Therapeutics

vTv Therapeutics (VTVT)

June 2019

NASDAQ: VTVT

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Unwavering Commitment to Science, Patients and Families

Clinical stage pipeline of novel small molecule drug candidates targeting significant unmet medical needs: **Diabetes and Alzheimer's disease**

Positive phase 2 results in **type 2 diabetes (T2D)** with two novel oral candidates

Ongoing phase 2 study in **type 1 diabetes (T1D)** with TTP399 with **positive Part 1 readout**

Topline results from Part 2 expected in **Q1 2020**

Conducting start-up activities for a clinical trial in subjects with **mild Alzheimer's disease and type 2 diabetes** that consists of sequential phase 2 and phase 3 studies operationally conducted under a single protocol

Screening expected to begin for phase 2 in **June 2019**

Significant, long-term financial sponsor in MacAndrews and Forbes

Distinguished Management Team

Steve Holcombe, B.Sc.
President, Chief Executive Officer

Jeff Kindler, J.D.
Executive Chairman

Rudy Howard, B.A., C.P.A.
Executive Vice President, Chief Financial Officer

Rob Andrews, Ph.D.
Senior Vice President, Chemistry

Robin Abrams, J.D.
Executive Vice President, General Counsel

Imogene Dunn, Ph.D.
Senior Vice President, Biometrics and Regulatory

Carmen Valcarce, Ph.D.
Executive Vice President, Chief Scientific Officer

Sam Rollins, Ph.D., J.D.
Senior Vice President, Intellectual Property

Aaron Burstein, Pharm.D.
Senior Vice President, Clinical Development

Robust Pipeline of Novel Product Candidates

PROGRAM	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	PARTNER
Azeliragon (RAGE)	Alzheimer's Disease					
TTP399 (GKA)	Type 1 Diabetes					
TTP399 (GKA)	Type 2 Diabetes					
TTP273 (Oral GLP-1r)	Type 2 Diabetes					华东医药 HUADONG MEDICINE Asia
HPP593 (PPAR-δ)	Mitochondrial Diseases					Reneo Worldwide
HPP737 (PDE4i)	COPD					NEWSOARA 恒翼生物医药 Asia
Nrf2/Bach1 Program	Undisclosed					

Delivering on Milestones

2015

- ✓ IPO raised $117M with following goals:
  - Conduct phase 3 studies in AD
  - Conduct 2 phase 2 studies in T2D
  - Out-license certain pipeline programs

2016

- ✓ **Reported positive TTP399 phase 2 6-month study in T2D**
- ✓ Reported positive TTP273 phase 2 3-month study in T2D

2017

- ✓ Partnered with JDRF on TTP399 in T1D
- ✓ Out-licensed PPARd program to Reneo Pharmaceuticals
- ✓ Out-Licensed Pacific Rim rights for GLP-1R program to Huadong Medicine

2018

- ✓ Initiated phase 2 study of TTP399 in T1D
- ✓ Reported azeliragon phase 3 studies in AD
- ✓ Out-licensed Pacific Rim rights for PDE4 program to Newsoara Biopharma

2019

- ✓ Initiated Part 2 of TTP399 phase 2 T1D study
- ✓ **Reported positive results from Part 1 of TTP399 phase 2 T1D study in June 2019**
- ○ **Initiate phase 2 clinical trial with azeliragon in subjects with mild AD and T2D***

2020

- ○ Report results from Part 2 of TTP399 phase 2 T1D study*
- ○ Report results from phase 2 trial with azeliragon in subjects with mild AD and T2D*

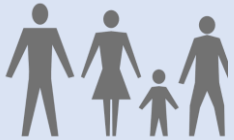
*ongoing /planned

Type 1 Diabetes Program

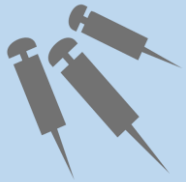
TTP399
Liver-Selective Glucokinase Activator (GKA)

Limited Treatment Options for a Significant Patient Population

T1D is an autoimmune disease in which the pancreas stops producing insulin, the hormone that controls blood-sugar levels (1)



Estimated **30 million** people suffer from T1D globally in 2017 (1)



Insulin is the current standard of care administered by multiple **daily injections** or **insulin pumps**

No FDA-approved oral therapies in the US that improve glycemic control in T1D. **SGLT-i recently approved in EU for T1D <u>with label limitations</u>**:

- Approved for T1D patients only with BMI ≥27
- Treatments increase risk of DKA, genital infections and amputations

(1) IDF DIABETES ATLAS 8th edition 2017

Need for Treatments that Improve Disease Management in T1D

"FDA recognizes there is an unmet need for patients with T1DM to help achieve glycemic goals and improve quality of life and treatment satisfaction"(1)

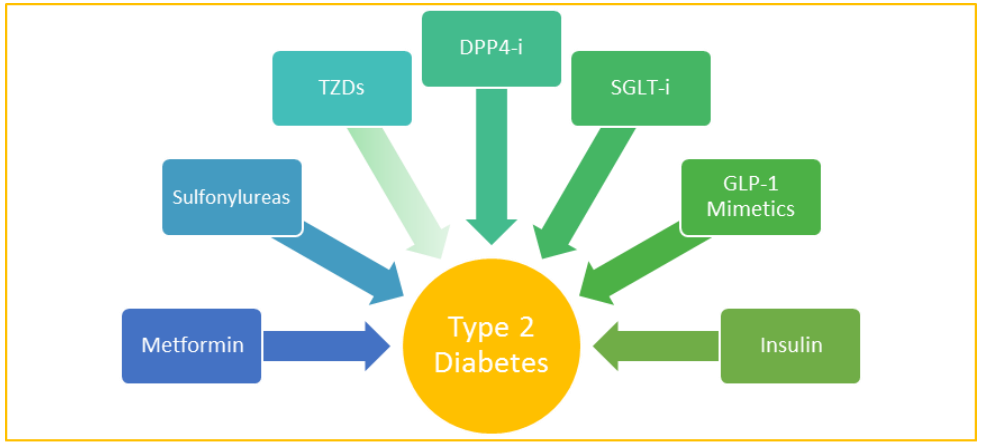
Goals for new therapies for treatment of T1D:

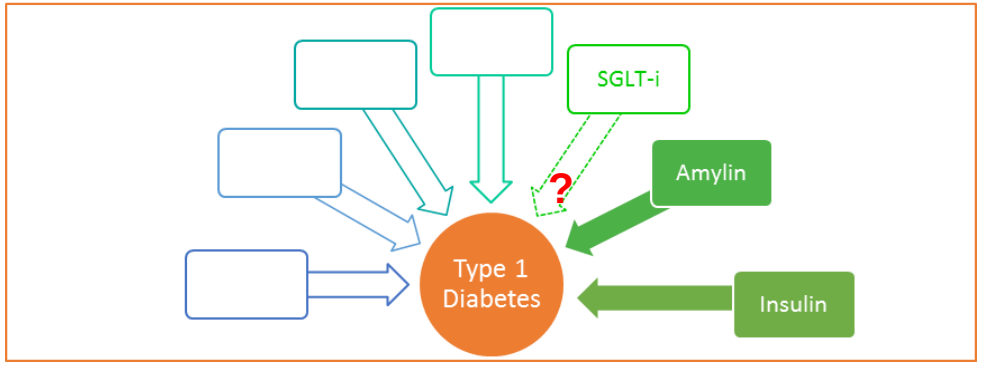
- Reduce A1C to ease achievement of target goals
- Improve time-in-glycemic range
- Reduce insulin dependence
- Reduce "highs" and "lows"
- Improve overall quality of life
- Oral treatment

❑ …while not increasing risks of:

- Weight gain
- Hypoglycemia
- Diabetic ketoacidosis ("DKA")

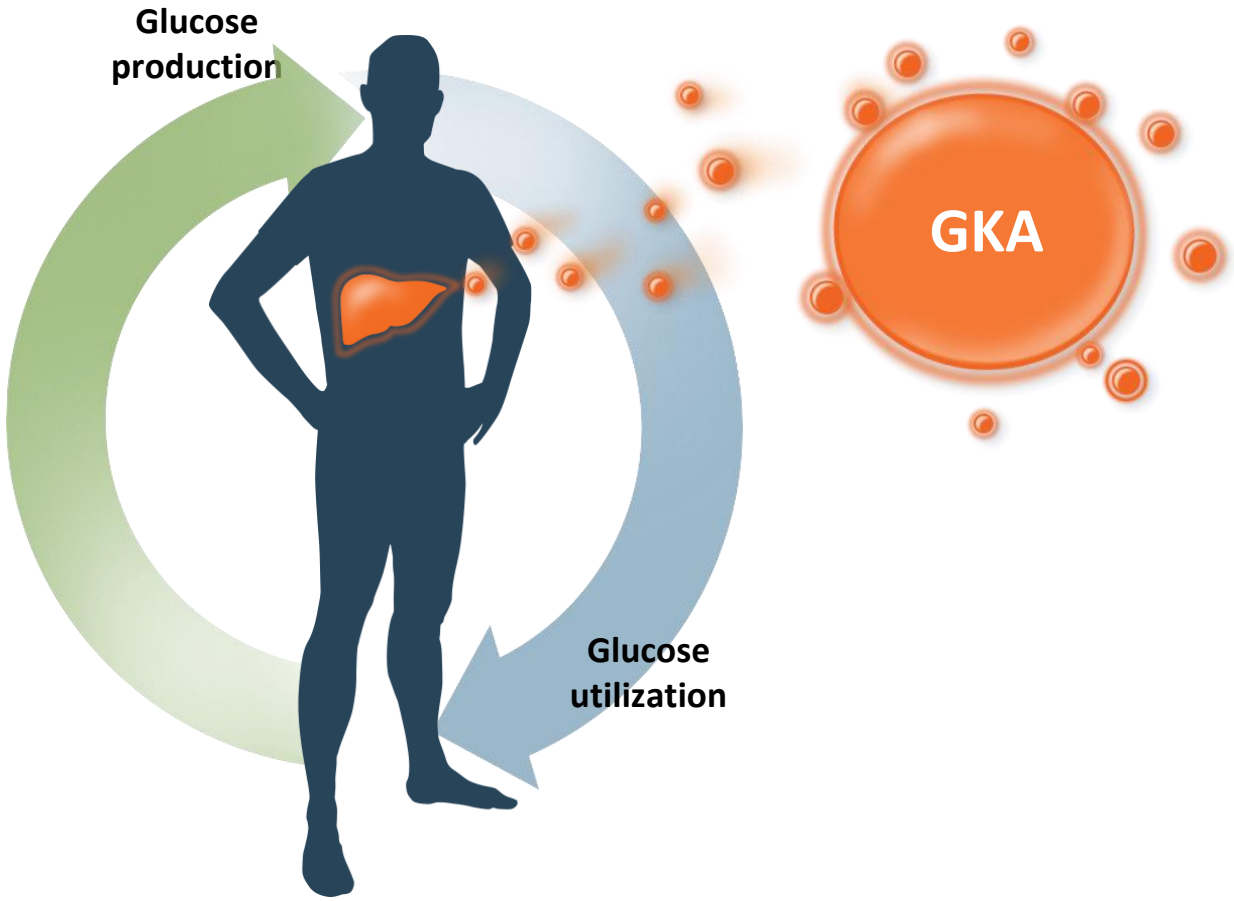
Approved Therapies for the Treatment of Diabetes in USA





(1) FDA Briefing Document, Endocrinologic and Metabolic Drugs Advisory Committee Meeting, January 17, 2019

Targeting Hepatic Glucokinase for the Treatment of Diabetes



Activating GK in the **liver restores the balance between glucose production and glucose utilization** by controlling glucose metabolism and gene expression of glucose dependent genes involved in:

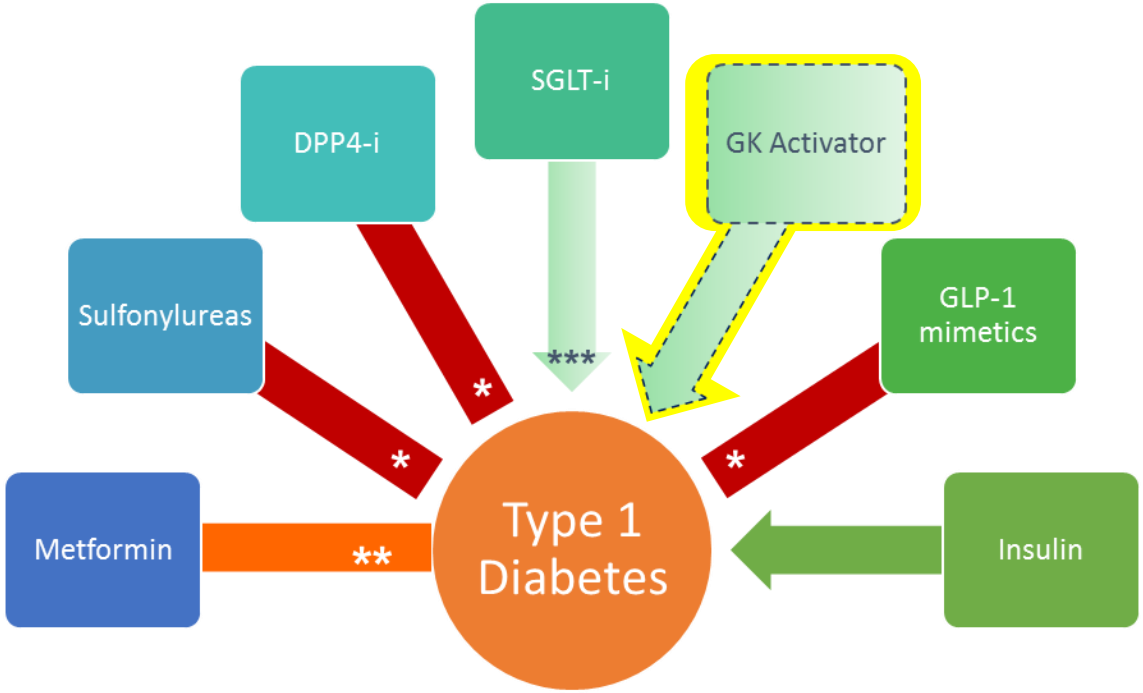
- ❑ **Glycolysis**
- ❑ **Gluconeogenesis**
- ❑ **Lipogenesis**
- ❑ **Ketogenesis**

Strong genetic validation of the target. GK is the **glucose-sensor** of the body.

TTP399: A Novel Hepato-selective GK Activator Being Developed for the Treatment Of Diabetes

Why Would TTP399 Work in Type 1 Diabetes?

- People with **type 1** diabetes have **lower GK activity**
- The mechanism of action of TTP399 **does not require increased insulin secretion**
- **Increasing glucose utilization** by the liver will **reduce** production of **ketone bodies**



* MoA **dependent on insulin secretion;** limited effect in T1D
** No effect on T1D
***Limited effect, with increase in DKA risk

Diabetes Care 2019 Jan; 42(Supplement 1): S90-S92.
https://doi.org/10.2337/dc19-S009

TTP399-203 (Simplici-T_1): Adaptive Phase 1b/2 Study Trial Design

In Collaboration with JDRF

Phase 1
(Sentinels)

Study Design:

- Open-label
- **7 day** dose escalation up to 1200mg QD
- **5** adult subjects with T1D on CSII and CGM

March 2018

TTP399 was well tolerated

- **No** incidents of **severe hypoglycemia or DKA**
- Indications of **improved glycemic control, while reducing insulin dose**
  - Increase % time in range
  - Reduce % time in hyperglycemia without increasing % time in hypoglycemia

Phase 2-Part 1
(Learning Phase)

Study Design:

- Double-blind Placebo control
- **12 weeks** dosing 800mg QD
- **~20** adult subjects with T1D on CSII and CGM
- **Primary Endpoint:** change in HbA1c

June 2019

Positive Results Reported June 2019

Phase 2-Part 2
(Confirming Phase)

Study Design:

- Double-blind Placebo control
- **12 weeks** dosing 800mg QD
- **~90** adult subjects with T1D (all comers)
- **Primary Endpoint:** change in HbA1c

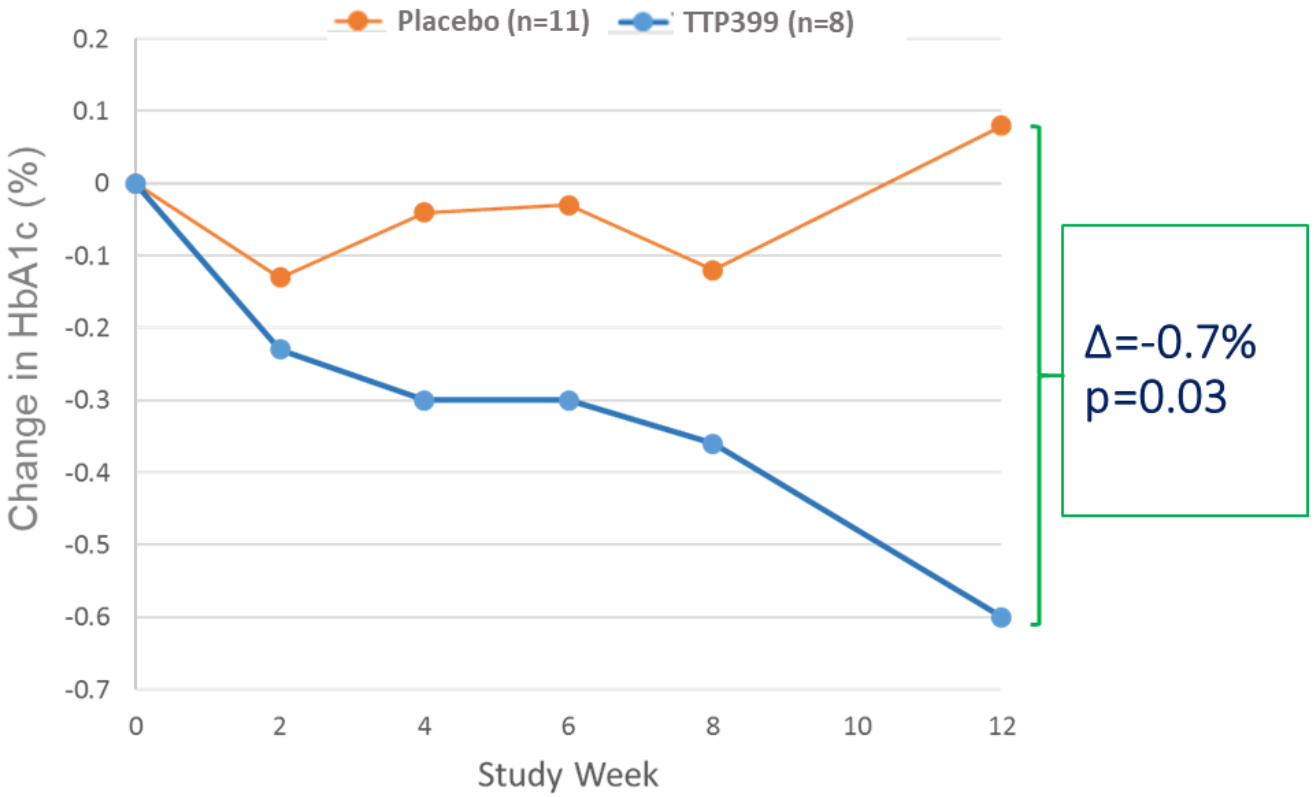
Q1 2020

Results expected in Q1 2020

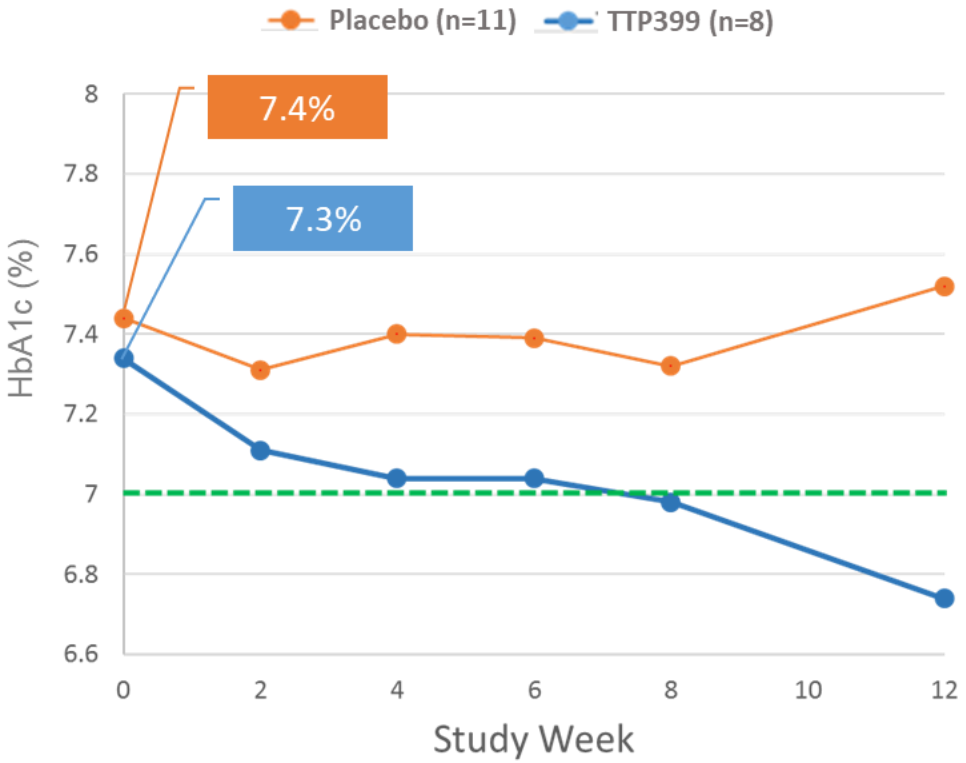
1. ClinicalTrials.gov Identifier: NCT03335371
2. Subjects with Continuous Subcutaneous Insulin Infusion (CSII) and Continuous Glucose Monitoring (CGM)

Simplici-T1 Part 1: Statistically Significant Reduction in HbA1c

Change in HbA1c



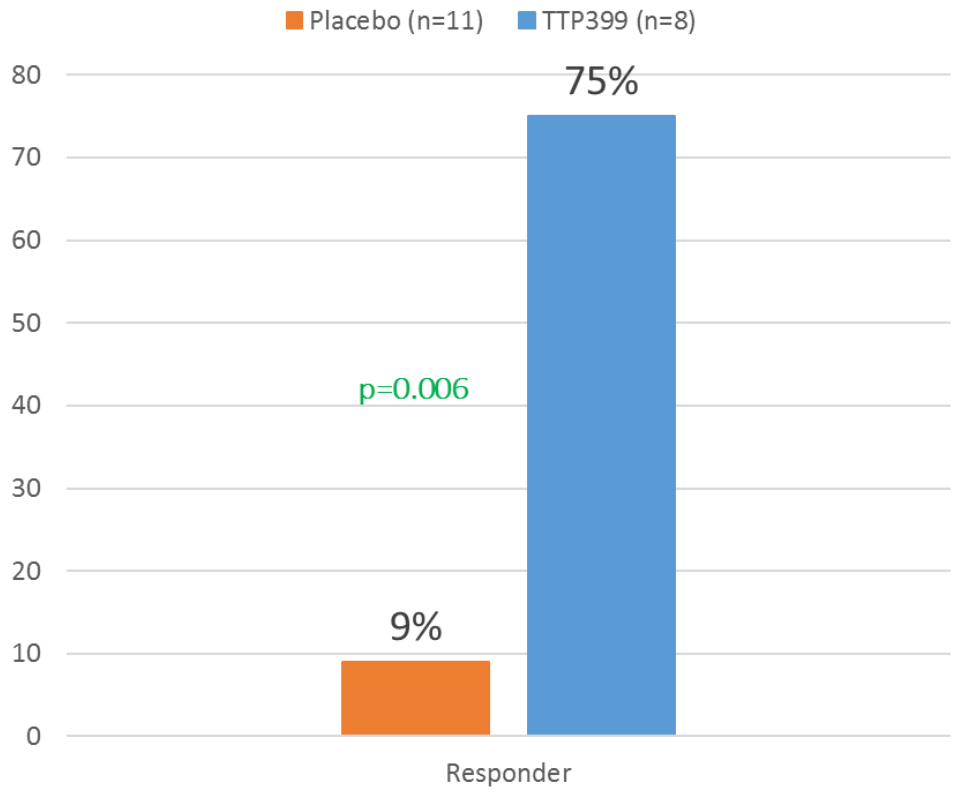
HbA1c



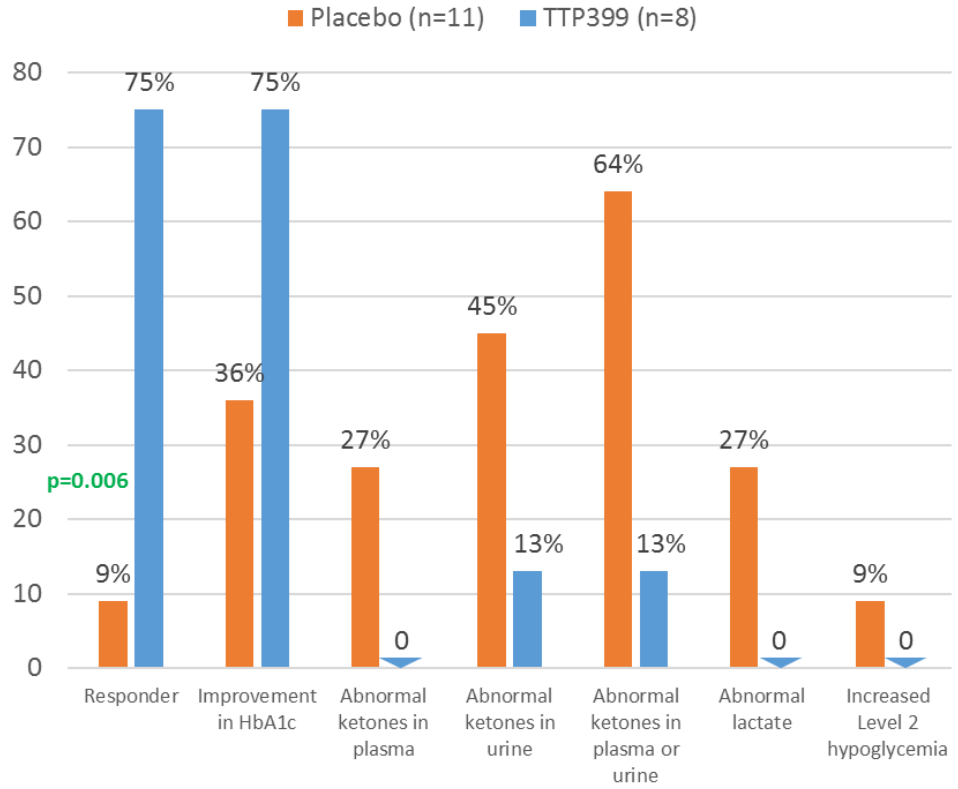
simplici-T1

Simplici-T_1 Part 1: Reduction HbA1c **without** Increases in Abnormal Ketones or Hypoglycemia

Responder Analysis



Responder Analysis and Individual Criteria



Responder definition:

Proportions of subjects with: improvement in HbA1c and without predefined risks:

- Abnormal ketones in urine or plasma
- Abnormal lactate in plasma
- Increase in time in level 2 hypoglycemia (glucose <54 mg/dl)

Safety:

- No SAEs
- No reported hypoglycemia
- No Diabetic Ketoacidosis (DKA)
- Similar profiles for reported TEAEs between TTP399 and placebo

Competitive Landscape in T1D

Product	MOA	Efficacy	Safety	T1D Status
ZYNQUISTA (sotagliflozin) *Sanofi & Lexicon*	SGLT1/SGLT2 Inhibitor	**0.36 to 0.41% A1c reduction** (pbo subtracted) in 24 week phase 3 studies (baseline A1c 8.2%-8.3%)*	DKA Adverse events (% of subjects): **3.4 – 3.8% active** **vs** **0 – 0.4% placebo***	• FDA did not approve NDA in current form in Mar 2019 • FDA Advisory Committee did not recommend due to risk/benefit assessment in Jan 2019 (1) • EU approved with limitation in use to patients with BMI ≥ 27
FARXIGA (dapagliflozin) *AstraZeneca*	SGLT2 inhibitor	**0.37% to 0.42% A1c reduction** (pbo subtracted) in 24 week phase 3 studies (baseline A1c 8.53%) **	DKA Adverse events (% of subjects): **1% to 2%** **vs** **1% placebo****	• US NDA submission complete • EU approved with limitation in use to patients with BMI ≥ 27
JARDIANCE (empagliflozin) *Lilly & BI*	SGLT2 inhibitor	**0.28% to 0.54% A1c reduction** (pbo subtracted) in 24 week phase 3 studies ***	DKA Adverse events (% of subjects): **0.8% to 4.3%** **vs** **1.2% placebo*****	• Two Phase 3 trials completed

*Diabetes Care. 2018 Sep;41(9):1970-1980. doi: 10.2337/dc18-0343 and Diabetes Care. 2018 Sep;41(9):1981-1990. doi: 10.2337/dc18-0342
**The Lancet 2017; 5:864-876 https://doi.org/10.1016/S2213-8587(17)30308-X
***Diabetes Care 2018 Oct; dc181749. https://doi.org/10.2337/dc18-1749

(1) FDA Briefing Document, Endocrinologic and Metabolic Drugs Advisory Committee Meeting, January 17, 2019

TTP399 Positioned as a Next Generation Treatment for T1D

Next Milestone

Part 2 of the 12-week phase 2 Simplici-T_1 study is ongoing with expected **read out in Q1 2020**

Market Opportunity

Estimated **30 million** people suffer from T1D globally(1)

Clinical Evidence

Evidence from 12 clinical studies conducted to date point to a **benefit of TTP399** in patients with T1D or T2D in both **glycemic control** and **safety profile**

Underserved Population

Insulin is the current standard of care with **risks of DKA, hypoglycemia and weight gain**

(1) IDF DIABETES ATLAS 8th edition 2017

Alzheimer's Disease Program

AZELIRAGON

Antagonist of RAGE (Receptor for Advanced Glycation Endproducts)

Targeting RAGE with Azeliragon

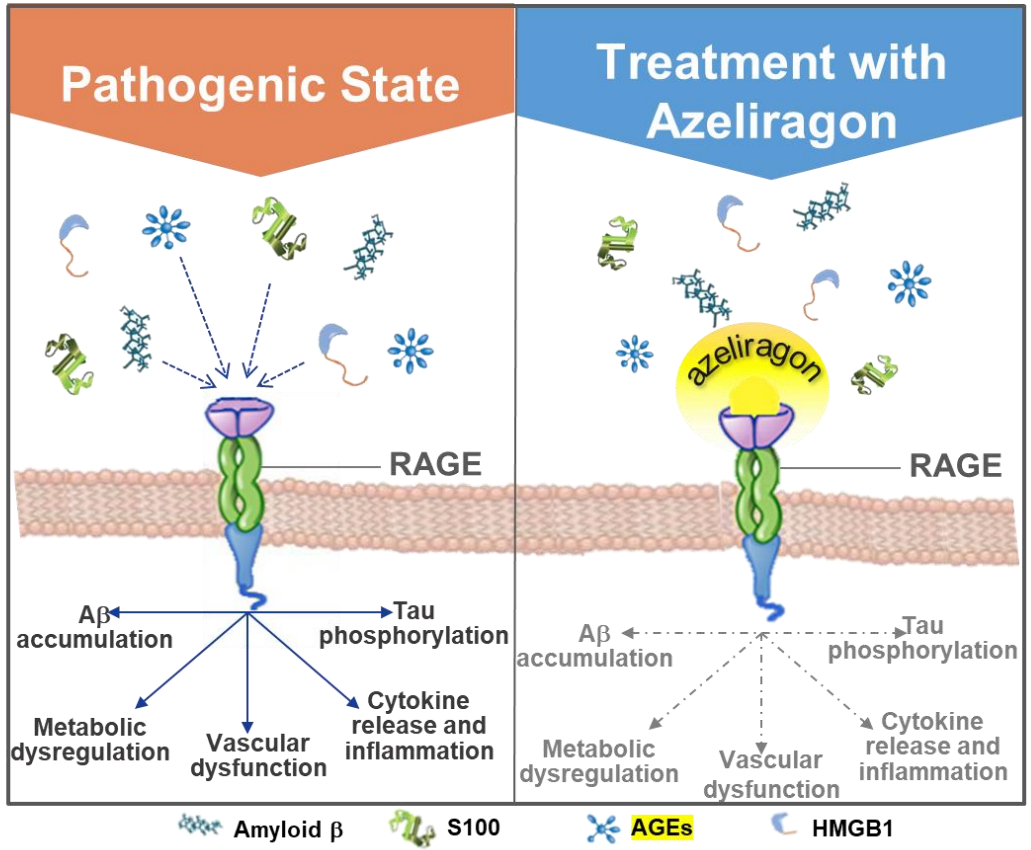
RAGE

- Receptor for Advanced Glycation Endproducts (RAGE) is expressed at low levels in healthy tissues (except skin and mucus membranes)
- **Increases** in the concentration of **RAGE ligands** (**AGEs**, HMGB1, S100 and Ab) **induce RAGE expression**
- **The interaction of AGEs (or other ligands) with RAGE** leads to sustained **cellular damage and inflammation**

RAGE in Alzheimer's Disease and Diabetes

- RAGE protein is increased in autopsied AD brains compared to controls with no AD[(1)]
- Increases in RAGE protein and percentage of RAGE-expressing microglia parallel the severity of disease[(1)]
- Patients with AD and diabetes show **increased hippocampal immuno-staining for RAGE protein**[(2)]
- **AGE** accumulation parallels the development of **cognitive impairment and dementia in individuals with diabetes**[(3)]

Azeliragon antagonizes RAGE, blocking ligands from binding to the receptor

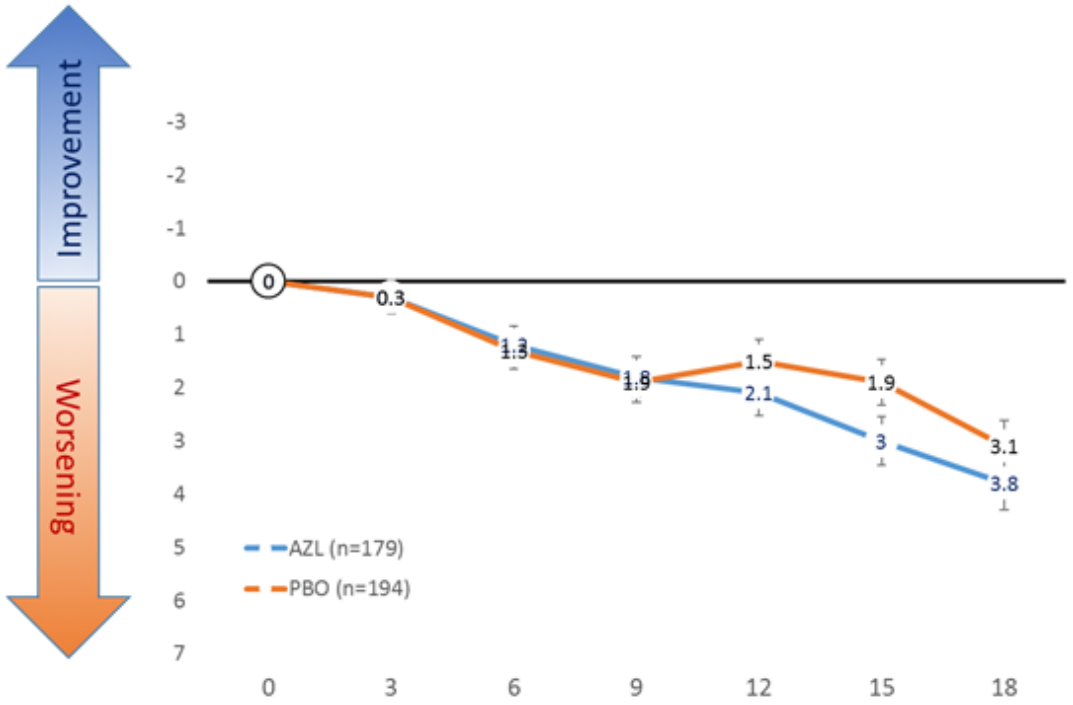


(1) Lue L-F. Curr.Drug Targets CNS Neurol.Disord. 2005 Jun;4 (3):249-66 . (2)Valente T. Neurobiology of Disease 37 (2010) 67–76. (3) Dhananjayan et al. (2018) Advance Glycation, Diabetes and Dementia https://doi.org/10.1016/B978-0-12-809454-9.00009-3

Potential Beneficial Effect on Cognition in Patients with Elevated HbA1c

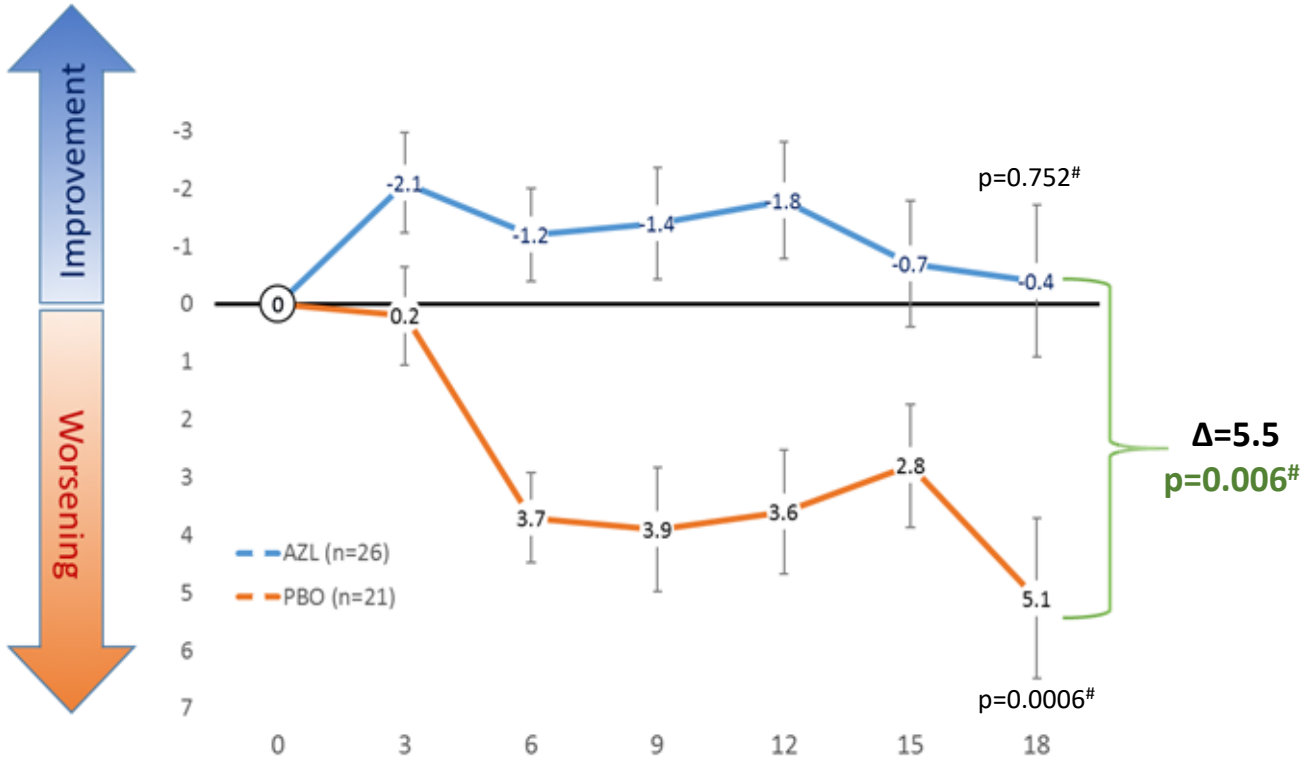
STEADFAST A-Study (FAS)

Change from Baseline in ADAS-cog11 (LSMEANS)



STEADFAST A-Study ADA-T2D Subgroup (FAS)

Change from Baseline in ADAS-cog11 (LSMEANS)



- Cognitive improvement cannot be explained by improvement in glycemic control

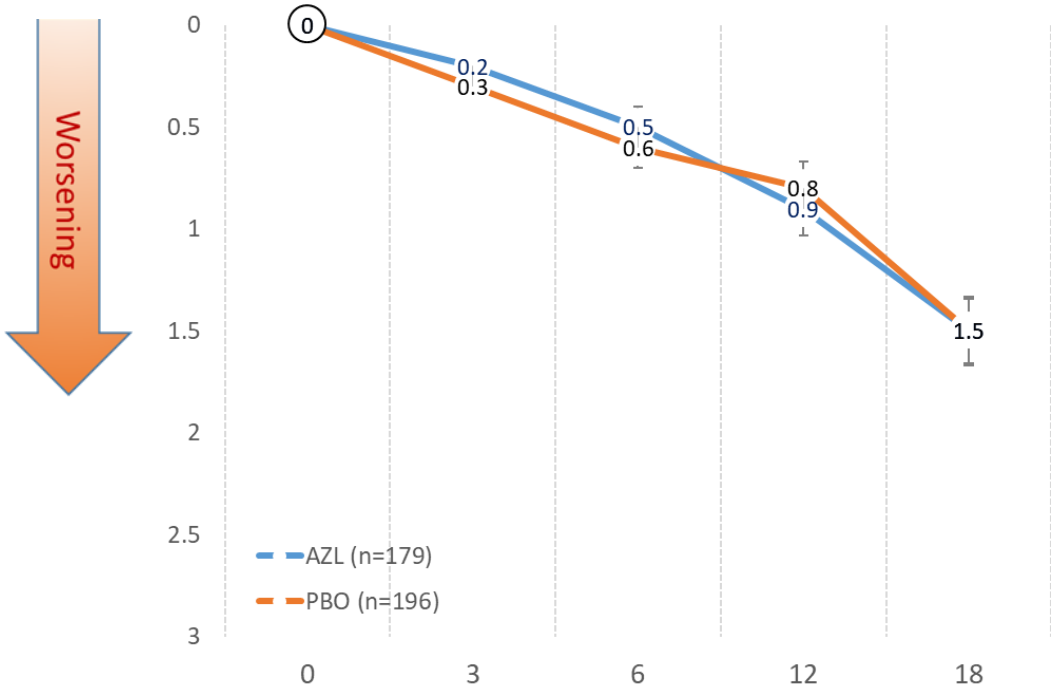
Analysis of Patients with Diabetes (HbA1c ≥ 6.5% at anytime during the study)
Results are LSMeans ± SE based on MMRM model.
All p values are nominal. FAS =Full Analysis Set

Data presented on March 30, 2019 at the 14th International Conference on Alzheimer's & Parkinson's Diseases held in Lisbon, Portugal

Potential Beneficial Effect on Function in Patients with Elevated HbA1c

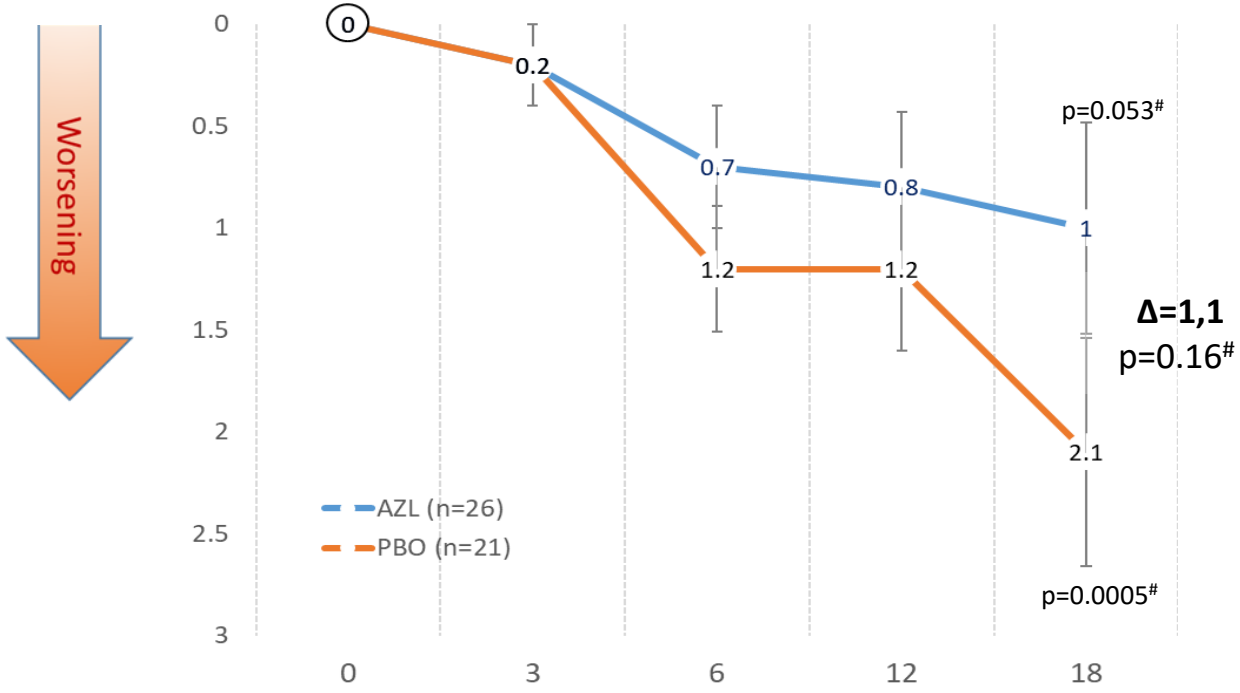
STEADFAST A-Study (FAS)

Change from Baseline in CDR-SB



STEADFAST A-Study ADA-T2D Subgroup (FAS)

Change from Baseline in CDR-SB



- Functional improvement cannot be explained by improvement in glycemic control

Analysis of Patients with Diabetes (HbA1c ≥ 6.5% at anytime during the study)
Results are LSMeans ± SE based on MMRM model.
***All p values are nominal**. FAS =Full Analysis Set

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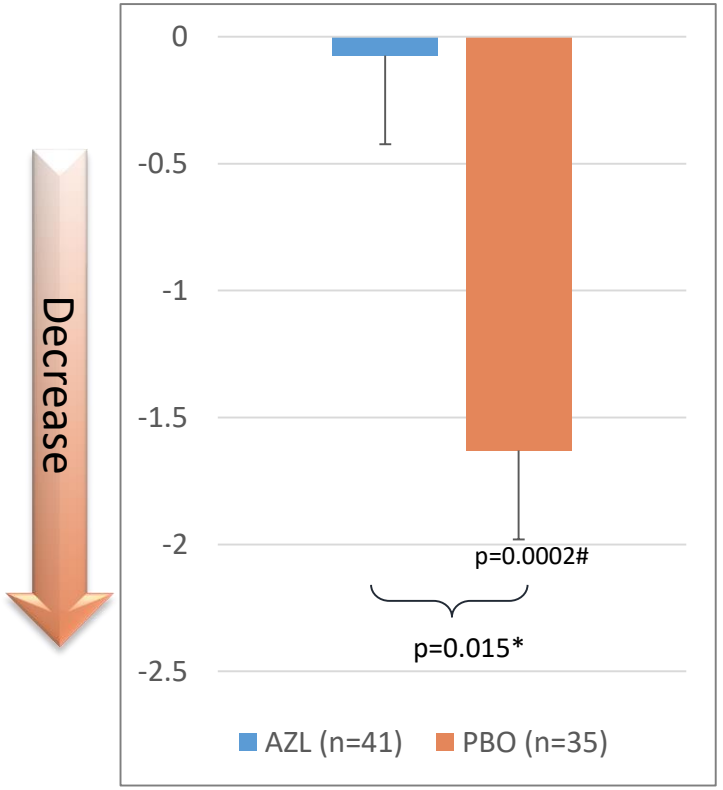
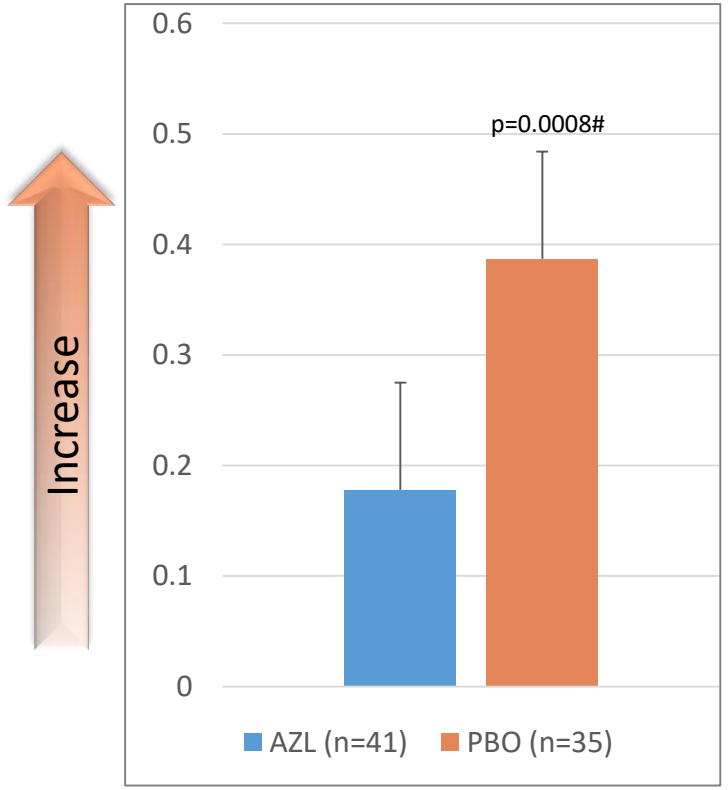
Change in MRI Brain Volume at Month 18 in the Diabetes Subgroup: Less Brain Atrophy in the AZL-treated Group

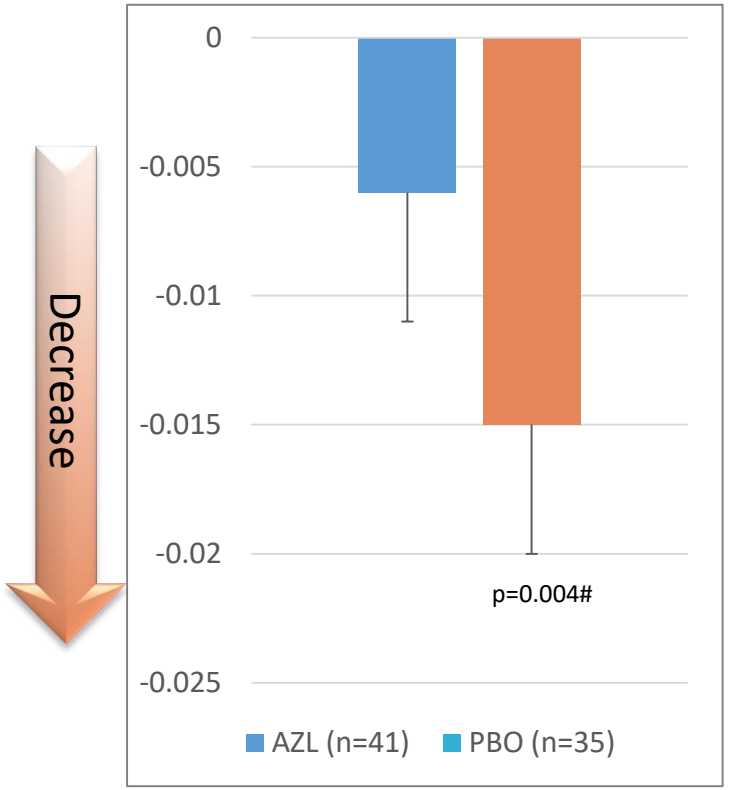
ADA-T2D Subgroup
Change in Whole Brain Volume (%)



ADA-T2D Subgroup
Ventricular Enlargement (%)



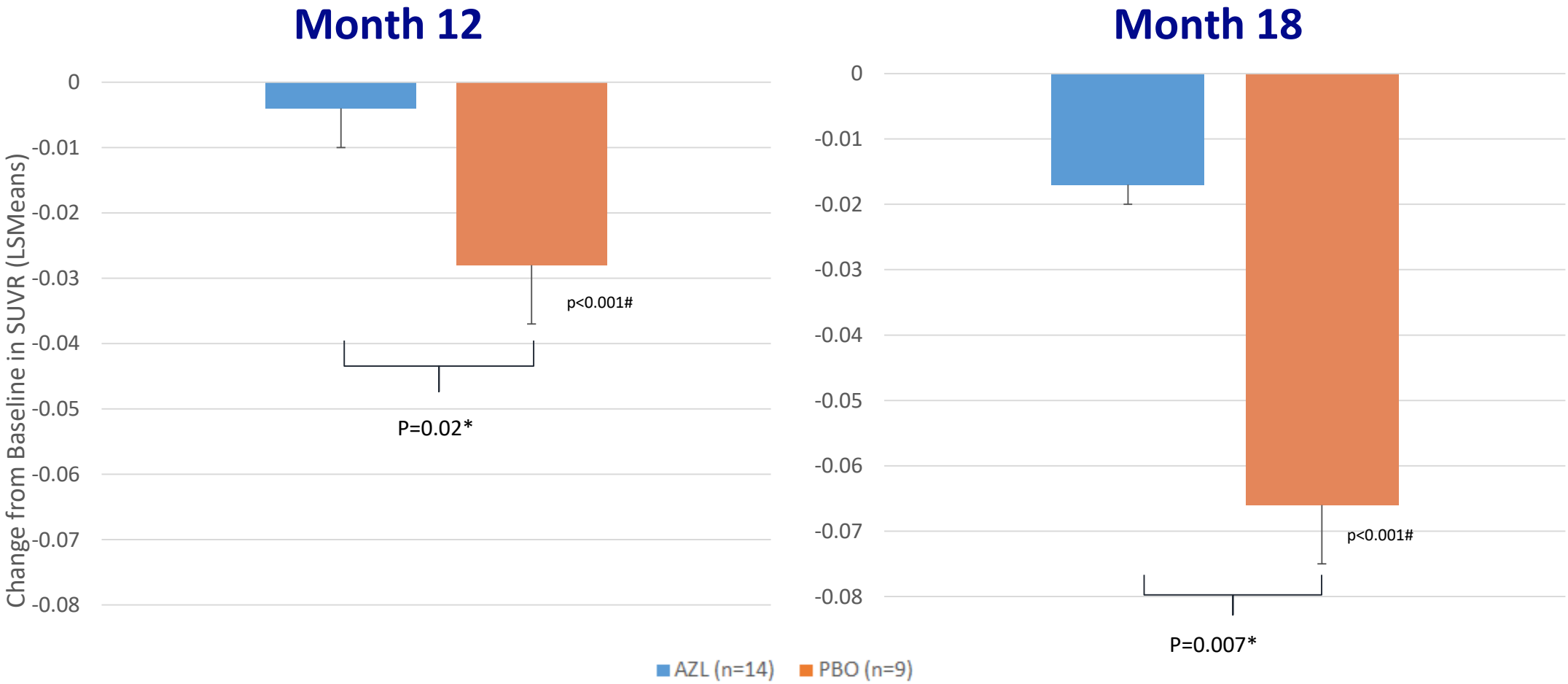
ADA-T2D Subgroup
Change in Total Hippocampus Volume (%)



Analysis of Patients with Diabetes (HbA1c ≥ 6.5% at anytime during the study). **Results are change from baseline LSMeans ± SE ANCOVA adjusted for baseline, FAS. #1-sample test nominal significance indicating worsening. ***All p values are nominal**

Data presented on March 30, 2019 at the 14th International Conference on Alzheimer's & Parkinson's Diseases held in Lisbon, Portugal

Change in FDG-PET SUVR in the Diabetes Subgroup: Less Reduction in Glucose Utilization in AZL-treated Group



- SUVR composite (unweighted combination of frontal, anterior/posterior cingulate, lateral parietal, lateral temporal, and hippocampus)

Results are LSMeans ± SE based on MMRM model, FAS. AD-T2D=HbA1c ≥6.5% at anytime during the study.
[#]1-sample test nominal significance indicating worsening. ***All p values are nominal**

Data presented on March 30, 2019 at the 14th International Conference on Alzheimer's & Parkinson's Diseases held in Lisbon, Portugal

Decreases in Inflammatory Biomarkers Consistent with RAGE Inhibition

Biomarker	Relation to RAGE	Predicted change upon RAGE inhibition
TNFb	Indirect	Decrease
TGF-a	Indirect	Decrease
sCD40L	**Direct**	Decrease
MIP-1b	**Direct**	Decrease
MCP-3	Indirect	Decrease
MCP-1	Indirect	Decrease
IL-6	**Direct**	Decrease
IL-2	Indirect	Decrease
IL-13	Indirect	Decrease
IL-12p70	**Direct**	Decrease
IL-12p40	**Direct**	Decrease
IFNg	**Direct**	Decrease
GM-CSF	Indirect	Decrease
FGF-2	Indirect	Decrease

*nominal p<0.05 Wilcoxon test

Results are Means

Biomarker Profile

Azeliragon treatment significantly decreased the following markers linked to RAGE:

- IL6
- IL12
- INFg
- CD40L
- MIP-1
- IL2
- TNFb

Each of these markers is a major player in the neuroinflammatory pathway[1]

[1]*Based on Ingenuity software predictions*

Data presented on March 30, 2019 at the 14th International Conference on Alzheimer's & Parkinson's Diseases held in Lisbon, Portugal

TTP488-305: Two Studies Operationally Conducted Under a Single Protocol

Study Objectives:

Phase 2:

- Proof of concept study to confirm the findings from the diabetes subgroup of the STEADFAST study

Phase 3:

- Demonstrate safety and efficacy with co-primary endpoints of cognition and function to support possible registration

Phase 2

(Part 1 / Proof of Concept)
Double-blind, placebo control

- 5mg QD or placebo for 6 months
- ~100 adult subjects with mild Alzheimer's disease and HbA1c ≥ 6.5%
- Primary Endpoint: ADAS-cog14
- Secondary Endpoints: CDR-sb, FAQ, Amsterdam-IADL, MMSE

Study start expected June 2019
Results expected 4Q2020

Phase 3

(Design may be adjusted based on Part 1 results)

- Double-blind, placebo control
- 5mg QD or placebo for 18 months
- ~200 adult subjects with mild Alzheimer's disease and HbA1c ≥ 6.5%
- Co-primary Endpoints:
  - Cognition: ADAS-cog14
  - Function: TBD

Study start expected 1Q2021

Dementia/AD and Diabetes in Numbers

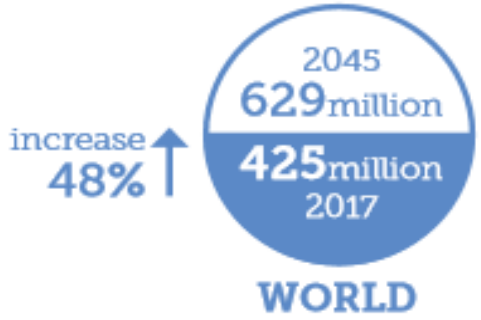
Dementia and AD[1][2]

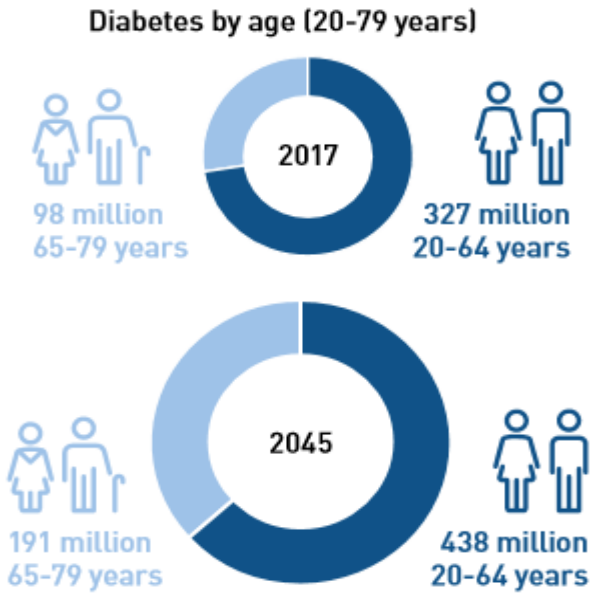
Alzheimer's disease is the most common form of dementia and may contribute **to 60–70% of cases**

5.8 MILLION Americans are living with Alzheimer's

BY 2050, this number is projected to rise to nearly 14 MILLION

Diabetes[3]



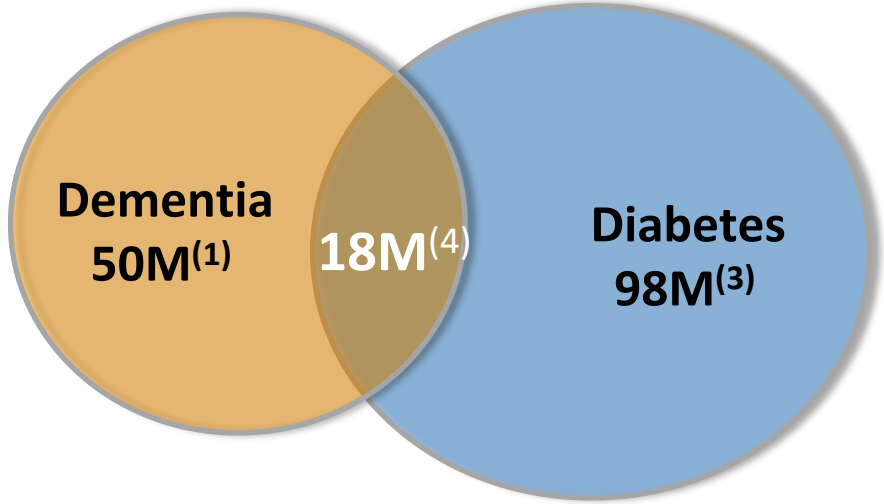


Diabetes & Dementia

Since the late '80s, case-control and prospective **epidemiologic studies** around the world **have reported an association between T2D and dementia** *Type 2 Diabetes and Dementia (2018)* *https://doi.org/10.1016/B978-0-12-809454-9.00001-9*

Number of People Living with Dementia

Number of People ≥65 Living with Diabetes



(1) Globally, number of people with dementia in 2017 (source: Dementia, key facts, WHO, 2017)
(2) 2019 Alzheimer's Disease Facts and Figures (source: Alzheimer's Association)
(3)Globally, number of people with diabetes 65-79 years of age (source: IDF Diabetes Atlas 8th Edition)
(4)Assumption based on 37% estimate of Medicare beneficiaries age 65 and older with dementia who also have diabetes in the US *(Alzheimer's Association. 2018 Alzheimer's Disease Facts and Figures)*

Azeliragon: Addressing Significant Unmet Medical Need in Alzheimer's Disease

Underserved Population

No new treatments for AD/dementia amid growing senior population and rising diabetes pandemic

Clinical Evidence

Results of STEADFAST subgroup analysis in subjects with Type 2 diabetes indicate a **potential benefit of treatment with azeliragon**

Market Opportunity

Nearly 40% of Medicare beneficiaries age 65 and older with dementia also have diabetes[1]

Next Steps

Conducting **start-up activities** for a clinical trial in subjects with mild AD and T2D that consists of sequential phase 2 and phase 3 studies operationally conducted under a single protocol

[1] *Alzheimer's Association. 2018 Alzheimer's Disease Facts and Figures*

Partnerships

Creating Value with Program Licenses

GLP-1r Agonist Program: Licensed Limited Territory Rights

Type 2 Diabetes Unmet Needs in China

- Over 100 million people with diabetes*
- China's diabetes drug market projected to reach $20B USD by 2025*
- Opportunity to introduce new drug classes to a market that has historically lagged behind in access to innovative drugs

华东医药
HUADONG MEDICINE

Huadong Medicine Co., Ltd

- One of the largest pharmaceutical companies in China
- A strategic focus in diabetes; >20 candidates in development

GLP-1r Program Exclusive License Agreement in China and Other Pacific Rim Territories

- In December 2017, vTv granted an exclusive license to Huadong to develop, manufacture and commercialize vTv's GLP-1r agonist program in China and 15 other regions in the Pacific Rim excluding Japan
- Huadong will develop the GLP-1r program for type 2 diabetes in its territory
- vTv is eligible to receive future development and commercialization milestones as well as royalties on sales of approved products
- vTv will utilize the pre-clinical and clinical data generated by this collaboration to continue the development and to seek partners in ROW

*Morgan Stanley China Healthcare Report; Diabetes 2025: China's Antidiabetic Market Set to Triple (October 4, 2017)

PDE4 Inhibitor Program: Licensed Limited Territory Rights

COPD Market in China

- 8.6% (~100 million) COPD patients in China[1]
- Annual sales of top 2 products (Seretide and Spiriva) greater than $132M USD
- Total COPD market at $4.5B USD

Newsoara Biopharma Co., Ltd.

NEWSOARA
恒翼生物医药

- Newsoara was established in 2018 to in-license innovative drug candidates for development and commercialization with focus in China and/or Asia Pacific region
- Hangzhou TigerMed, a public company (stock ChiNext: 300347), is a significant investor in Newsoara
- CEO and founder Dr. Benny Li has more than 20 years of extensive drug research, development and regulatory experience with global leading pharmaceutical companies such as Takeda and Alcon

PDE4 Program Exclusive License Agreement in China and Other Pacific Rim Territories

- In May 2018, vTv granted an exclusive license to Newsoara to develop, manufacture and commercialize vTv's PDE4 Inhibitor program in China and 14 other regions in the Pacific Rim excluding Japan
- Newsoara will develop the PDE4 program for COPD and one other indication in its territory
- vTv is eligible to receive future development and commercialization milestones as well as royalties on sales of approved products
- vTv will utilize the pre-clinical and clinical data generated by this collaboration to continue the development and to seek partners in ROW

[1] The Lancet Respiratory Medicine, 2018: DOI, April 09, 2018

PPAR-δ Agonist Program: Licensed Worldwide Rights

Reneo Pharmaceuticals, Inc.

- San Diego-based clinical stage pharmaceutical company focused on the development of therapies for patients with genetically defined orphan diseases
- Founded by Mike Grey, an experienced VC and entrepreneur with deep biotech experience, and a strong team who have worked together and collaborated on previous successful programs
- Funded by multi-national investor group including Pappas, Rivervest, Lundbeckfonden Ventures and New Enterprise Associates

PPAR-δ Program Worldwide Exclusive License Agreement

- In December 2017, vTv granted an exclusive worldwide license to Reneo to develop, manufacture and commercialize vTv's PPAR-δ program
- Reneo is developing the program to treat genetically defined rare mitochondrial diseases such as fatty acid oxidation disorders (FAOD) and primary mitochondrial myopathies (PMM)
- vTv holds an equity interest in Reneo and is eligible to receive future development and commercialization milestones as well as royalties on sales of approved products

Discovering and Developing Innovative Therapies for Substantial Markets

vTv is a small and nimble company that has integrated innovative science with clinical drug discovery in challenging areas like **Diabetes and Alzheimer's disease**

vTv has a novel pipeline of programs including its **liver-selective GKA** for type 1 and type 2 diabetes and its **RAGE program** for mild Alzheimer's disease and type 2 diabetes

vTv has a track record of **strategic partnerships** with leading biopharmaceutical companies, academic institutions and patient advocacy groups

Appendix

Comparison with SGLT1-2 Inhibitors Regarding Potential for Ketoacidosis