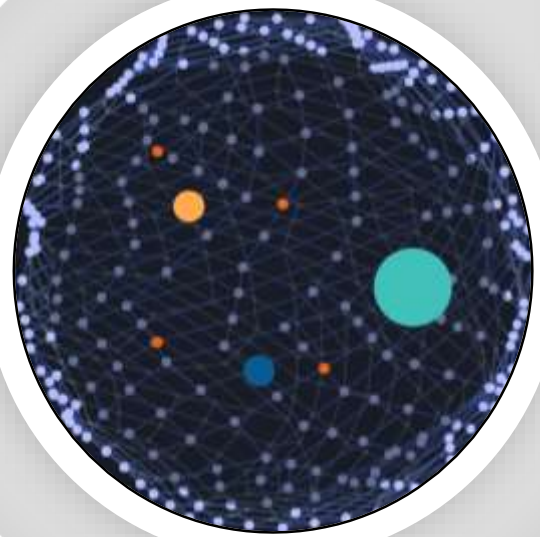
Unleashing the Power of Tregs



COYA THERAPEUTICS, INC.

NASDAQ: COYA | Investor Presentation

June 2023

www.coyatherapeutics.com

COYA THERAPEUTICS

Cautionary Note of Forward-Looking Statements and Disclaimers

This presentation and the accompanying oral presentation contain “forward-looking” statements that are based on our management’s beliefs and assumptions and on information currently available to management. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our current and future financial performance, business plans and objectives, current and future clinical and preclinical development activities, timing and success of our ongoing and planned clinical trials and related data, the timing of announcements, updates and results of our clinical trials and related data, our ability to obtain and maintain regulatory approval, the potential therapeutic benefits and economic value of our product candidates, competitive position, industry environment and potential market opportunities. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” and similar expressions are intended to identify forward-looking statements.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors including, but not limited to, those related to the success, cost and timing of our product candidate development activities and ongoing and planned clinical trials; our plans to develop and commercialize targeted therapeutics; the progress of patient enrollment and dosing in our clinical trials; the ability of our product candidates to achieve applicable endpoints in the clinical trials; the safety profile of our product candidates; the potential for data from our clinical trials to support a marketing application, as well as the timing of these events; our ability to obtain funding for our operations; development and commercialization of our product candidates; the timing of and our ability to obtain and maintain regulatory approvals; the rate and degree of market acceptance and clinical utility of our product candidates; the size and growth potential of the markets for our product candidates, and our ability to serve those markets; our commercialization, marketing and manufacturing capabilities and strategy; future agreements with third parties in connection with the commercialization of our product candidates; our expectations regarding our ability to obtain and maintain intellectual property protection; our dependence on third party manufacturers; the success of competing therapies or products that are or may become available; our ability to attract and retain key scientific or management personnel; our ability to identify additional product candidates with significant commercial potential consistent with our commercial objectives; and our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. Moreover, we operate in a very competitive and rapidly changing environment, and new risks may emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed herein may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Although our management believes that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. We undertake no obligation to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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We have filed a registration statement on Form S-1 (including a preliminary prospectus) with the SEC for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the preliminary prospectus in the registration statement (including the risk factors described therein) and other documents we have filed with the SEC for more complete information about our company and the offering. You may get these documents for free by visiting EDGAR on the SEC web site at http://www.sec.gov/. The preliminary prospectus, as amended, is available on the SEC website at http://www.sec.gov. When available, electronic copies of the preliminary prospectus supplement and the accompanying prospectus may also be obtained from the offices of Chardan Capital Markets at 17 State Street Suite 2130, New York, NY, 10004; by telephone at +1 646-465-9000; by email at prospectus@chardan.com.

Coya Therapeutics' Highlights



Focused on Regulatory T Cells (Tregs)

- **Most clinically-advanced company focused on Treg-modulating therapies**
- Multi-modality approach:
  - Biologics (COYA 300 series)
  - Exosomes (COYA 200 series)



Strong Early Clinical Data

- **COYA 301 completed PoC** IIT study* in Alzheimer's Disease (AD)
- **COYA 302 completed PoC** IIT study* in Amyotrophic Lateral Sclerosis (ALS)
- COYA 200 series for neurodegenerative diseases, autoimmune / inflammatory conditions, and metabolic diseases



Multiple Near-Term Catalysts (12-18 months)

- **COYA 301** clinical Phase 1 PoC data in Alzheimer's Disease (AD): AAIC (July 2023), ANA (September 2023), Peer-Reviewed publication (2H 2023), Academic double-blind Phase 2 PoC top-line data (2H 2024)
- **COYA 302** PoC biomarker data release (2H 2023), IND filing and Phase 2 initiation in ALS (Q1 2024), Peer-Reviewed publication (2H 2023)
- **COYA 200** Platform Series animal model validation data/ out-license discussions
- **COYA 206** target validation & custom cargo validation (2H 2023)/ out-license discussions

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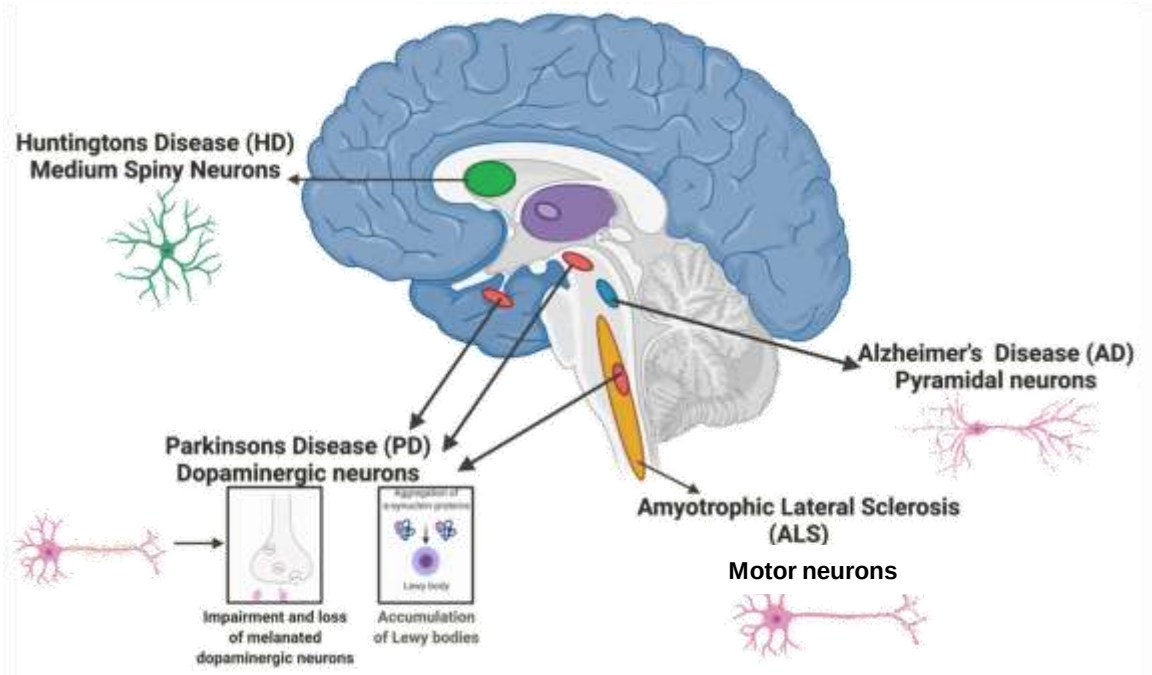
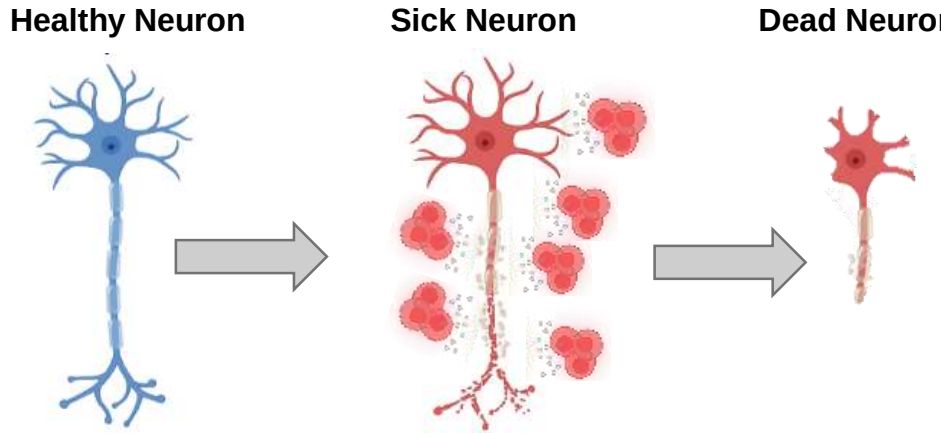
IIT: Investigator Initiated Trial
AAIC: Alzheimer's Association International Conference
PoC: Proof of Concept
*Open label academic studies with commercially available product

Inflammation Plays a Critical Role in Neurodegeneration

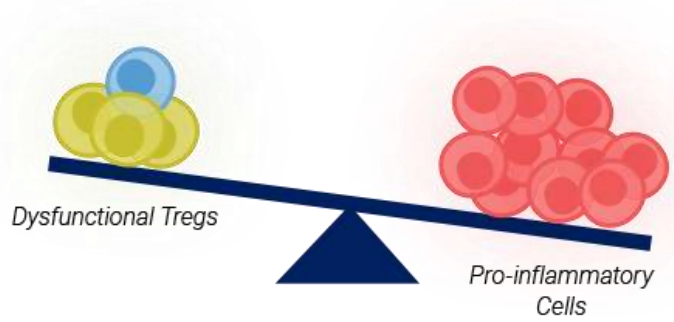
Neurodegeneration: Loss of Selective Population of Neurons



Inflammation in the Nervous System



Dysfunctional Tregs play central role in inflammation and progression of neurodegeneration



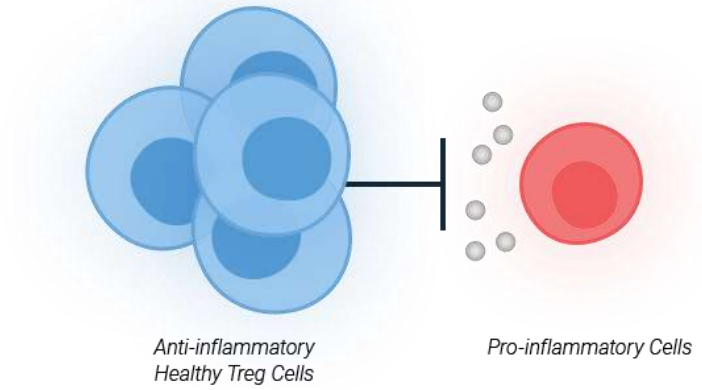
Materials 2022, 15(3), 804; https://doi.org/10.3390/ma15030804
Heidi Cartwright, Prince of Wales Medical Research Institute, Sydney Australia
Graphics created with BioRender.com

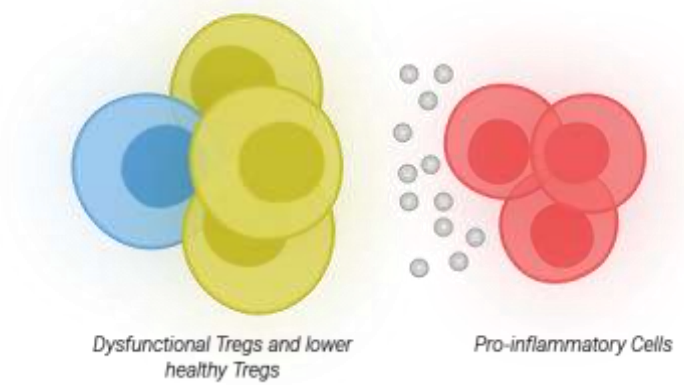
What Are Tregs and How They Are Dysfunctional

Tregs are a type of lymphocyte that modulate the body's immune response

The main functions of Tregs are:

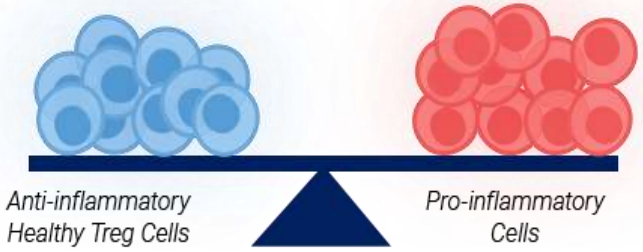
- *Ameliorate inflammatory mechanisms and reactions*
- *Inhibit the release of pro-inflammatory cytokines*
- *Maintain self-tolerance*





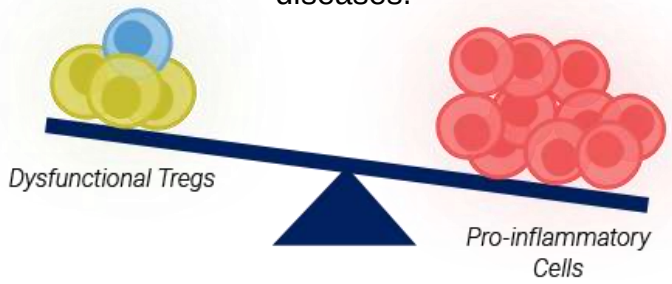
Healthy Tregs

Tregs are important anti-inflammatory immune cells involved in homeostasis. Tregs act on multiple immune cells to down-regulate the release of pro-inflammatory cytokines.



Dysfunctional Tregs

When Tregs become dysfunctional, a cytokine-mediated inflammatory state can arise leading to neurodegenerative, autoimmune, and metabolic diseases.



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Strong Proof-of-Concept Clinical Data

COYA 302 for the Treatment of Amyotrophic Lateral Sclerosis*

- Open-label academic study in 4 ALS patients, conducted at Houston Methodist
- Results were presented at MDA Conference in March 2023
- No disease progression at week 24 and minimal progression at week 48 (by mean ALSFRS-R score)
- Consistent and significant Treg function enhancement and increased Treg numbers
- Expression of blood biomarkers of inflammation were downregulated, correlating with disease severity and treatment response
- Safe and well tolerated

Coya 301 for the Treatment of Alzheimer's disease*

- Open-label academic study in 8 mild-to-moderate AD patients, conducted at Houston Methodist
- Results were presented at Keystone Conference in May 2023 and at Alzheimer's Association International Conference in July 2023
- Statistically significant improvement in cognitive function, as measured by the Mini-Mental State Examination test (MMSE)
- Restored peripheral Treg function and numbers, and lowered the levels of systemic pro-inflammatory chemokines and biomarkers
- Safe and well tolerated

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* Studies were conducted with commercially available product.

Robust Treg-focused Pipeline

Product Type	Discovery	Preclinical	IND-Enabling	Phase 1	Phase 2a	Phase 2b/3	Partnerships / Collaborations	Upcoming Milestones
Treg-Enhancing / T Effector & Macrophage Depleting Biologics	**COYA 302** (Biologic Combination) ***Amyotrophic Lateral Sclerosis (ALS)*** **Completed POC IIT open label study in patients with ALS***						Dr.Reddy's Houston Methodist	**H2 2023**: *PoC Biomarker data release:* **Q1 2024:** *IND filing and Ph2 initiation* ***H2 2023:*** *PoC Peer-Reviewed publication*
Treg-Enhancing Biologic	**COYA 301** ***Alzheimer's Disease (AD)*** **Completed POC IIT open label study in patients AD*** **Ongoing IIT double-blind study in patients with AD***						ARSCIENCE BIO Houston Methodist	**July 2023:** *Report Ph1 POC data in AD (AAIC), (ANA)* **H2 2023:** Ph1 PoC Peer-Reviewed publication **H2 2024:** Academic double blind Ph2 top-line data
Allogeneic Treg-Derived Exosomes	**COYA 201** *Neurodegenerative, Autoimmune, and Metabolic Diseases*						Houston Methodist	**H1 2023:** *Completion of Therapeutic Animal Model Studies*
Antigen-Directed Allogeneic Treg-Derived Exosomes	**COYA 206** *Undisclosed Indications*						Carnegie Mellon University	**H1 2023:** *Target & Cargo Validation*

Robust POC results warrant conducting a larger and well-controlled study for COYA 302 in ALS

POC- Proof of Concept; IIT- Investigator Initiated Trial

* Conducted using commercially available products

COYA THERAPEUTICS

Coya's Leadership Has Demonstrated Deep Expertise in Biotech

Management Team



Howard Berman, Ph.D.
Chief Executive Officer & Chairman of the Board



Adrian Hepner, M.D., Ph.D.
President & Chief Medical Officer



David Snyder
Chief Financial Officer & Chief Operating Officer



Arun Swaminathan, Ph.D.
Chief Business Development Officer



John Centanni
Vice President of Regulatory Affairs

Prior Experience*

abbvie · Lilly · NOVARTIS · MD Anderson Cancer Center · imaware

EAGLE · AVANIR · UCB · PHARNEXT

DisperSol · exicure · Cellular Dynamics International · NimbleGen

ALTEOGEN Inc. · Actinium Pharmaceuticals, Inc.

CardinalHealth · NEURONA THERAPEUTICS · axogen

Board of Directors



Ann Lee, Ph.D.
Chief Technical Officer of Prime Medicine



Anabella Villalobos, Ph.D.
Head of Biotherapeutics and Medicinal Sciences of Biogen



Dov Goldstein, M.D., MBA
Chief Financial Officer of BioAge Labs



Hideki Garren, M.D., Ph.D.
Chief Medical Officer of Prothena Biosciences

Prior Experience*

Bristol Myers Squibb · Genentech · MERCK · juno

Pfizer

Vicuron · INDAPTA · SCHRÖDINGER · AISLING CAPITAL

BAYHILL THERAPEUTICS · Roche · NOVARTIS · Genentech

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*Logos illustrated represent past experience

SAB Comprised of Seminal Leadership in Tregs

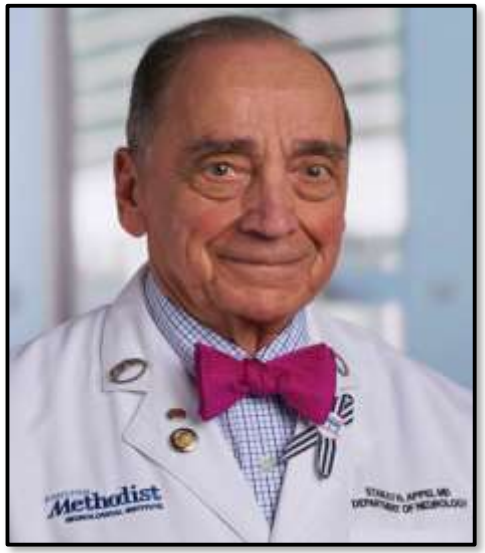
Following the discoveries of Dr. Sakaguchi and Dr. Appel, Coya is developing multiple product modalities to enhance the therapeutic potential of Tregs for the treatment of disorders of high unmet need



Shimon Sakaguchi, MD, PhD

Distinguished Professor at the World Premier International Research Initiative (WPI)-Immunology Frontier Research Center (IFReC) at Osaka University

Discovered Tregs in 1995 and their role in inflammation and autoimmune conditions



Stanley Appel, MD

Former Chair of the Stanley H. Appel Department of Neurology
Director of the Ann Kimball & John W. Johnson Center for Cellular Therapeutics
Houston Methodist Hospital

Pioneered research in neuro-inflammation and the development of Treg targeted therapies

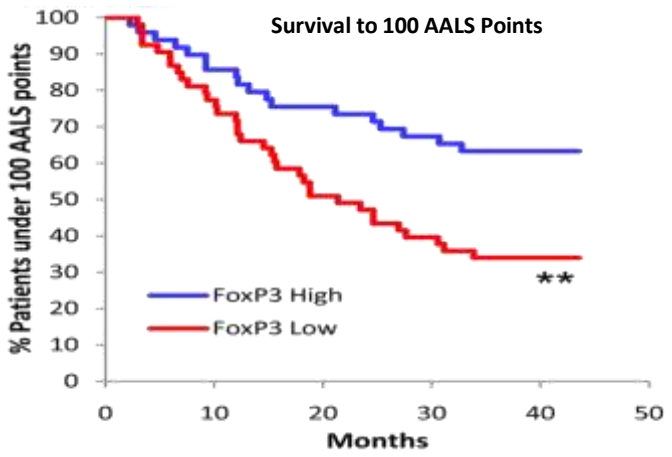
SAB: Scientific Advisory Board

Treg Dysfunction Is a Core Driver of Neurodegeneration

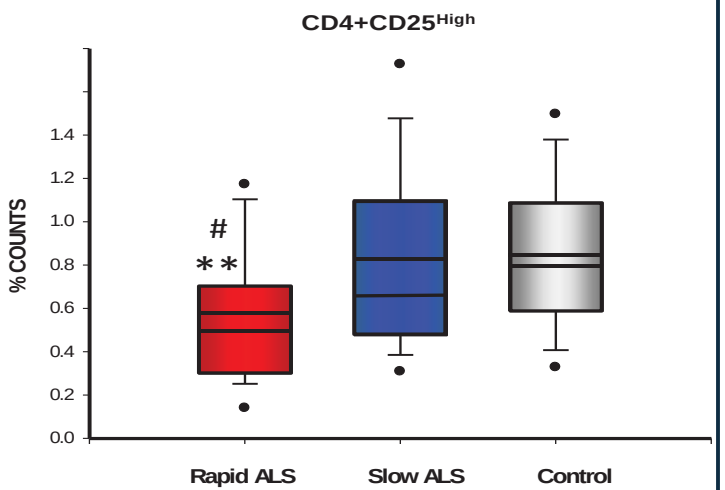
Treg dysfunction is associated with ALS disease progression and burden of disease…

…and is similarly associated in other neurodegenerative diseases

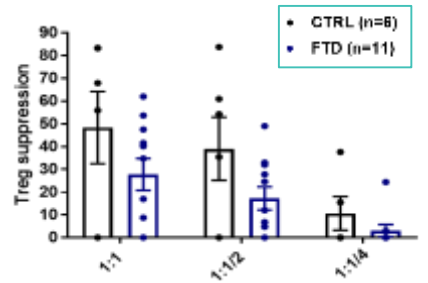
Treg Dysfunction is Associated with ALS Survival



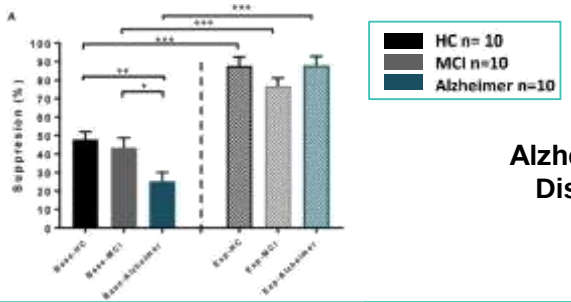
Treg Dysfunction Plays a Role in the Rate of Decline in ALS



Treg Dysfunction Is Implicated in FTD & AD



Frontotemporal Dementia



Alzheimer's Disease

Henkel et al, EMBO Mol Med. 2012 Nov 9
Faridar et al, Brain Communications, Volume 2, Issue 2, 2020, fcaa112

Initial Findings → Diverse Pipeline Addressing Treg Dysfunction

Key Learnings From Two IIT Studies Conducted at Houston Methodist under Dr. Stanley Appel…

- **Treg Cell Therapy was well-tolerated** with no Serious Adverse Events (SAEs) reported across both studies
- **Discovery of Biomarkers:** High levels of proinflammatory (IL-17F, IL-17C, OLR-1) and oxidative stress (Ox-LDL, 4-HNE) biomarkers were associated to poor therapeutic response
- **Phase 1 Proof of Concept**: Three patients received 4 bi-weekly infusions over 8 weeks; 16 weeks later, patients received 4 monthly infusions. **Infusions halted ALS progression**
- **Phase 2a + Open-Label Extension**: 4/8 (50%) patients had a mean change in ALSFRS-R score of +0.2 points; 75% of patients (responders) showed a mean change in ALSFRS-R score of -2.7 points over 24 weeks, while 25% of patients did not respond to therapy.

…Led to the Discovery and Advancement of COYA 300 Series

Our initial learnings demonstrate targeting Tregs has a meaningful affect on ALS progression and other neurodegenerative diseases

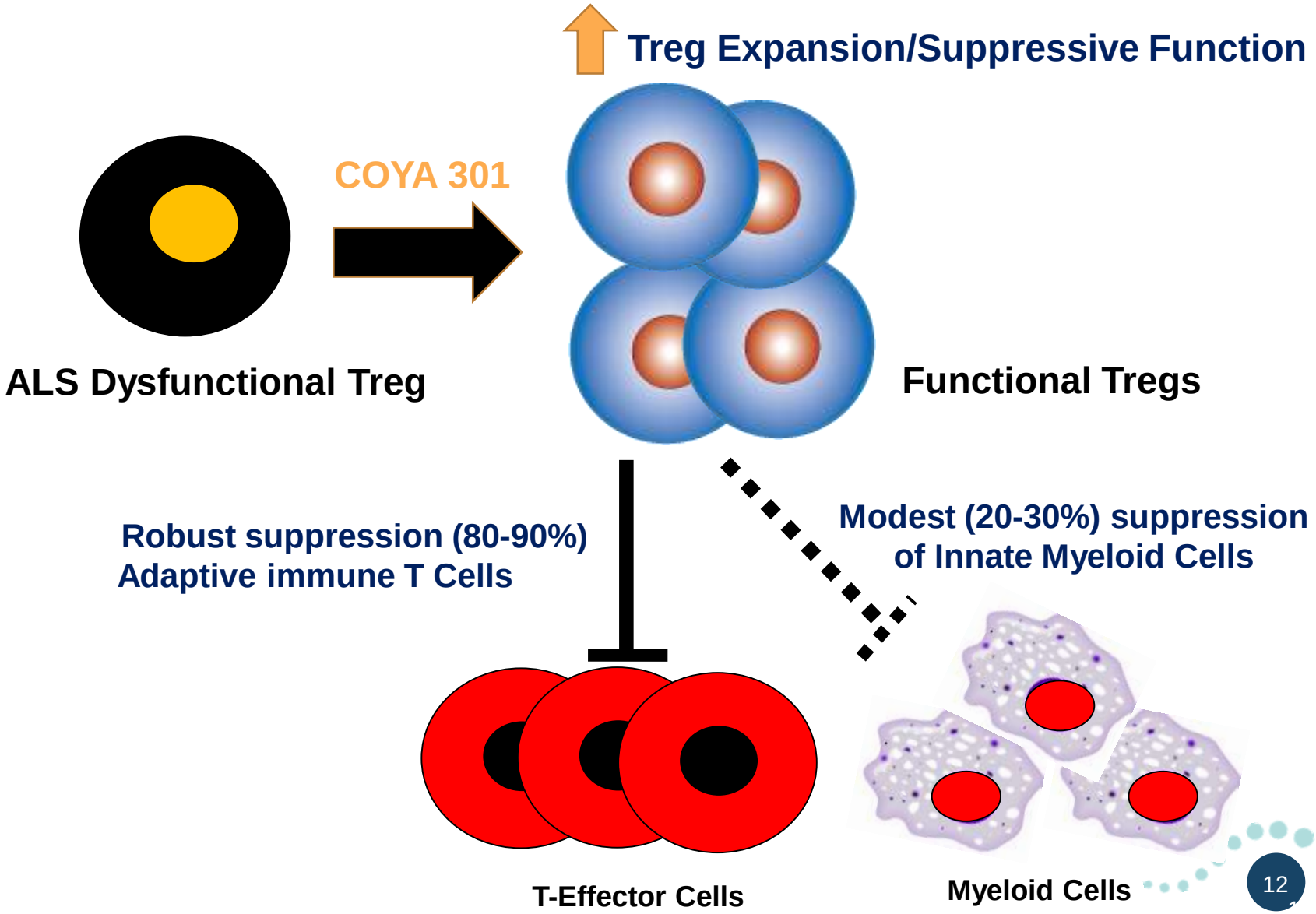
Biologic programs (COYA 300 series) represent:

- **Targeted pathway in Treg Dysfunction**
- **Multi-Pathway** approach to addressing Treg dysfunction in vivo
- **Cost-effective** clinical development and manufacturing
- **More scalable** approach for commercialization
- **Biomarker enrichment** for efficient clinical development
- **Defined and supportive regulatory** environment in ALS

IL-17F: Interleukin 17F protein
IL-17C: Interleukin 17c protein
OLR-1: Oxidized Low-Density Lipoprotein Receptor 1
Ox-LDL: Oxidized Low-Density Lipoprotein
4-HNE: 4-Hydroxynonenal

COYA 301: Proprietary Treg Enhancing Low-Dose Il-2 Suppresses Adaptive Immunity - Robustly - and Innate Immunity - Modestly

Dysfunctional Tregs are associated with neuroinflammation promoted by activated T effector cells and activated innate myeloid cells



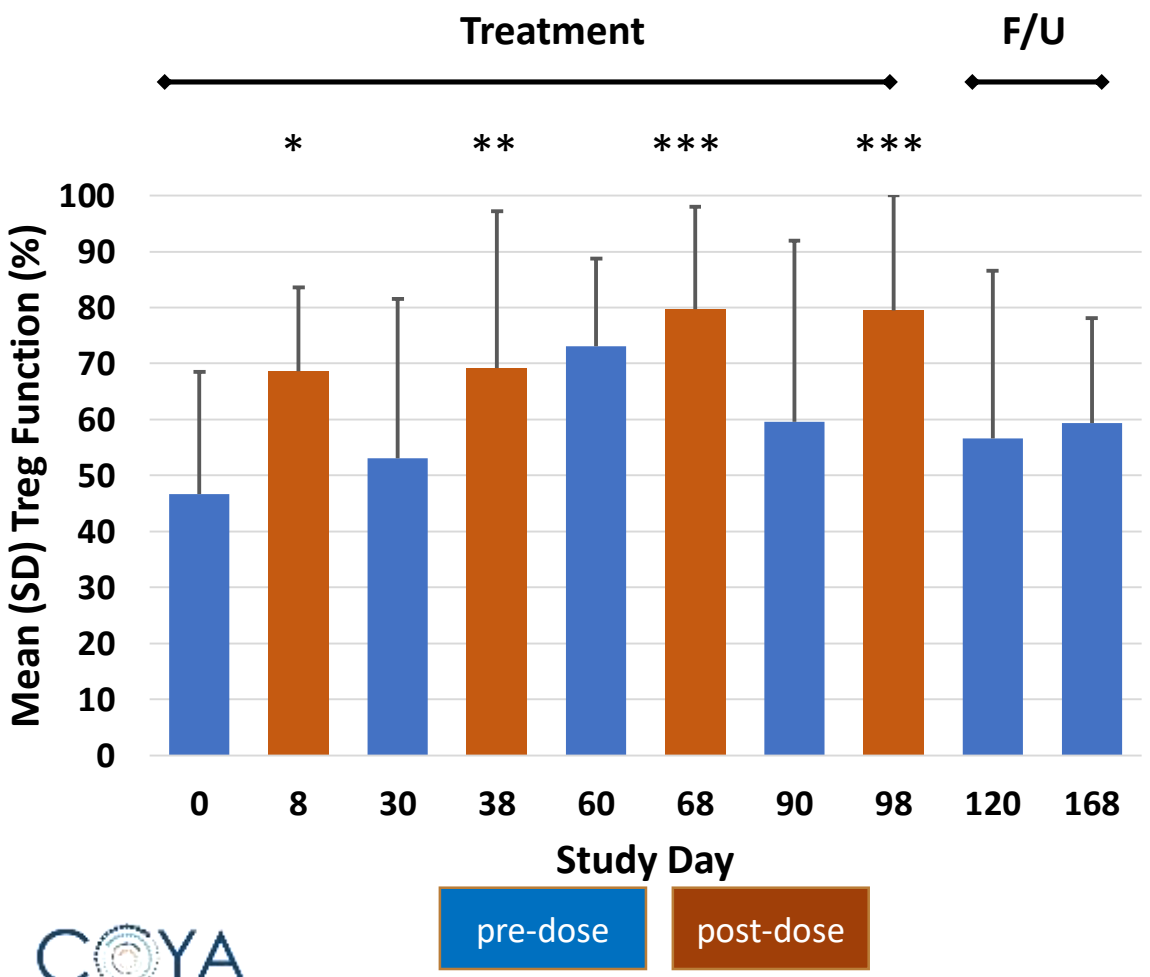
COYA 301: Investigator-Initiated Study in Alzheimer's Disease (AD)

Overall Study Design

- Proof-of-Concept open-label study, conducted at Houston Methodist Hospital
- Population: 8 patients with mild-to-moderate AD
- Treatment: 4 monthly COYA 301 cycles administered subcutaneously, followed by 2-month post-treatment observation. The study was conducted with commercially available product.
- Assessments:
  - Treg suppressive function and Treg numbers
  - Peripheral proinflammatory biomarkers
  - Cognitive status
  - Safety and tolerability

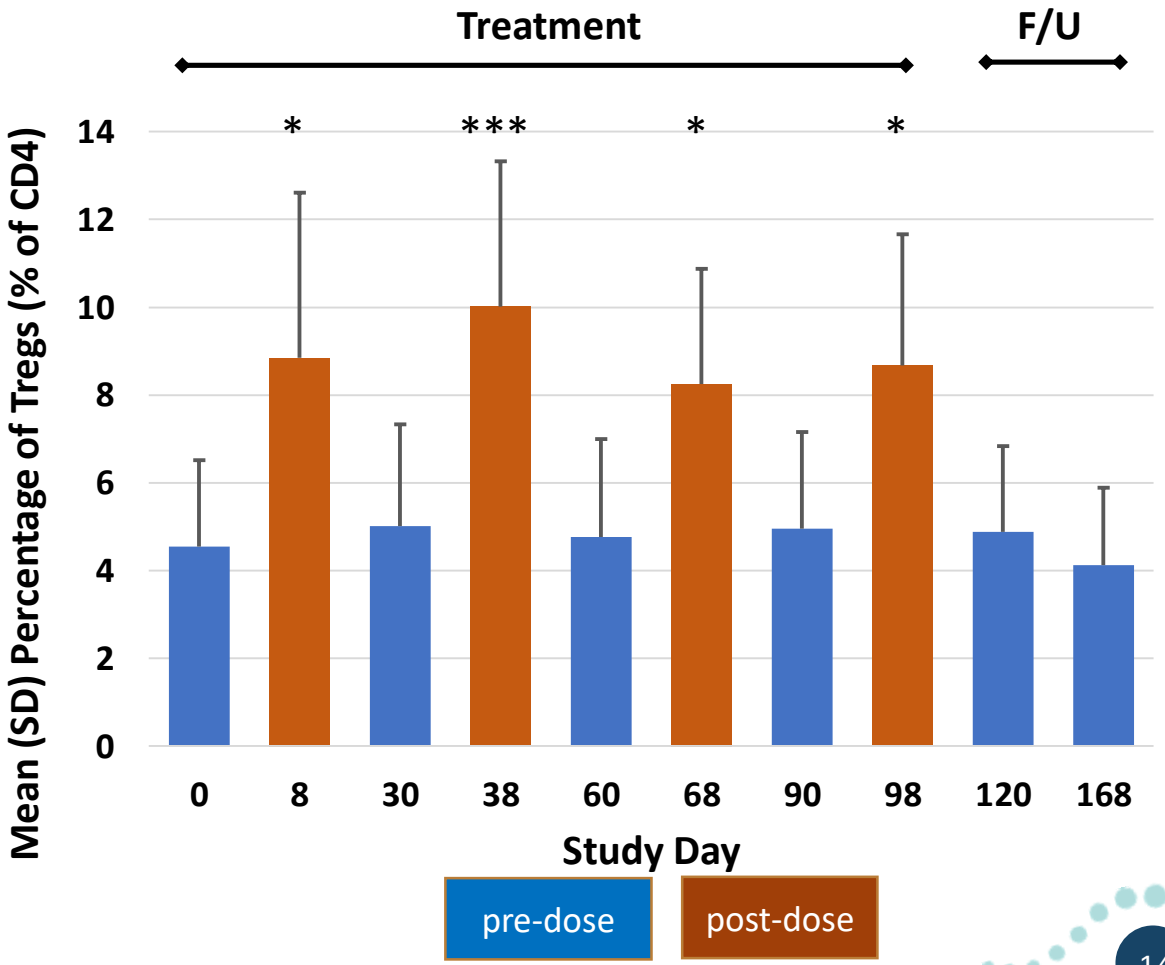
COYA 301 Enhances Treg Function and Numbers *in vivo* in AD Patients (N=8)

Statistically Significant Enhancement of Treg Suppressive Function



*p<0.05, **p<0.01, ***p<0.001

Statistically Significant Enhancement of Treg Numbers



*p<0.05, ***p<0.001

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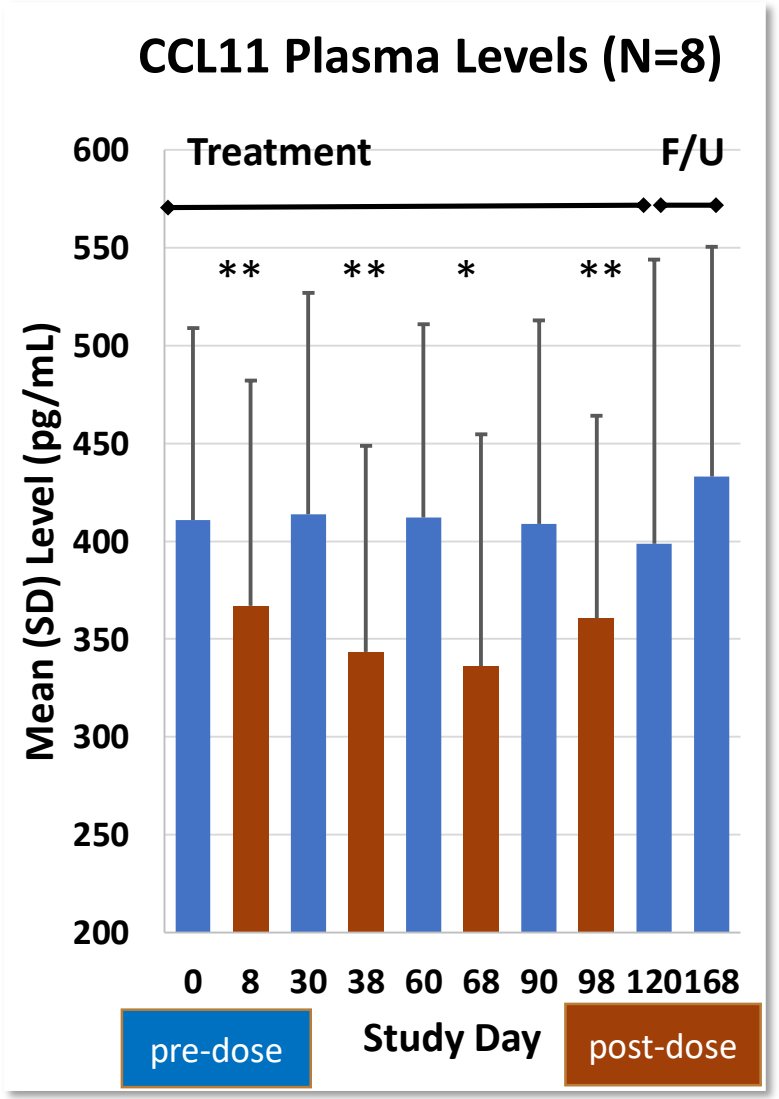
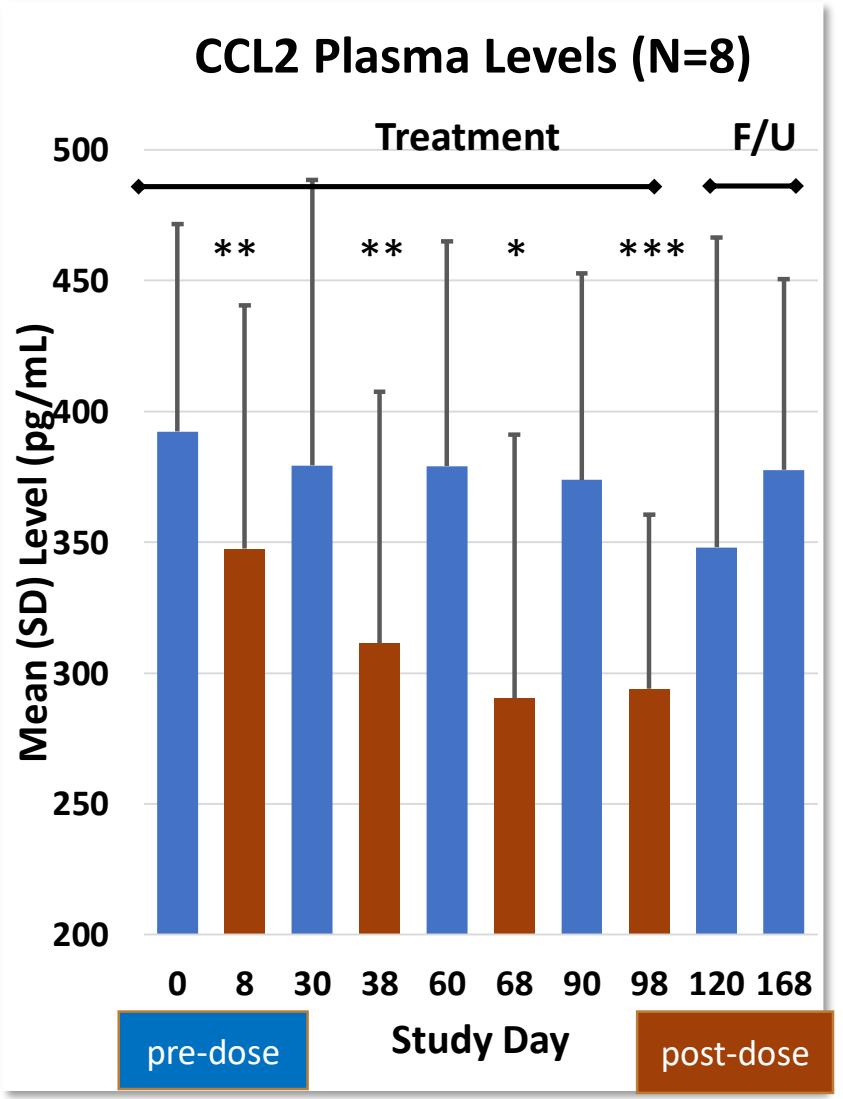
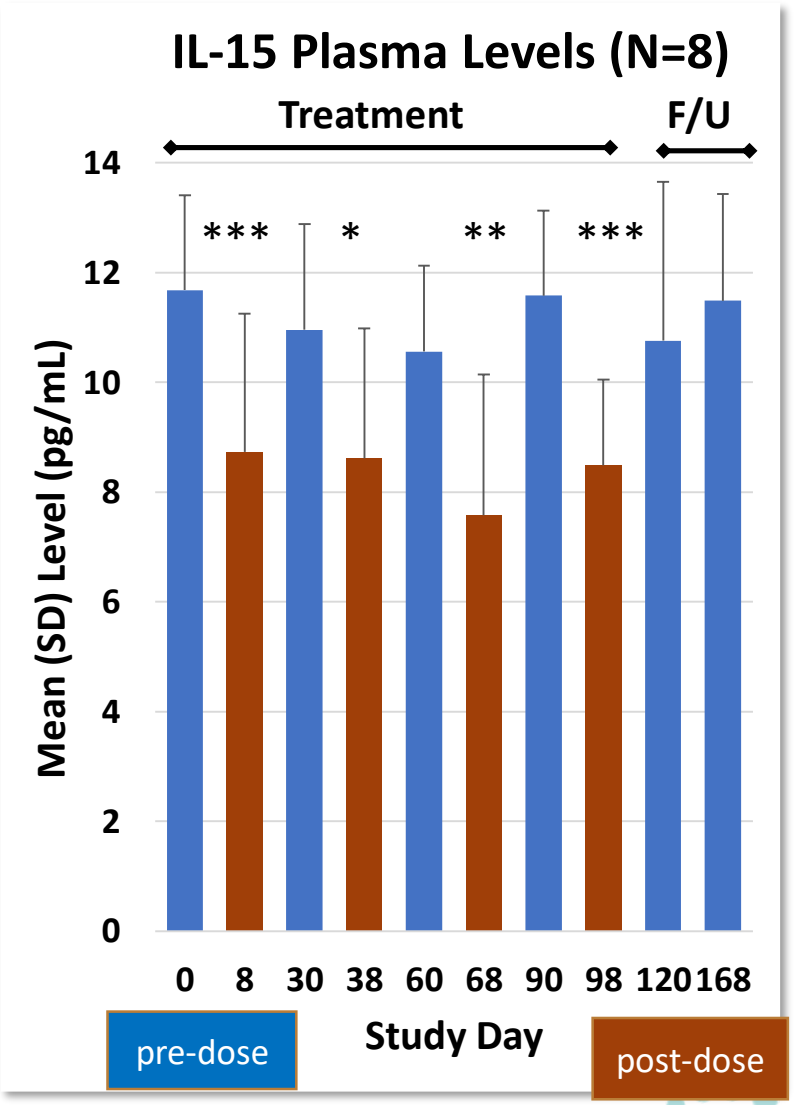
COYA 301 Significantly Lowers Plasma Proinflammatory Chemokines and Cytokines in AD Patients



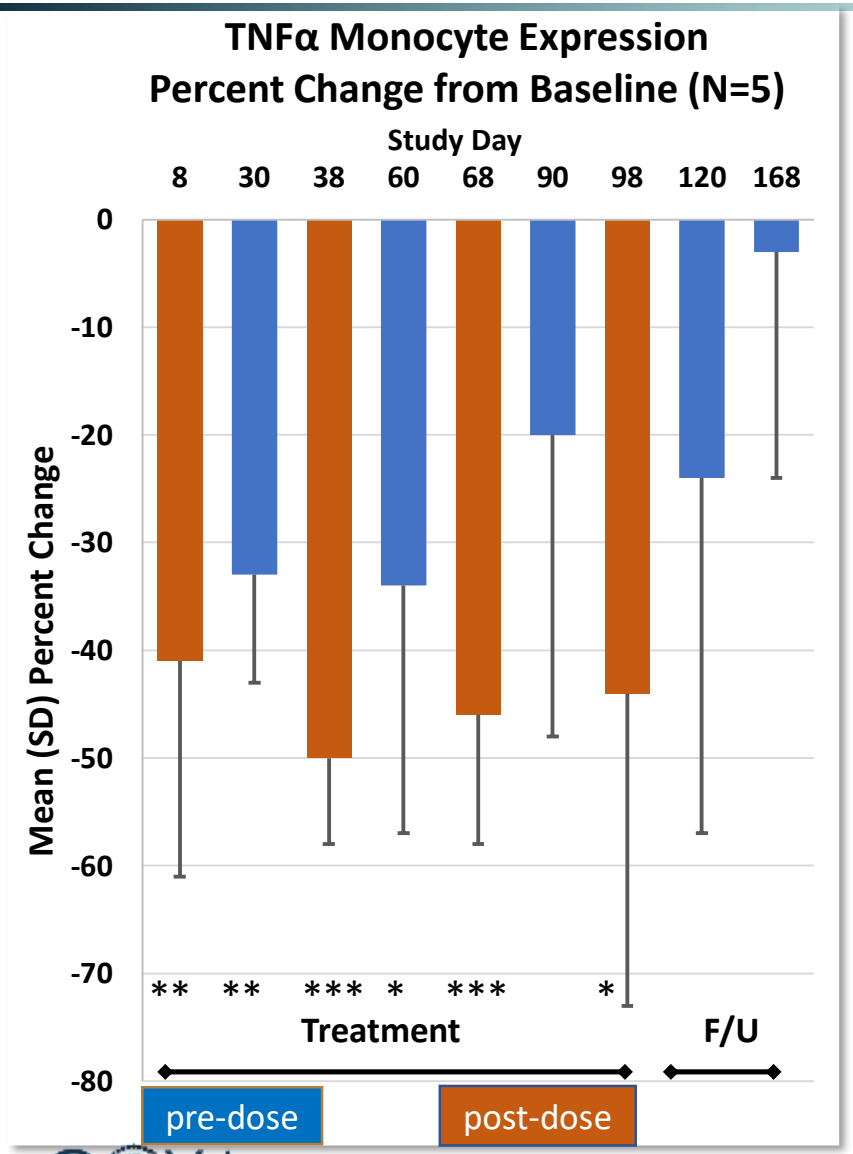


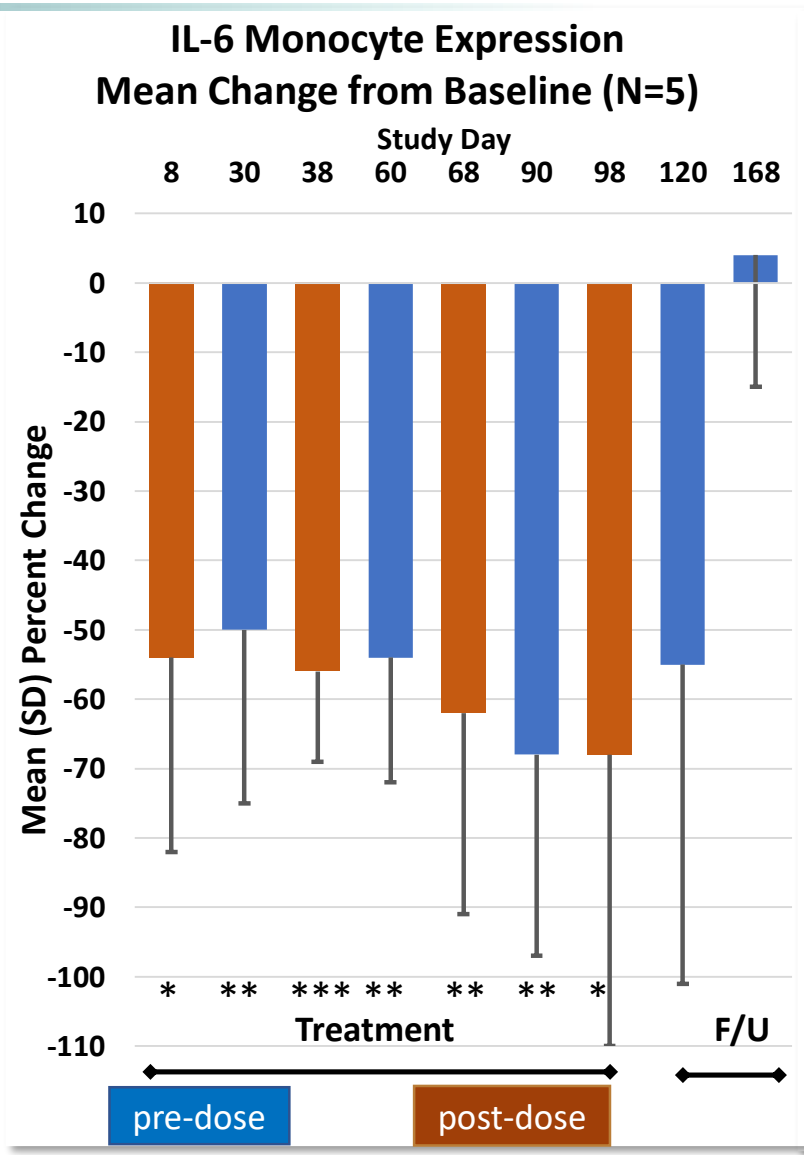


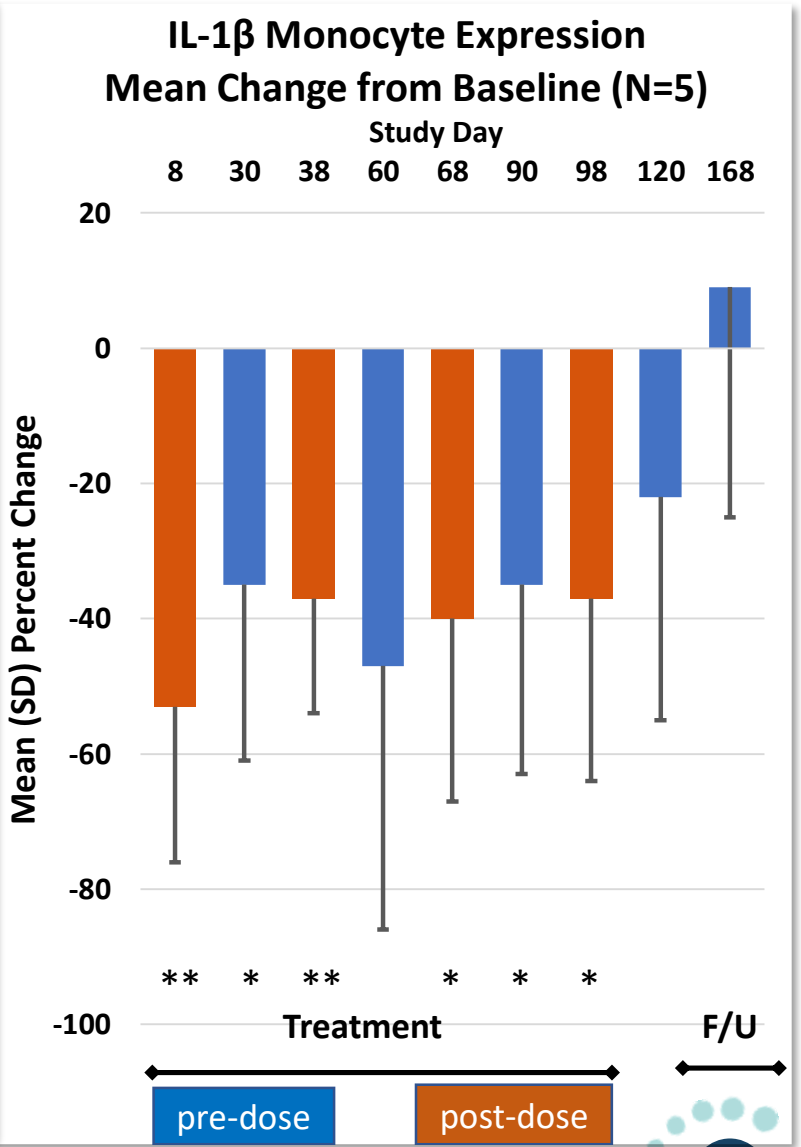
CCL11: chemokine C-C motif ligand 11 (eotaxin-1); CCL2: chemokine monocyte chemoattractant protein 1
IL-15: interleukin 15

*p<0.05, **p<0.01, ***p<0.001

COYA 301 Significantly Lowers Expression of Proinflammatory Cytokines in AD Patients



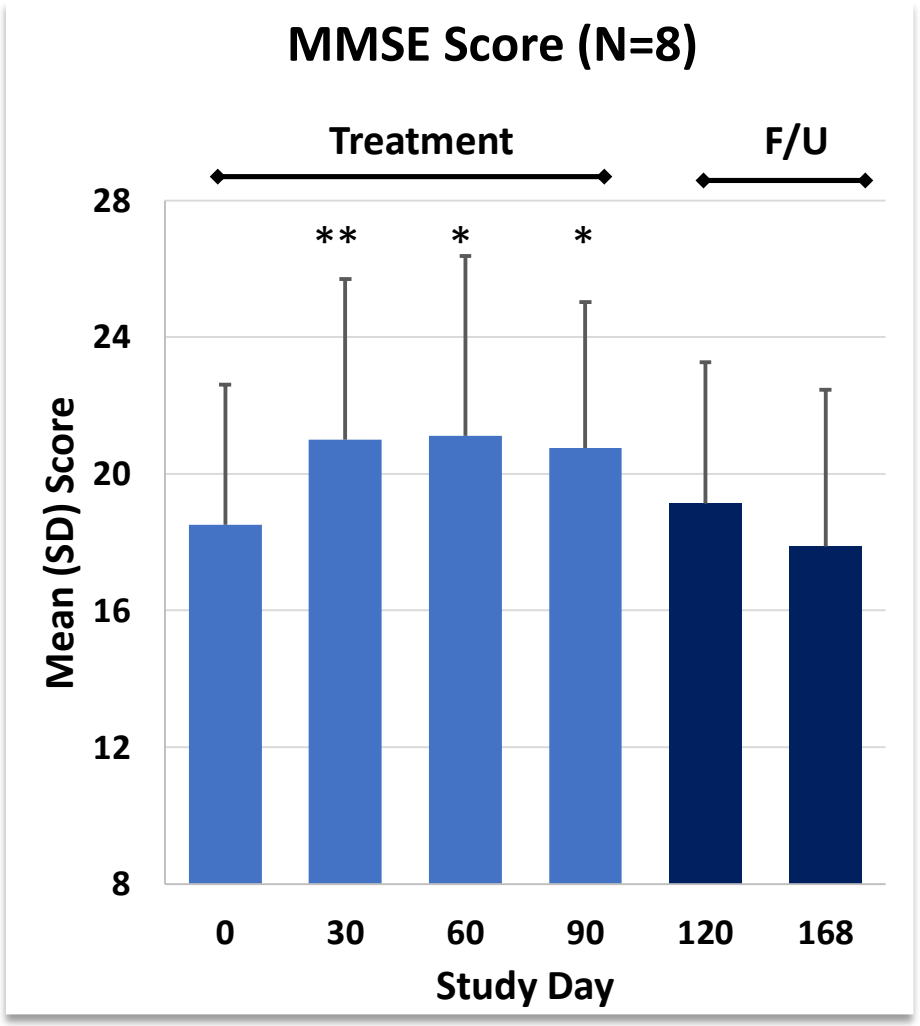


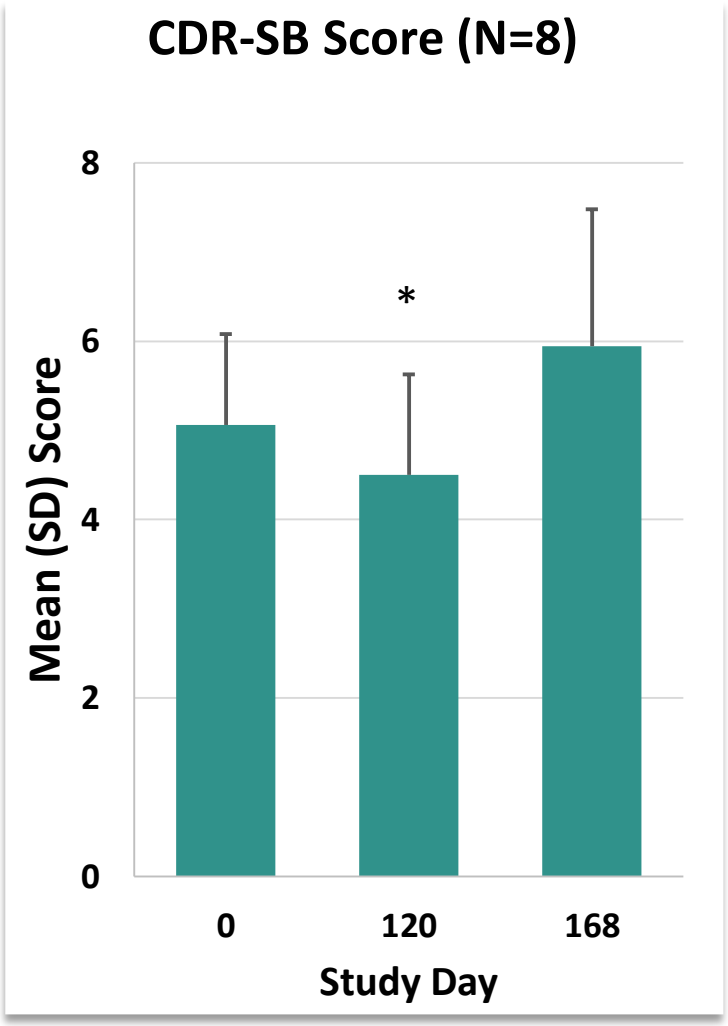


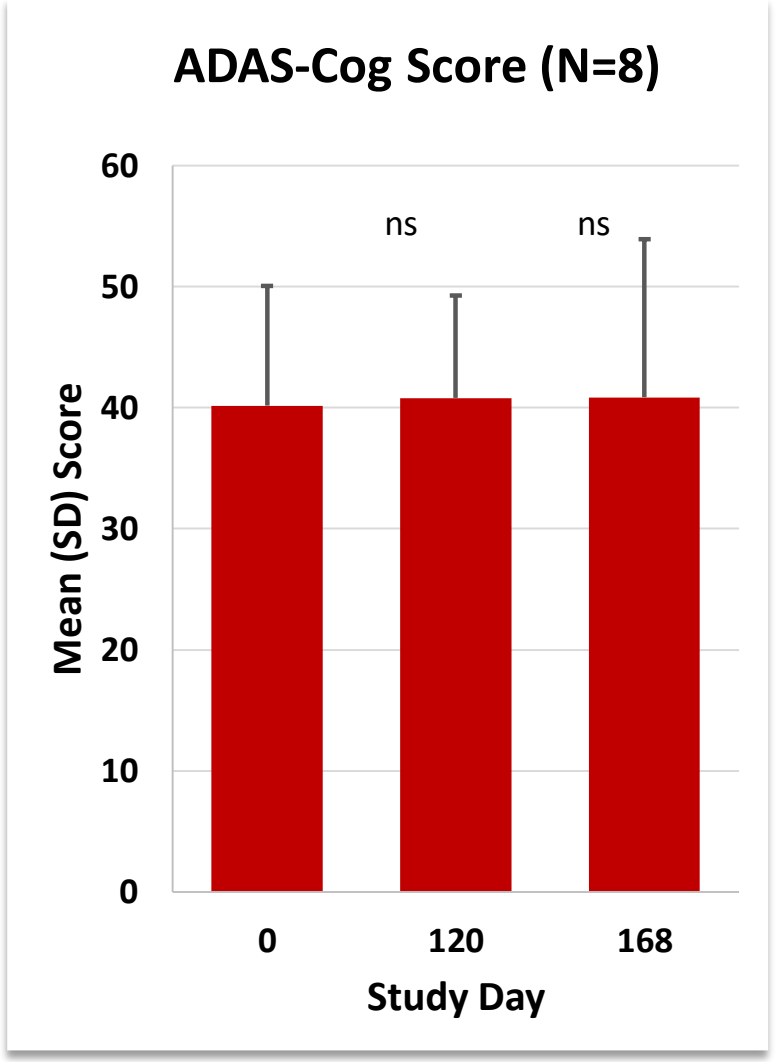
TNFα: tumor necrosis factor alpha; IL-6: interleukin 6; IL-1β: interleukin 1 beta

*p<0.05, **p<0.01, ***p<0.001

COYA 301 Improved or Halted Cognitive Decline in AD Patients





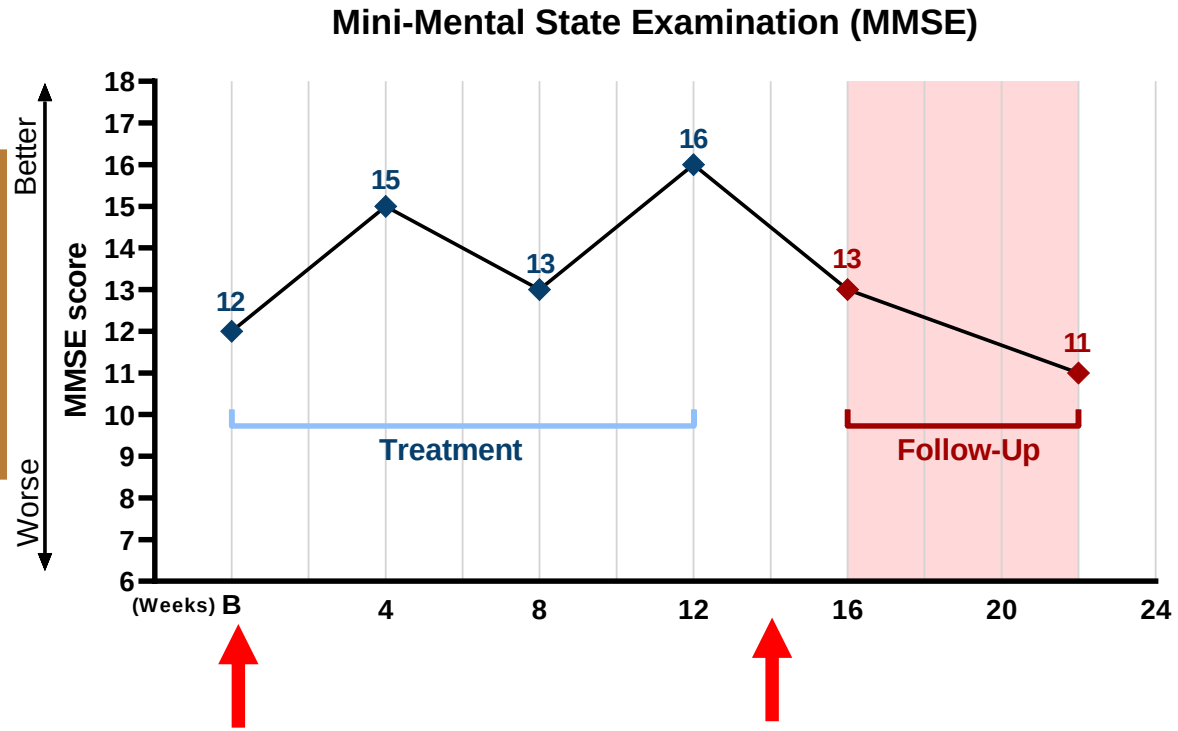


*p<0.05, **p<0.01 ns: not significant

MMSE: Mini-Mental State Examination, ADAS-Cog: Alzheimer's Disease Assessment Scale-Cognitive Subscale
CDR-SB: Clinical Dementia Rating scale – Sum of Boxes

Case Study of Brain Imaging of AD Patient before and after COYA 301 treatment

70-Year-Old Male
Baseline MMSE: 12
Positive PIB PET Scan
Positive Neurodegeneration MR
Other Rx: Donepezil 10mg

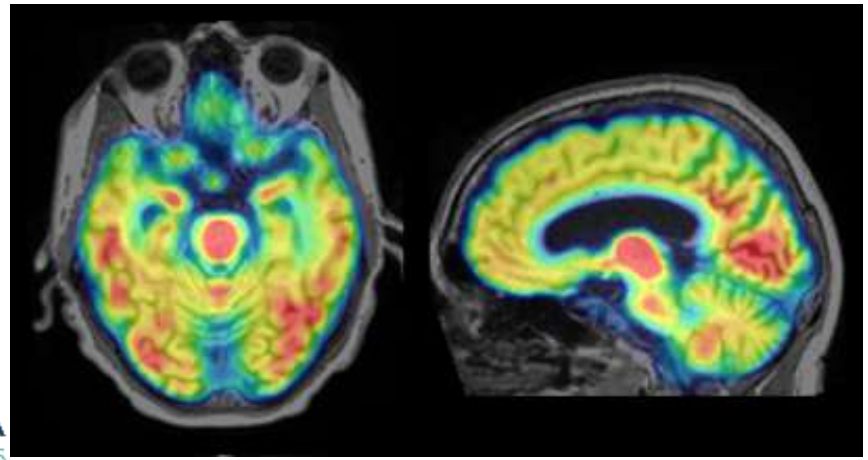


Neuroinflammation (TSPO) (^{11}C) ER-176 PET Scan at baseline and after 4-monthly cycles of low dose IL-2.

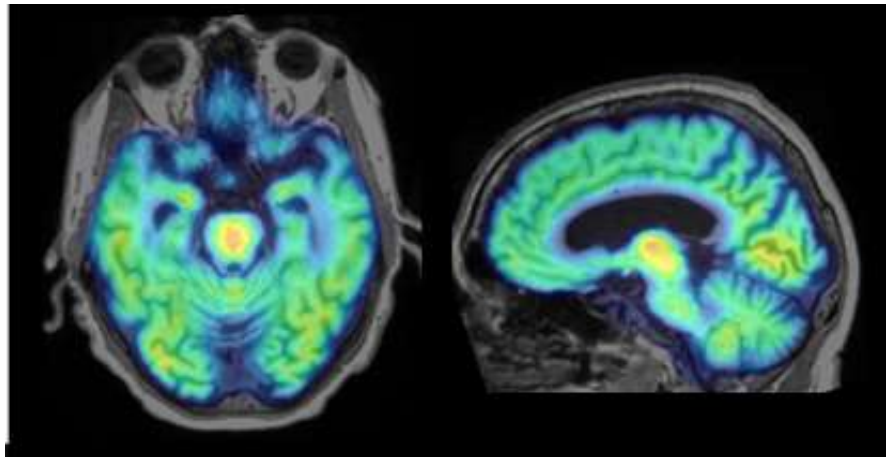
The second PET scan was done 2 weeks after last dose.

PET: Positron Emission Tomography
TSPO: translocator protein

PET Scan (Baseline)



PET Scan (2 weeks after last dose)



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COYA 301 Safety & Tolerability

- Overall, COYA 301 was well tolerated in patients with AD.
- Most common adverse events (AEs) were mild injection site reactions and mild leukopenia.
- All patients completed the study.
- No death or other serious AE occurred over the course of the study.

COYA 301 as a Backbone for Combination Immunotherapy

Activated T effector Cells

Activated Macrophages/Microglia

Treg Function and numbers

COYA 301

Subcutaneous Low-Dose Interleukin-2

Backbone Therapy

\+

CTLA4 Ig	→	COYA 302	Shown therapeutic benefit in ALS patients
Cytokine Inhibition	→	COYA 303*	Neurodegenerative Autoimmune Metabolic
Ferroptosis Inhibitor	→	COYA 304*	Neurodegenerative Autoimmune Metabolic

Multifactorial inflammatory pathways may require synergistic combination therapies

* Opportunities for additional indications and partnerships

COYA THERAPEUTICS

COYA 302 Addresses Dysfunctional Tregs and Pro-inflammatory Macrophages

COYA 302 =

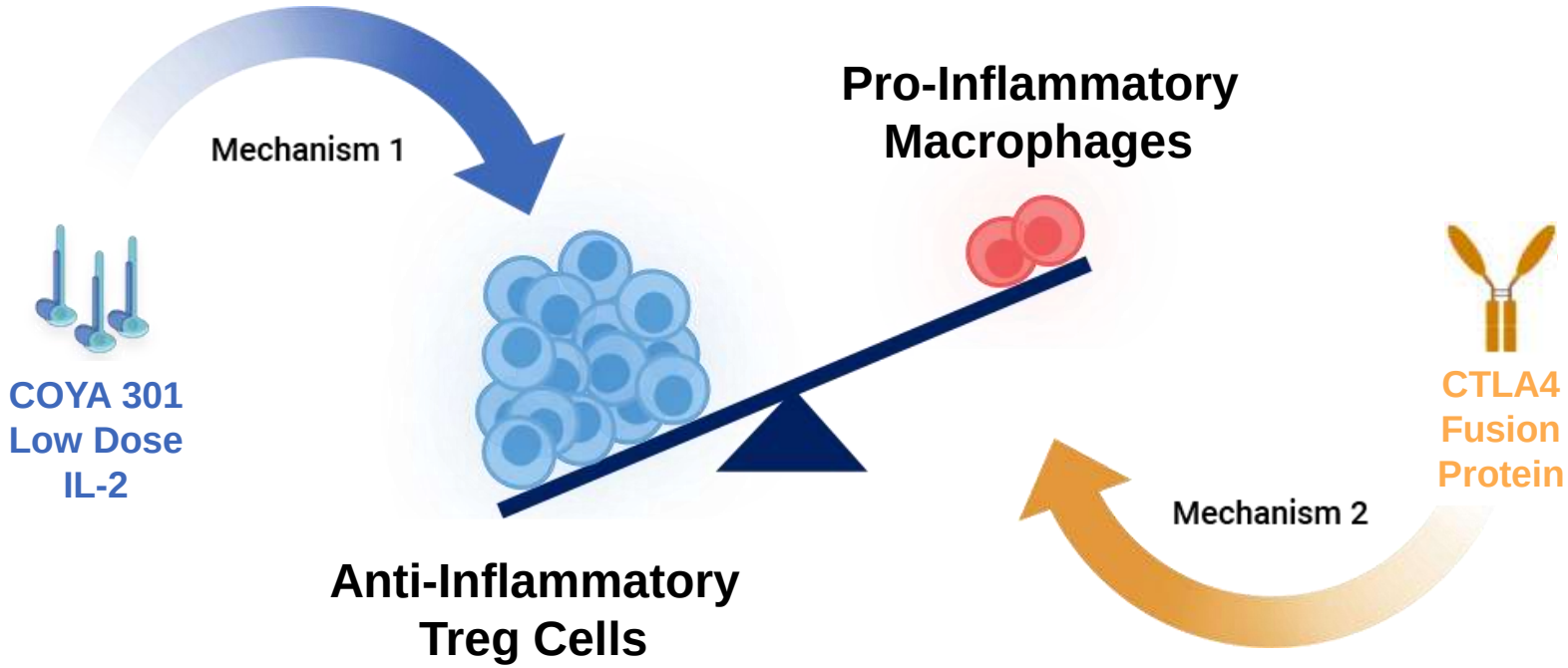
Low Dose IL-2

↓ Dysfunctional Tregs
↑ Treg Numbers & Suppressive Function

+

CTLA4-Ig

↓ Pro-Inflammatory Macrophages
↑ Anti-Inflammatory Macrophages



COYA THERAPEUTICS

COYA 302: A Novel Approach to the Treatment of Neurodegenerative Diseases

Unique products compared to commercial IL-2 (High Dose Lyophilized Format) or CTLA4-Ig (Orencia)

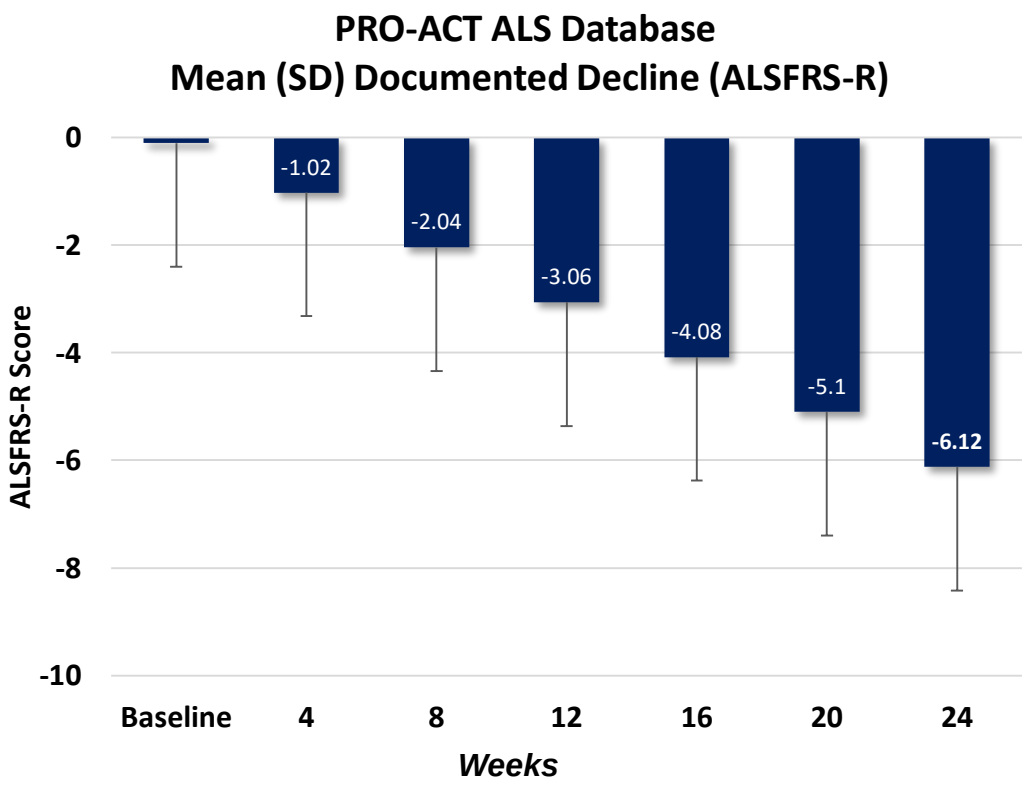
- New Indications including ALS, Alzheimer's, other ND diseases
- Unique low dose strength and dosing regimen
- Ready-to-administer stable subcutaneous formulation
- Well-established GMP manufacturing
- Strong IP

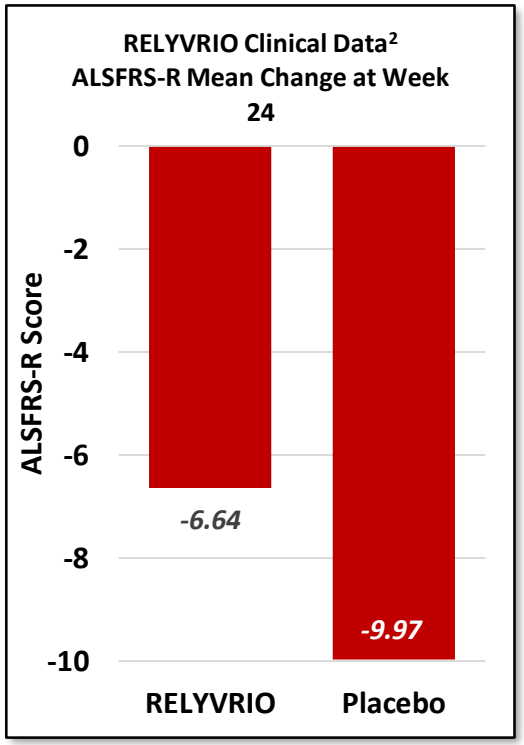
COYA 302 is an investigational product, not yet approved by the US Food and Drug Administration

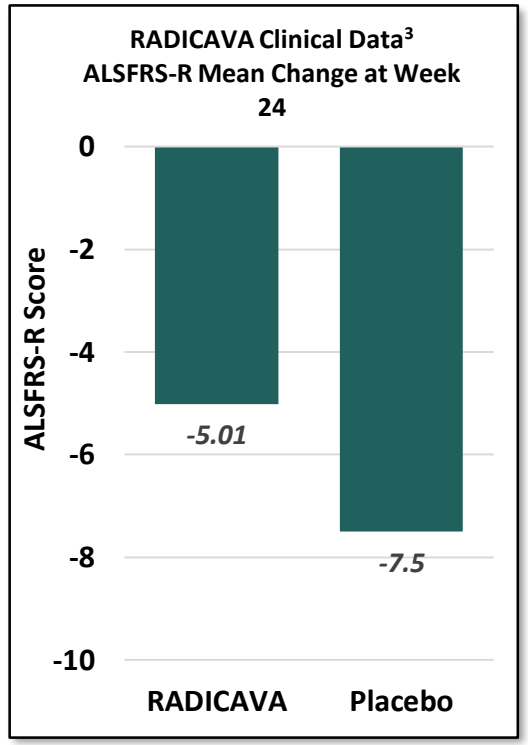
COYA THERAPEUTICS

Current Therapies for ALS Aim to Slow Disease Progression

Many companies have garnered significant value by demonstrating a *limited* benefit of slowing the rate of ALS progression







Average rate of patient decline is 1.02 points/month in ALSFRS-R score[1]

1. The PRO-ACT database is the largest ALS data repository (Atassi et al, 2014)
2. Relyvrio US Prescribing Information (9/2022)
3. Radicava US Prescribing Information (5/2022)

COYA 302: Open-Label, Single-Arm PoC Clinical Study in ALS Patients (N=4)

Screening	Treatment Period	Follow-Up
20 weeks	***COYA 302** was administered via subcutaneous injection over 48 weeks*	*8 weeks*

Screening Assessments	Treatment Period Assessments	Post-Treatment Assessments
✓ Clinical Labs ✓ ALSFRS-R Score ✓ Electrocardiogram (ECG) ✓ Physical & Neurological Exam	✓ Safety and Tolerability ✓ Treg Function and Numbers ✓ Serum Biomarkers ✓ ALSFRS-R Score	✓ Safety and Tolerability ✓ Treg Function & Numbers ✓ Serum Biomarkers ✓ ALSFRS-R Score

Study patients had well-documented disease progression prior to treatment (-1.1 points/month prior to treatment with COYA 302)

Safety and tolerability assessments included reported adverse events, periodic physical and neurological exams, clinical labs, and ECGs

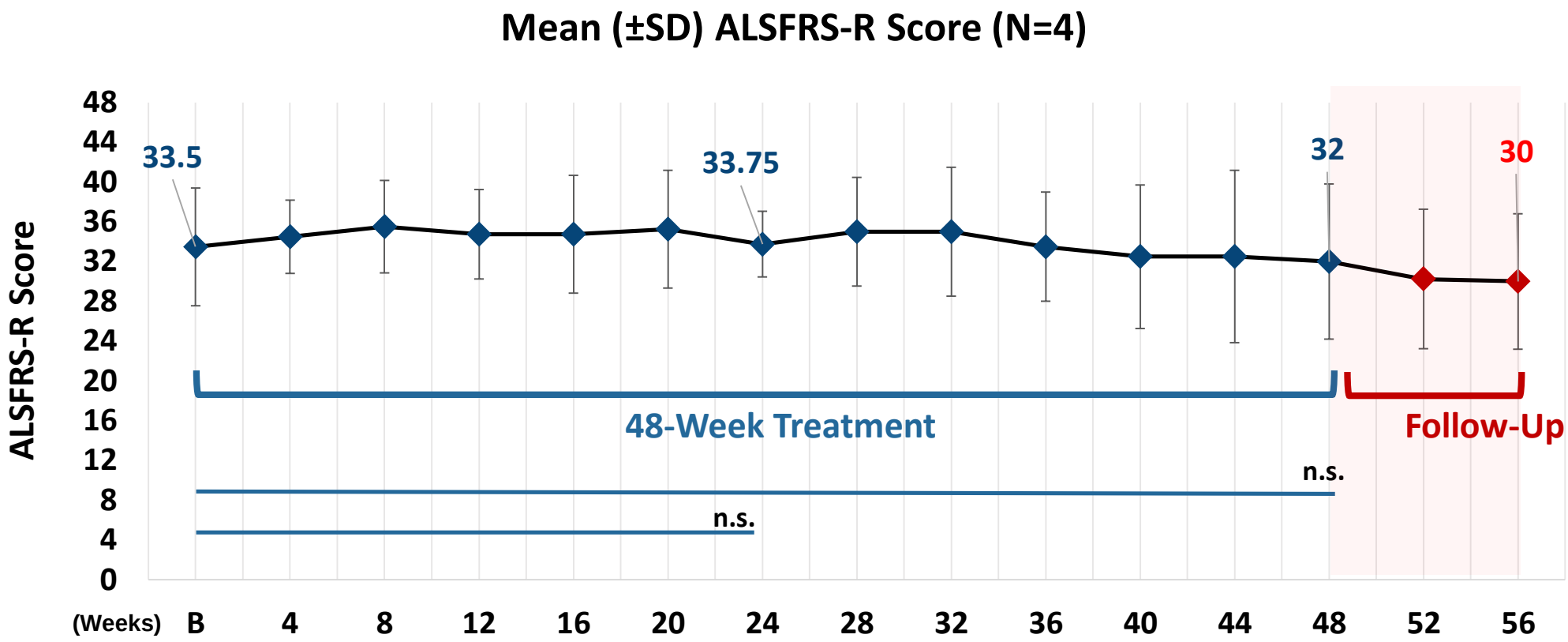
COYA THERAPEUTICS

COYA 302: Patients' Demographics and Baseline Characteristics

	Age (years)	Sex	Type	Onset	ALS Progression Prior to Baseline (ALSFRS-R score)	Respiratory Status	Respiratory Support
Patient 1	47	Female	Familial	Limb	-1.6 points / month	No Respiratory Insufficiency	None
Patient 2	54	Male	Sporadic	Limb	-1 points / month	Respiratory Insufficiency	Non-invasive Ventilation
Patient 3	57	Female	Sporadic	Bulbar	-1 point / month	Respiratory Insufficiency	Non-invasive Ventilation
Patient 4	84	Female	Sporadic	Bulbar	-0.7 points / month	Respiratory Insufficiency	None

COYA THERAPEUTICS

COYA 302: Appears to Ameliorate ALS Progression Over 48-weeks



COYA 302 was well tolerated over 48 weeks; the most common AE was mild injection site reaction. All patients completed the study; no death or serious AEs (SAEs) occurred over the course of the study.

B: Baseline
n.s.: not significant (paired t test)

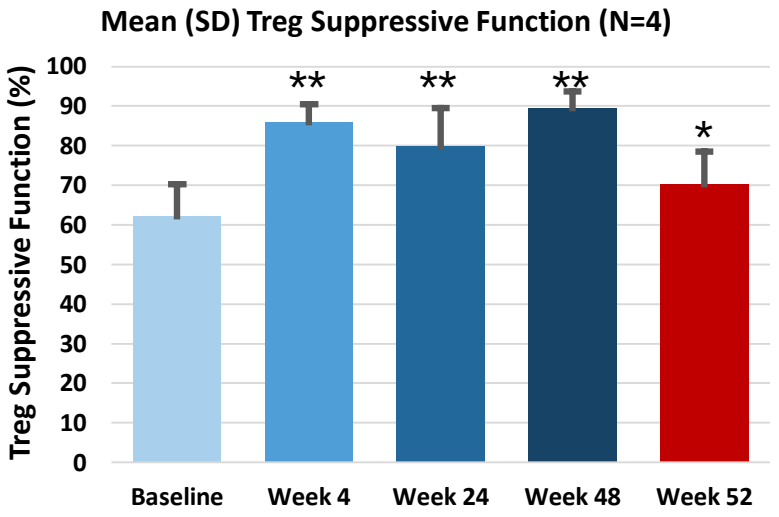
COYA 302: Enhanced Biologic Activity

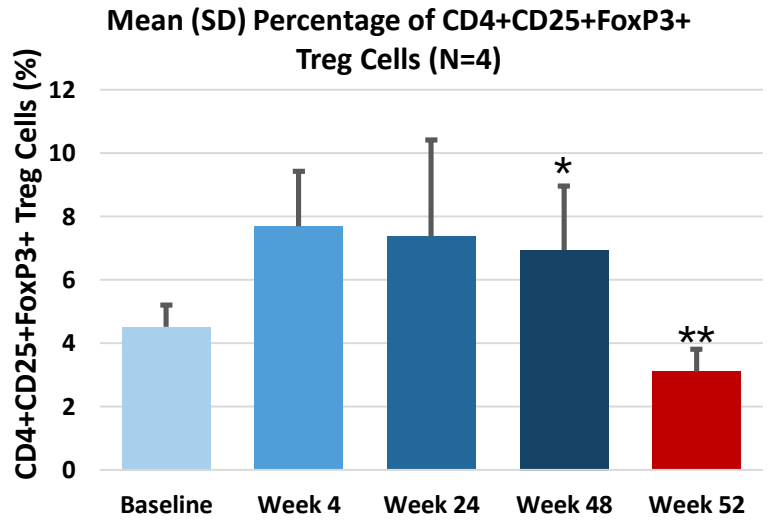
Key Takeaways

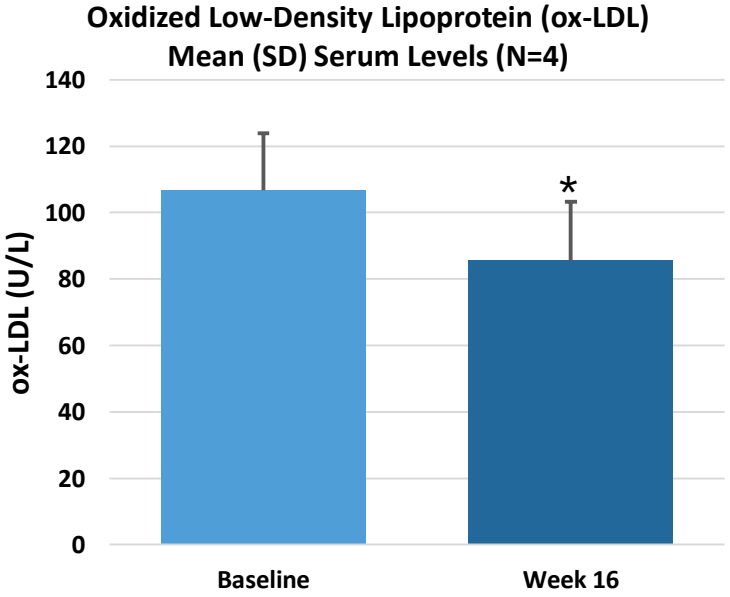
✓**COYA 302 significantly expands Treg suppressive function** as early as 4 weeks after initiation of treatment and maintained a significantly increased Treg function.

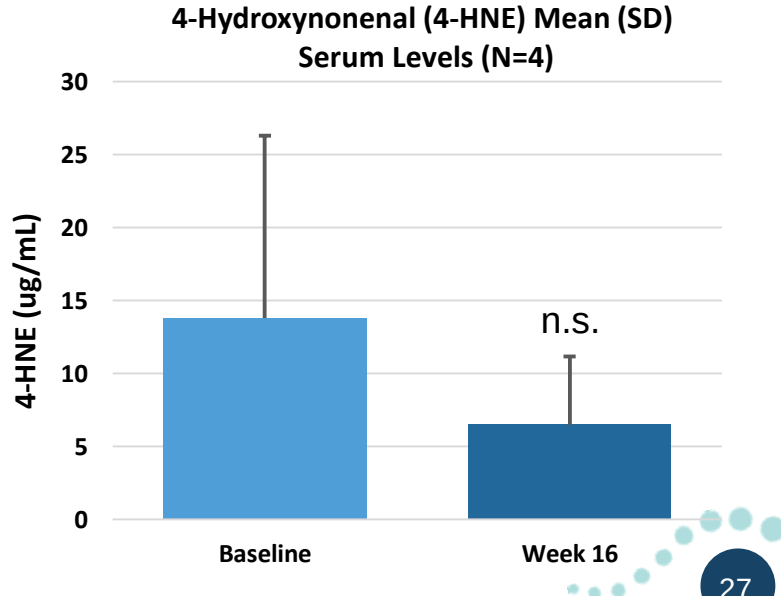
✓**COYA 302 increased Treg numbers as early as 4 weeks** after initiation of treatment and maintained a higher number over the course of treatment.

✓**COYA 302 enhanced suppression** of macrophage-mediated **oxidative stress and proinflammatory cytokine biomarkers** over 48 weeks









n.s.: not significant (paired t test)
*p <0.05
** p <0.01 (paired t test)

COYA 302: Overview of Phase 2 Study Design in ALS



Study Objectives

- Efficacy
- Safety and tolerability
- Biological activity
- Biomarkers

Primary Efficacy Endpoint

- Combined Assessment of Function (ALSFRS-R) and Survival (CAFS)

Main Inclusion Criteria

- Diagnosis of sporadic or familial ALS
- Time since onset of ALS symptoms ≤ 24 months from Screening
- ALSFR-R score ≥ 35 at Screening
- A score of at least 2 points in each ALSFRS-R item
- Forced vital capacity (FVC) ≥ 70% of predicted capacity for age, height, and gender at Screening
- Documented disease progression (by ALSFR-R score) for at least 16 weeks prior to Screening

COYA THERAPEUTICS

Total Addressable Market Exceeding $7B

In the United States Alone:

ALS — Estimated 30k people in the US; The global market size is **$673mm** in 2022[1]

FTD — Estimated 60k people in the US; US market size extrapolated to be **$600mm**[2,6]

SLE — Estimated 1.5 million Americans and at least 5 million people worldwide have a form of lupus; Currently the US market is **$2.8b**[3]

SSc — Estimated 125k cases in the US and perhaps 2.5 million worldwide; US market alone is **$1.4b**[4]

HI&F — Estimated Liver Inflammation & Fibrosis' global market was **$1.6b** in 2021, increasing to **$24b** by 2028[5]



1. CDC & Grand View Research
2. Alzheimer's Association & PRNews Release
3. Lupus Foundation & Coherent Market Insights
4. University of Michigan Health & Grand View Research
5. Science Direct & Global News Release
6. Orphan Drug Designation Pricing based on IQVIA Report, assuming $100k price

Multiple Near-Term Preclinical and Clinical Catalysts

	H1 2023	H2 2023	2024
COYA 302	▪ Amyotrophic Lateral Sclerosis PoC IIT data presented (MDA Conference, March 2023)	• Amyotrophic Lateral Sclerosis PoC IIT data publication in peer reviewed journal • Biomarker data release for PoC study • Pre-IND meeting with FDA	• IND Filing (Q1 2024) • Initiate Phase 2 trial in Amyotrophic Lateral Sclerosis (Q1 2024)
COYA 301	• Alzheimer's Disease PoC IIT data presented (Keystone Conference, May 2023)	• Alzheimer's Disease PoC IIT data presentation (AAIC, July 2023), (ANA, September 2023) • Alzheimer's Disease PoC IIT data publication in peer reviewed journal	• Topline data of academic investigator Initiated Phase 2 double blind trial in Alzheimer's Disease (1H 2024)
COYA 201 (Neurodegenerative, Autoimmune, Metabolic Diseases)		• Preclinical in-vivo efficacy data • Disease-specific Animal Model Validation	• Completion of pharmacology in multiple models
COYA 206 (Undisclosed)		• Target validation • Customized cargo validation • Data presentation at scientific symposia	

Coya Therapeutics' Highlights



Focused on Regulatory T Cells (Tregs)

- **Most clinically-advanced company focused on Treg-modulating therapies**
- Multi-modality approach:
  - Biologics (COYA 300 series)
  - Exosomes (COYA 200 series)



Strong Early Clinical Data

- **COYA 301 completed PoC** IIT study* in Alzheimer's Disease (AD)
- **COYA 302 completed PoC** IIT study* in Amyotrophic Lateral Sclerosis (ALS)
- COYA 200 series for neurodegenerative diseases, autoimmune / inflammatory conditions, and metabolic diseases



Multiple Near-Term Catalysts (12-18 months)

- **COYA 301** clinical Phase 1 PoC data in Alzheimer's Disease (AD): AAIC (July 2023), ANA (September 2023), Peer-Reviewed publication (2H 2023), Academic double-blind Phase 2 PoC top-line data (2H 2024)
- **COYA 302** PoC biomarker data release (2H 2023), IND filing and Phase 2 initiation in ALS (Q1 2024), Peer-Reviewed publication (2H 2023)
- **COYA 200** Platform Series animal model validation data/ out-license discussions
- **COYA 206** target validation & custom cargo validation (2H 2023)/ out-license discussions

IIT: Investigator Initiated Trial
AAIC: Alzheimer's Association International Conference
PoC: Proof of Concept
*Open label academic studies with commercially available product