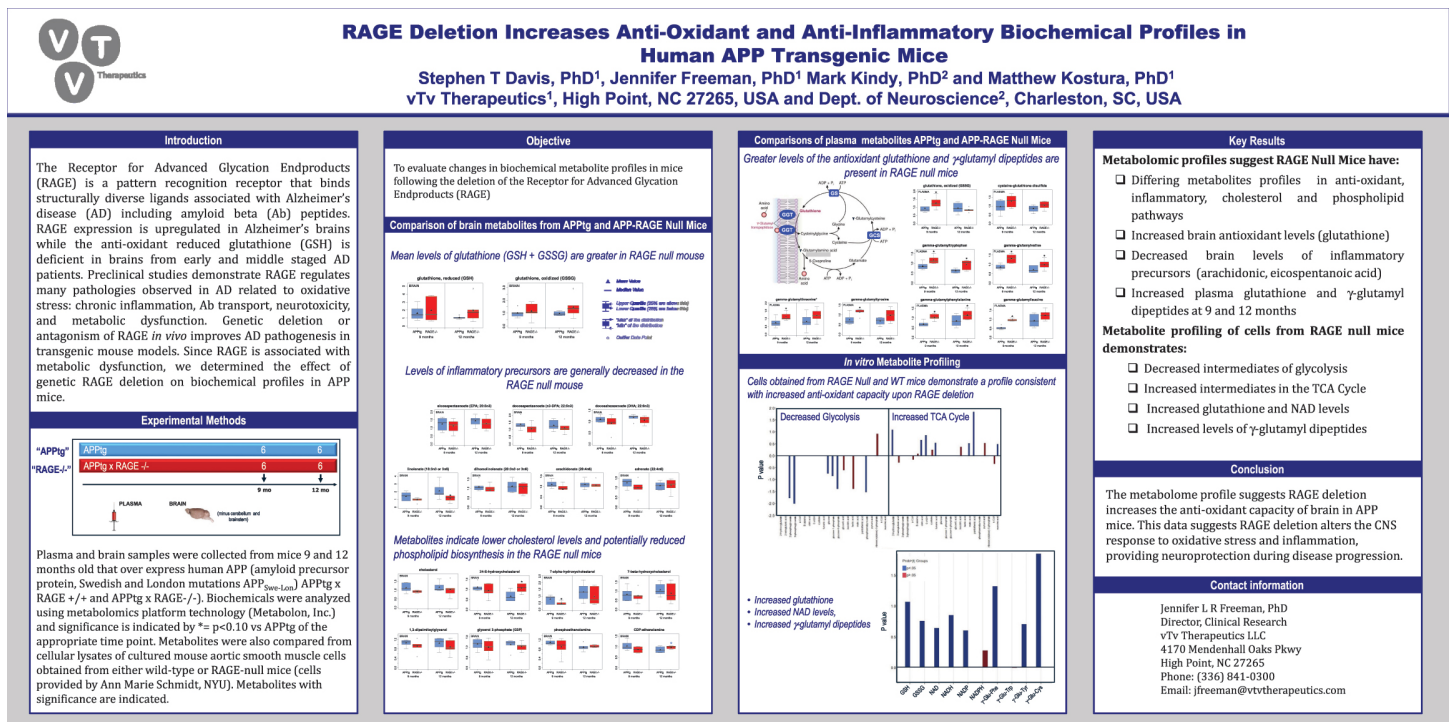


Explanatory Note: The following clinical posters regarding the Receptor for Advanced Glycation Endproducts (RAGE) and *azeligaron* (TTP488) have been prepared by vTv Therapeutics, Inc. (the “Company”) or with the Company’s participation. The Company expects that the posters regarding RAGE and TTP488 will be posted at the Alzheimer’s Association International Conference on or about July 20, 2015 and July 21, 2015, respectively. These posters are being provided to supplement certain information in the Company’s preliminary prospectus filed by the Company with the United States Securities and Exchange Commission on July 20, 2015, and are thus deemed to be a free writing prospectus. For additional information regarding the Company and the offering to which this free writing prospectus relates, please see the information below under the caption, “Free Writing Prospectus.”



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TTP488 Path to Registration: Leveraging Enrichment Strategies

Marwan N Sabbagh, MD¹, Aaron H Burstein, PharmD², Imogene Dunn, PhD², Carmen Valcarce, PhD², Rachelle S Doody, PhD³, Mary Sano, PhD⁴, Lon S Schneider, MD⁵, Douglas Galasko, MD⁶, Eric Rose, MD⁷
(1) Banner Sun Health Research Institute, Sun City, AZ; (2) vTv Therapeutics, High Point, NC; (3) Baylor College of Medicine, Houston, TX; (4) Icahn School of Medicine at Mount Sinai, New York, NY; (5) Keck School of Medicine of USC, Los Angeles, CA; (6) UC San Diego / VA San Diego Healthcare System, San Diego, CA; (7) MacAndrews & Forbes, New York, NY.



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Introduction: Background

Regulatory Background: The FDA issued a draft guidance Enrichment Strategies for clinical trials to Support Approval of Human Drugs and Biological Products (draft guidance, December 2012), which was designed to help drug companies speed development. The essence of the guidance on enrichment strategies was done by the FDA as a part of meeting CDTP goals under Clinical Trial initiatives. The "enrichment strategies" are intended to improve the efficiency of drug trials. Robert Temple of the FDA commented that "these are potentially powerful strategies for the pharmaceutical industry because appropriate use of enrichment could result in smaller studies, shortened drug development times, and lower development costs," as reported by *MedWatch* February 2013.

Program Background: Axitrigon (TTP488), an antagonist at the Receptor for Advanced Glycation End products, was evaluated as a potential treatment for patients with mild-to-moderate Alzheimer's disease (AD). A previous report describes decreased decline in ADAS-COG₁ (delta=-3.1, p=0.008 at 18 months, ANCOVA with multiple imputation), relative to placebo. Although, the Phase 2 clinical trial demonstrated efficacy in mild-to-moderate AD, leveraging enrichment strategies, the phase 3 clinical trial will include patients with mild AD only. The objectives of the clinical trial design were to minimize variance and optimize standardization, while fulfilling the registration requirements to demonstrate the efficacy of axitrigon (TTP488) on cognitive (ADAS-COG₁) and global function (CDR-SB) measures in patients with mild AD.

Strategy: As a part of the speed-to-market strategy, the trial was designed leveraging enrichment design strategies. The basis of the planning for the protocol was the phase 2 study, which had statistically significant treatment effects favoring axitrigon (TTP488) in the phase 2 study population, which included mild-to-moderate AD patients. More pronounced effects were observed in the subpopulation of mild AD patients. Using the enrichment design, a smaller, more homogeneous (hence less variable) population, can result in a faster trial with shorter recruitment period and less complexity to support an earlier NDA filing.

Conclusions: This study is the first phase 3 clinical trial investigating a RAGE inhibitor in the treatment of AD. Two studies under a single protocol ensure consistency and reduce variability. The enrichment design was granted agreement under the Special Protocol Assessment by the FDA.

Phase 2b Design

- Randomized, double-blind, placebo-controlled trial
- Mild to moderate AD (MMSE 14-26), N=399
 - Power of 80% to detect a treatment benefit of 3 points on the ADAS-COG₁
 - Stable background therapy with cholinesterase inhibitors and/or memantine
- Three arms (1:1:1):
 - 60mg/d x 6 days, 20 mg/day x 18 months (discontinued due to increase incidence of confusion, falls and greater ADAS-COG₁ decline not seen with 5 mg/d or placebo) (n=133)
 - 15 mg/d x 6 days, 5 mg/day x 18 months (n=131)
 - Placebo x 18 months (n=133)
- Objectives:
 - ADAS-COG₁ after 18 months of treatment with axitrigon (TTP488) vs placebo
 - Safety/tolerability of treatment with axitrigon (TTP488) vs placebo
- Primary analysis: ANCOVA with multiple imputation

Phase 2b Results

Mild-to-Moderate:

- 20 mg/day dose associated with falls, confusion, increased incidence of ADAS-COG₁ change from baseline ≥ 10 pts
- Statistically significant difference in ADAS-COG₁ @ 18 months for 5 mg/day vs placebo

Mild subset of overall population: more robust effect than mild-to-moderate

- Statistically significant differences in ADAS-COG₁ and CDR-SB @ 18 months for Enriched vs. placebo

STEADFAST Phase 3 Trial Design

Clinical and safety evaluations, plasma for axitrigon (TTP488) PK and biomarkers

- Randomized, double-blind, parallel group, 18-month trial in 800 patients with mild AD (MMSE 21-26)
- Two independently powered (for co-primary endpoints) sub-studies under a single protocol:
 - Each study (n=400) will have 2 arms
 - 5 mg/day of axitrigon (TTP488) and placebo x 18 months
 - All patients will remain stable doses of acetylcholinesterase inhibitors ± memantine

Co-Primary Endpoints: ADAS-COG₁ and CDR-SB

Secondary Endpoints:

- Imaging: MRI volumetric measures, FDG-PET
- ADCS-ADL, NPI, MMSE, COWAT, CFT, RUD, DEMOOL
- Biomarkers: Plasma A β

Enrichment of Clinical Trials

- For the purposes of the guidance, the term enrichment is defined as the prospective use of any patient characteristics to select a study population in which detection of a drug effect (if one is in fact present) is more likely than it would be in an unselected population.
- In general, enrichment studies should incorporate the established principles of well-controlled studies, controlling bias (randomization and blinding), and study-type type I error.
- An enrichment design should be explicitly described in the protocol and study report and should fully detail the enrichment measures and their impact on interpretation of results.
- In general, FDA is prepared to approve drugs studied primarily or even solely in enriched populations and will seek to ensure truthful labeling that does not overstate either the likelihood of a response or the predictiveness of the enrichment factor. But the extent of data that should be available on the non-enriched subgroups should always be considered.
- Postmarket commitments or requirements may be requested to define better the full extent of a drug's effect (including efficacy and safety studies and trials in a broader population).

Traditional vs. Enrichment Strategies

Comparison of sample sizes using enrichment design versus traditional design per study (sample size estimate must be doubled for the program to have two pivotal studies)

Variables	Population	Total N for 80% power at 5% error	Dependent Total N (20% 80% in favor)	Difference between whole population and enriched population
Whole population (mild-to-moderate)	819 (409 per group)	1638	1026 (1708 would be randomized)	819 (84%)
Enriched population (mild)	304 (152 per group)	608	385 (488 would be randomized)	223 (36%)

Savings in recruitment time (assumes 18 months for recruitment of N=800 patients without adjustment for startup and end-game recruitment strategies)

Savings in Total Sample Size for 2 Pivotal Studies

Savings in \$5 Millions for 2 Pivotal Studies

Savings in Recruitment Resources for 2 Pivotal Studies

ClinicalTrials.gov identifier: NCT02080364

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