

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (date of earliest event reported): **February 19, 2019**

vTv Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37524
(Commission File No.)

47-3916571
(IRS Employer
Identification No.)

4170 Mendenhall Oaks Pkwy
High Point, NC 27265
(Address of principal executive offices)

(336) 841-0300
(Registrant's telephone number, including area code)

NOT APPLICABLE
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01**Regulation FD Disclosure**

On February 19, 2019, vTv Therapeutics Inc. (the "Company") posted an updated investor presentation to its website at <http://ir.vtvtherapeutics.com/phoenix.zhtml?c=254081&p=irol-irhome>. A copy of the investor presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed subject to the requirements of amended Item 10 of Regulation S-K, nor shall it be deemed incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing. The furnishing of this information hereby shall not be deemed an admission as to the materiality of any such information.

Item 9.01**Financial Statements and Exhibits**

(d) Exhibits

99.1 vTv Therapeutics' Investor Presentation dated February 2019.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

VTV THERAPEUTICS INC.

By: /s/ Rudy C. Howard
Name: Rudy C. Howard
Title: Chief Financial Officer

Dated: February 19, 2019



vTv Therapeutics (VTVT)

February 2019

NASDAQ: VTVT

The statements made in this presentation may include forward-looking statements regarding the Alzheimer's and diabetes markets, the development and attributes of investigational and marketed products to treat Alzheimer's disease, diabetes and other conditions, and the future operations, opportunities or financial performance of vTv Therapeutics Inc. These forward-looking statements are only estimations based upon the information available to vTv Therapeutics Inc. as of the date of this presentation. Except as required by law, we expressly disclaim any responsibility to publicly update or revise our forward-looking statements, whether as a result of new information, future events or otherwise. Thus, the forward-looking statements herein involve known and unknown risks and uncertainties and other important factors such that actual future operations, opportunities or financial performance may differ materially from these forward-looking statements.

For a more detailed discussion of our risks, see the Risk Factors section in our prospectus filed with the SEC and our other filings with the SEC, including our most recent 2017 Annual Report on Form 10-K. Undue reliance should not be placed on forward-looking statements, which speak only as of the date hereof. All forward-looking statements contained herein are qualified in their entirety by the foregoing cautionary statements.

Any statements contained in this presentation will superseded by any statements on the same subject matter contained in our 2018 Annual Report on Form 10-K when it is filed. Please read our 2018 Annual Report on Form 10-K in its entirety.

This presentation is being provided to you for information purposes only. This presentation does not constitute an offer or sale of (or the solicitation of an offer to buy) any securities of vTv Therapeutics Inc. or any of its subsidiaries.

By accepting this presentation, you acknowledge and agree that (i) you will not rely on this presentation for making any investment decision with respect to any securities of vTv Therapeutics Inc. or any of its subsidiaries, and (ii) any investment decision made by you with respect to any such securities will be based solely on a prospectus (or other offering document) relating to such securities (if any), including the information incorporated by reference therein



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



Subgroup results from azeliragon phase 3 STEADFAST trial in mild Alzheimer's disease suggest potential **benefit in patients with concurrent diabetes**

Planning a study to evaluate the efficacy of azeliragon in patients with **Alzheimer's disease and diabetes**



Positive phase 2 results in diabetes with two novel oral candidates

Ongoing phase 2 study in **type 1 diabetes** with TTP399



Significant, long-term financial sponsor in MacAndrews and Forbes

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



| PROGRAM | PRECLINICAL | PHASE 1 | PHASE 2 | PHASE 3 | STATUS | MILESTONES |
|---|-------------|---------|---------|---------|---|---|
| Alzheimer's Disease | | | | | | |
| Azeliragon (TTP488): RAGE Antagonist | | | | | A-Study completed B-Study stopped at 12 months | Planning a study to evaluate the efficacy of azeliragon in patients with Alzheimer's disease and diabetes |
| Type 2 Diabetes (T2D) | | | | | | |
| TTP399: Glucokinase Activator | | | | | Phase 2b study completed | Reported Positive Results August 2016 |
| TTP273: Oral GLP-1r Agonist | | | | | Planning for Phase 2b study | Licensed China/Pacific Rim rights to Huadong Pharmaceuticals |
| Type 1 Diabetes (T1D) | | | | | | |
| TTP399: Glucokinase Activator | | | | | Adaptive phase 2 study ongoing | Part 1 results expected June 2019 Part 2 startup activities initiated |
| Other Programs | | | | | | |
| HPP593: PPAR-δ Agonist | | | | | Phase 1 | Worldwide License to Reneo Pharmaceuticals |
| HPP737: PDE4 Inhibitor | | | | | Phase 1 | Licensed China/Pacific Rim rights to Newsoara Biopharma |
| HPP971: Nrf2 Activators/ Bach1 Inhibitors | | | | | Phase 1 | Several other compounds in pre-clinical development |



Alzheimer's Disease Program

AZELIRAGON

Antagonist of RAGE (Receptor for Advanced Glycation Endproducts)

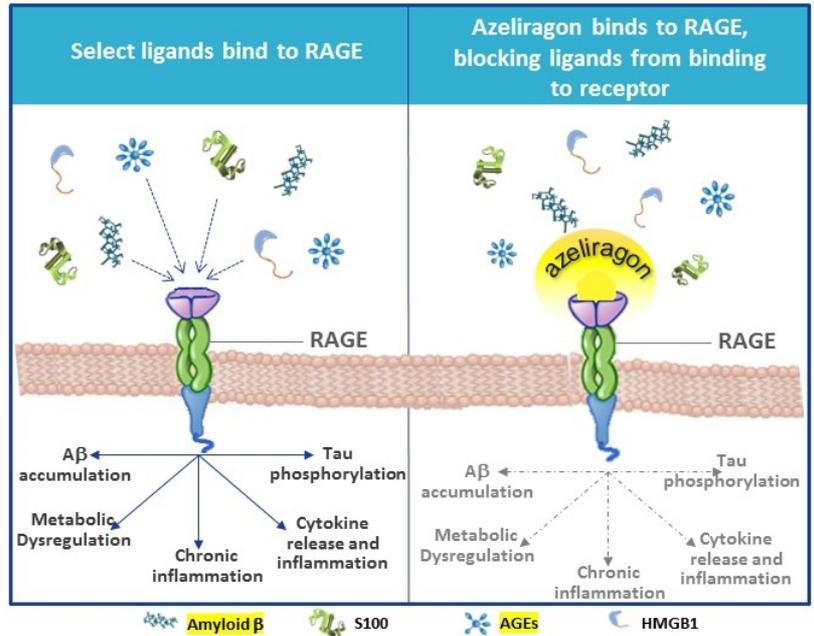


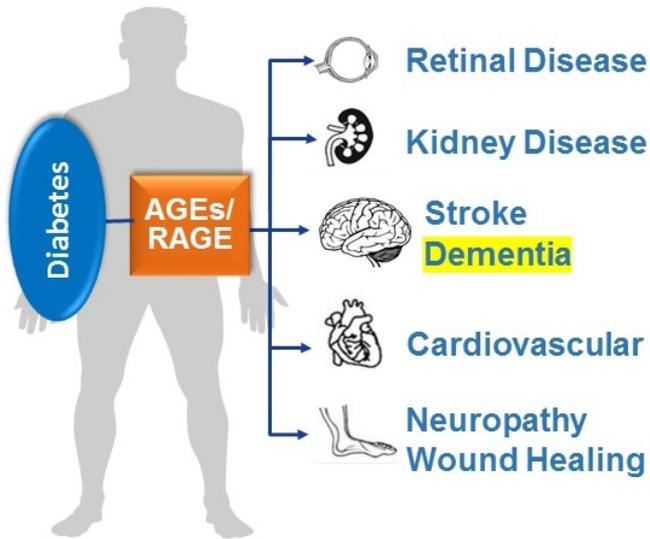
- Azeliragon's **novel MOA**: antagonizing the Receptor for Advanced Glycation Endproducts (RAGE)
- Inhibiting RAGE **reduces** transport of amyloid into the brain, inflammation and tau phosphorylation
- Unlike most investigational treatments, azeliragon does not rely on just one hypothesis of AD (e.g., amyloid or tau), but it targets **three components** of AD pathology
- RAGE is a **well-studied** hypothesis – numerous peer-reviewed studies have been published on the role of RAGE in Alzheimer's disease and diabetic complications*

*Ramasamy R, Shekhtman A, Schmidt AM. The Multiple Faces of RAGE - Opportunities for Therapeutic Intervention in Aging and Chronic Disease. *Expert Opin Ther Targets*. 2016; 20(4): 431-446

*Schmidt AM, Sahagan B, Nelson RB, Selmer J, Rothlein R, Bell JM. The role of RAGE in amyloid-beta peptide-mediated pathology in Alzheimer's disease. *Curr Opin Investig Drugs*. 2009 Jul; 10(7):672-80.

Azeliragon Mechanism of Action





- Advanced Glycation Endproducts (AGEs) accumulate in tissue in people with diabetes
- AGE receptor (RAGE) expression **increases in response to injury and increases in ligand concentrations**
- The **interaction of AGEs** (or other ligands) **with RAGE** leads to **sustained cellular damage and inflammation**
- **AGEs have a major role in the complications of diabetes** such as retinopathy, neuropathy and nephropathy
- **AGE accumulation** parallels the development of **cognitive impairment and dementia** in individuals with diabetes

For review see Dhananjayan et al. (2018) *Advance Glycation, Diabetes and Dementia*
<https://doi.org/10.1016/B978-0-12-809454-9.00009-3>

The role of inflammation and RAGE expression/signaling associated with AD and diabetes raises the question of whether RAGE could be a common factor between dementia and diabetes and whether treatment with azeliragon, an oral RAGE-inhibitor or antagonist, could have a distinct effect in patients presenting with both diabetes and AD.

Phase 2B

Findings:

- “Faster progressors” (Placebo decline 10.5 points/18 months)¹
- Azeliragon potentially delayed cognitive and functional decline¹
- Patients with glucose intolerance showed more pronounced response

Hypothesis:

- Potential **higher concentrations of RAGE/RAGE-ligands**
- Potential **higher degree of inflammation** and cell death

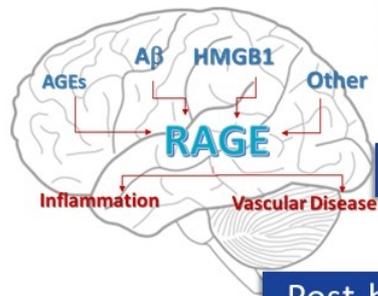
Phase 3

Findings:

- “Non/slow progressors” (Placebo decline 3 points/18 months)
- Azeliragon did not affect cognitive or functional decline
- Patients with diabetes were included in the study

Hypothesis:

- Potential **lower concentrations of RAGE/RAGE-ligands**
- Potentially **lower degree of inflammation** and cell death



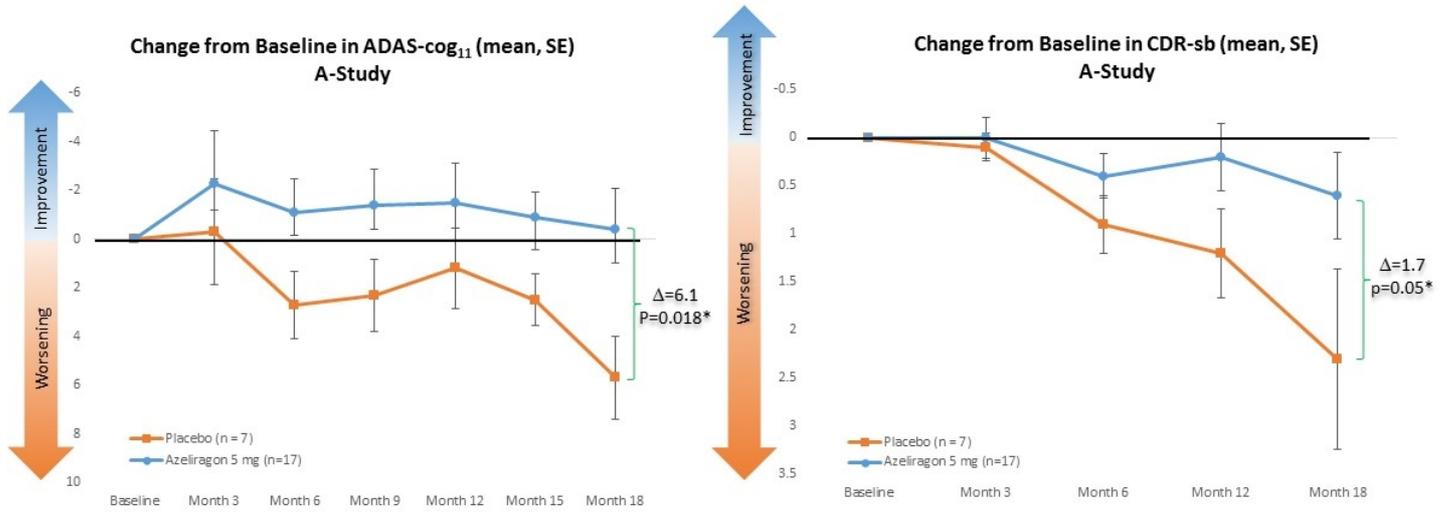
Hypothesis: High plasma concentrations of RAGE-ligands should identify responders to azeliragon

HbA1c chosen as a surrogate marker for AGEs

Post-hoc analysis of Phase 3 patients with baseline HbA1c \geq 6.5%

¹ Burstein AH¹, Grimes I, Galasko DR, Aisen PS, Sabbagh M, Mjallii AM. Effect of TTP488 in patients with mild to moderate Alzheimer's disease. *BMC Neurol.* 2014; 14: 12.

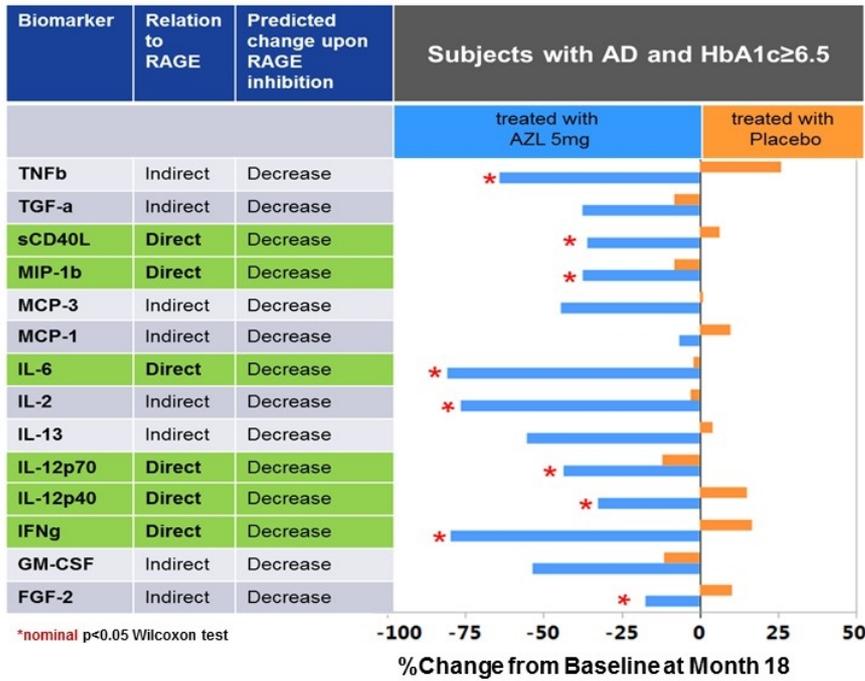
Analysis of Patients with Diabetes (HbA1c \geq 6.5%) and Baseline Cognitive Deficit (ADAS-cog \geq 10)



*All p values are nominal

B-study terminated and limited data are available beyond month 9 for this subgroup

Data presented at CTAD 2018



Biomarker Profile¹

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

¹Based on Ingenuity software predictions

Mechanism of Action

- RAGE implicated in both the pathogenesis of AD and diabetic complications
- RAGE could be a meaningful link between diabetes and dementia

Clinical Evidence

- Results of phase 3 A-Study subgroup analysis in patients with diabetes indicate a potential benefit of treatment with azeliragon
- Similar effects seen in patients with glucose intolerance in the phase 2b AD study
- Integrated clinical safety database with over 1,000 patients dosed with azeliragon
- Azeliragon 5 mg/day well tolerated

Underserved Population

- Growing senior population and growing pandemic of diabetes
- No drugs for the treatment of dementia in association with diabetes

Market Opportunity

- Nearly 40 percent of Medicare beneficiaries age 65 and older with dementia also have diabetes (*Alzheimer's Association. 2018 Alzheimer's Disease Facts and Figures*)
- 2010 costs of dementia world wide ~\$604 billion and expected to reach \$1.2 trillion by 2030 (*WHO, 2015*)

Next Steps

- vTv currently planning a study to evaluate efficacy of azeliragon in patients with mild Alzheimer's disease and [Type 2/elevated HbA1c greater than 6.5] diabetes

Dementia⁽¹⁾

What does it cost?

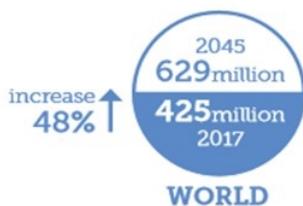


Who is affected?

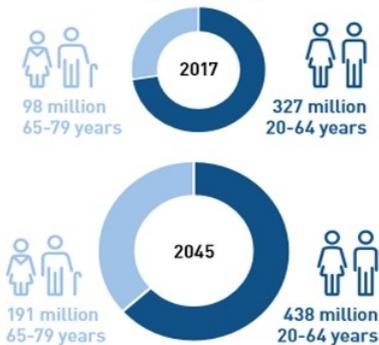


Alzheimer's disease is the most common form of dementia and may contribute to 60–70% of cases

Diabetes⁽²⁾



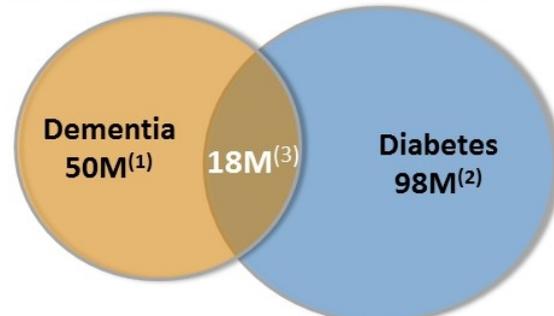
Diabetes by age (20-79 years)



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. Globally, number of people with diabetes 65-79 years of age (source: *IDF Diabetes Atlas 8th Edition*)
 3. 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*)

Expert Opin Ther Targets, 2016;20(4):431-46. doi: 10.1517/14728222.2016.1111873. Epub 2015 Nov 11.

The multiple faces of RAGE--opportunities for therapeutic intervention in aging and chronic disease.

Ramasamy R¹, Shekhtman A², Schmidt AM¹.
<https://www.ncbi.nlm.nih.gov/pubmed/26558318>

Evidence for neuroinflammation in Alzheimer's disease

Anna Walters MChB, MRCPsych, Emma Phillips MChB, BSc Neuroscience, MRCPsych, Rui Zheng, MSc MRCPsych, Maya Biju MBS, MRCPsych, Tarun Kuruvilla MRCPsych
<https://onlinelibrary.wiley.com/doi/epdf/10.1002/pnp.444>



Contents lists available at ScienceDirect

Biochimica et Biophysica Acta

journal homepage: www.elsevier.com/locate/bba



Review

Is Alzheimer's disease a Type 3 Diabetes? A critical appraisal[☆]

Ramesh Kandimala^{☆,*}, Vani Thirumala^{☆,†}, P. Hemachandra Reddy^{☆,‡}

[☆] Geriatric Institute on Aging, Texas Tech University Health Sciences Center, 3601 4th Street, MS 9426 Lubbock, TX 79409 United States

[†] All Neuroscience, University of Texas at Austin, Austin, TX 78712, USA

[‡] Department of Cell Biology & Biochemistry, Neuroscience & Pharmacology and Neurology, Texas Tech University Health Sciences Center, 3601 4th Street, MS 9426, Lubbock, TX 79409 United States

<https://www.ncbi.nlm.nih.gov/pubmed/27567931>

Type 2 Diabetes and Dementia
 2018, Pages 169-193



Chapter 9 - Advanced Glycation, Diabetes, and Dementia

Karthik Dhananjayan¹, Josephina Forbes^{2,3}, Gerald Münch¹

<https://www.sciencedirect.com/science/article/pii/B9780128094549000093?via%3Dihub>

HbA_{1c}, diabetes and cognitive decline: the English Longitudinal Study of Ageing.

Zheng F^{1,2}, Yan L³, Yang Z³, Zhong B⁴, Xie W^{5,6}.
<https://www.ncbi.nlm.nih.gov/pubmed/29368156>



RESEARCH ARTICLE

RAGE and AGEs in Mild Cognitive Impairment of Diabetic Patients: A Cross-Sectional Study

Pin Wang^{1*}, Rong Huang¹, Sen Lu², Wengjing Xia¹, Rongrong Cai¹, Haisie Sun¹, Shaohua Wang^{1*}

¹ Department of Endocrinology, Affiliated ZhongDa Hospital of Southwest University, Nanjing, PR China.

² Department of the Intensive Care Unit, Sichuan Academy of Medical Science & Sichuan Provincial People's Hospital, Chengdu, Sichuan Province, PR China

* Current address: Department of Endocrinology, Sichuan Academy of Medical Science & Sichuan Provincial People's Hospital, East District, Chengdu, Sichuan Province, PR China

† This author is first author on this work.

* wangpin@163.com

<https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0145521&type=printable>



Diabetes Programs

Exploring Next-Generation Treatments

Diabetes

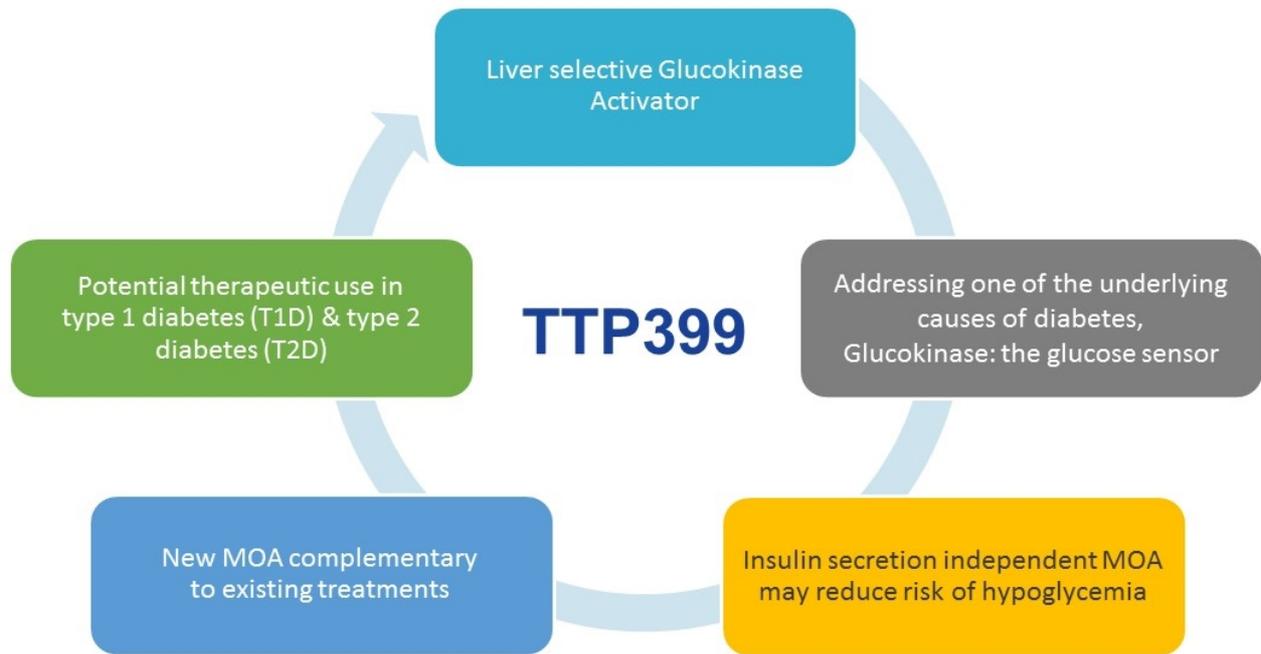
- More than 400 million people were living with diabetes as of 2015¹
- Diabetes remains the 7th leading cause of death in the United States, costing the healthcare system \$245 billion annually²
- Type 2 diabetes represents 90 percent of people around the world who have diabetes²
- Approximately 1.25 million Americans have type 1 diabetes, and an estimated 40,000 people will be newly diagnosed each year in the U.S.²
- Existing therapies are available to control glucose in type 2 diabetes, but use may be hindered by the route of administration and side effects³

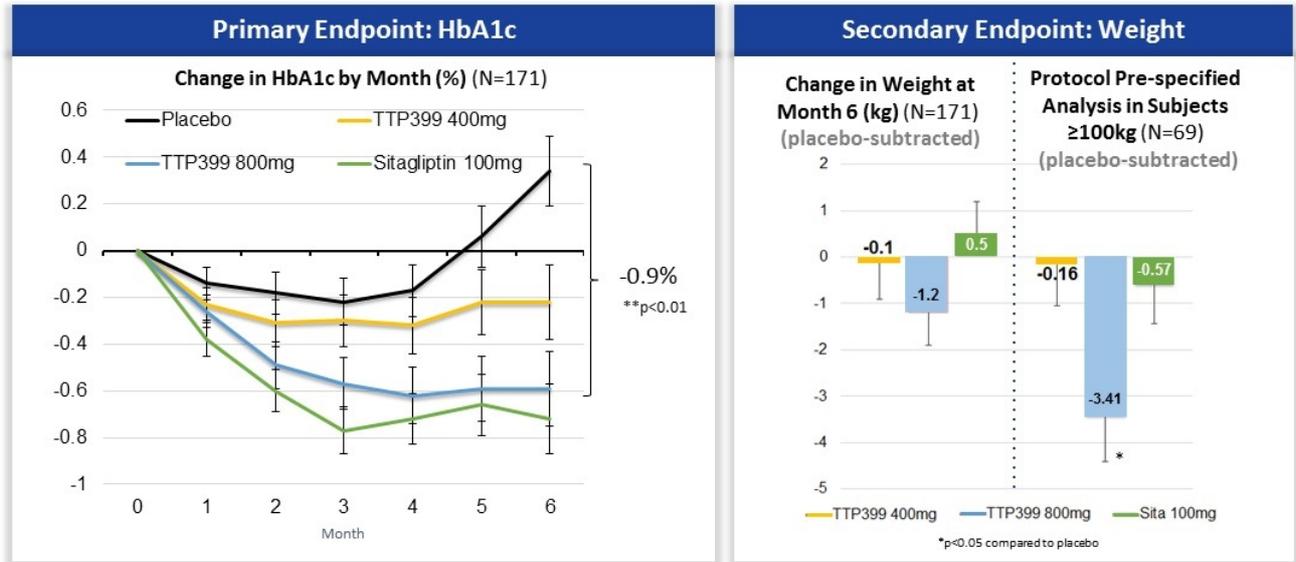


¹ World Health Organization

² American Diabetes Association

³ Global Data, PharmaPoint: Type 2 Diabetes - Global Drug Forecast and Market Analysis to 2026, July 2017





Well-tolerated: negligible incidences of hypoglycemia and hyperlipidemia



Phase 1 (Sentinels)

- Open-label
- Dose escalation
- 5 adult patients with T1DM on CSII and CGM



Phase 2-Part 1 (Learning Phase)

- Double-blind Placebo control
- 800mg QD for 12 weeks
- ~20 Adult patients with T1DM on CSII and CGM



Phase 2-Part 2 (Confirming Phase)

- Double-blind Placebo control
- 800mg QD for 12 weeks (may be adjusted)
- ~90 Adult patients with T1DM

Sep
2017



June
2019

Q1
2020

TTP399 was well tolerated

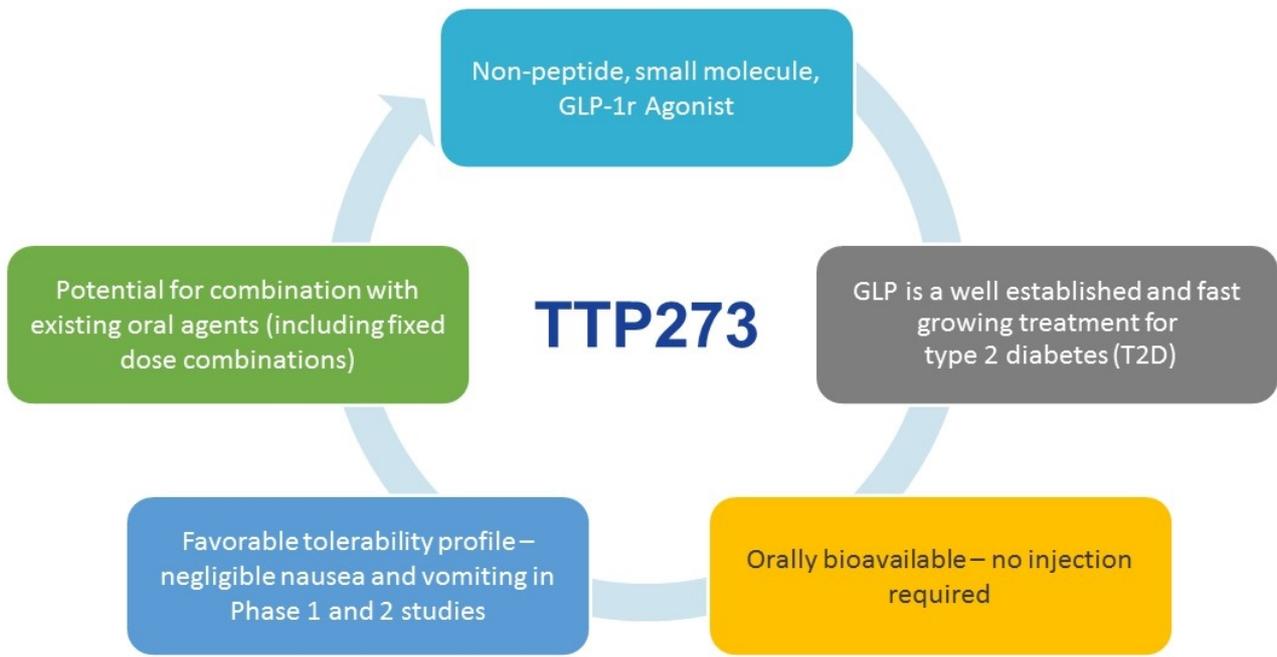
- No incidents of **severe hypoglycemia** or DKA
- No detrimental effect on liver function or plasma lipids
- Indications of **improved glycemic control, while reducing insulin dose**
 - Increase % time in range
 - Reduce % time in hyperglycemia without increasing % time in hypoglycemia

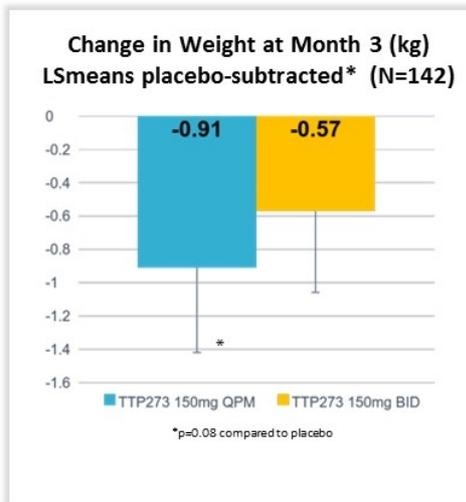
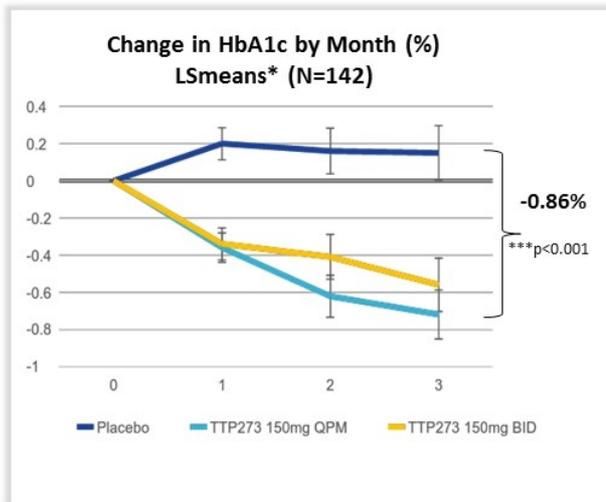
Results expected in June 2019

Results expected in Q1 2020



Simplici-T₁ study conducted under industry partnership with the JDRF





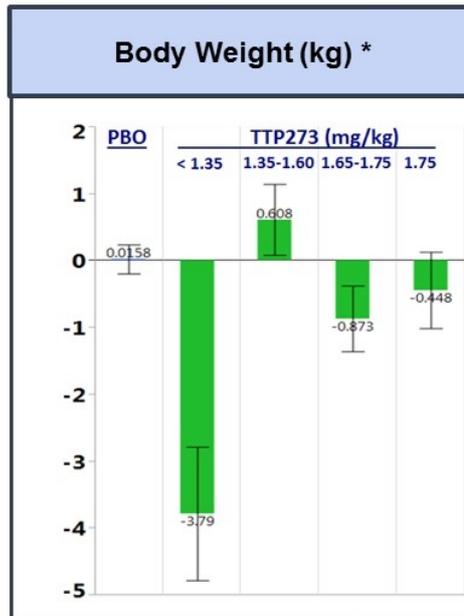
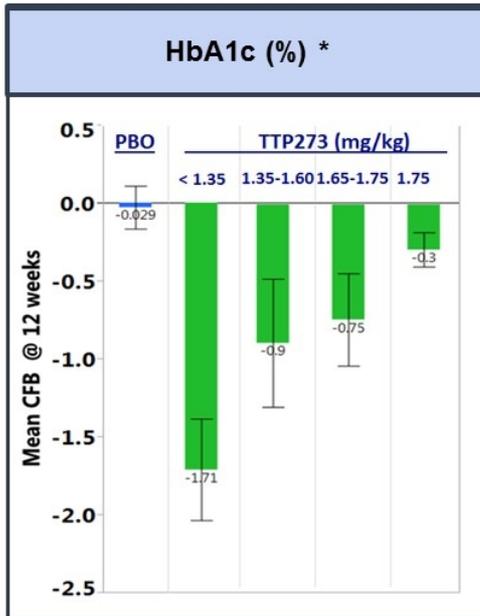
Safety Profile

- TTP273 was well tolerated
- No incidences of vomiting in the TTP273 treated arms
- Nausea less than placebo: 7.3% in the Placebo arm, 3.4% in QPM arm and 5.0% in the BID arm

*Efficacy parameters are reported for the per protocol set

Improved Glycemic Control, Weight Loss, Attractive Safety Profile

Presented at the American Diabetes Association 77th Scientific Sessions 2017



Additional Analyses

- Trends confirmed when correlating TTP273 plasma concentration with efficacy
- No increase in GI AEs with improved efficacy
- Trends are not dependent on age, sex, race, duration of diabetes

■ PBO
■ TTP273

*Quartile analysis for complete cases for 150QPM and PBO groups (approximately 40 per group)



Partnerships

Creating Value with Program Licenses

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



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)

COPD Market in China

- 8.6% (~100 million) COPD patients in China¹
- Annual sales of top 2 products (Seretide and Spiriva) greater than \$132M USD
- Total COPD market at \$4.5B USD

Newsara Biopharma Co., Ltd.

- Newsara 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 Newsara
- 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 Newsara to develop, manufacture and commercialize vTv's PDE4 Inhibitor program in China and 14 other regions in the Pacific Rim excluding Japan
- Newsara 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

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



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 will develop the program in orphan diseases associated with deficits in cellular metabolism and energy production
- 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

Stock Information

- NASDAQ Capital Market (Ticker: VTVT)
- Market cap: \$129.4 million
- Shares outstanding: 45.1 million
- Stock price: \$2.87

(share data as of 1/31/2018)

Q3 2018 Financial Information (in thousands)

| | |
|------|----------|
| Cash | \$3,766 |
| Debt | \$18,208 |

MacAndrews Equity Commitment (as of 2/14/2019)

| <i>Date of Commitment</i> | <i>Total Commitment</i> | <i>Remainder Available</i> |
|---------------------------|-------------------------|----------------------------|
| Dec 5, 2017 | \$10 million | \$ – |
| Jul 30, 2018 | \$10 million | \$ – |
| Dec 11, 2018 | \$10 million | \$4 million |



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



vTv has a novel pipeline of programs including its **RAGE antagonist** for Alzheimer's disease, **small molecule GLP-1r** for type 2 diabetes, and **liver-selective GKA** for type 1 and type 2 diabetes



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

