ELI LILLY AND COMPANY

DIABETES

TIRZEPATIDE SURPASS PHASE 3 PROGRAM OVERVIEW

November 20, 2020

Lilly

Agenda

Introduction
Mike Mason, President, Lilly Diabetes

Phase 2 Data Recap
Dr. Jeff Emmick, Vice President, Lilly Diabetes Product Development

SURPASS in Context
Jamie Croaning, Global Development Leader, Tirzepatide

Next Steps

Q&A

SAFE HARBOR PROVISION

This presentation contains forward-looking statements that are based on management's current expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development, approval and commercialization. Among other things, there can be no guarantee that the studies will continue as planned, that future study results will be consistent with the results to date or that tirzepatide will receive regulatory approvals. The company's expectations regarding the timing of potential regulatory submissions and approval may also change. Additionally, the company's results may be affected by factors including, but not limited to, the risks and uncertainties in pharmaceutical research and development; competitive developments; regulatory actions; the extent and duration of the effects of the COVID-19 pandemic; litigation and investigations; business development transactions; economic conditions; and changes in laws and regulations, including health care reform.

For additional information about the factors that affect the company's business, please see the company's latest Forms 10-K,10-Q, and any 8-Ks filed with the Securities and Exchange Commission.

The company undertakes no duty to update forward-looking statements except as required by applicable law

TIRZEPATIDE INTRODUCTION

LEVEL SETTING

WE DON'T HAVE PHASE 3 RESULTS YET!

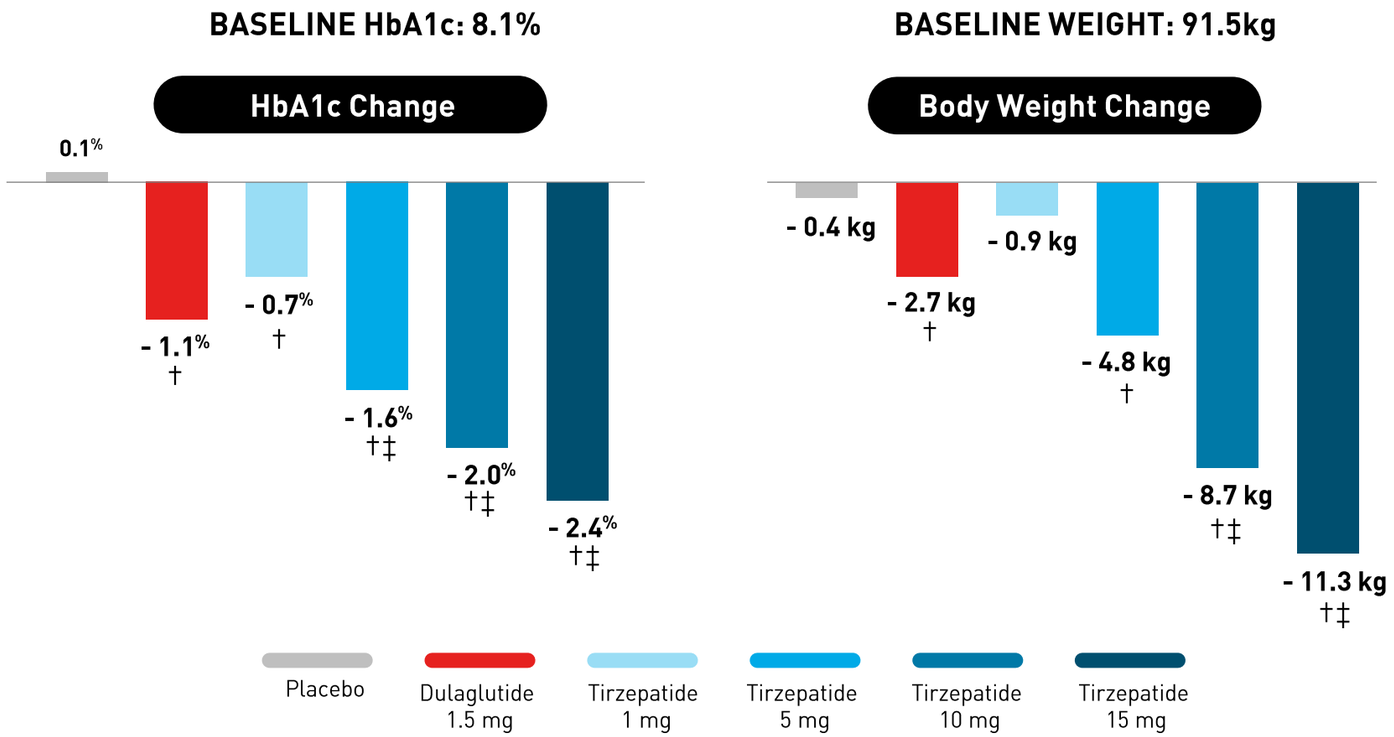
SURPASS-1 HAS NOT ACHIEVED DATABASE LOCK

TIRZEPATIDE PHASE 2 DATA

TIRZEPATIDE PHASE 2B DATA

TIRZEPATIDE DEMONSTRATED SIGNIFICANT CHANGE IN HBA1C AND BODY WEIGHT

PHASE 2B DATA AT 26 WEEKS



Initiated Multiple Development Programs

2018 — Type 2 Diabetes - SURPASS

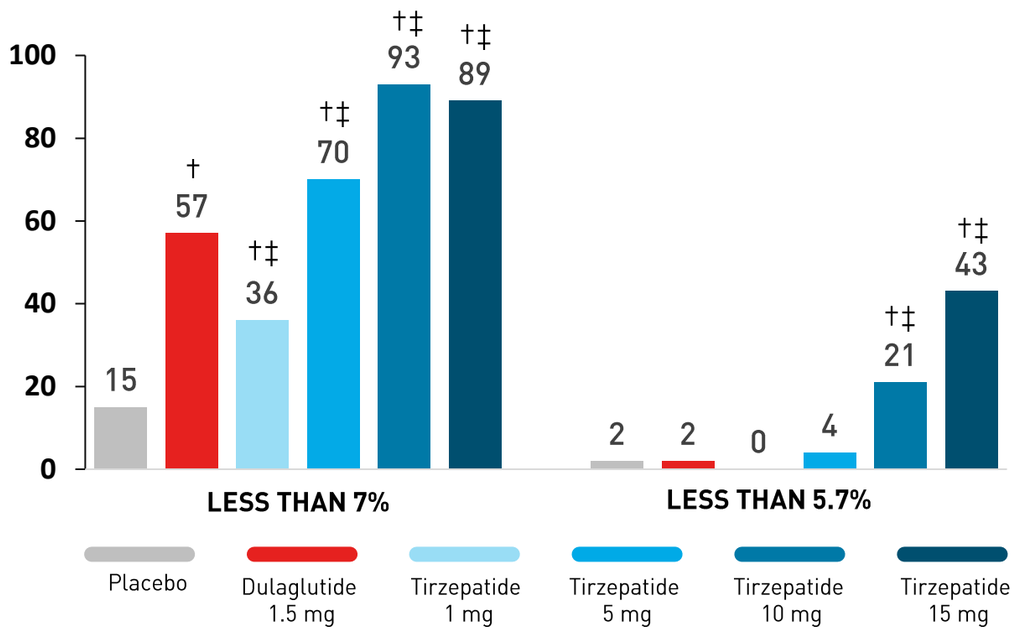
2019 — Obesity – SURMOUNT
NASH – SYNERGY NASH

Data for change in HbA1c and bodyweight presented are LS mean, MMRM on treatment analysis. † p<0.05 vs placebo and ‡ p<0.05 vs. dulaglutide 1.5 mg
Frias al. Lancet 2018;392(10160):2180-2193

TIRZEPATIDE PHASE 2B DATA

POTENTIAL TO CHANGE THE WAY DIABETES IS TREATED

PHASE 2B DATA AT 26 WEEKS



Data presented are from logistic regression, on treatment analysis
† p<0.05 vs placebo and ‡ p<0.05 vs. dulaglutide 1.5 mg

- Over 40% of 15 mg dose patients achieved HbA1c of less than 5.7%, a mark of normal glucose level
- Nearly 90% of 10 and 15mg patients achieved HbA1c of less than 7%

TIRZEPATIDE SAFETY AND TOLERABILITY DATA

TIRZEPATIDE 5MG AND 10MG COMPARABLE SAFETY AND TOLERABILTY TO DULAGLUTIDE

PHASE 2B DATA AT 26 WEEKS

	Dulaglutide 1.5mg	Tirzepatide 5mg	Tirzepatide 10mg	Tirzepatide 15mg
Adverse Events (AE) (%)	74.1	72.7	78.4	84.9
Serious AEs (%)	5.6	1.8	5.9	3.8
Discontinued Treatment due to AE (%)	11.1	9.1	5.8	24.5
Nausea (%)	29.6	20.0	21.6	39.6
Diarrhea (%)	16.7	23.6	23.5	32.1
Vomiting (%)	9.3	7.3	15.7	26.4

- Nausea, vomiting, and diarrhea occurred early, were largely mild-to-moderate and transient
- Tirzepatide 5mg and 10mg discontinuation rates due to AE similar to dulaglutide
- Additional Phase 2 dosing study initiated to further explore approach to dose escalation

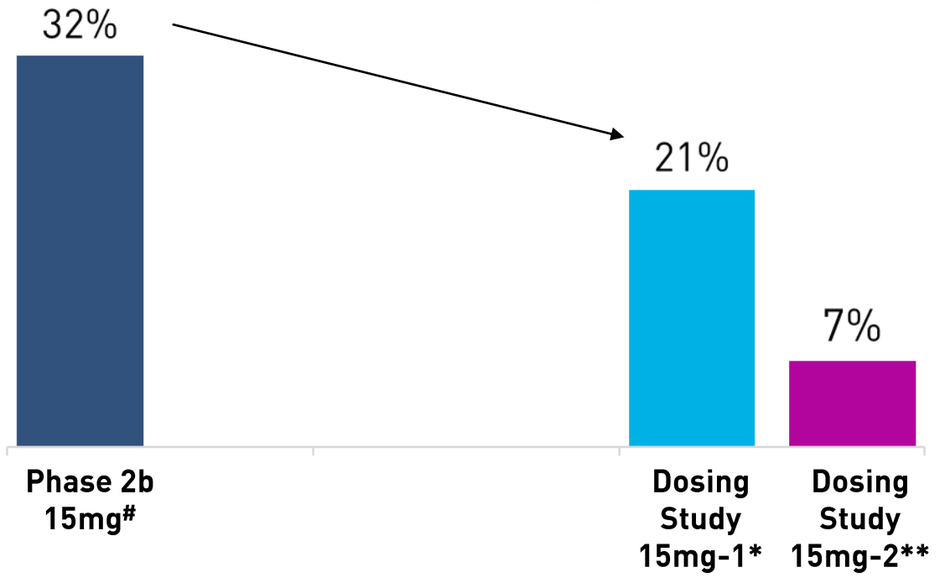
Study identifier NCT03131687
Frias al. Lancet 2018;392(10160):2180-2193

TIRZEPATIDE PHASE 2 DOSING STUDY

LOWER STARTING DOSE AND SLOWER ESCALATION IMPROVED TOLERABILITY

TREATMENT DISCONTINUATIONS

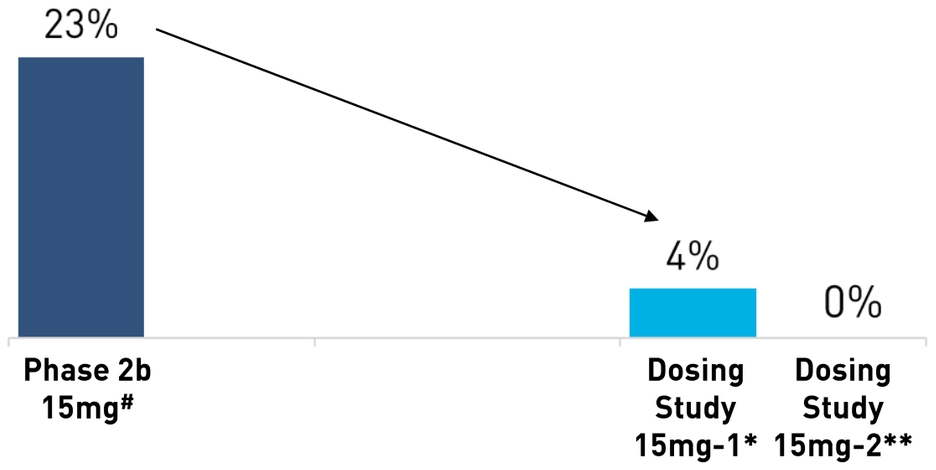
12 week data comparison



- Observed GI side effects were mild-to-moderate and less frequent than in Phase 2b study

DISCONTINUATION DUE TO AEs

12 week data comparison



- Comparable efficacy to Phase 2b trial, while demonstrating improved tolerability
- Discontinuation due to adverse events was below 4% in all three escalation schemes assessed

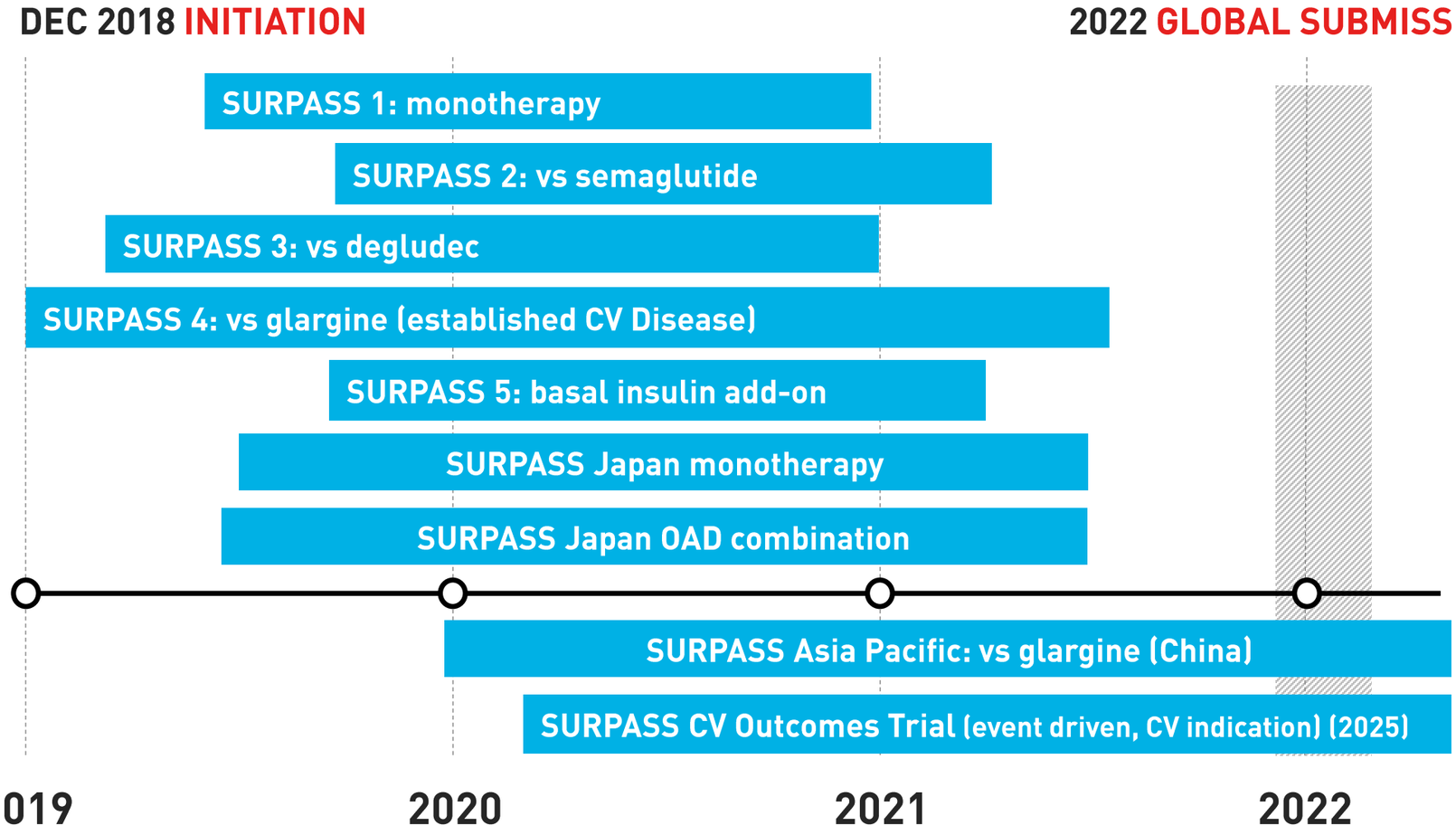
#15mg arm in the Phase 2b assessed escalating doses of 5mg (2 weeks), 10mg (2 weeks) and then 15mg (for rest of study duration)
*15mg-1 arm assessed escalating doses of 2.5mg (2 weeks), 5mg (2 weeks), 10mg (4 weeks) and 15mg (4 weeks)
**15mg-2 arm assessed escalating doses of 2.5mg (4 weeks), 7.5mg (4 weeks) and 15mg (4 weeks)
Diabetes, Obesity and Metabolism 2020 Jun;22(6):938-946. doi: 10.1111/dom.13979. Epub 2020 Feb 11
Study identifier: NCT03311724

AE = Adverse Event
GI = Gastrointestinal

SURPASS CLINICAL PROGRAM

DESIGNED TO DELIVER ROBUST DATASET WITH MULTIPLE HEAD-TO-HEAD TRIALS

SURPASS TYPE 2 DIABETES PROGRAM



OTHER INDICATIONS

2022

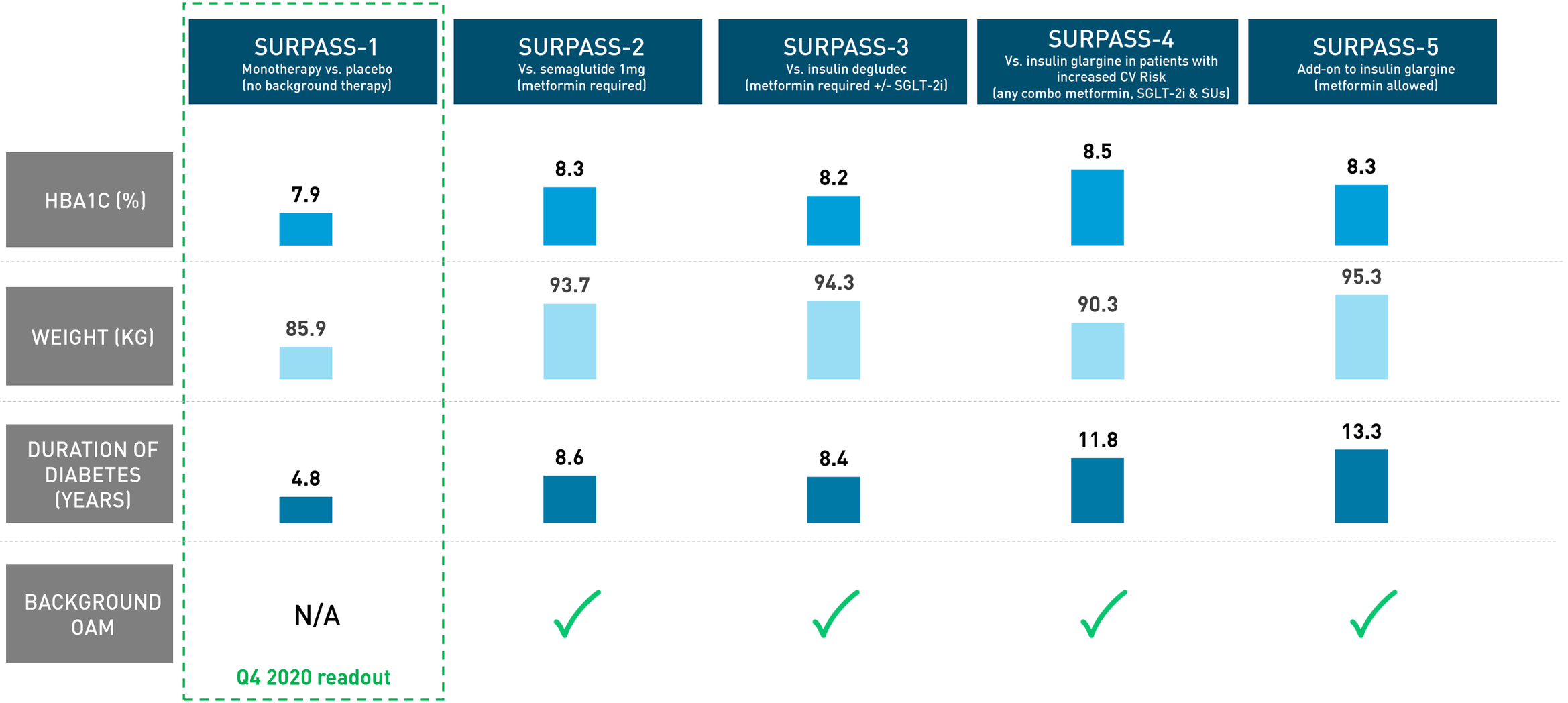
Obesity **Phase 3** – initial SURMOUNT readout

NASH **Phase 2** – SYNERGY-NASH readout

SURPASS IN CONTEXT

SURPASS KEY BASELINE CHARACTERISTICS

THERE IS A RANGE OF BASELINE CHARACTERISTICS ACROSS SURPASS TRIALS



Note: Baseline has not been fully validated, as database lock has not occurred

SU = Sulphonylureas
SGLT2i = Sodium-glucose Cotransporter-2 inhibitors
OAM = Oral Antidiabetic Medication

SURPASS PROGRAM INDIRECT TRIAL COMPARISONS

BACKGROUND THERAPY, COMPARATOR AND PATIENT POPULATIONS IMPORTANT TO CONSIDER

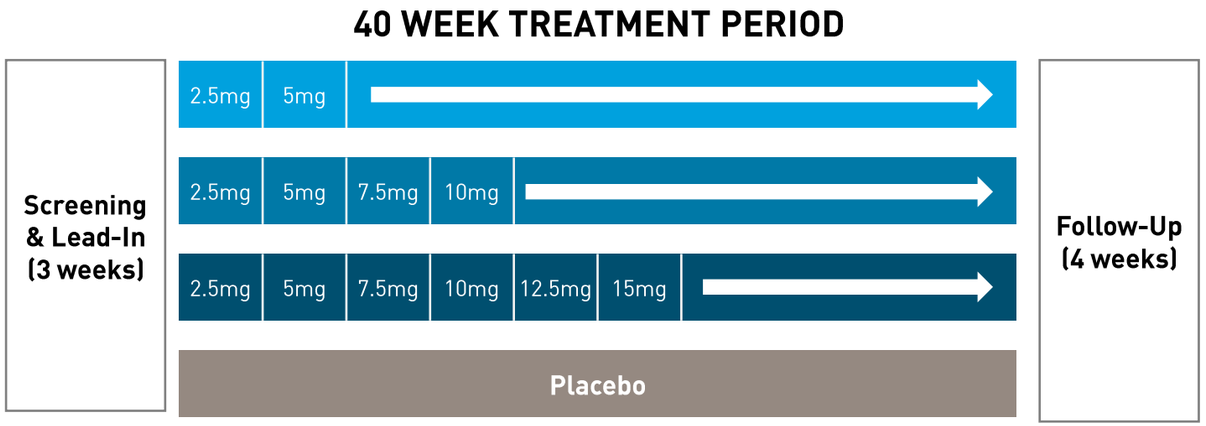
TIRZEPATIDE TRIALS	"MOST COMPARABLE" SEMAGLUTIDE TRIAL*	KEY LIMITATIONS
SURPASS-1 Monotherapy vs. placebo (no background therapy) 40 weeks	**SUSTAIN-1** Monotherapy vs. placebo (no background therapy) 30 weeks	
SURPASS-2 Vs. semaglutide 1mg (metformin required) 40 weeks	▪ SURPASS-2 is head-to-head study, which is gold standard of comparing agents	
SURPASS-3 Vs. insulin degludec (metformin required + /- SGLT-2i) 52 weeks	**SUSTAIN-4** Vs. insulin glargine (metformin and SUs allowed) 30 weeks	▪ SUSTAIN-4 insulin glargine as comparator ▪ SURPASS-3 insulin degludec as comparator
SURPASS-4 Vs. insulin glargine in patients with increased CV Risk (any combo of metformin, SGLT-2i & SUs allowed) 52 weeks	**SUSTAIN-4** Vs. insulin glargine (metformin and SUs allowed) 30 weeks	▪ SUSTAIN-4 did not include a population with increased CV risk
SURPASS-5 Add-on to insulin glargine (metformin allowed) 40 weeks	**SUSTAIN-5** Add-on to basal insulin (metformin allowed) 30 weeks	▪ SUSTAIN-5 allowed insulin glargine, insulin detemir, insulin degludec and/or NPH insulin ▪ SURPASS-5 specified insulin glargine

*Framework to provide context. Cross-trial comparison subject to limitations.
SU = Sulphonylureas
SGLT2i = Sodium-glucose Cotransporter-2 inhibitors

SURPASS-1 TRIAL OVERVIEW

TIRZEPATIDE IN PATIENTS WITH TYPE 2 DIABETES VERSUS PLACEBO

TRIAL DESIGN



- Tirzepatide patients begin on 2.5mg dose, increasing every 4 weeks until reaching target dose
- Results will be analyzed using the efficacy estimand[1] and treatment regimen estimand[2]

INCLUSION CRITERIA

- Naïve of injectable therapy and have not used any oral antidiabetic medications within 3 months
- HbA1c ≥7.0% to ≤9.5%
- BMI ≥23 kg/m^2 with stable weight

[1]Efficacy estimand represents efficacy prior to discontinuation of study drug or initiating rescue therapy for persistent severe hyperglycemia
[2]Treatment regimen estimand represents the efficacy irrespective of adherence to investigational product or introduction of rescue therapy for persistent severe hyperglycemia

INDIRECT TRIAL COMPARISONS

SUSTAIN-1 MOST RELEVANT SEMAGLUTDIE INDIRECT TRIAL COMPARISON TO SURPASS-1

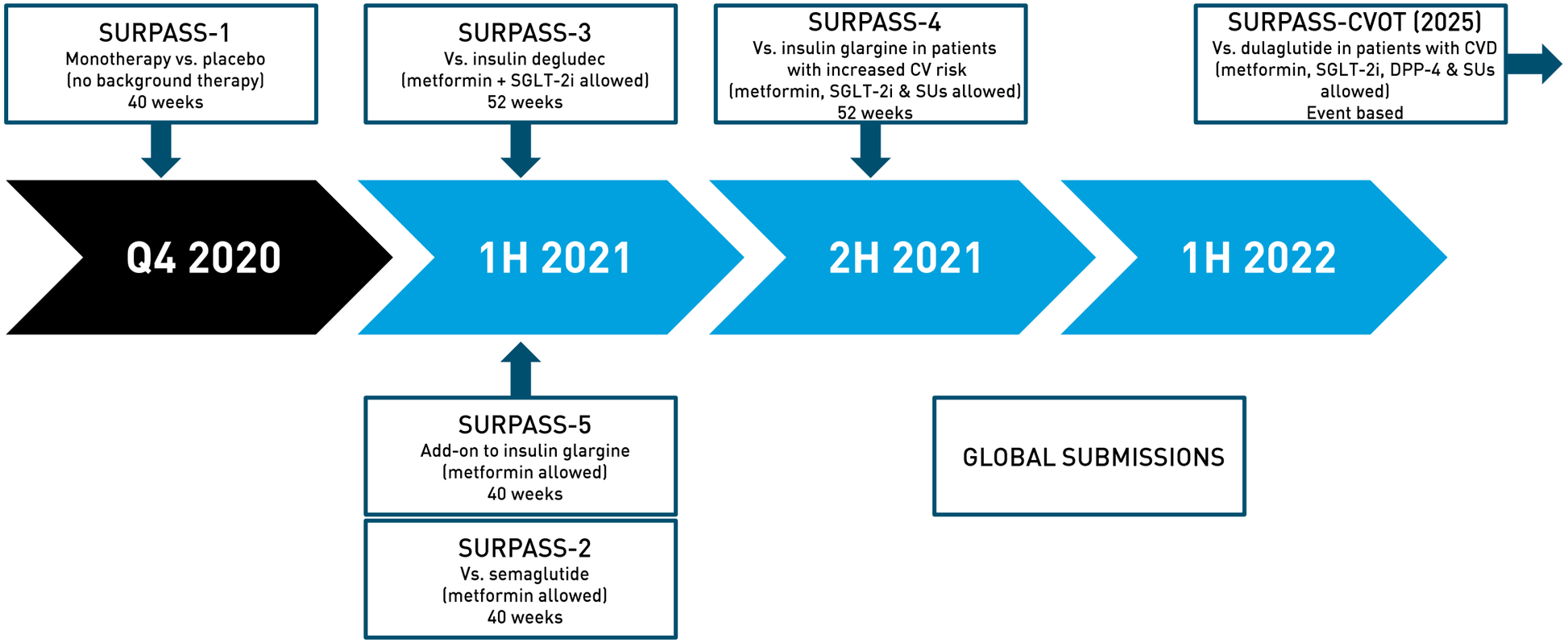
	TIRZEPATIDE PHASE 2B*	SURPASS-1	SUSTAIN-1**
Investigational Agent / Comparison	Tirzepatide / Dulaglutide / Placebo	Tirzepatide / Placebo	Semaglutide / Placebo
Primary Endpoint	Δ baseline HbA1c at 26 weeks	Δ baseline HbA1c at 40 weeks	Δ baseline HbA1c at 30 weeks
Sample Size	318	478	387
Doses Studied	1mg, 5mg, 10mg & 15mg	5mg, 10mg & 15mg	0.5mg & 1mg
Duration of Diabetes (years)	8.5 years	4.8 years	4.2 years
Baseline HbA1c (%)	8.1%	7.9%	8.1%
Background Therapy	Metformin	None	None
BMI Inclusion Criteria (kg/m^2)	23-50	≥23	No BMI criteria
Baseline BMI (kg/m^2)	32.6	31.9	32.9
Baseline Weight (kg)	91.5	85.9	91.9

Note: Baseline data for SURPASS-1 has not been fully validated, as database lock has not occurred. Cross-trial comparison subject to limitations

* Frias al. Lancet 2018;392(10160):2180-2193

** Sorli al. Lancet 2017 Apr;5(4):251-260

ROBUST PHASE 3 DIABETES PROGRAM



PROGRAM EXPECTATIONS: Replicate HbA1c reduction and weight loss seen in tirzepatide Phase 2 trials, with tolerability that is similar to GLP-1 therapies

SU = Sulphonylureas
SGLT2i = Sodium-glucose Cotransporter-2 inhibitors
CVD = Cardiovascular Disease

NEXT STEPS

NEXT STEPS

SURPASS-1

- On track for topline results by the middle of December
- Topline disclosure will include key efficacy and safety data with aim to characterize results while balancing disclosure plans
- Study discontinuation rate across program has not been impacted by COVID-19

ADDITIONAL DATA READ OUTS

- Additional topline data readouts expected in 1H 2021, with detailed data presentations at major medical meetings in 2021 and 2022
- Global submissions for type 2 diabetes contingent on CV events in SURPASS-4, anticipate late 2021/early 2022 submission
- Initial Phase 3 obesity data and Phase 2 NASH data expected in 2022

KEY TAKEAWAYS

We remain excited about and confident in tirzepatide
Results from the placebo-controlled monotherapy trial, SURPASS-1 will read out by the middle of December

SURPASS development program will generate a robust dataset to characterize the clinical profile of tirzepatide in type 2 diabetes patients
SURPASS-1 is the first trial to read out from the global registration program

We expect to establish a new bar for HbA1c reduction and weight loss, with GLP-1 tolerability
Simple and step-wise dose escalation expected to produce tolerability profile similar to GLP-1s

QUESTIONS AND ANSWERS