# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, DC 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): January 8, 2021**

# Athira Pharma, Inc.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-39503** | **45-3368487** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

**18706 North Creek Parkway, Suite 104**
**Bothell, WA 98011**
**(Address of principal executive offices, including zip code)**

**(206) 221-8112**
**(Registrant's telephone number, including area code)**

**4000 Mason Road, Suite 300**
**Seattle, WA 98195**
**(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))

Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock, $0.0001 par value per share | ATHA | The Nasdaq Stock Market LLC (The Nasdaq Global Select Market) |

Indicate by check mark whether the registrant is an emerging growth company 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On January 8, 2021, the compensation committee (the "Committee") of the board of directors (the "Board") of Athira Pharma, Inc. (the "Company") approved 2020 bonus payments for the Company's executive officers as set forth in the table below. The Committee approved the bonus payments in recognition of the executive team's achievements in 2020, including the advancement of the Company's product candidates and completion of certain financing and other corporate objectives.

| Name | Title | 2020 Bonus |
|---|---|---|
| Dr. Leen Kawas | President and Chief Executive Officer | $ 357,000 |
| Ms. Glenna Mileson | Chief Financial Officer | $ 215,600 |
| Dr. Hans Moebius | Chief Medical Officer | $ 190,120 |
| Dr. Mark Litton | Chief Operating Officer | $ 172,000 |
| Dr. Kevin Church | Vice President of Discovery | $ 57,500 |

**Item 7.01 Regulation FD Disclosure.**

Commencing on or after January 11, 2021, members of the Company's management will be providing a corporate update to analysts and investors through a series of one-on-one meetings.

The information in Item 7.01 of this Current Report on Form 8-K, including the slides to be used in such one-on-one meetings attached as Exhibit 99.1 hereto, are being furnished and not filed pursuant to Item 7.01 of Form 8-K. Such information shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act whether made before or after the date hereof and regardless of any general incorporation language in such filings, except to the extent expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Athira Pharma, Inc. Presentation Slides |

**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.

**Athira Pharma, Inc.**

Date: January 11, 2021

By: /s/ Leen Kawas
Leen Kawas
President and Chief Executive Officer


Athira PHARMA

# Restoring Lives by Advancing Bold Therapies

Corporate Presentation, January 2021

# Disclaimer

This presentation and the accompanying oral commentary contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expect," "plan," anticipate," "believe," "estimate," "predict," "intend," "potential," "would," "continue," "ongoing" or the negative of these terms or other comparable terminology. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our future financial performance, business plans and objectives, timing and success of our planned development activities, our ability to obtain regulatory approval, the potential therapeutic benefits and economic value of our product candidates, potential growth opportunities, competitive position, industry environment and potential market opportunities, and the impact of the COVID-19 pandemic on our business and operations.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors. 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. These factors, together with those that are described in greater detail in our filings with the Securities and Exchange Commission ("SEC") may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this presentation, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and readers are cautioned not to unduly rely upon these statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

By attending or receiving this presentation you acknowledge that you will be solely responsible for your own assessment of the market and our market position and that you will conduct your own analysis and be solely responsible for forming your own view of the potential future performance of our business.

This presentation contains estimates, projections and other information concerning market, industry and other data. We obtained this data from our own internal estimates and research and from academic and industry research, publications, surveys, and studies conducted by third parties, including governmental agencies. These data involve a number of assumptions and limitations, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed in our filings with the SEC. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us. While we believe such information is generally reliable, we have not independently verified any third-party information.

This presentation concerns drug candidates that are under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration. The drug candidates are currently limited by federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

We announce material information to the public through a variety of means, including filings with the SEC, press releases, public conference calls, our website (www.athira.com/), our investor relations website (investors.athira.com), and our news site (investors.athira.com/news-and-events/press-releases). We use these channels, as well as social media, including our Twitter account (@athirapharma) and Facebook page (https://www.facebook.com/athirapharmainc), to communicate with investors and the public about Athira, our products, and other matters. Therefore, we encourage investors, the media, and others interested in Athira to review the information we make public in these locations, as such information could be deemed to be material information.

# Overview of Athira Pharma

**Pipeline focused on regeneration of neuronal damage in CNS and peripheral diseases to restore function**

**ATH-1017 LEAD INDICATION:**
Alzheimer's disease

**POTENTIAL FOLLOW-ON INDICATIONS:**
Parkinson's dementia, ALS, MS, neuropathy, and neuropsychiatric (additional compounds in development)

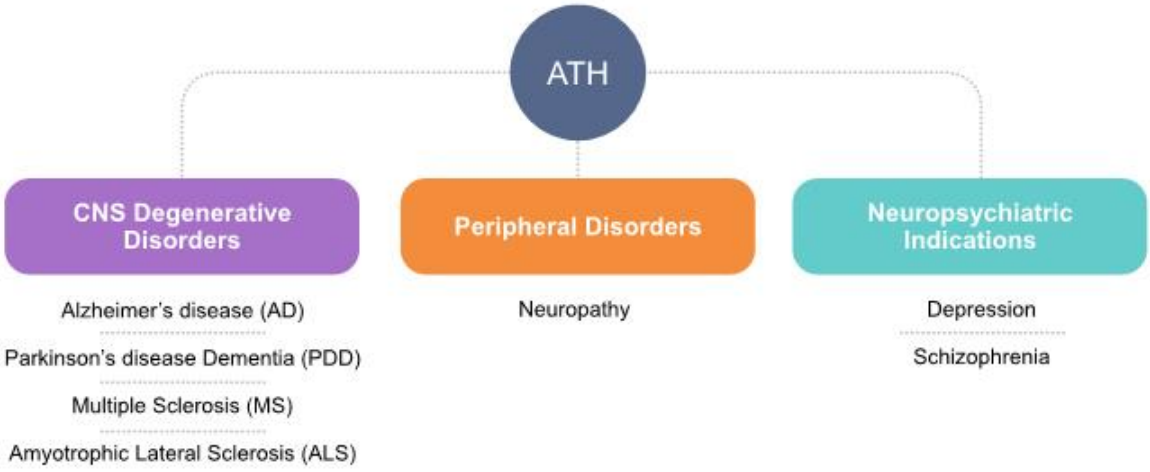
## Lead asset ATH-1017 in potentially pivotal Phase 2/3 clinical trial

- LIFT-AD trial initiated in Sept. 2020
- ACT-AD trial initiated in Nov. 2020
- Phase 1a/b results
  - Encouraging data in AD subjects (double blind study)
  - Rapid improvement in EEG/ERP P300 latency
  - Supports CNS penetration and target engagement
  - Generally well-tolerated

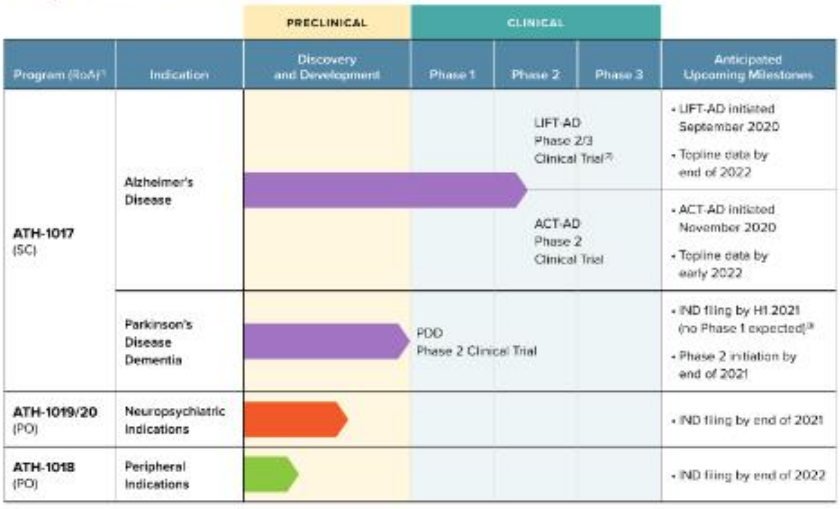
## Efficient clinical development strategy

- Cost and time efficient clinical trials
- Established regulatory pathway (4 marketed drugs for AD)
- Designed for faster timeline for data readout

# ATH Compounds Have Therapeutic Potential in a Broad Range of Clinical Applications



# Current Development Stage of ATH Compounds and Discovery Research Programs to Improve Neuronal Health




(1) RoA: route of administration; SC: subcutaneous; PO: oral.
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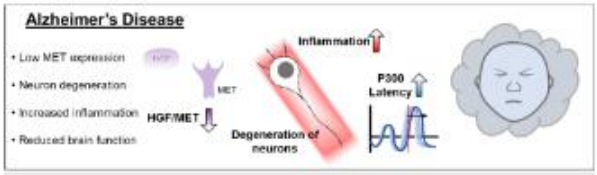
# Athira's Target, HGF/MET, is a Vital Neuronal Growth Factor that Promotes Neuronal Health and Regeneration

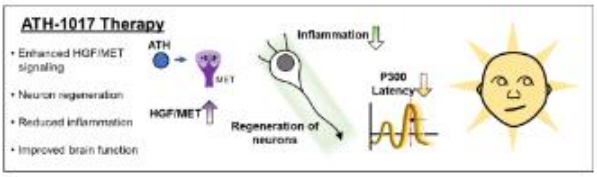
## Hepatocyte* Growth Factor (HGF)/MET Receptor

- **Vital neurotrophic factor system**
  *Critical to neuron function, learning, and memory*
- **Stable expression in healthy CNS**
  *Neuronal MET expression is reduced in Alzheimer's*
- **Beneficial impacts on multiple systems**




## Demonstrated Effects of HGF/MET in Animal Models

- **Alleviation of Aβ-induced cognitive impairment**
- **Prevention of onset of Parkinson's disease**
- **Prolongs life span in a transgenic mouse model of ALS**
- **Improved learning and memory dysfunction of microsphere-embolized rats**



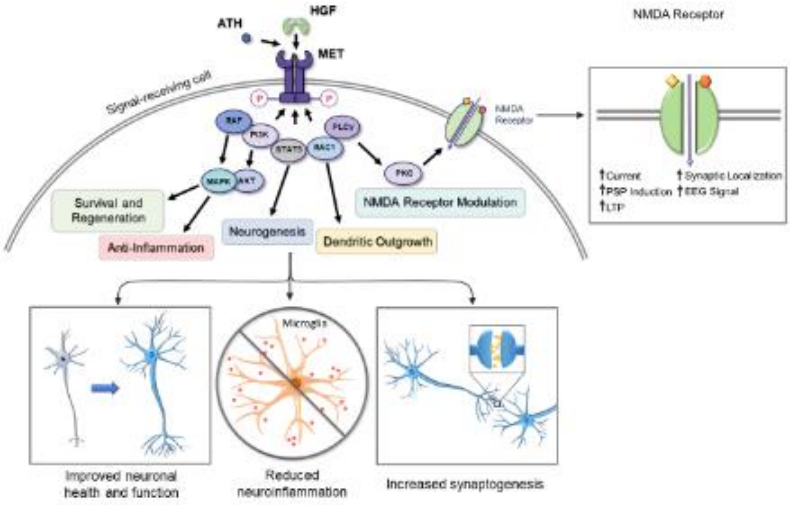

*Historically termed

# Promoting the HGF/MET Neurotrophic System has been Shown to have Multiple Downstream Beneficial Effects

## Acute and Sustained Effects on Synaptic and Network Function

- Fast-acting positive modulator
- **Protective and regenerative**
- **Procognitive (Symptomatic)**
- EEG biomarker

## ATH Platform Is Designed to Enhance HGF/MET







Improved neuronal health and function

Reduced neuroinflammation

Increased synaptogenesis

# Lead Program:
# ATH-1017 – Dementia

# ATH-1017 Program Summary

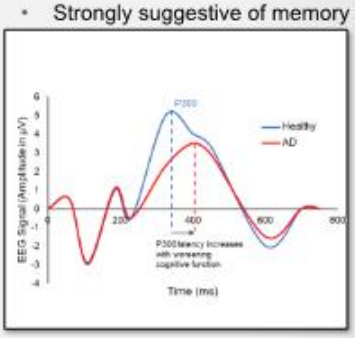
- Initiation of LIFT-AD trial in September 2020 and ACT-AD trial in November 2020
- Completed nonclinical GLP long term toxicology and safety pharmacology studies; Phase 2/3 trial initiated
- In Phase 1a/b trial ATH-1017 was generally well-tolerated with no serious adverse events (SAEs)
- Data showing ERP P300, a functional measure that is highly correlated with cognition, improved with treatment ($p<0.05$)
- PK/PD modeling defined active dose range for potentially pivotal LIFT-AD trial and ACT-AD trial (20-90 mg, OD)

# Clinical Development Plan Includes Predictive Measures of Cognitive Improvement and Translatable Tools to Guide Dose Selection

## EEG measures electrical activity from firing neurons in the brain

### EVENT RELATED POTENTIALS (ERP): P300 Latency

- Functional measurement for working memory access and executive function
- Strongly suggestive of memory improvement



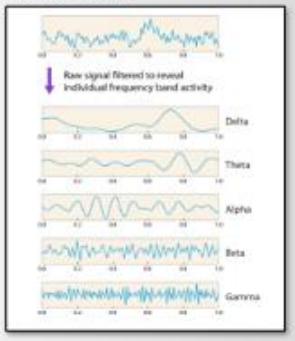

Pathological changes in P300 latency correlate with cognitive impairment

Noninvasive EEG recordings reflect brain activity and function

EEG records brain electrical activity from electrodes placed on the scalp

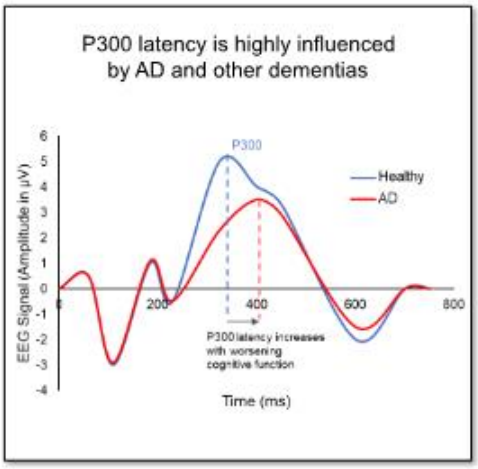
### QUANTITATIVE EEG (qEEG)

- Translational tool from rodents to humans
- PK/PD modeling for dose selection



# P300 Latency as a Functional Measure of Working Memory Processing Speed that Highly Correlates with Cognition

## Pathological changes in P300 latency correlate with cognitive impairment




- Recording brain activity while a subject is presented with a task reveals neural activity related to cognitive processing
- Time to peak positive wave response (following an external stimulus) is ~300 ms
- **Approved therapies have demonstrated parallel improvement in P300 latency and cognition**

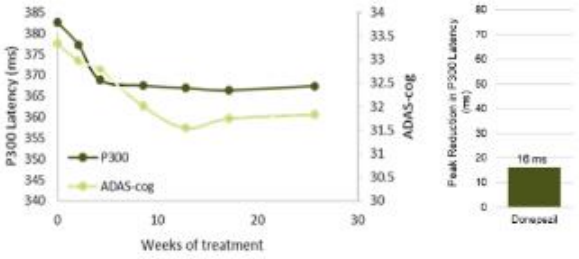
Athira utilized P300 Latency in its ATH-1017 Phase 1 clinical trial as a predictive measure of cognition

# Changes in P300 Latency Correlate with Cognitive Outcomes with Treatment of Approved Therapies in AD Subjects

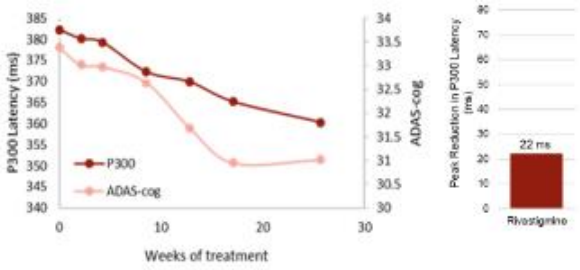
Previously published results support the correlation of P300 latency and cognition in AD subjects

- Donepezil and Rivastigmine
- Improvement in cognition (ADAS-cog ↓) is correlated with reduction in P300 latency

## DONEPEZIL




## RIVASTIGMINE




Note: Results from donepezil and rivastigmine adapted from Thomas et al., 2007.

# ATH-1017 Treatment Improved P300 Latency in AD Subjects-CTAD 2019

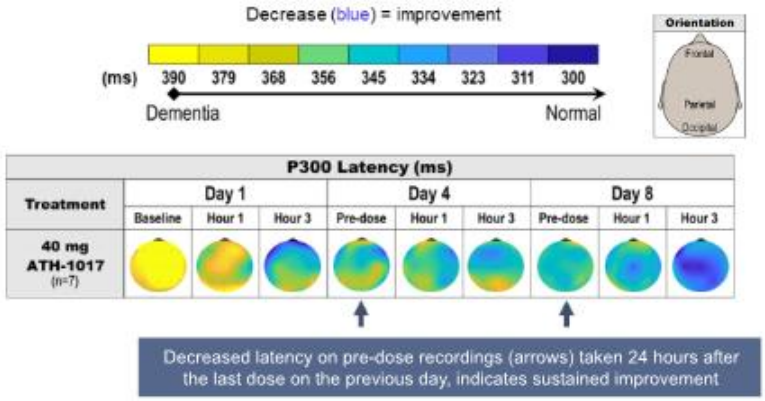
## Phase 1b – AD Subjects

- **ATH-1017 – 40 mg**
- **(SC, OD, 8 days, n=7)**

### ERP OBSERVATIONS

ERP analysis to date suggests treatment effects on P300 latency

- Gradual decrease in latency over time in the treated group (n=7)



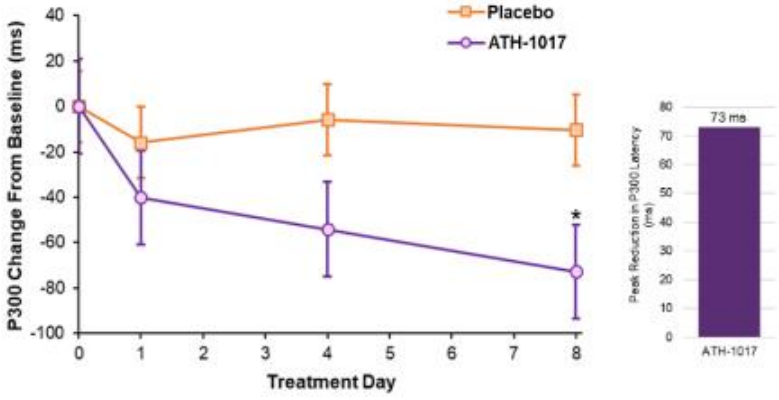

Decreased latency on pre-dose recordings (arrows) taken 24 hours after the last dose on the previous day, indicates sustained improvement

# ATH-1017 Treatment Improved P300 Latency in AD Subjects-CTAD 2019

## Phase 1b – AD Subjects

**P300 Latency: AD Subject ATH-1017 Treated and AD Subject Placebo**

- Group averages of AD subjects receiving ATH-1017 (n=7) demonstrate decreased P300 over time
  - **Significant change from baseline observed on Day 8**
- AD subjects receiving placebo (n=4) had no consistent change from baseline to study end



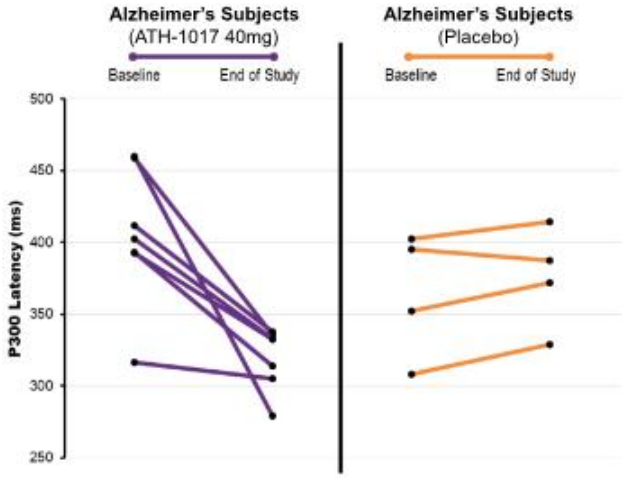

Note: P300 data from FZ, CZ, and PZ electrodes. Data plotted as mean +/- SE.. *p<0.05 with MMRM.

# ATH-1017 Treatment Improved P300 Latency in AD Subjects-CTAD 2019

## Phase 1b – AD Subjects

- Every AD subject receiving ATH-1017 had a level of improvement in P300 latency
- AD patients receiving placebo had no consistent response from baseline to end of study

**P300 Latency: AD Subject ATH-1017 Treated and AD Subject Placebo**




Note: P300 data from FZ, CZ, and PZ electrodes.

# Studies Suggest Changes in P300 Latency Have Been Predictive of Changes in Cognition

Previously published results support the correlation of P300 latency and cognition in AD subjects

| Treatment | P300 Latency Effect | Change in P300 Latency | Population | Cognitive Effect | Summary |
|---|---|---|---|---|---|
| Donepezil | Improved | (16) ms | AD | Improved | P300 latency and cognition both improved in mild-to-moderate AD, though improvements were modest. |
| Rivastigmine | Improved | (22) ms | AD | Improved | P300 latency and cognition both improved in mild-to-moderate AD, though improvements were modest. |
| Memantine | Improved | (15) ms | AD | Improved | P300 latency and cognition both improved in moderate to severe AD, though improvements were modest. |
| Scopolamine | Worsened | 50 ms | Healthy | Worsened | Scopolamine offers a counter example, P300 latency increases while cognitive performance is reduced. |

Note: Results from donepezil and rivastigmine adapted from *Thomas et al., 2001*; results from memantine adapted from *Saltach et al., 2011*; and results from scopolamine adapted from *Potter et al., 2000*.

# LIFT AD ATH-1017 Phase 2/3 Trial for AD Initiated in Sep-2020

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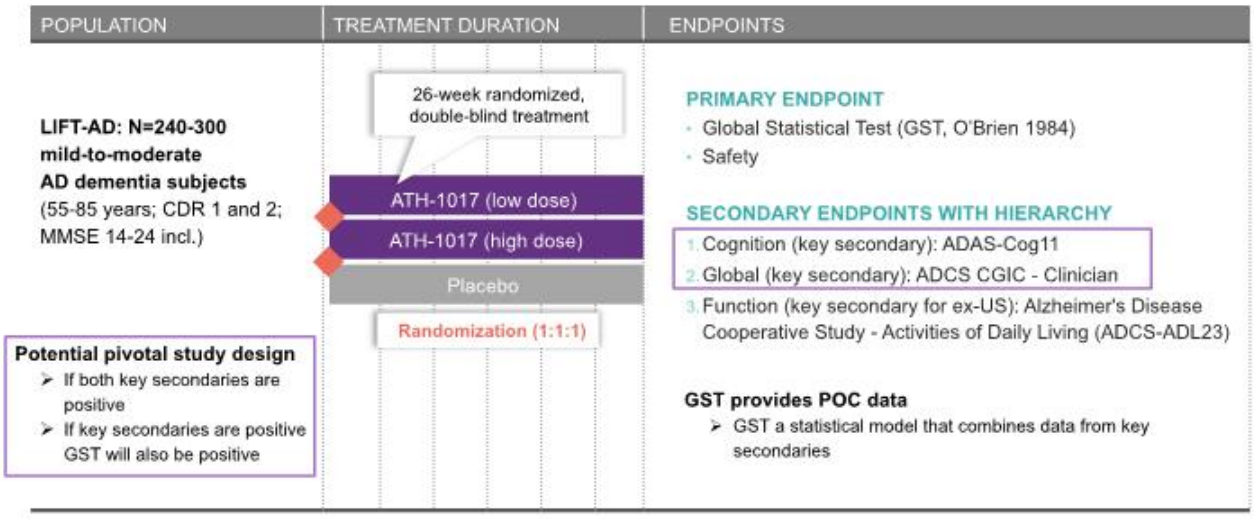
## Trial may provide pivotal evidence to support product registration



# ACT-AD ATH-1017 Phase 2 Trial for AD Initiated in Nov-2020

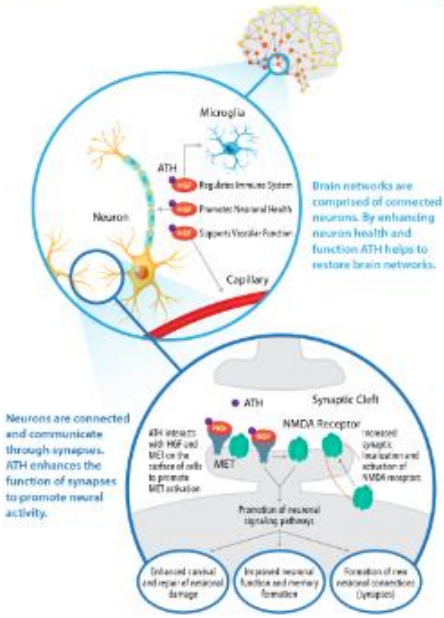
## Trial can help strategic decisions around additional clinical trials

| POPULATION | TREATMENT DURATION | ENDPOINTS |
|---|---|---|
| **ACT-AD: N=60-75 mild-to-moderate AD dementia subjects** (55-85 years; CDR 1 and 2; MMSE 14-24 incl.)<br><br>• **Enables readout ahead of LIFT-AD**<br>• **Enables earlier strategic decisions** | 26-week randomized, double-blind treatment, + optional 26-week OLEX<br><br>ATH-1017 (low dose)<br>ATH-1017 (high dose)<br>Placebo<br><br>Randomization (1:1:1) | **PRIMARY ENDPOINT**<br>• Change of P300<br>• Safety<br><br>**SECONDARY ENDPOINTS (NO HIERARCHY)**<br>1. Global Statistical Test (GST, O'Brien 1984)<br>2. Cognition: ADAS-Cog11<br>3. Global clinical change: ADCS CGIC - Clinician<br>4. Function: ADCS-ADL23 |

# ATH-1019/20 – Neuropsychiatric Indications

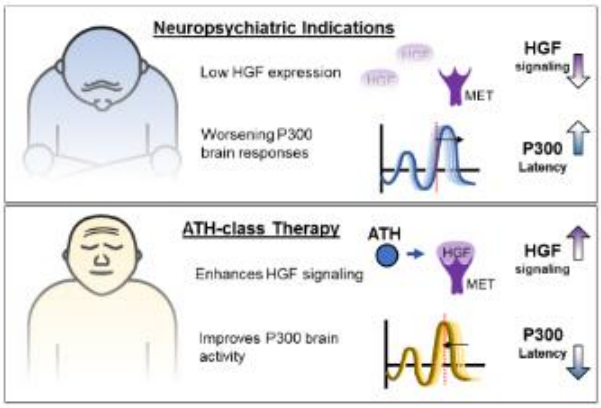
# ATH Small Molecules Enhance HGF/MET Activity

- ATH small molecules promote HGF/MET, which has the potential to promote multiple beneficial effects and improve neuronal function
- Activity can apply to promote nerve cell health in several indications
- Improvement of neuronal health and function may be relevant to several neuropsychiatric indications



# Rationale for Targeting HGF/MET for Neuropsychiatric Indications

- Preclinical studies demonstrate enhancing HGF/MET activity has anti-depressant and anxiolytic effects in rodents
  - Isogawa et al., 2005; Wakatsuki et al., 2007
- Clinical trials show an association between reduced HGF/MET expression levels and depression/anxiety
  - Russo, 2010; Ciuculete et al., 2019; Ramsey et al., 2016
- Neuropsychiatric patients often exhibit worsened P300 latency, a marker of impaired cognitive processing
- ATH activity has the potential to rescue HGF/MET signaling, promote neuronal health and function, and restore P300 latency and cognitive function

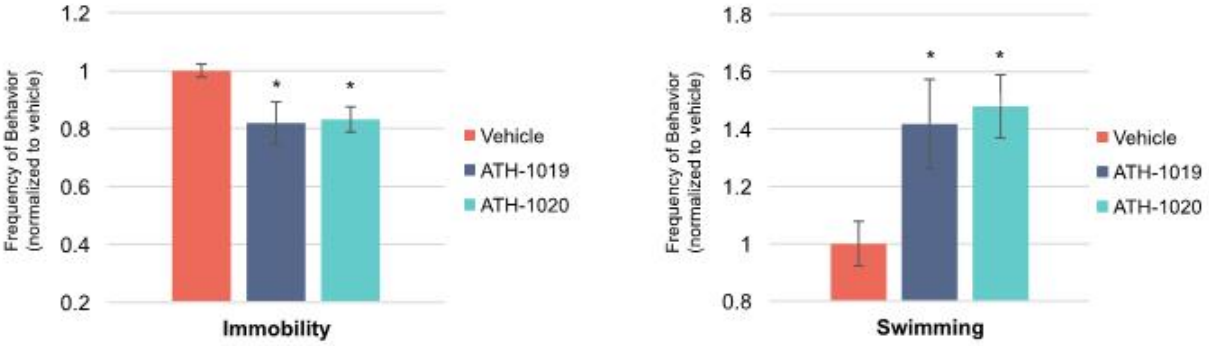


# Novel ATH Potential Candidates

- **ATH-1019 and ATH-1020** are in development as potential candidates for neuropsychiatric indications, including depression, anxiety, and potentially schizophrenia
  - Activate HGF/MET
  - Orally bioavailable
  - Distribute to the brain
  - Neuroactive in animal models
    - Procognitive effects in scopolamine-induced amnesia model of dementia in rats
    - Anti-depressant activity in forced swim test in rats
  - Selection of lead candidate and specific indication(s) following further development

# ATH-1019 and ATH-1020 Demonstrated Anti-Depressant Effects in Animal Models

- Treatment with ATH-1019 and ATH-1020 led to significant improvement from depressive -like behaviors in the rat forced swim model of depression
  - ATH-1019 and ATH-1020 were delivered orally




*p<0.05 compared to Vehicle

# ATH-1019/20 Potential Product Profile

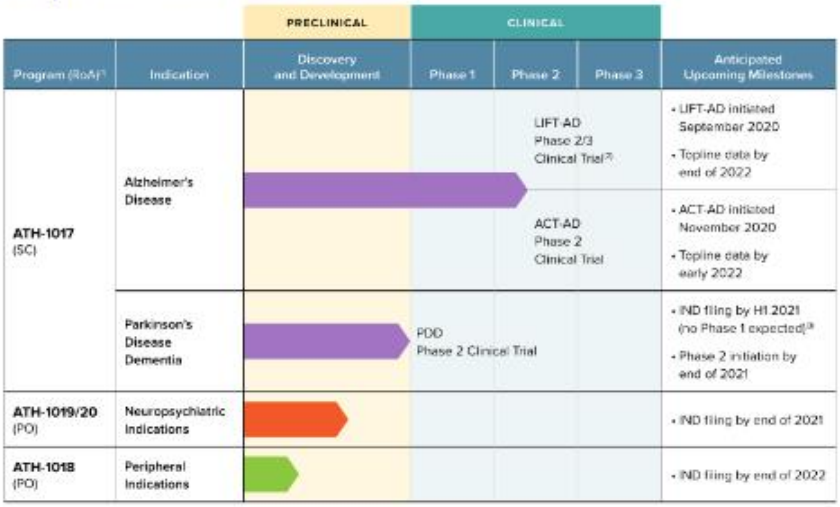
**INDICATIONS**
Neuropsychiatric disorders

**DELIVERY MODE**
Oral

**MOA**
Small molecule agonist of HGF/MET

**REGIMEN**
Targeting once per day

# Current Development Stage of ATH Compounds and Discovery Research Programs to Improve Neuronal Health

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(2) ATH-1017 for AD is moving from Phase 1b to a Phase 2/3 clinical trial that may provide pivotal data in support of registration based on discussions with FDA.
(3) We plan to initiate a Phase 2 clinical trial in PDD based on results from Phase 1a and 1b clinical trials in AD with ATH-1017. A second IND for PDD can cross-reference the already active IND for AD. It is not required that we repeat any studies or trials that are applicable across the two indications for the second IND for PDD, including a Phase 1 clinical trial.

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Thank you!

# Appendix

# ATH-1017 Phase 1a/b Trial Overview

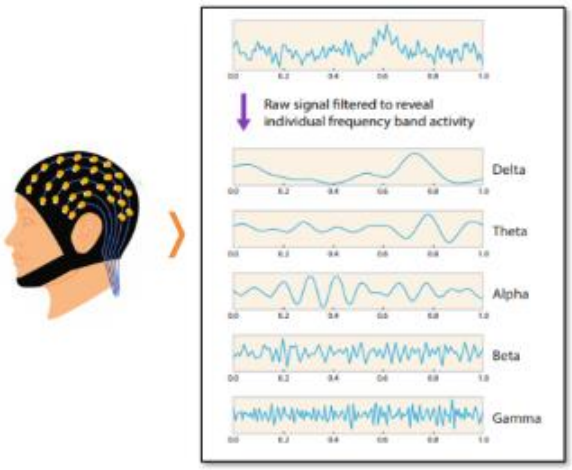
## Phase 1 – Active IND

- Randomized, placebo-controlled, double-blinded, single-ascending dose (Part A) and multiple-ascending dose (Part B) (SC, OD)
- Safety, pharmacokinetics, and pharmacodynamics measures, i.e., qEEG/ERP

| STUDY | POPULATION | DOSE | Treatment Day D1 D2 D3 D4 D5 D6 D7 D8 D9 | STATUS |
|---|---|---|---|---|
| **Part A: single-dose** SAD | 48 healthy young (6:2 active vs. placebo) | 2-90 mg (6 doses) | | Complete |
| **Part B: multiple-dose (9 days)** MAD | 24 healthy elderly (6:2) | 20 mg<br>40 mg<br>60 mg | | Complete |
| | 5 healthy elderly (4:1) | 80 mg | | |
| | 11 AD subjects (7:4), 5 male, 6 female; baseline mini mental scale examination = 18.7 ±6.4 | 40 mg | | Complete |

# EEG as a Translatable Measure of Functional Recovery in the Brain

## Noninvasive EEG recordings reflect brain activity and function




- EEG captures electrical activity in the brain and displays these electrical impulses as waves
- Gamma waves are the faster, higher frequency waves associated with learning, memory and higher cognitive functions
- Gamma power is reduced in AD patients
- **A shift from low to high frequency bands is indicative of network recovery**

Athira utilized qEEG in its ATH-1017 Phase 1 clinical trial as a measure of CNS penetration and target engagement



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# ATH-1017 Increased the Levels of the High Frequency Gamma Power Across all Treated Cohorts- CTAD 2019

## Phase 1a

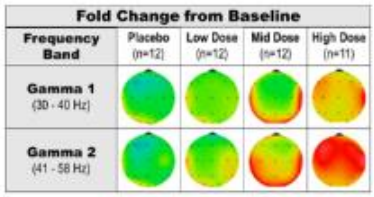
**ATH-1017: single dose EEG, 1-hour post-dose**

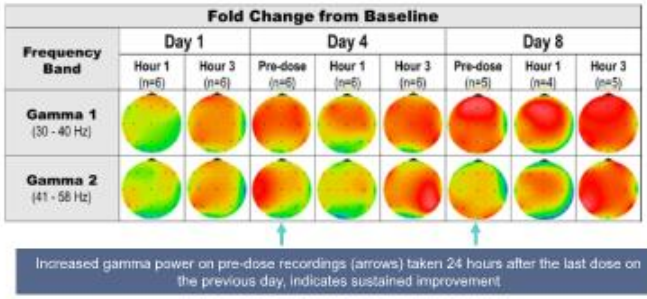
- Placebo, n=12
- Low doses pooled (2 & 6 mg), n=12
- Mid doses pooled (20 & 40 mg), n=12
- High doses pooled (60 & 90 mg), n=11
- Gamma ↑ at 20, 40, 60, 90 mg (>50%)
  - Dose-dependent increase
  - Statistically significant at 90 mg (n=6)
- Indicate CNS penetration and target engagement

## Phase 1b

**Phase 1b qEEG in Healthy Elderly and AD Subjects**

- Increased gamma power observed in healthy elderly and AD subjects treated with ATH-1017 in the MAD study

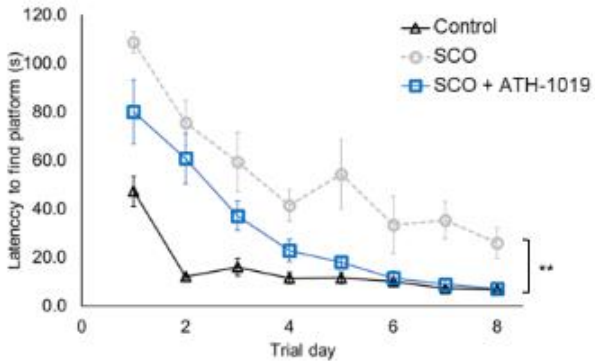




Increased gamma power on pre-dose recordings (arrows) taken 24 hours after the last dose on the previous day, indicates sustained improvement

# ATH-1019 Demonstrated Procognitive Activity in Animal Models

- Oral delivery of ATH-1019 significantly improved performance of rats in the Morris water maze test of spatial memory
  - Scopolamine (SCO) treatment blocks spatial memory formation
  - ATH-1019 treatment reversed the effects of scopolamine, indicating procognitive activity




**p<0.01 SCO + ATH-1019 compared to SCO alone