>(1)</sup>: Oral, Once Daily Inhibitor of GCS with Potential Across Multiple Rare Diseases



Expected to address CNS manifestations of LSDs and related disorders

## Venglustat Clinical Development



**Registrational Phase 2/3 expected to start in 2018 for ADPKD, filing targeted for 2021**

# Sanofi's Strong Commitment to Oncology Expected to Begin to Deliver in 2018

## 7 Pre-clinical programs enter Phase 1

- T-cell engager in AML/MDS (Sanofi)
- Immunostimulatory mRNA (BioNTech)
- T-cell engager<sup>(2)</sup> in Ovarian Cancer
- Checkpoint inhibitor<sup>(2)</sup>
- cemiplimab + DNA vaccine<sup>(2)</sup>
- cemiplimab + oncolytic<sup>(2)</sup>
- cemiplimab + ISA101<sup>(2)</sup>

## 14 New proof of concept indications

- Isatuximab + Checkpoint inhibitor (9)
- Anti-TGF $\beta$  monotherapy
- Anti-TGF $\beta$  + cemiplimab (2)
- SERD monotherapy
- SERD + palbociclib

## 4 Potential proof of concept study readouts

- Anti-LAG3 monotherapy and combination with other checkpoint inhibitors in solid tumors/lymphoma<sup>(2)</sup>
- SERD in metastatic Breast Cancer
- CEACAM5 ADC in Solid Tumors
- CA6 ADC in metastatic Breast Cancer

## 9 Pivotal studies ongoing or planned

- Isatuximab: 4 MM
- Cemiplimab<sup>(2)</sup>: 3 NSCLC, 1 BCC, 1 Cervical Cancer

## 3 BLA/MAA submissions

- Cemiplimab<sup>(2)</sup> CSCC: U.S., EU
- Isatuximab RRMM: U.S.

## 1 U.S. launch

- Cemiplimab<sup>(2)</sup> CSCC<sup>(1)</sup>

SERD= Selective Estrogen Receptor Degradar; NSCLC= Non-Small Cell Lung Cancer; BCC= Basal Cell Carcinoma; CSCC= Cutaneous Squamous Cell Carcinoma; RRMM= Relapsed Refractory Multiple Myeloma; MDS= Myelodysplastic Syndrome; AML= Acute Myeloid Leukemia

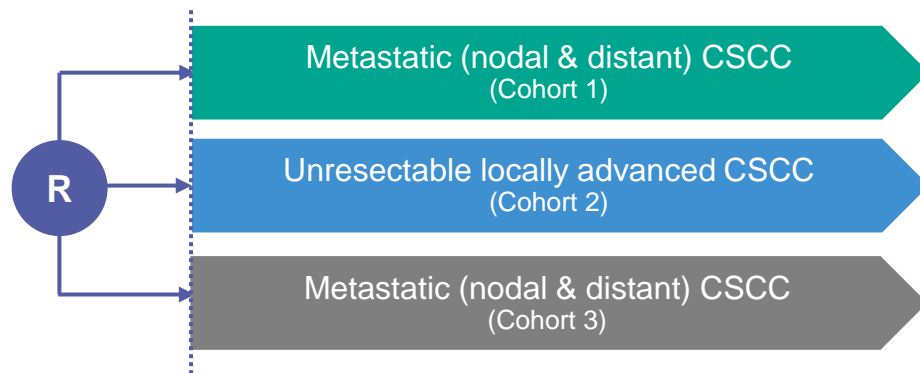
(1) Subject to U.S. FDA approval

(2) Collaboration with REGN

# Pivotal Results for Cemiplimab<sup>(1)</sup> in Advanced CSCC Show High Response Rate and Durable Responses

- If approved cemiplimab expected to be the first anti-PD-1 indicated for advanced CSCC
- Results from 82 patients in the pivotal Phase 2 trial
  - 46.3% ORR by independent review
  - 33 of 38 responses ongoing (with at least 6 months of follow up)
  - Safety profile generally consistent with approved anti-PD1 drugs
- Second most common skin cancer in U.S.<sup>(2)</sup>
  - 5,000 to 13,000 metastatic or locally advanced

## Pivotal Phase 2 Trial

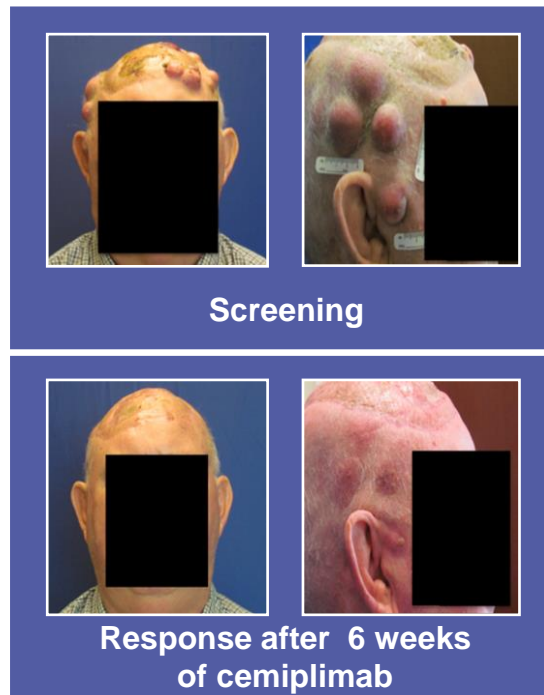


Primary Endpoint: Objective Response Rate  
Regimen: Cohort 1&2: 3mg/kg cemiplimab every 14 days  
Cohort 3: 350mg flat dose cemiplimab every 3 weeks

**FDA and EMA submissions planned in Q1 2018**

# Cutaneous Squamous Cell Carcinoma (CSCC) is a Disease with Significant Unmet Medical Need

- 2nd most common skin cancer in U.S.<sup>(1)</sup>
  - 200K to 400K new cases/year in the U.S.
  - 5,000 to 13,000 metastatic or locally advanced
  - ~35% may be immune compromised and ineligible for PD1
- Primary management is surgical
  - No SOC and high patient burden in locally advanced and metastatic disease
- Severe morbidity and mortality with recurrence
  - Mortality: ~3,900-8,800 deaths/year in US<sup>(1)</sup>





# Cemiplimab<sup>(1)</sup> First-in-Class Opportunity in CSCC, Expansion into Other Untapped Opportunities in IO

## 2<sup>nd</sup> Line Advanced Metastatic Basal Cell Carcinoma<sup>(2)</sup>

- 28,000 patients diagnosed in U.S. with metastatic BCC
- 3,000 estimated deaths in the U.S. annually

Study expected to complete H2 2018

## Platinum-Refractory Cervical Cancer<sup>(3)</sup>

- 25,000 patients diagnosed in U.S. and Western EU
- 35% of patients are Stage IV at diagnosis

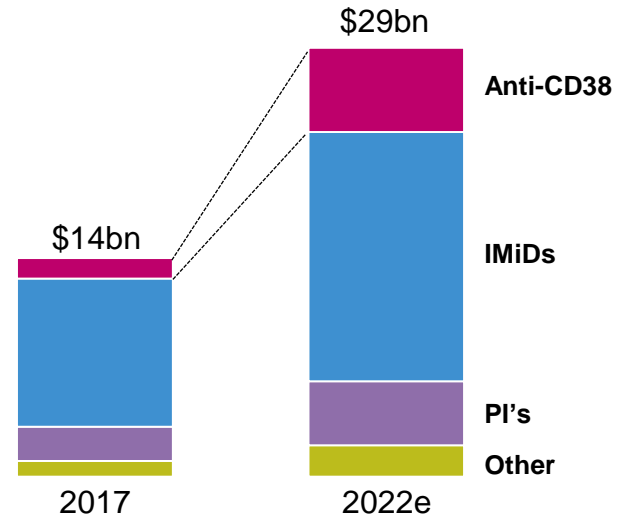
Study expected to complete H1 2020

# Opportunity for Isatuximab in Large and Growing Multiple Myeloma Market and Potential Use in Solid Tumors

- Worldwide Multiple Myeloma market expected to reach \$29bn in 2022 driven by:
  - Double/triple branded combination use
  - New options with prolonged PFS benefit
  - Globally ~114k new cases diagnosed annually
- Anti-CD38 class becoming standard of care
  - Combinability without increased toxicity
  - Unprecedented PFS prolongation
- Combination use of isatuximab in solid tumors to evaluate whether it can enhance response to immuno-oncology agents



## Estimated Worldwide Multiple Myeloma Market<sup>(1)</sup>



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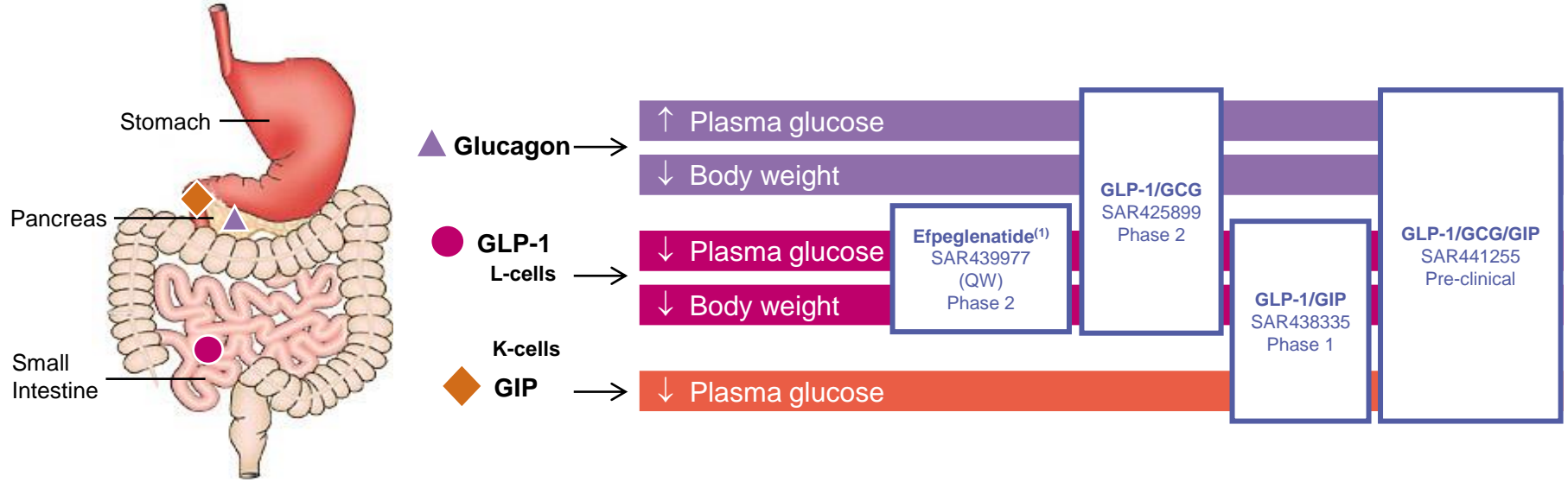
Strengthening the portfolio in Diabetes



Conclusion



# Novel Peptide Platform to Potentially Result in Innovative Diabetes, Obesity and NASH Therapies



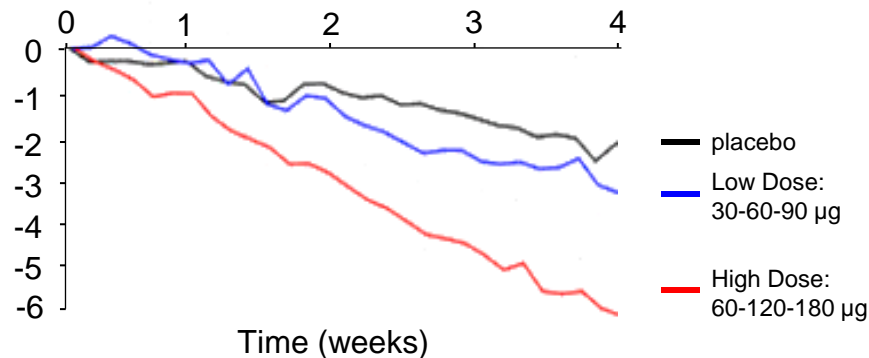
## Dual and Triple Agonist adding Pharmacology of GIP and/or Glucagon

# Dual Agonist<sup>(1)</sup> Shows Significant Body Weight Reduction in Overweight/Obese Diabetic Patients

## Change in Body Weight from Baseline

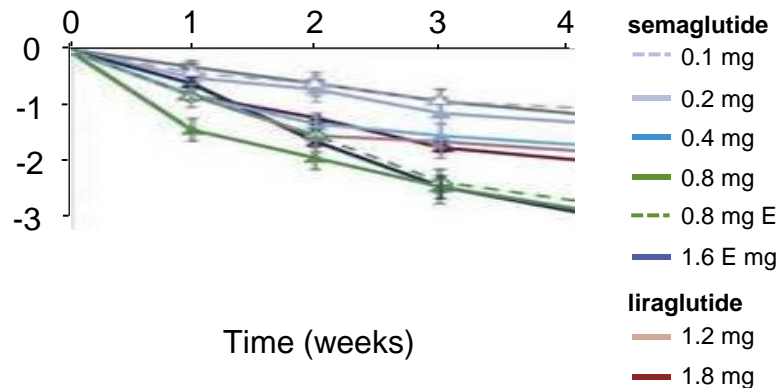
### GLP-1/GCG agonist<sup>(1,2)</sup>

Change in body weight (kg)



### semaglutide and liraglutide<sup>(3)</sup>

Change in body weight (kg)



(1) SAR425899 is an investigational agent and has not been evaluated by any regulatory authority. Adverse events observed most frequently were related to GI disorders

(2) Phase 1 Results; 4-week study in overweight to obese T2DM, 2-step up-titration after 7 days - Lindauer K et al, Oral presentation #109, European Association for the Study of Diabetes (EASD) 52nd Annual Meeting, September 14, 2016, Munich, Germany; BMI at baseline: 32 kg/m<sup>3</sup>

(3) Nauck et al. Diabetes Care 2016; BMI at baseline: ~31 kg/m<sup>3</sup>

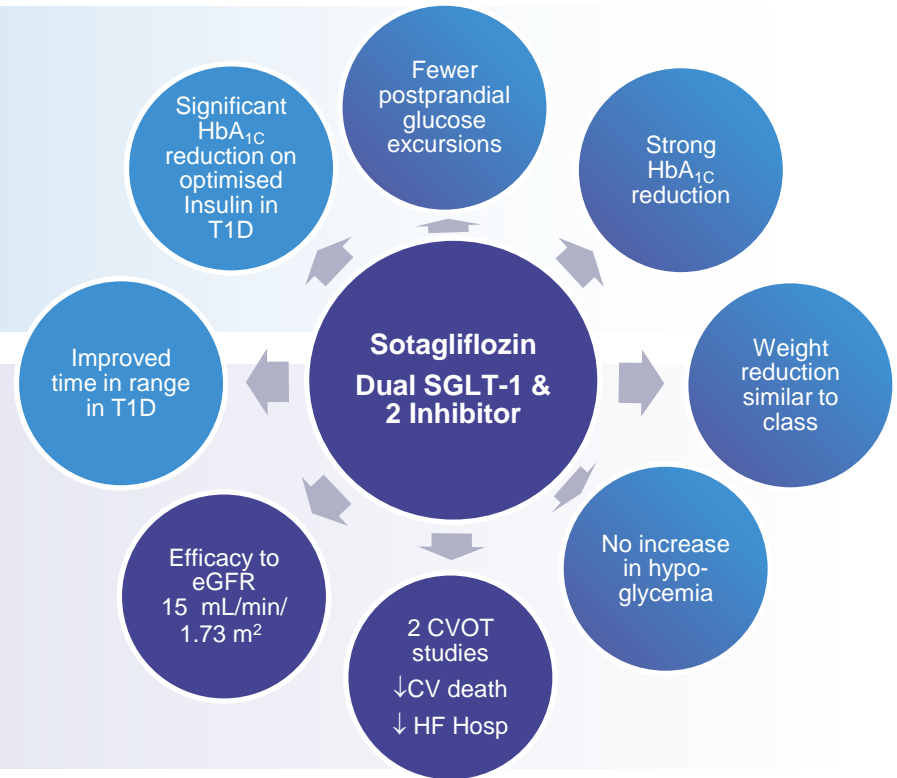
# Sotagliflozin<sup>(1)</sup>: A Potentially Differentiated Value Proposition in Type 1 and Type 2 Diabetes

## Potential in Type 1 Diabetes

- HbA<sub>1C</sub> control as an adjunct to insulin
- Potent effect on PPG
- Weight reduction

## Potential in Type 2 Diabetes

- Efficacy through HbA<sub>1C</sub>
- Efficacy in patients with renal impairment
- Weight reduction comparable to class
- CV outcomes data in renal and Heart Failure population
- Low risk of hypoglycemia



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# Sanofi Focused on Delivering Value to Shareholders

## 2016-2017 Roadmap Achievements

- ➔ Captured efficiencies through simplification
- ➔ Sustaining double-digit growth in Specialty Care
- ➔ Maintaining mid to high-single digit sales increase in Vaccines and Emerging Markets
- ➔ Advancing R&D pipeline with high value assets
- ➔ TSR<sup>(1)</sup> supported by progressive dividend policy and ~€5bn of share buybacks executed
- ➔ Steady financial performance despite expected decline in diabetes of 6% to 8% in 2015-2018<sup>(2)</sup>

## Continued focus on value creation

- Future growth in Specialty Care
- Maximize opportunity for Praluent®
- Diminished headwind from diabetes sales
- Full benefit of existing savings program and increased focus on cost base
- Productive R&D pipeline with innovative molecules and platform technologies
- Strong balance sheet creates flexibility