



Alterity Therapeutics Reports New Commercial Assessment for ATH434 in Multiple System Atrophy

– Potential global peak sales estimated at USD \$2.4 Billion –

– Over 70% of neurologists surveyed were “extremely likely” or “very likely” to prescribe ATH434 based on Phase 2 data –

MELBOURNE, AUSTRALIA AND SAN FRANCISCO, USA – 29 September 2025: [Alterity Therapeutics](#) (ASX: ATH, NASDAQ: ATHE) (“Alterity” or “the Company”), a biotechnology company dedicated to developing disease modifying treatments for neurodegenerative diseases, today announced it has released the highlights of its recently completed assessment of the market opportunity for ATH434 in Multiple System Atrophy (MSA), as well as a revised corporate presentation. Alterity has reported positive results from two Phase 2 clinical trials of its lead asset, ATH434, in MSA this year.

The revised presentation provides a comprehensive overview of the Company’s current status along with the results of the commercial market opportunity assessment and upcoming milestones. The corporate presentation can be accessed [here](#).

“We are very pleased with the outcome of the new commercial assessment for ATH434 that results in a potential worldwide peak sales opportunity in multiple system atrophy of USD \$2.4 billion dollars, if approved,” said, David Stamler, M.D., Chief Executive Officer of Alterity. “We engaged an independent marketing research and forecasting firm who conducted the evaluation using rigorous methods to ensure data quality and integrity. The strongly positive data from our double-blind Phase 2 clinical trial, which demonstrated a slowing of disease progression and stabilization of orthostatic hypotension, were clear drivers of interest in ATH434. The complete profile for ATH434 resulted in more than 70% of surveyed physicians ‘extremely likely’ or ‘very likely’ to prescribe the drug if available.”

The marketing research and forecasting used both qualitative and quantitative research methods to understand clinical needs, competitive landscape, and patient dynamics in MSA in order to characterize the commercial opportunity for ATH434 in Multiple System Atrophy. The quantitative survey utilized industry standard methods to forecast the peak sales estimate including: assessing the unmet need and competitive landscape in MSA, developing a target product profile, and surveying 100 physicians including general neurologists and both movement disorder and autonomic specialists regarding unmet needs in treating MSA and their reactions to the target product profile.

Key characteristics of MSA and ATH434 stood out in the results. Because MSA is such a severely debilitating illness with no approved treatment there is a critical need for a tolerable, disease modifying therapy and the market is ripe for new entrants. Physicians surveyed noted the importance of inhibiting α -synuclein aggregation to address the underlying pathology of disease as addressed by the targeted mechanism of action of ATH434. In addition, the key driver of physician interest in ATH434 results from the promising Phase 2 clinical data that demonstrated a slowing of disease progression and stabilization of orthostatic hypotension, one of the most challenging symptoms to manage in MSA.

About ATH434

Alterity's lead candidate, ATH434, is an oral agent designed to inhibit the aggregation of pathological proteins implicated in neurodegeneration. ATH434 has been shown preclinically to reduce α -synuclein pathology and preserve neuronal function by restoring normal iron balance in the brain in preclinical models. As an iron chaperone, it has excellent potential to treat Parkinson's disease as well as various Parkinsonian disorders such as Multiple System Atrophy (MSA). Phase 1 studies have demonstrated the agent is well tolerated and achieved brain levels comparable to efficacious levels in animal models of MSA. Positive results from the randomized, double-blind, placebo-controlled Phase 2 clinical trial in patients with MSA demonstrated robust clinical efficacy, target engagement on key biomarkers, and a favorable safety profile. Positive data from a second Phase 2 open-label biomarker trial in patients with more advanced MSA reinforced these results. ATH434 has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA), and Orphan Drug Designation by the FDA and the European Commission for the treatment of MSA.

About Multiple System Atrophy

Multiple System Atrophy (MSA) is a rare, neurodegenerative disease characterized by failure of the autonomic nervous system and impaired movement. The symptoms reflect the progressive loss of function and death of different types of nerve cells in the brain and spinal cord. It is a rapidly progressive disease and causes profound disability. MSA is a Parkinsonian disorder characterized by a variable combination of slowed movement and/or rigidity, autonomic instability that affects involuntary functions such as blood pressure maintenance and bladder control, and impaired balance and/or coordination that predisposes to falls. A pathological hallmark of MSA is the accumulation of the protein α -synuclein within glia, the support cells of the central nervous system, and neuron loss in multiple brain regions. MSA affects up to 50,000 individuals in the U.S., and while some of the symptoms of MSA can be treated with medications, currently there are no drugs that are able to slow disease progression and there is no cure.¹

¹[Multiple System Atrophy | National Institute of Neurological Disorders and Stroke \(nih.gov\)](https://www.ninds.nih.gov/health-information/disorders/multiple-system-atrophy)

About Alterity Therapeutics Limited

Alterity Therapeutics is a clinical stage biotechnology company dedicated to creating an alternate future for people living with neurodegenerative diseases. The Company is initially focused on developing disease modifying therapies in Parkinson's disease and related disorders. Alterity has demonstrated clinically meaningful efficacy for its lead asset, ATH434, in a randomized, double-blind, placebo-controlled Phase 2 clinical trial in participants with Multiple System Atrophy (MSA), a rare and rapidly progressive Parkinsonian disorder. ATH434 recently reported positive data in its open label Phase 2 clinical trial in advanced MSA. In addition, Alterity has a broad drug discovery platform generating patentable chemical compounds to treat the underlying pathology of neurological diseases. The Company is based in Melbourne, Australia, and San Francisco, California, USA. For further information please visit the Company's website at www.alteritytherapeutics.com.

Authorisation & Additional information

This announcement was authorized by David Stamler, CEO of Alterity Therapeutics Limited.

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Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of section 27A of the Securities Act of 1933 and section 21E of the Securities Exchange Act of 1934. The Company has tried to identify such forward-looking statements by use of such words as "expects," "intends," "hopes," "anticipates," "believes," "could," "may," "evidences" and "estimates," and other similar expressions, but these words are not the exclusive means of identifying such statements.

Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements are described in the sections titled "Risk Factors" in the

Company's filings with the SEC, including its most recent Annual Report on Form 20-F as well as reports on Form 6-K, including, but not limited to the following: statements relating to the Company's drug development program, including, but not limited to the initiation, progress and outcomes of clinical trials of the Company's drug development program, including, but not limited to, ATH434, and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to the difficulties or delays in financing, development, testing, regulatory approval, production and marketing of the Company's drug components, including, but not limited to, ATH434, the ability of the Company to procure additional future sources of financing, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's drug compounds, including, but not limited to, ATH434, that could slow or prevent products coming to market, the uncertainty of obtaining patent protection for the Company's intellectual property or trade secrets, the uncertainty of successfully enforcing the Company's patent rights and the uncertainty of the Company freedom to operate.

Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Corporate Presentation

September 2025



Forward looking statements

This presentation may contain some statements that may be considered “Forward-Looking Statements”, within the meaning of the US Securities Laws. Thus, any forward-looking statement relating to financial projections or other statements relating to the Company’s plans, objectives, expectations or intentions involve risks and uncertainties that may cause actual results to differ materially. For a discussion of such risks and uncertainties as they relate to us, please refer to our 2025 Form 20-F, filed with US Securities and Exchange Commission, in particular Item 3, Section D, titled “Risk Factors.”





Alterity is a late clinical stage biopharmaceutical company dedicated to developing treatments for neurodegenerative diseases

 Alterity means the state of being different

 Our goal is to slow the course of disease

 We strive to create an alternate future and improve patient quality of life

Investment highlights



**Positive Phase 2 data in
Multiple system atrophy,
a Parkinsonian disorder**

Robust efficacy on
functional endpoint in
double-blind study



**Large market potential
in neurodegenerative
diseases**

Potential to treat Parkinson's
disease and related disorders



**Oral administration
preferred over
competition**

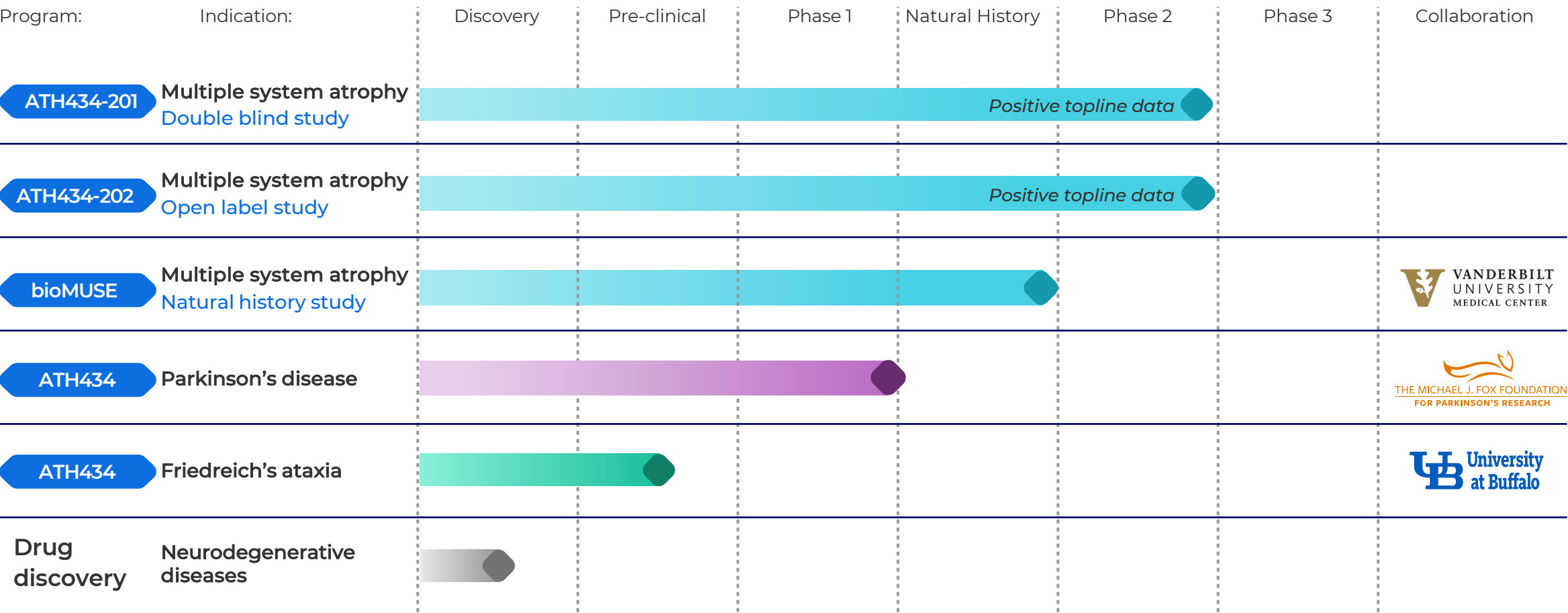
Patient friendly
administration



**Highly experienced
leadership team in
movement disorders**

Three FDA approvals in
neurology

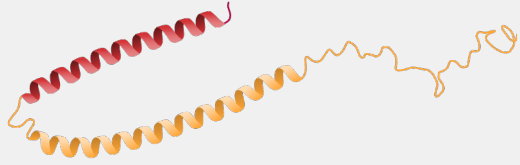
Promising portfolio in neurodegenerative diseases



Targeting the pathology in Parkinsonian disorders

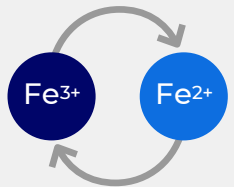


Alpha-synuclein and iron balance vital for normal CNS function



α -Synuclein protein:

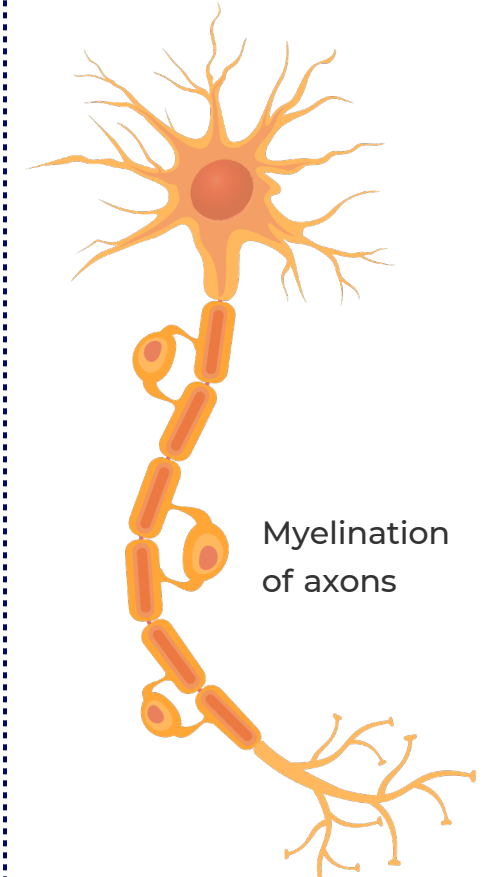
- Present in all neurons
- Regulates neurotransmitter release
- Facilitates neuronal communication



Fe^{2+} Reactive
 Fe^{3+} Stable

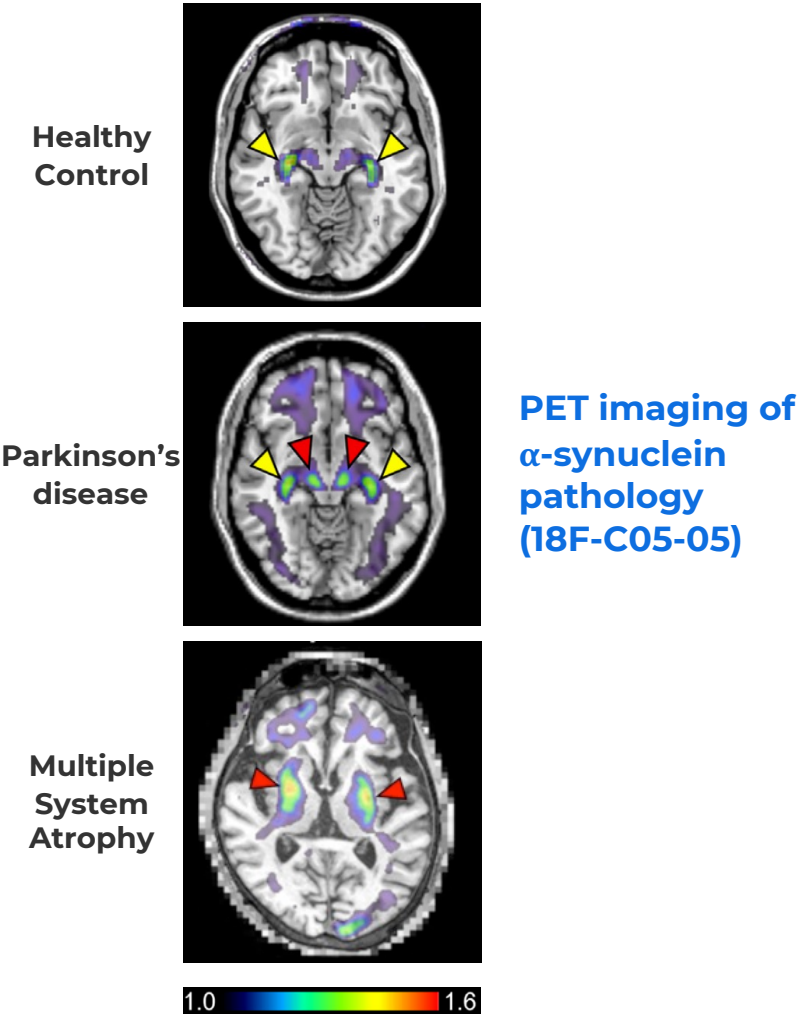
Two forms of iron required for cellular function:

- Energy production and activity of many enzymes
- Neurotransmitter synthesis (e.g., dopamine)
- Myelin synthesis

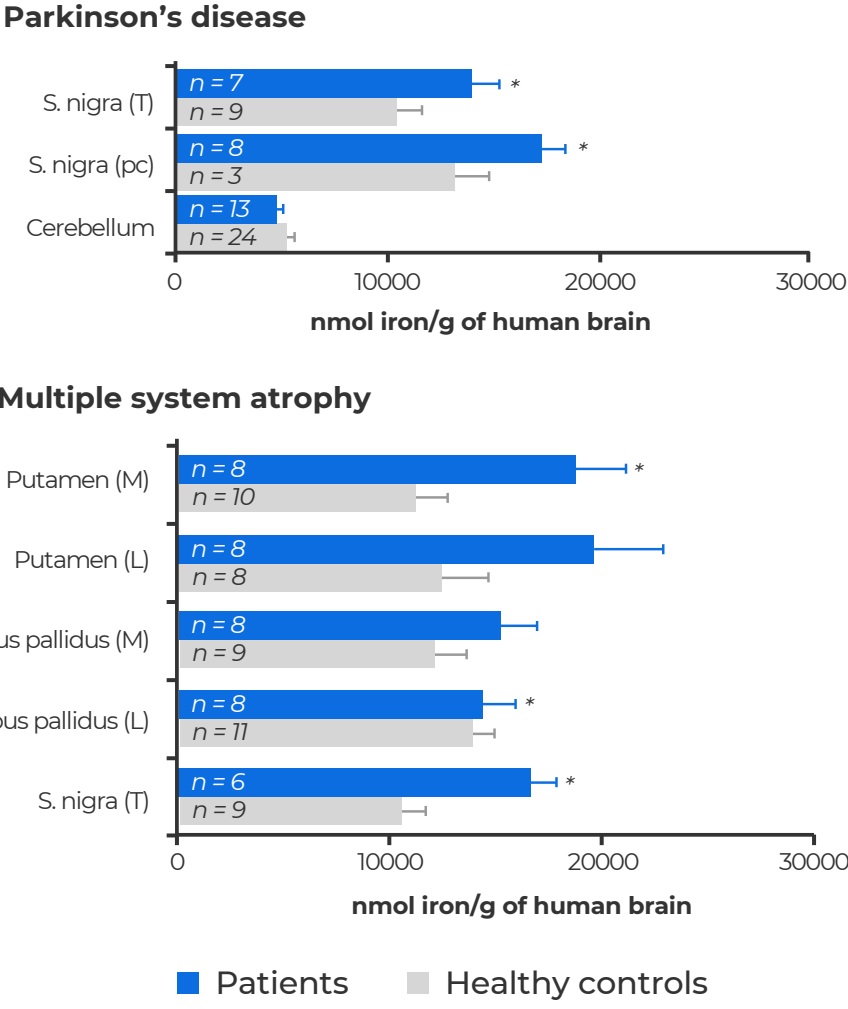


Pathology of Parkinsonian disorders

α -synuclein Aggregation



Increased Brain Iron



Role of iron and α -synuclein in disease pathogenesis

The Relevance of Iron in the Pathogenesis of Multiple System Atrophy: A Viewpoint

Christine Kaindlstorfer¹, Kurt A Jellinger², Sabine Eschlböck¹, Nadia Stefanova¹, Günter Weiss³, Gregor K Wenning¹

Iron converts native α -SYN into a β -sheet conformation and promotes its aggregation either directly or via increasing levels of oxidative stress.

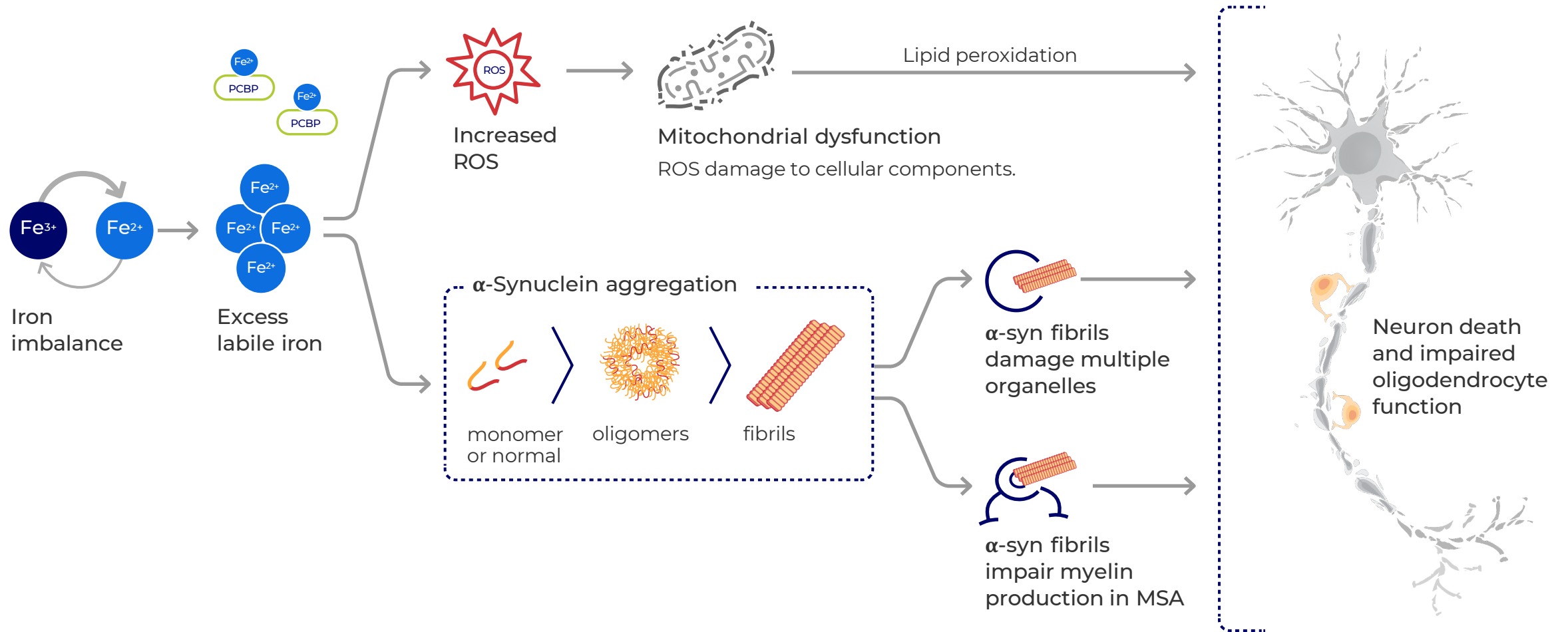
The disturbance of iron homeostasis leads to abnormal iron deposition in the brain and causes neurotoxicity via generation of free radicals and oxidative stress.

The Irony of Iron: The Element with Diverse Influence on Neurodegenerative Diseases

Seojin Lee^{1 2}, Gabor G Kovacs^{1 2 3}

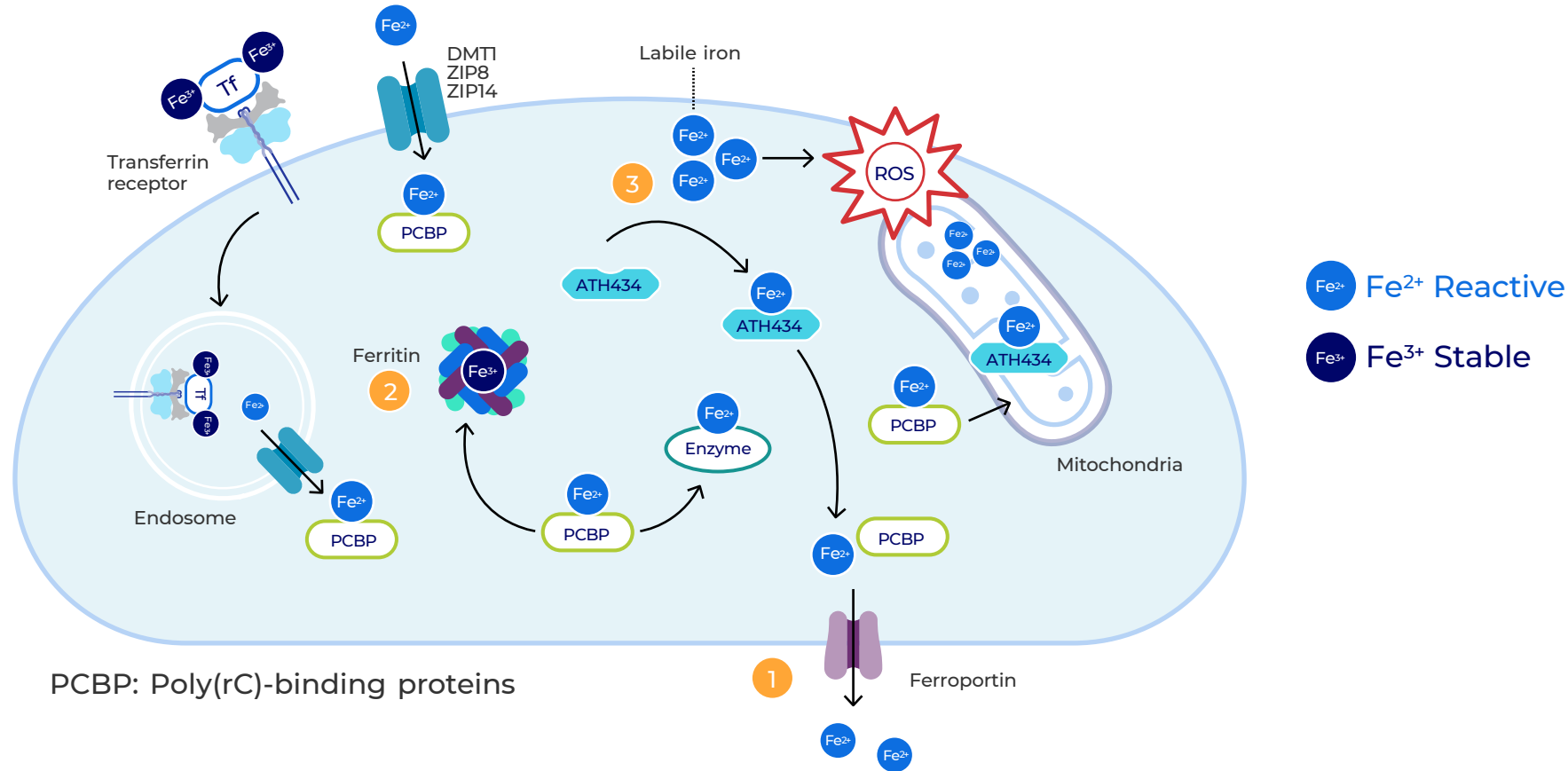
The close association of iron accumulation with distinct α -synuclein-pathology-related anatomical regions of the two disease subtypes supports the critical involvement of pathological iron in disease progression and further suggests the two disease subtypes as distinct pathological identities in relation to disease pathogenesis.

Excess labile iron is the key driver of pathology causing oxidative damage and α -Synuclein aggregation



ATH434 mechanism of action: iron chaperone

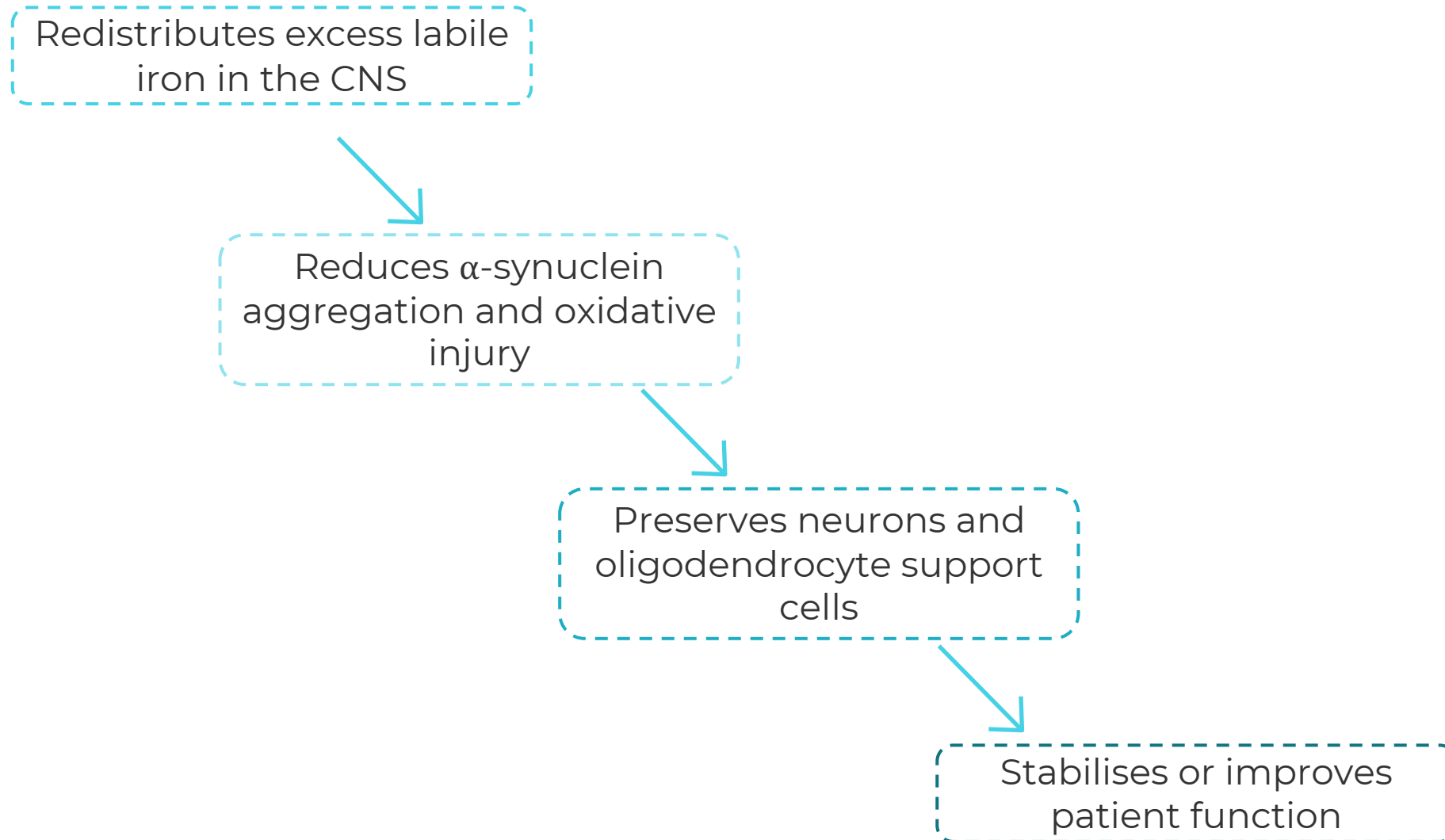
ATH434 redistributes excess labile (reactive) iron to reduce neuronal injury



Redistribution mechanisms:

- 1 Efflux iron from cell (ferroportin)
- 2 Increase iron storage (ferritin)
- 3 Buffering Fe²⁺ in labile iron pool

Treatment approach: address underlying pathology



Based on mechanism of action, ATH434 is a potential disease modifying therapy

ATH434: Small molecule drug candidate



Oral administration

Preferred by patients and doctors vs infusions (IV, intrathecal) or injections



Blood-brain barrier penetrant

Acts intracellularly to address underlying pathology



Iron chaperone

Moderate binding affinity, *redistributes* excess labile iron in CNS



Broad treatment potential

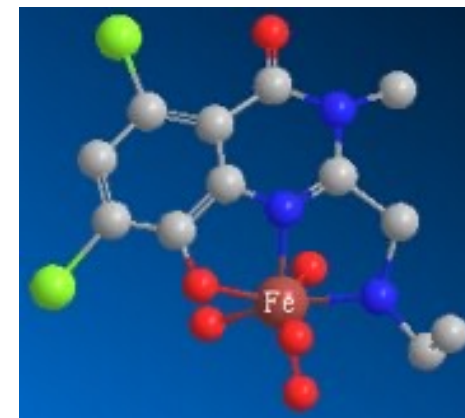
Potential to treat many neurodegenerative diseases (e.g., Parkinson's, Frederick Ataxia)



Orphan & Fast Track designations

US FDA Fast Track Designation and Orphan drug designation in U.S. and EU

ATH434 binding to labile iron



Accumulated evidence of ATH434 efficacy

Target disease	Model	Midbrain iron incl. s. nigra	α -Synuclein	Preserve neurons / function	Clinical observations
Parkinson's disease	Monkey MPTP	↕	n/a	↑	Improved motor performance
Parkinson's disease	Mouse MPTP	↓	↓	↑	Improved motor performance
Parkinson's disease	Mouse A53T	↓	↓	↑	Improved motor performance
Parkinson's disease	Mouse tau knockout	↓	↓	↑	Improved motor performance
MSA ¹	PLP- α -syn	↓	↓	↑	Improved motor performance
MSA ²	PLP- α -syn	↕	↓	↑	Improved motor performance

↕ Stable

ATH434 consistently improved motor performance by reducing α -synuclein aggregation and preserving neurons



ATH434 clinical development program in MSA

Multiple System Atrophy (MSA): Parkinsonian disorder with no approved treatment

Highly debilitating
and rapidly progressive

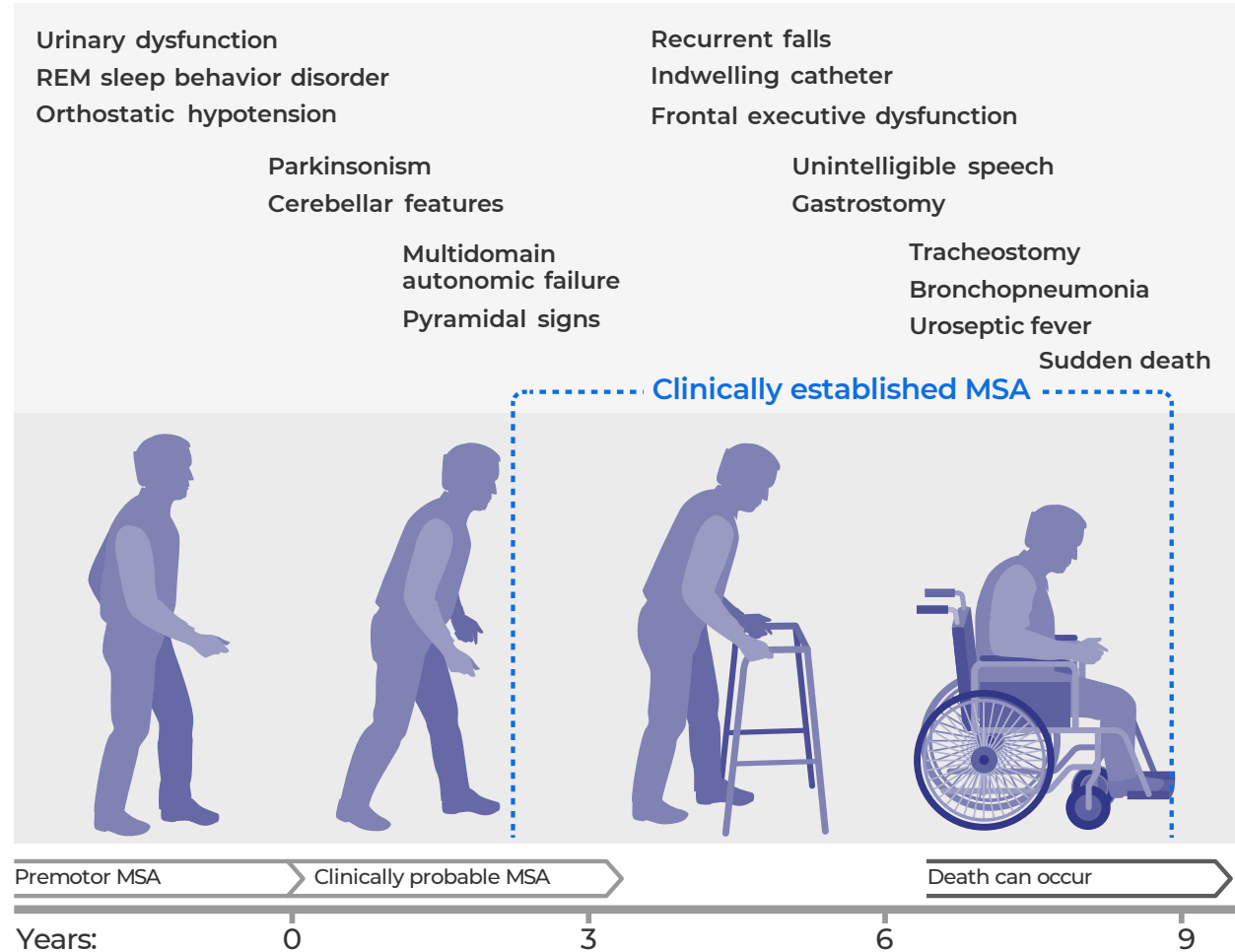
Up to 50,000
patients in U.S.

Disease characteristics:

- Motor: Parkinsonism, uncoordinated movements, balance problems, falls
- Autonomic dysfunction: blood pressure maintenance, bladder control, bowel function
- Atrophy and α -synuclein accumulation in multiple brain regions

7.5 years
median survival
after symptom onset

Over 50%
require wheelchair
in 5 years



Diligent approach to de-risk development program

Natural History Study

bioMUSE

- Observational study in individuals with MSA
- Designed to de-risk clinical development program
- Identify biomarkers to improve accuracy of patient selection

Phase 2

ATH434-201

Randomized double-blind placebo-controlled trial

Results: clinically meaningful efficacy on MSA rating scale, measures of orthostatic hypotension, disease severity

ATH434-202

Open label trial in advanced MSA patients

Results: showed improved neurological symptoms in more advanced patients and favorable safety

BioMUSE natural history study informs and de-risks clinical development program

bioMUSE



Patient criteria:

Clinically Probable MSA

Biomarkers:

- MRI: iron, volume, glial pathology
- Fluid: NfL, aggregated α -synuclein
- Digital: Wearable movement sensors

Clinical: UMSARS 1, autonomic function, motor function
global measures



12 months of observation



Objectives:

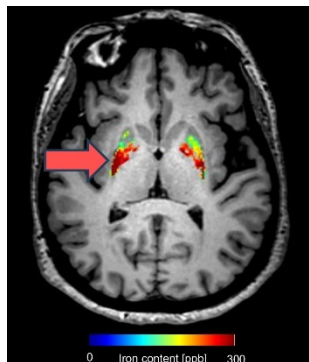
Optimize patient selection and endpoints for Phase 2

BioMUSE natural history study allowed us to optimize patient selection in our Phase 2 trials

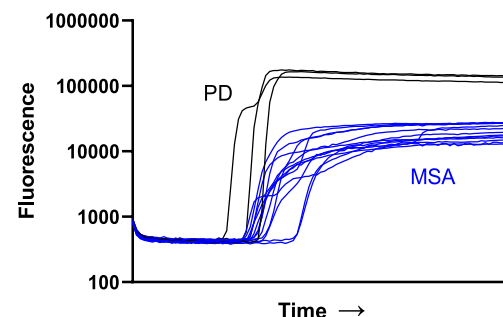
BioMUSE natural history study results

Optimized patient selection in Phase 2 trials

Advanced MRI methods



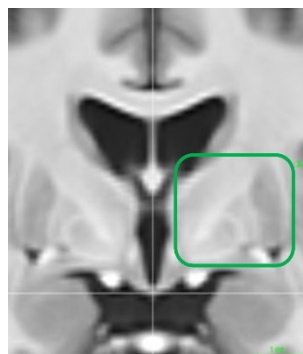
α -synuclein in CSF



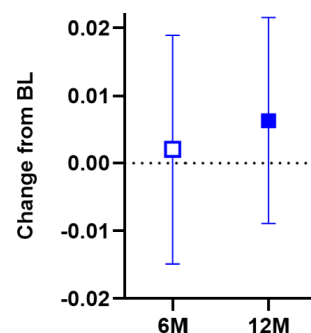
- ✓ Identified "iron signature" of early MSA
- ✓ Differentiated MSA from Parkinson's disease (PD)
- ✓ Revised selection criteria in ATH434-201 and ATH434-202 protocols to exclude PD patients

Precision biomarker assessment

Structural mapping



Iron content in pallidum

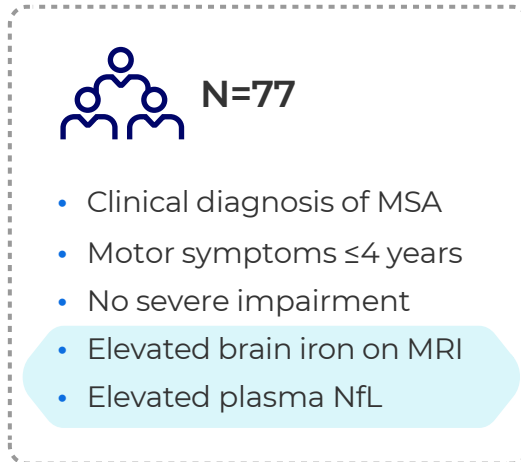


- ✓ Improved precision of volume measurements
- ✓ Novel strategies for measuring brain iron in individual regions
- ✓ State of the art methods enabled precise measurements of brain iron and volume with MRI

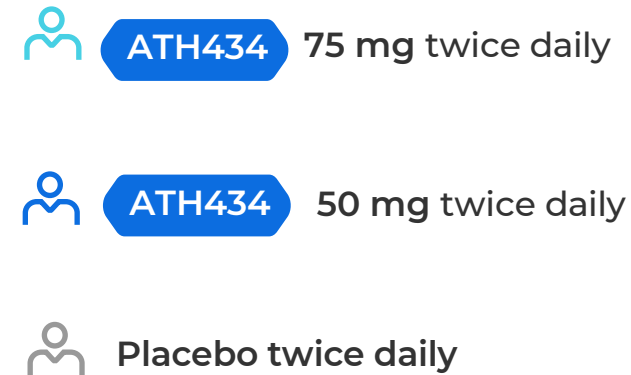
ATH434-201 randomized, double-blind, placebo-controlled trial

ATH434-201

Patient criteria:



Study design:



12 months treatment

Endpoints:

- ✓ **Key clinical endpoint:** modified UMSARS Part 1
- ✓ **Additional secondary endpoints:** CGI-S, OHSA, Wearable Sensors, Safety
- ✓ **Key biomarker endpoint:** brain iron content by MRI

Importance of the Unified MSA Rating Scale Part I (UMSARS I)

ATH434-201

UMSARS Part I Items:

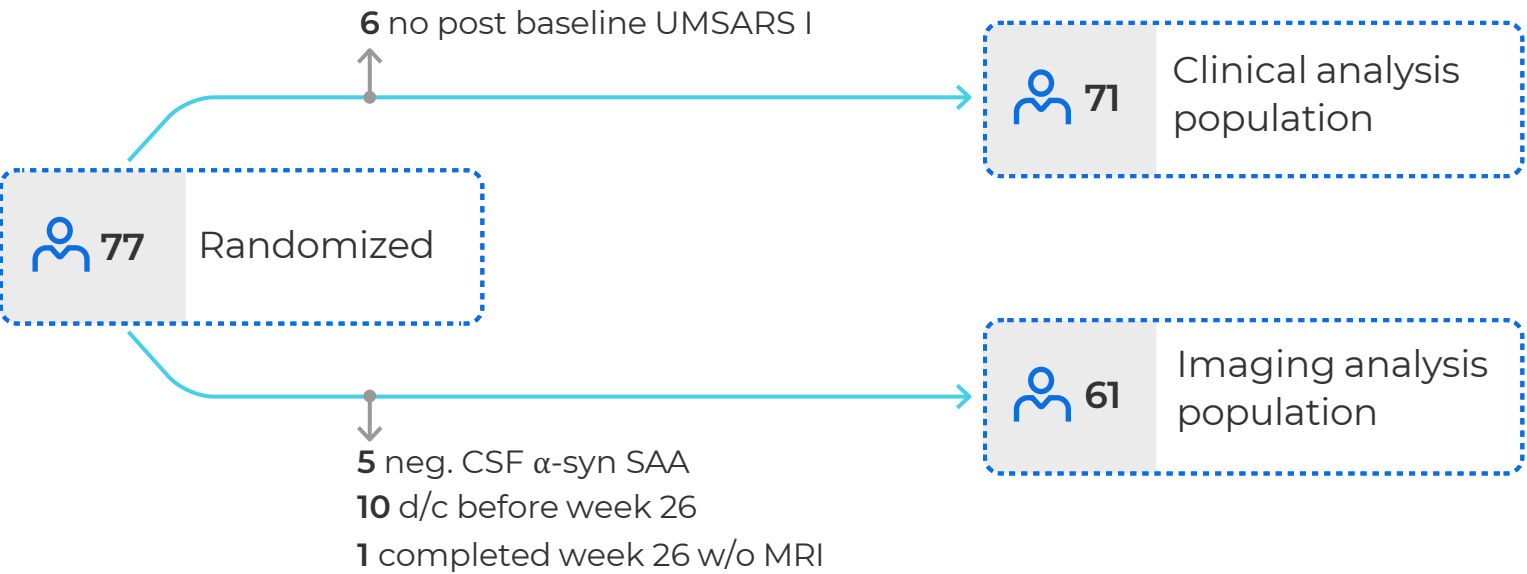
- | | |
|------------------------------------|--|
| ☐ Speech | ☐ Walking |
| ☐ Swallowing | ☐ Falling |
| ☐ Handwriting | ☐ Orthostatic symptoms |
| ☐ Cutting food | ☐ Urinary function |
| ☐ Dressing | ☐ Bowel function |
| ☐ Hygiene | ☐ Sexual function^ |

Rated from 0 to 48
higher scores worse

**UMSARS is the
FDA endorsed
clinical endpoint
to support
approval for the
treatment of MSA**

Validated rating scale to assess MSA disease severity
Rates functional impairment in domains affected in MSA

Populations and key endpoints



Endpoint:	Change from BL to week 52:	Population:	Criteria*
Primary (Biomarker)	Iron content in s. nigra by MRI	Imaging	≥ 1 post-baseline MRI (26 weeks) (+) aggregating α-synuclein SAA
Key secondary (Clinical)	Change in Modified UMSARS Part I	Clinical	≥ 1 post-baseline UMSARS I (13 weeks)

Baseline characteristics

ATH434-201

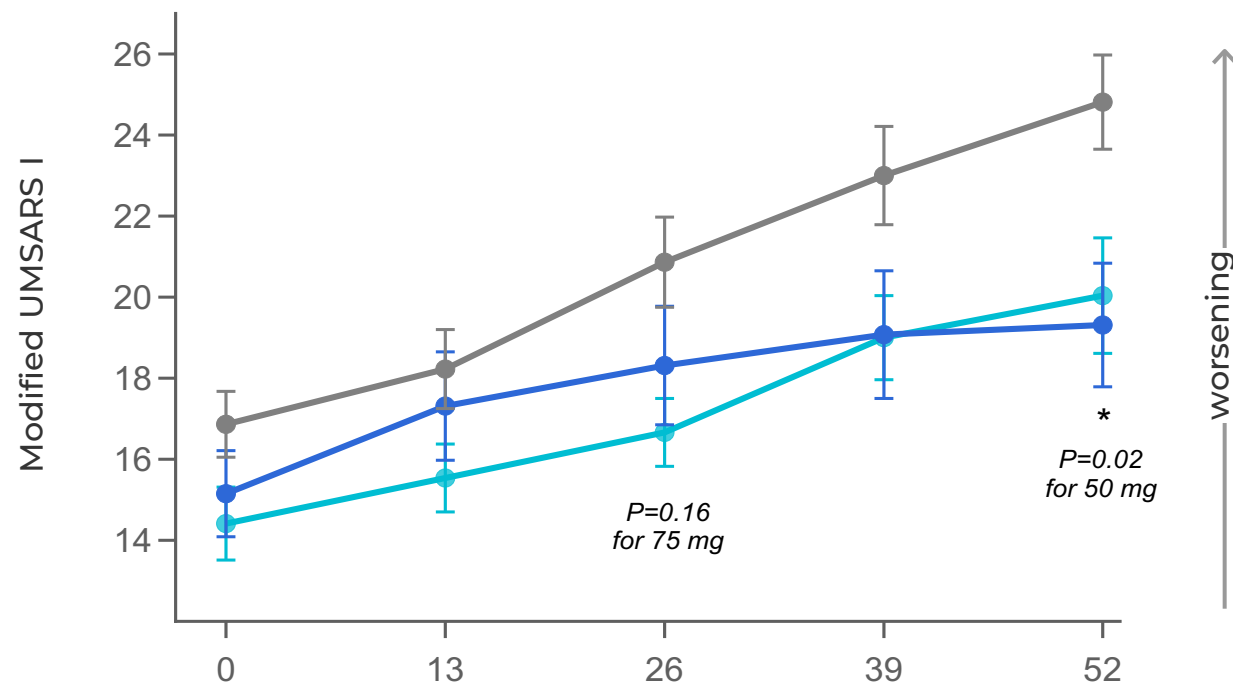
	Placebo N=22	ATH434-201 50 mg twice daily N=25	ATH434-201 75 mg twice daily N=24
Age (y)	61.3 (6.6)	63.1 (6.1)	63.9 (6.7)
Gender (% male)	63.6%	52.0%	62.5%
Duration of motor symptoms (y)	2.5 (0.8)	2.6 (0.8)	2.3 (0.9)
Modified UMSARS II	16.9 (3.9)	15.2 (5.4)	14.4 (4.4)
Motor score of Parkinson plus scale ¹	57.6 (14.2)	47.8 (18.4)	48.9 (16.8)
Plasma NfL (pg/mL)	34.9 (12.5)	31.1 (9.1)	32.3 (9.0)
CSF aggregating α -syn SAA (+)	91%	92%	96%
OH symptom assessment	13.5 (9.8)	13.8 (13.2)	15.0 (12.2)
Clinical phenotype: MSA-P (%)	59.1%	60.0%	70.8%
Severe orthostatic hypotension	4.5%	4.0%	29.2% ↑

Groups balanced at baseline except for severe orthostatic hypotension – a predictor of rapid disease progression

Clinically significant efficacy on modified UMSARS Part I

Change from baseline to week 52

ATH434-201



Placebo N=22	Difference vs. placebo LS mean (SE)	Relative treatment effect
ATH434-201 50 mg N=25	- 3.8 (1.6)	48%
ATH434-201 75 mg N=24	- 2.4 (1.7)	30%

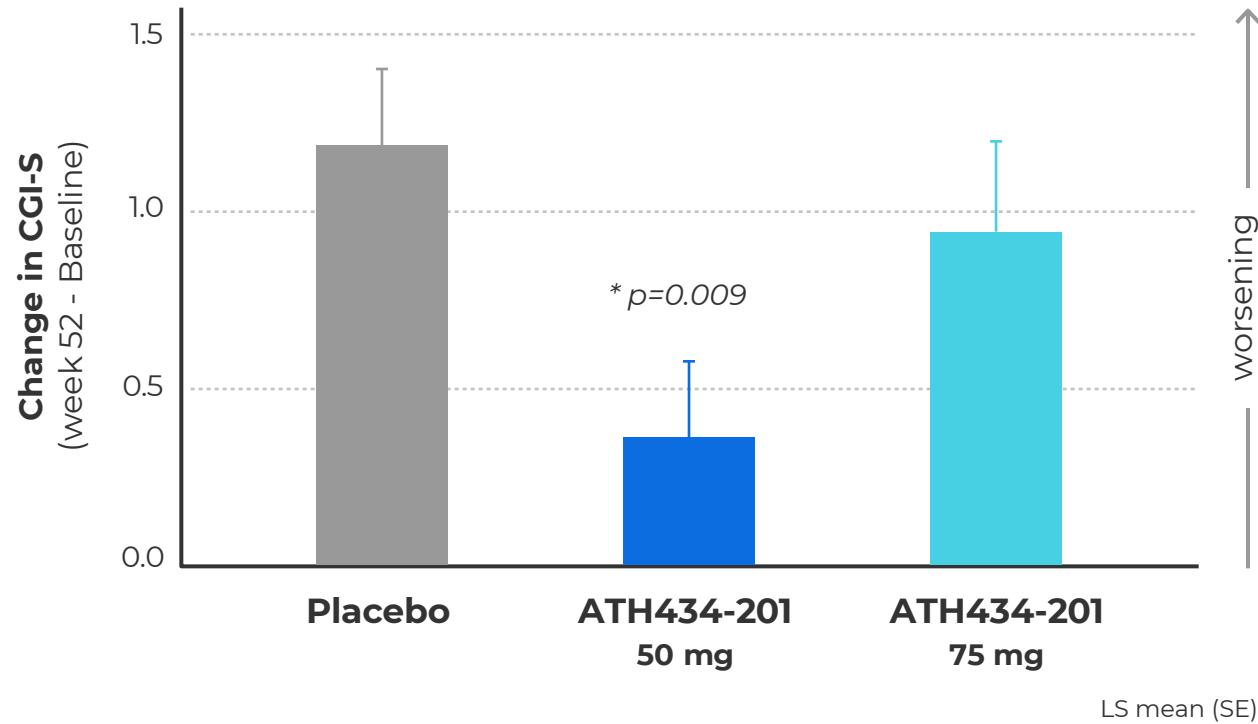
Relative Treatment Effect

$$\frac{\text{Change}_{\text{ATH434}} - \text{Change}_{\text{Placebo}}}{\text{Change}_{\text{Placebo}}}$$

Efficacy on Clinical Global Impression of Severity (CGI-S) scale

ATH434-201

Change from baseline to week 52

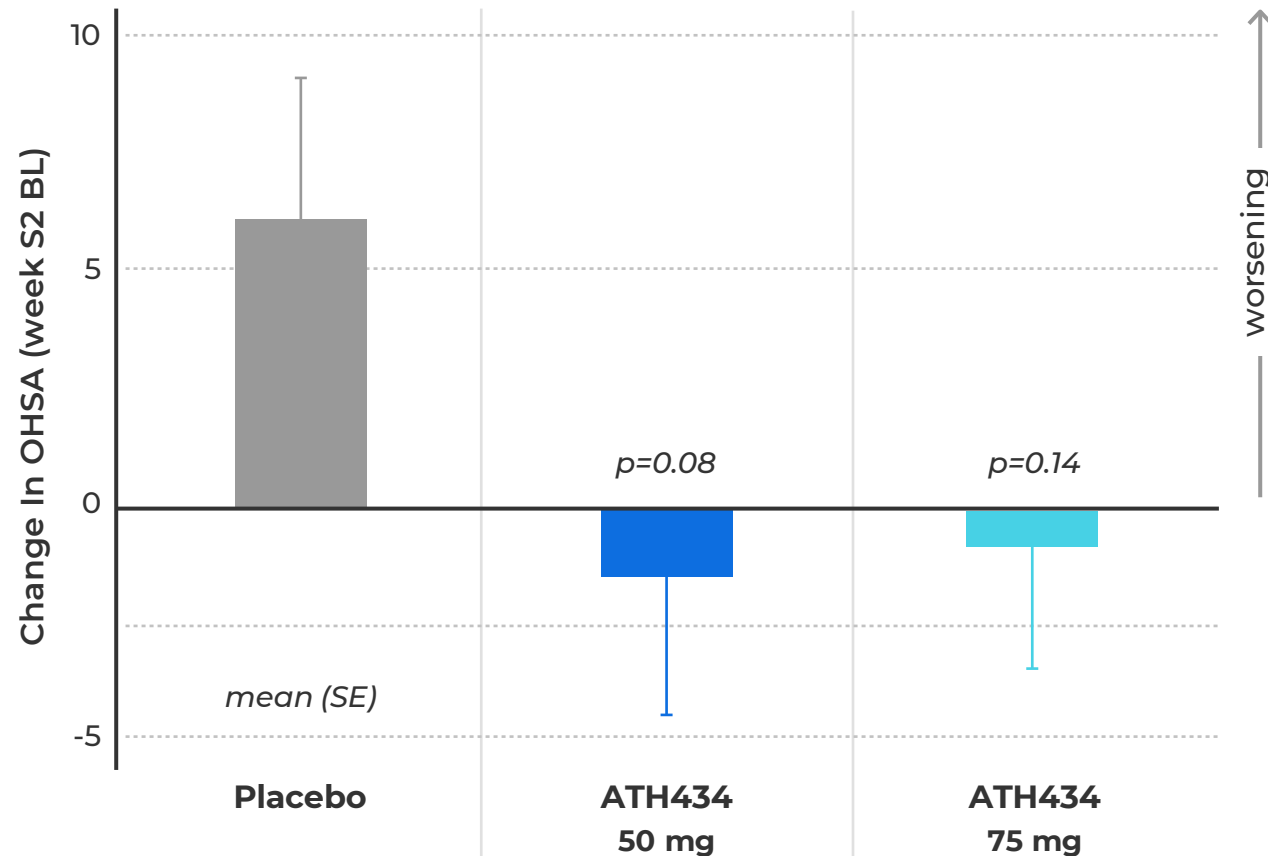


- CGI-S
 - 7-point scale, ranging from 1 to 7
 - higher score indicates a worse outcome
- Assesses total picture over prior 28 days
 - illness severity, impact of illness on function, level of distress and any other aspects of impairment

Orthostatic Hypotension Symptom Assessment (OHSA)

change from baseline to week 52

ATH434-201

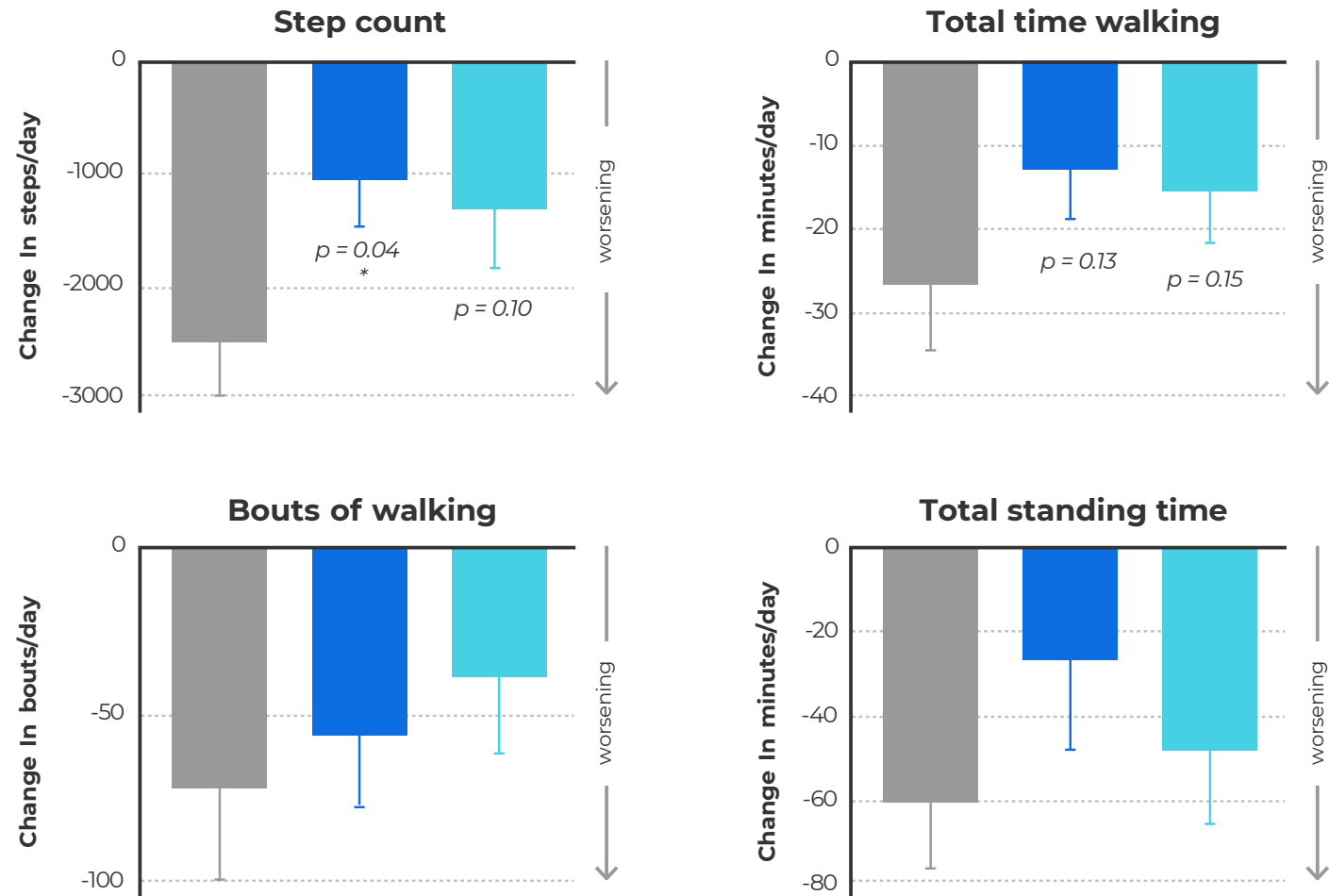


- Assesses symptoms of low blood pressure when going from sitting to standing (e.g., dizziness / feeling faint / lightheadedness)
- Patient reported outcome

ATH434 preserved walking in outpatient setting

Change from baseline to week 52

ATH434-201



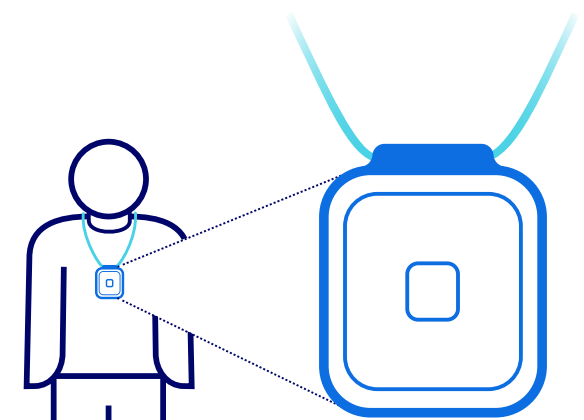
Placebo

ATH434-201
50 mg

ATH434-201
75 mg

Pendant

Wearable movement sensor



Adverse Events

ATH434-201

	Placebo twice daily  N=26	ATH434-201 50 mg  N=25	ATH434-201 75 mg  N=26
N (%) of subjects ¹			
Any Adverse Event (AE)	24 (92.3%)	21 (84.0%)	25 (96.2%)
UTI	14 (53.8%)	10 (40.0%)	7 (26.9%)
Fall	8 (30.8%)	7 (28.0%)	8 (30.8%)
Covid-19	1 (3.8%)	6 (24.0%)	4 (15.4%)
Fatigue	2 (7.7%)	1 (4.0%)	5 (19.2%)
Back pain	1 (3.8%)	3 (12.0%)	2 (7.7%)
Severe AEs ²	8 (30.8%)	3 (12.0%)	6 (23.1%)
Serious AEs ²	10 (38.5%)	5 (20.0%)	7 (26.9%)

- Similar rates of AEs in ATH434 and placebo participants
- No severe or serious AEs related to study drug

1 - Reporting one or more event
2 - None related to Study Drug

Change in Iron Content by MRI

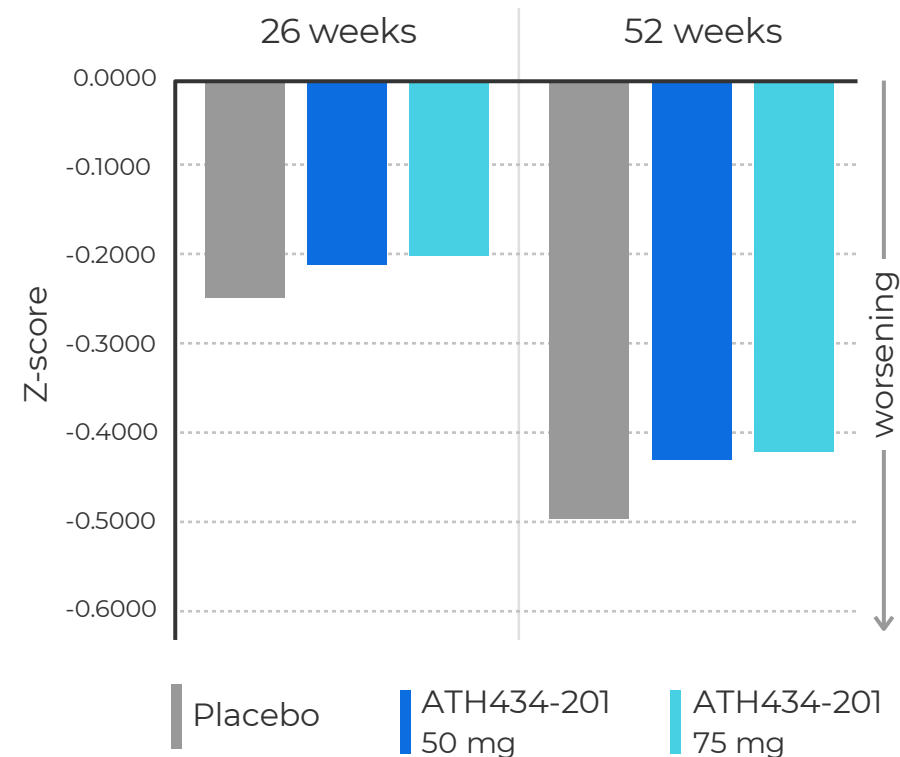
Region	50 mg		75 mg	
	Week 26	Week 52	Week 26	Week 52
Pallidum	↓	↓ [¶]	↓	↓
Putamen	↓ [^]	↓	↔	↔
S. nigra	↔	↓	↔	↔

Compared to placebo: ↓ Iron content, ↔ No observable difference, [^]p = 0.03, [¶]p = 0.08

ATH434 demonstrated target engagement on reducing iron on MRI

- Reduced/stabilized iron content in Pallidum (GP) > Putamen
- Reduced iron content in s. nigra at 50 mg dose but not 75 mg (primary endpoint)

Change in Brain Volume*



ATH434 showed trends in preserving brain volume

ATH434-202: Baseline characteristics

Design	Single arm, open-label
Population	Advanced MSA (n=10)
Treatment	ATH434 75 mg BID x 12 months
Brain MRI Biomarkers	Iron, volume
Clinical Measures	UMSARS I, clinical/patient global impressions of change

Parameter	ATH434-202 75 mg BID  N=10	ATH434-201 75mg BID  N=24
Age (yr)	64.5 (7.5)	63.9 (6.7)
Duration of motor symptoms (yr)	3.9 (1.8)	2.3 (0.9)
Modified UMSARS I ¹	19.2 (5.3)	14.4 (4.4)
Motor score of Parkinson Plus Scale2	57.5 (20.4)	48.9 (16.8)
Plasma NfL (pg/mL)	42.1 (14.1)	32.3 (9.0)
OH Symptom Assessment	16.7 (14.8)	15.0 (12.2)
Severe Orthostatic Hypotension	40.0%	29.2%

Mean (SD)

Key objective was to assess efficacy and safety of ATH434 75 mg dose for comparison to 75 mg dose in 201 double-blind study

¹MSA affected areas by MSA-atrophy index. Trujillo, P. et al Annals of Clin and Trans Neuro, 2025

ATH434-202: Key data at 75 mg dose

Comparison to double blind study at 12 mo

Change over 12 Months	ATH434-202 75 mg BID  N=10	ATH434-201 75mg BID  N=24
Modified UMSARS I	3.5 (4.7)	5.6 (5.6)
Clinical global impression of change (% stable)	30%	21%
Patient global impression of change (% stable)	30%	26.4%
Brain volume ¹	-0.44 (0.14)	-0.42 (0.29)
Mean (SD)		

The 75 mg dose demonstrated comparable efficacy to that observed in the double-blind study

- No serious AEs related to study drug
- AEs consistent with underlying disease

¹In MSA affected areas by MSA-atrophy index. Trujillo, P. et al. Annals of Clin and Trans Neuro, 2025

ATH434 Phase 2 summary



Double-blind trial: ATH434 demonstrated clinically significant efficacy in slowing disease progression in MSA

- Both dose levels efficacious on UMSARS I and important secondary endpoints
- Demonstrated target engagement with reduced iron accumulation in MSA affected brain regions
- Showed trends in preserving brain volume in MSA affected brain regions
- No safety signals and was well-tolerated



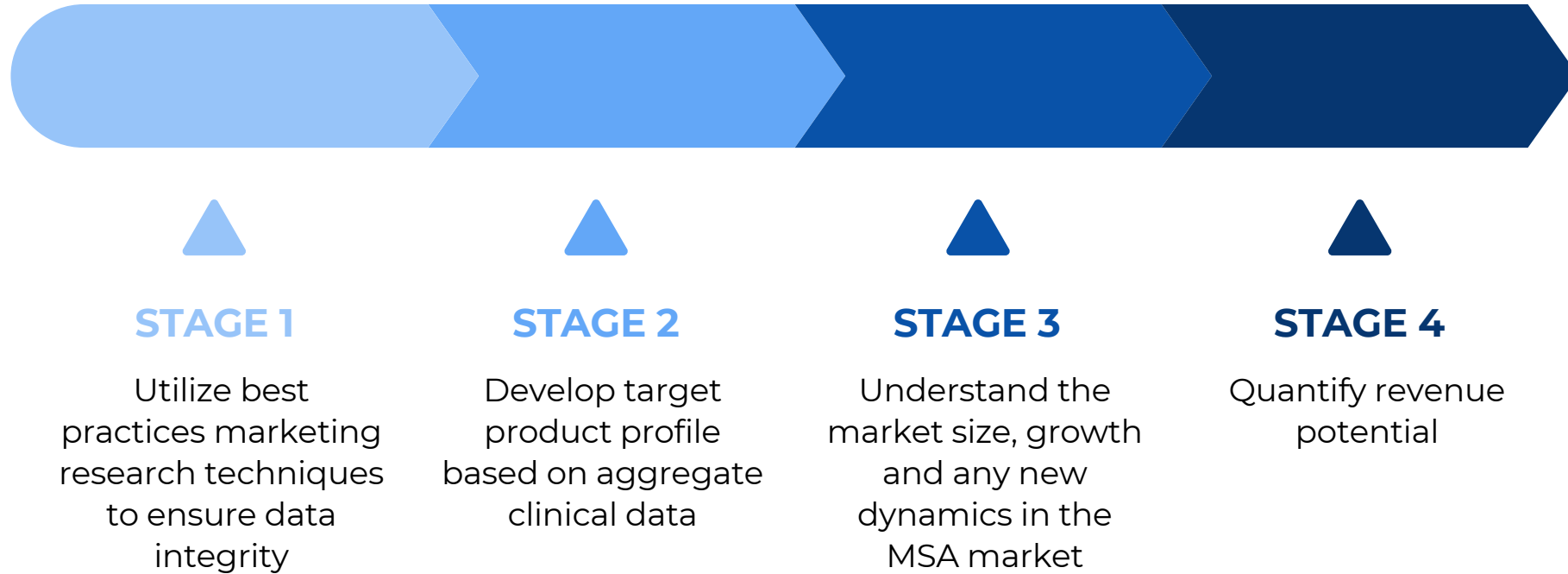
Open-label trial: Similar efficacy in advanced MSA as observed in double-blind study

- Data consistent on key efficacy endpoints
- Biomarkers demonstrated target engagement and similar effect on brain volume
- Comparable safety to double-blind study



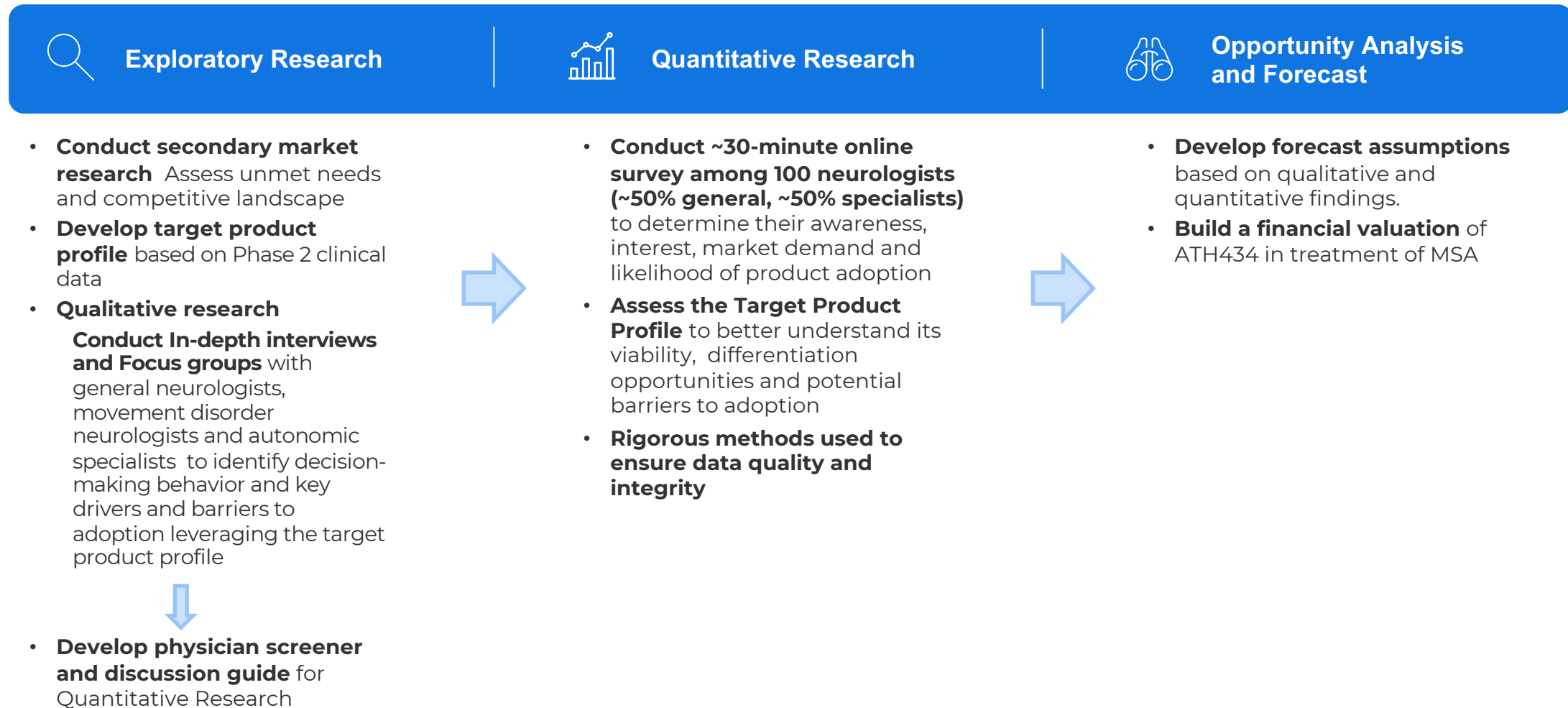
Commercial assessment & corporate overview

Determining the market opportunity for ATH434 in MSA



Approach to Commercial Assessment

Conducted by independent marketing research and forecasting group



Key attributes of ATH434 drive significant commercial opportunity in MSA



Substantial Unmet Need

Severely debilitating illness with no approved treatment ripe for new entrants

Critical need for a tolerable, disease modifying therapy



Targeted Mechanism of Action

Importance of inhibiting α -synuclein aggregation to address the underlying pathology of disease



Efficacy is the Key Driver

Slowing disease progression is key driver of physician interest

Stabilizing orthostatic hypotension[^], one of the most challenging symptoms in MSA, strongly positions ATH434



Strong Intent to Prescribe

Over 70% of neurologists were “extremely likely” or “very likely” to prescribe ATH434 based on its profile

USD \$2.4 Billion

Potential worldwide annual peak sales for ATH434 in MSA

Creating strong momentum in 2025

1

Robust efficacy in Phase 2 double-blind trial

2

Open label trial and Natural History study support ATH434 clinical development

3

Lead indication MSA is an Orphan Disease with no approved treatment

4

Highly experienced development team with multiple FDA approvals in neurology

5

Cash Balance:
A \$40.7M as of 30 June
A \$20M raised in Sept. 2025

Multiple Meaningful Milestones Achieved

ATH434-201 Positive Topline Data

FDA Fast Track designation in MSA

ATH434-202 Positive Topline Data

Data presentations at AAN and MSA Congress

Upcoming Catalysts

Data presentations:
American Neurological Association H2 25
American Autonomic Society

Platform presentation: Int'l Congress of Parkinson's Disease & Movement Disorders Q4 25

FDA End-of-Phase 2 Meeting Q4 25

ASX: ATH
NASDAQ: ATHE

