
**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): June 22, 2022

Athira Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39503
(Commission
File Number)

45-3368487
(IRS Employer
Identification No.)

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

(425) 620-8501
(Registrant's telephone number, including area code)

(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 8.01 Other Events.

On June 22, 2022, Athira Pharma, Inc. (the “Company”) issued a press release announcing the topline results from the Company’s exploratory ACT-AD Phase 2 study of fosgonimeton in mild-to-moderate Alzheimer’s Disease.

A copy of the Company’s press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

The Company will host a live webcast to discuss the ACT-AD results in greater detail at 8:30 a.m. ET today, Wednesday, June 22, 2022. To access the live webcast, please visit the "Events and Presentations" page within the Investors section of the Athira website <https://investors.athira.com/news-and-events/events-and-presentations>. As part of the webcast, the Company will present certain slides relating to the ACT-AD results, which slides are attached as Exhibit 99.2 hereto.

The information in Item 7.01 of this Current Report on Form 8-K, including the slides to be used during the webcast and attached as Exhibit 99.2 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.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Athira Pharma, Inc. press release dated June 22, 2022.
99.2	Athira Pharma, Inc. presentation slides.
104	Cover Page Interactive Data File (formatted as Inline XBRL)

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.

Date: June 22, 2022

Athira Pharma, Inc.

By: /s/ Mark Litton

Mark Litton

President and Chief Executive Officer



Athira Pharma Announces Topline Results from ACT-AD Phase 2 Proof of Concept Study of Fosgonimeton in Mild-to-Moderate Alzheimer's Disease

Primary endpoint of change in biomarker ERP P300 latency was not statistically significant for the full study population as combination of fosgonimeton and standard-of-care (AChEIs) given together showed potential diminished effect of fosgonimeton

A pre-specified subgroup analysis of patients on fosgonimeton monotherapy suggests improvement in both ERP P300 latency and ADAS-Cog11 at week 26 compared to placebo indicating pharmacological activity

Fosgonimeton had a favorable safety profile over 26 weeks and ACT-AD provides important learnings for ongoing LIFT-AD study

Athira to host live webcast today at 8:30 am Eastern time

BOTHELL, Wash., June 22, 2022 -- Athira Pharma, Inc. (NASDAQ: ATHA), a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration, today announced topline results from its exploratory ACT-AD Phase 2 study of fosgonimeton (ATH-1017) in patients with mild-to-moderate Alzheimer's disease (AD). Fosgonimeton is a small molecule designed to enhance the activity of Hepatocyte Growth Factor (HGF) and its receptor, MET, which are expressed in the central nervous system to promote brain health and function.

"Following compelling ERP P300 latency biomarker data from a small Phase 1b trial over eight days in Alzheimer's patients on fosgonimeton monotherapy, this Phase 2 trial provides valuable insights into the nature of this novel intervention over 26 weeks. ACT-AD was designed as a learning study to further investigate the ERP P300 biomarker signal over 6 months, assess safety in a patient population more representative of the real world, by allowing the use of add-on standard-of-care acetylcholinesterase inhibitors (AChEIs, e.g., donepezil), and explore fosgonimeton's effect on psychometric outcomes, including ADAS-Cog11, to inform the ongoing Phase 3 LIFT-AD study. To that end, this study achieved its goal," said Hans Moebius, M.D., Ph.D., Chief Medical Officer of Athira.

"The study was intended to show differences on the biomarker ERP P300 latency. This primary endpoint was not met by protocol analysis, however a pre-specified subgroup analysis indicated a potential diminished effect of fosgonimeton when given in combination with AChEIs. A subsequent post hoc analysis of the data from patients on fosgonimeton monotherapy showed a meaningful improvement in both ERP P300 latency (-28 milliseconds) and cognitive performance (ADAS-Cog11: -3.3 points) compared to placebo at 26 weeks.

“These data points are very encouraging as they indicate the expected pharmacological activity of fosgonimeton by parallel improvement on ERP P300 latency and ADAS-Cog11 and show a favorable safety profile over six months. This is the first time monotherapy fosgonimeton has shown an effect on ADAS-Cog11, suggesting a potential cognitive benefit. We will use these insights for a rational optimization of the ongoing LIFT-AD trial. We plan to seek advice from our scientific advisors, investigators, and ultimately regulators on how to expeditiously analyze and potentially adapt the LIFT-AD study,” added Dr. Moebius.

“The data from the fosgonimeton monotherapy analysis are encouraging and show biologic activity that may support the potential role of the HGF/MET pathway in neurodegenerative diseases,” said Marwan Sabbagh, M.D., FAAN, professor of neurology at Barrow Neurological Institute, Phoenix, AZ. “ACT-AD adds to the body of literature suggesting ERP P300 latency as an important biomarker for cognitive status.”

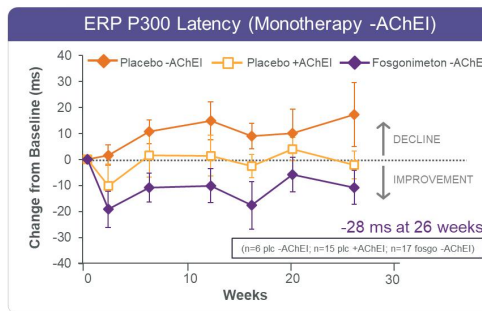
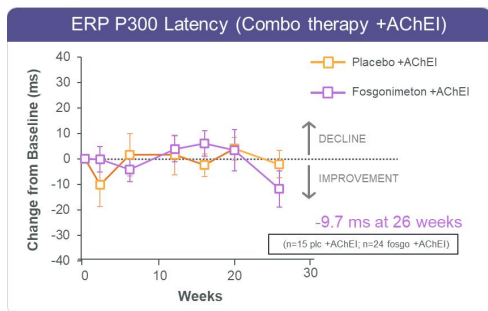
ACT-AD Study Design and Results

ACT-AD was an exploratory, randomized, double-blind, placebo-controlled, parallel-group 26-week trial evaluating fosgonimeton compared to placebo in patients with mild-to-moderate Alzheimer’s disease. The study enrolled 77 patients in the United States and Australia (age 55 to 85 years, Mini-Mental State Exam (MMSE) score of 14-24 and Clinical Dementia Rating (CDR) scale global score of 1 or 2). Patients were allowed to continue standard-of-care therapy (AChEIs), with 60 percent remaining on stable doses of AChEIs and 40 percent not receiving AChEIs during the study. Patients were randomized 1:1:1 to receive placebo or fosgonimeton at either 40 mg/d or 70 mg/d. The primary endpoint for ACT-AD was Event-Related-Potential (ERP) P300 Latency, a functional measure of working memory processing speed. Secondary endpoints included ADAS-Cog11, a measure of cognition; ADCS-CGIC, a measure of global clinical change; and ADCS-ADL23, a measure of functional change. Safety data were evaluated throughout. The study was only powered to show statistical significance for change in ERP P300 latency.

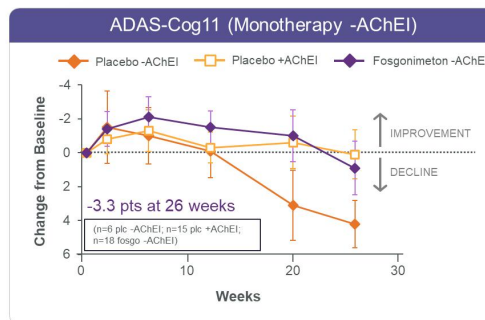
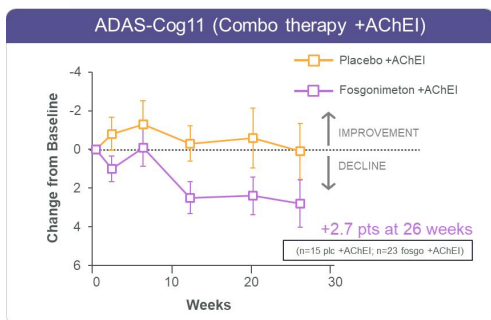
The ACT-AD study did not meet the primary endpoint of a statistically significant change in ERP P300 Latency for the modified intent to treat (mITT) population by a mixed model repeated measures (MMRM) analysis (-6.02 milliseconds) when compared with placebo at 26 weeks in a pooled analysis of the 40 mg and 70 mg dose groups. Secondary endpoints, including ADAS-Cog11, ADCS-CGIC, and ADCS-ADL23, were not significant in treated subjects compared with placebo at 26 weeks. A pre-specified subgroup analysis identified a potential diminished effect of the combination of standard-of-care (AChEIs) and fosgonimeton. Other subgroup analyses, to-date, including dose, disease severity and APOE genotype, did not show differences between groups.

A post hoc analysis, based on the mITT population on fosgonimeton monotherapy, showed a potentially beneficial change in ERP P300 compared to placebo at 26 weeks (-28 milliseconds) as well as cognitive improvement as measured by ADAS-Cog11 (-3.3 points) compared with placebo at 26 weeks.

ACT-AD ERP P300 Latency_post hoc analysis: mITT population, Wilcoxon analysis



ACT-AD ADAS-Cog11_post hoc analysis: mITT population, Wilcoxon analysis



Fosgonimeton was generally well tolerated, with a favorable safety profile. There were no treatment related Serious Adverse Events or deaths observed in the study. Participants treated with fosgonimeton at 40mg or 70mg for 26 weeks showed a higher incidence of treatment emergent adverse events compared to placebo. The most frequent adverse event was injection site reaction, sometimes associated with transient and asymptomatic increases in absolute Eosinophil count. The study had a 14 percent early termination rate.

Full analysis results are scheduled to be presented at the Alzheimer’s Association International Conference (AAIC) taking place July 31 – August 4, 2022.

“As planned, the ACT-AD study results have provided us with important insights that we will use to inform our ongoing LIFT-AD study, which is enrolling mild-to-moderate AD patients. We are encouraged by these data as they show more than just biologic activity; although a small sample size, they suggest a potentially beneficial treatment effect as a monotherapy that in the ACT-AD study was similar to standard-of-care with a favorable safety profile,” said Mark Litton, Ph.D., President and Chief Executive Officer of Athira.

“We are in the fortuitous situation that we have a much larger trial ongoing with more than 200 patients completing at least 20 weeks of treatment providing us with an opportunity to obtain more insights in an expedited manner. Our strong cash position allows us to continue to progress fosgonimeton development.

“In addition to the biomarker results from both the Phase 1b and this study, these data are the first to show fosgonimeton’s potential effect on a key measure of cognitive improvement in Alzheimer’s disease patients by positive modulation of the HGF/MET receptor by fosgonimeton as a monotherapy. We continue to enroll in the open-label extension study that was recently extended to 18 months. We are grateful to the clinicians and patients, along with their families and caregivers, who participated in this trial and continue to support the scientific community in our endeavors to bring new options to patients in need,” concluded Dr. Litton.

Additional information on the ACT-AD study can be found at: [NCT04491006](#). The ACT-AD trial is supported by a grant from the National Institute on Aging of the National Institutes of Health under Award Number R01AG06268. The information presented in this press release is solely the responsibility of Athira and does not necessarily represent the official views of the National Institutes of Health.

About the Phase 3 LIFT-AD Clinical Study

LIFT-AD is a randomized, double-blind, placebo-controlled, parallel-group Phase 3 study of fosgonimeton for patients with mild-to-moderate Alzheimer’s disease. The study will enroll approximately 420 patients in the United States, with enrollment ongoing. Patients are randomized across two dose groups and one placebo group on a 1:1:1 basis to receive a subcutaneous injection of fosgonimeton or placebo once daily over a treatment course of 26 weeks. The primary endpoint for LIFT-AD will be measured by the Global Statistical Test, which is a mathematical algorithm that combines the scores from cognition (Alzheimer’s Disease Assessment Scale-Cognitive Subscale [ADAS-Cog11]), and either global impression of change (Alzheimer’s Disease Cooperative Study-Clinical Global Impression of Change [ADCS-CGIC]), or function (Alzheimer’s Disease Cooperative Study-Activities of Daily Living [ADCS-ADL23]). Additional information on the study can be found at: [NCT04488419](#).

About Fosgonimeton (ATH-1017)

Fosgonimeton (ATH-1017) is a small molecule designed to enhance the activity of hepatocyte growth factor (HGF) and its receptor, MET, to impact neurodegeneration and regenerate brain tissue. The function of the HGF/MET receptor system may be impaired in the brain under conditions of neurodegeneration. In addition to Alzheimer’s disease, fosgonimeton has the potential to address the broader dementia population, including Parkinson’s disease dementia and Dementia with Lewy bodies, as the mode of action focuses on network recovery and synaptic signal transmission in the brain.

About Alzheimer's Disease

Alzheimer's disease (AD) is a progressive neurodegenerative disorder that currently affects an estimated 6.5 million Americans aged 65 and older, according to the Alzheimer's Association. AD has multifactorial and complex pathologies that involve the nervous system, vasculature, immune system and neurotransmitters. One early event of AD progression is the loss of 25-36% of synapses, which impacts several brain regions, including the hippocampus and frontal cortex, regions important for learning and memory. In AD, the expression of neuronal MET is reduced by 75% in the hippocampus and 25% in the frontal cortex, suggesting that dysregulation of HGF/MET could be implicated in AD and other brain pathologies.

Live Webcast

Athira will host a live webcast to discuss the ACT-AD results in greater detail at 8:30 a.m. ET today, Wednesday, June 22, 2022. To access the live webcast, please visit the "Events and Presentations" page within the Investors section of the Athira website <https://investors.athira.com/news-and-events/events-and-presentations>. An archived replay will also be available on the website for at least 90 days following the event.

About Athira Pharma, Inc.

Athira Pharma, Inc., headquartered in the Seattle area, is a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration. Athira aims to provide rapid cognitive improvement and alter the course of neurological diseases with its novel mechanism of action. Athira is currently advancing its lead candidate, fosgonimeton, a novel small molecule for Alzheimer's, Parkinson's disease dementia and Dementia with Lewy bodies. For more information, visit www.athira.com. You can also follow Athira on Facebook, LinkedIn and @athirapharma on Twitter and Instagram.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements are not based on historical fact and include statements regarding fosgonimeton as a potential treatment for Alzheimer's disease, Parkinson's disease dementia and Dementia with Lewy bodies, and other dementias; Athira's platform technology and potential therapies; future development plans; clinical and regulatory objectives and the timing thereof; expectations regarding the potential efficacy and commercial potential of Athira's product candidates; the anticipated reporting of data; the potential learnings from the ACT-AD trial and their ability to inform and improve future clinical development plans; and Athira's ability to advance its product candidates into later stages of development. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "plan," "believe," "intend," "pursue," "continue," and other similar expressions, among others. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the preliminary data for Athira's fosgonimeton product candidate from the Phase 1a/b and Phase 2

ACT-AD trials will not continue or persist in current or planned clinical trials; cessation or delay of any of the ongoing clinical trials and/or Athira's development of fosgonimeton and other product candidates may occur; the impact of the COVID-19 pandemic on Athira's business, research and clinical development plans and timelines, and the regulatory process for Athira product candidates; Athira may not be able to recruit sufficient patients for its clinical trials; future potential regulatory milestones of fosgonimeton and other product candidates, including those related to current and planned clinical studies may be insufficient to support regulatory submissions or approval; the outcome of legal proceedings which have been or may in the future be instituted against us and certain of our directors and officers; clinical trials may not demonstrate safety and efficacy of any of Athira's product candidates; possible negative interactions of Athira's product candidates with other treatments; Athira's assumptions regarding the sufficiency of its cash, cash equivalents and investments to fund its planned operations may be incorrect; while P300 latency is a functional measure that is highly correlated with cognition, Athira may not successfully establish a connection between these P300 latency results and improved cognition; adverse conditions in the general domestic and global economic markets; the impact of competition; regulatory agencies may be delayed in reviewing, commenting on or approving any of Athira's clinical development plans as a result of the COVID-19 pandemic, which could further delay development timelines; the impact of expanded product development and clinical activities on operating expenses; the impact of new or changing laws and regulations; as well as the other risks detailed in Athira's filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and Athira undertakes no obligation to update forward-looking statements. Athira may not actually achieve the plans, intentions, or expectations disclosed in its forward-looking statements, and you should not place undue reliance on the forward-looking statements.

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ACT-AD Topline Results

Investor Webinar
June 22, 2022



ADVANCING NEW THERAPIES FOR NEURONAL HEALTH

Forward Looking Statements

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, fosgonimeton as a potential treatment for Alzheimer's disease and other dementias; the potential learnings from the ACT-AD trial and their ability to inform and improve future clinical development plans; the anticipated reporting of data; 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.

The ACT-AD trial is supported by a grant from the National Institute on Aging of the National Institutes of Health under Award Number R01AG06268. The information presented in this press release is solely the responsibility of Athira and does not necessarily represent the official views of the National Institutes of Health.

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.

The ACT-AD trial is supported by a grant from the National Institute on Aging of the National Institutes of Health under Award Number R01AG06268. The information presented in this presentation is solely the responsibility of Athira and does not necessarily represent the official views of the National Institutes of Health.



ACT-AD Topline Results

Hans Moebius, M.D., Ph.D.
Chief Medical Officer



ACT-AD Executive Summary

Proof of concept ACT-AD trial (N=77) provides important insights for further fosgonimeton development program

- Phase 1b study conducted with fosgonimeton as a monotherapy; Phase 2 allowed for add-on standard of care (AChEIs) to obtain safety data in a more representative real-world patient population
- Primary analysis not statistically significant; fosgonimeton suggests potentially beneficial treatment effect as a monotherapy
- By pre-specified analysis, fosgonimeton and background standard of care both showed positive treatment effects in ERP P300 latency and ADAS-Cog11 as monotherapies, but not in combination
- By post hoc analysis, the parallel ERP P300 latency (-28 ms) and ADAS-Cog11 (-3.3 points) signals appear more pronounced in fosgonimeton monotherapy
- Treatment with fosgonimeton was well tolerated, without typical CNS adverse effects, and safety profile was favorable
- Results will help inform LIFT-AD and optimize chances for success

Fosgonimeton Phase 2 Trial (ACT-AD)



PROOF-OF-CONCEPT TRIAL TO HELP BETTER UNDERSTAND NATURE OF NOVEL INTERVENTION

POPULATION	TREATMENT DURATION	ENDPOINTS AND TIMELINE
<p>ACT-AD: N=77 (recruitment complete) mild-to-moderate AD dementia subjects (55-85 years; CDR 1 and 2; MMSE 14-24 incl.)</p> <p>Potential Pathways to success:</p> <ul style="list-style-type: none"> • Achieves statistical significance on primary endpoint • Key secondary endpoints trending • Functions as "interim analysis" for LIFT-AD without statistical penalty 	<p>26-week randomized, double-blind treatment, + optional 18-months OLEX</p> <p>Fosgonimeton (40 mg)</p> <p>Fosgonimeton (70 mg)</p> <p>Placebo</p> <p>Randomization (1:1:1)</p>	<p>PRIMARY ENDPOINT</p> <ul style="list-style-type: none"> • Change of P300 latency • Safety <p>SECONDARY ENDPOINTS</p> <ul style="list-style-type: none"> • Cognition: ADAS-Cog11 • Global clinical change: ADCS CGIC - Clinician • Function: ADCS-ADL23 • Plasma PK



Phase 2 ACT-AD: baseline demographics



Baseline demographics consistent with appropriate mild-to-moderate Alzheimer's population

	Overall (N = 77)
Age at informed consent (years); mean (SD)	71.4 ± 7.3
Body mass index (kg/m ²), mean (SD)	25.4 ± 3.7
Sex, n (%)	
Female	39 (50.6%)
Male	38 (49.4%)
Years of education, mean (SD)	14.9 ± 2.8
Baseline MMSE, mean (SD)	19.0 ± 2.9
Concomitant AChEI, n (%)	47 (61%)
P300 Latency (SD)	376 ± 38.8



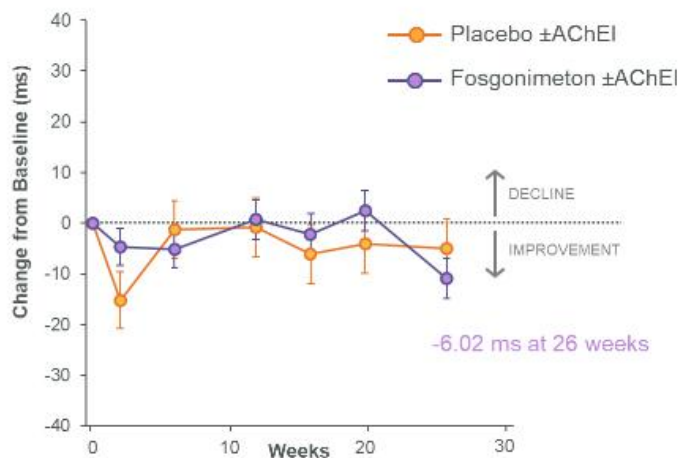
AChEI, acetylcholinesterase inhibitor; AD, Alzheimer's disease; MMSE, Mini-Mental State Examination; SD, standard deviation.

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Primary endpoint of a statistically significant change in biomarker ERP P300 latency was not met

Modified intent to treat (mITT) population by a mixed model repeated measures (MMRM) analysis

ERP P300 Latency per Protocolled Analysis



	Visit	W2	W6	W12	W16	W20	W26
Placebo ±AChEI	CFB	-15.22	-1.26	-0.75	-6.06	-4.01	-4.95
	SE	5.582	5.601	5.817	5.812	5.912	5.839
	N	23	23	21	21	20	21

	Visit	W2	W6	W12	W16	W20	W26
Fosgonimeton ±AChEI	CFB	-4.75	-5.08	0.74	-2.13	2.50	-10.97
	SE	3.649	3.717	3.902	4.021	3.983	3.965
	N	50	48	44	40	41	41

MMRM p-values: 0.124, 0.579, 0.837, 0.588, 0.373, 0.406

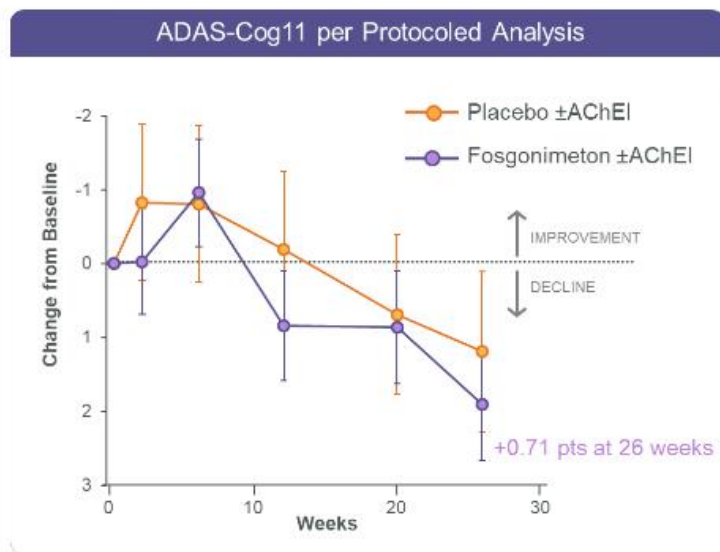


Data plotted as LS mean ± SE

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No signal identified in key secondary endpoint of ADAS-Cog11

Modified intent to treat (mITT) population by a mixed model repeated measures (MMRM) analysis



	Visit	W2	W6	W12	W20	W26
Placebo ±AChEI	CFB	-0.83	-0.81	-0.19	0.69	1.19
	SE	1.052	1.052	1.067	1.083	1.082
	N	23	23	22	21	21
Fosgonimeton ±AChEI	CFB	-0.03	-0.96	0.84	0.86	1.9
	SE	0.716	0.724	0.745	0.761	0.763
	N	50	48	44	41	41
MMRM p-values		0.514	0.9032	0.407	0.888	0.577



Data plotted as LS mean ± SE

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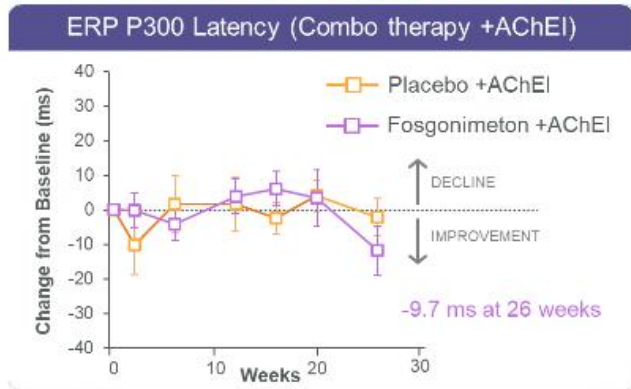
Subgroup analysis was performed per protocol SAP

Pre-specified subgroup analysis suggested differential effects with concomitant standard of care

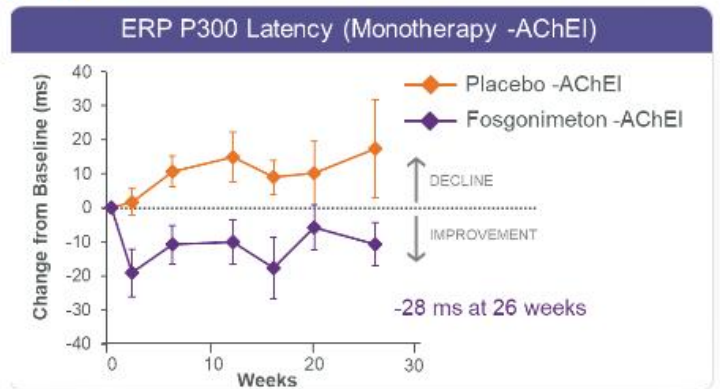
- Severity (mild or moderate)
 - ApoE (carriers or non-carriers)
 - AChEI use (+/- current use of acetylcholinesterase inhibitors including donepezil, rivastigmine, or galantamine)
-
- Analysis of the subgroups suggest AChEI use may impact outcomes
 - No notable patterns observed in other subgroups to date

Subgroup analysis suggests differential ERP P300 latency effect

Modified intent to treat (mITT) population by Wilcoxon analysis



	Visit	W2	W6	W12	W16	W20	W26
Placebo +AChEI	CFB	-10.2	1.6	1.5	-2.5	4.0	-2.1
	SD	32.97	32.03	30.3	17.38	16.07	20.87
	SEM	8.51	8.27	7.82	4.49	4.46	5.39
	N	15	15	15	15	13	15
Fosgonimeton +AChEI	CFB	-0.3	-4.2	3.9	6	3.4	-11.8
	SD	27.31	25.6	25.83	25.29	40.28	34.71
	SEM	4.99	4.75	5.07	5.06	8.06	7.09
	N	30	29	26	25	25	24
Wilcoxon p-values		0.3539	0.7289	0.6357	0.0993	0.5182	0.3193



	Visit	W2	W6	W12	W16	W20	W26
Placebo -AChEI	CFB	1.7	10.7	14.9	9.0	10.2	17.3
	SD	11.27	12.88	17.76	12.13	24.57	35.4
	SEM	3.98	4.55	7.25	4.95	9.29	14.45
	N	8	8	6	6	7	6
Fosgonimeton -AChEI	CFB	-19.1	-10.8	-10.1	-17.6	-5.8	-10.7
	SD	31.13	24.3	27.83	35.34	26.35	26.71
	SEM	6.96	5.57	6.56	9.12	6.59	6.48
	N	20	19	18	15	16	17
Wilcoxon p-values		0.0565	0.024	0.0255	0.0216	0.2703	0.1952

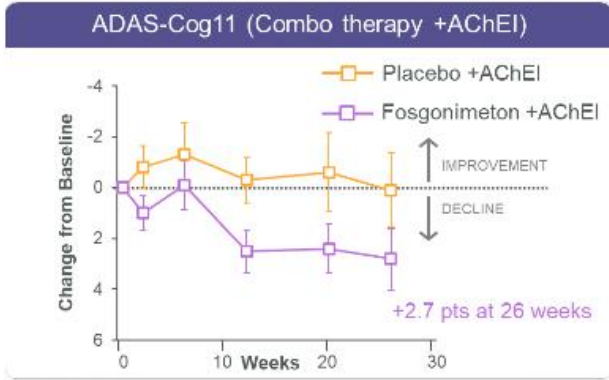


Data presented as unadjusted mean ± SEM

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Subgroup analysis suggests differential ADAS-Cog11 effect

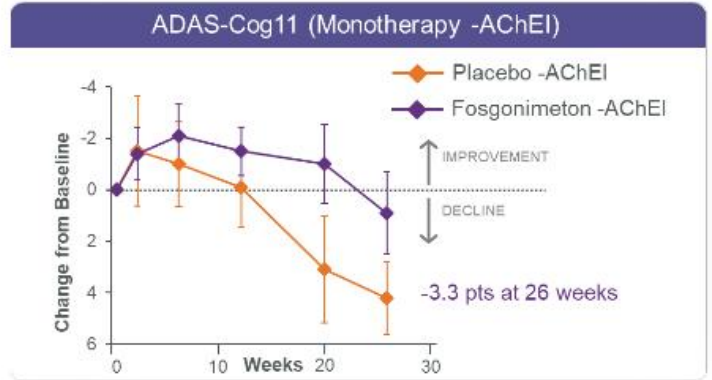
Modified intent to treat (mITT) population by Wilcoxon analysis



Placebo +AChEI	Visit	W2	W6	W12	W20	W26
	CFB	-0.8	-1.3	-0.3	-0.6	0.1
SD	3.28	4.78	3.52	5.79	5.62	
SEM	0.85	1.23	0.91	1.55	1.45	
N	15	15	15	14	15	

Fosgonimeton +AChEI	Visit	W2	W6	W12	W20	W26
	CFB	1.0	-0.1	2.5	2.4	2.8
SD	3.6	5.09	4.23	4.75	5.79	
SEM	0.66	0.96	0.83	0.97	1.21	
N	30	28	26	24	23	

Wilcoxon p-values: 0.1567, 0.6266, 0.04, 0.0919, 0.3157



Placebo -AChEI	Visit	W2	W6	W12	W20	W26
	CFB	-1.5	-1.0	-0.1	3.1	4.2
SD	6.05	4.69	4.14	5.49	3.43	
SEM	2.14	1.66	1.56	2.08	1.40	
N	8	8	7	7	6	

Fosgonimeton -AChEI	Visit	W2	W6	W12	W20	W26
	CFB	-1.4	-2.1	-1.5	-1.0	0.9
SD	4.6	5.45	4.03	6.3	6.74	
SEM	1.03	1.22	0.95	1.53	1.59	
N	20	20	18	17	18	

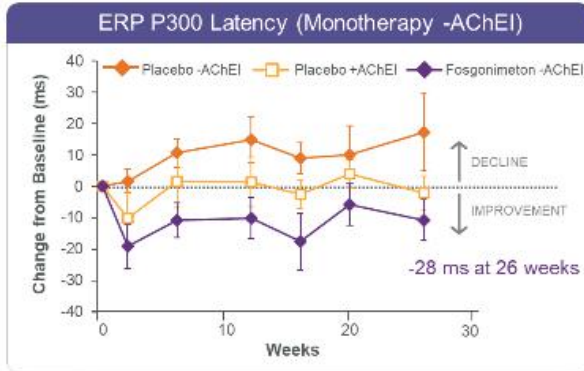
Wilcoxon p-values: 0.6827, 0.6643, 0.4647, 0.0642, 0.1412



Data presented as unadjusted mean ± SEM

Fosgonimeton and standard of care monotherapy suggests positive treatment effects in ERP P300 latency and ADAS-Cog11

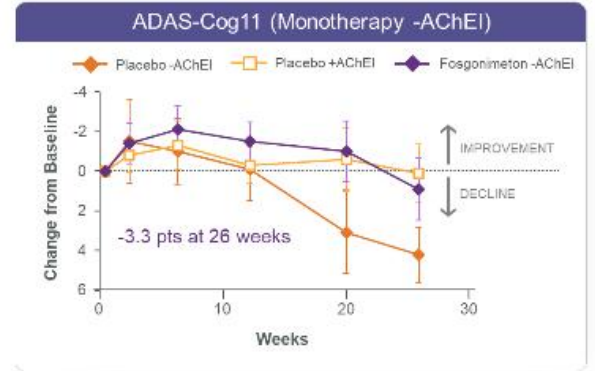
AChEI and placebo effects consistent with published literature; provide external validation of experiment



	Visit	W2	W6	W12	W16	W20	W26
Placebo -AChEI	CFB	1.7	10.7	14.9	9.0	10.2	17.3
	SD	11.27	12.88	17.76	12.13	24.57	30.15
	N	8	8	6	6	7	6

	Visit	W2	W6	W12	W16	W20	W26
Placebo +AChEI	CFB	-10.2	1.6	1.5	-2.5	4.0	-2.1
	SD	32.97	32.03	30.3	17.38	16.07	20.87
	N	15	15	15	15	13	15

	Visit	W2	W6	W12	W16	W20	W26
Fosgonimeton -AChEI	CFB	-19.1	-10.8	-10.1	-17.6	-5.8	-10.7
	SD	31.13	24.3	27.83	35.34	26.35	26.71
	N	20	19	18	15	16	17



	Visit	W2	W6	W12	W20	W26
Placebo -AChEI	CFB	-1.5	-1.0	-0.1	3.1	4.2
	SD	6.05	4.69	4.14	5.49	3.43
	N	8	8	7	7	6

	Visit	W2	W6	W12	W20	W26
Placebo +AChEI	CFB	-0.8	-1.3	-0.3	-0.6	0.1
	SD	3.28	4.78	3.52	5.79	5.62
	N	15	15	15	14	15

	Visit	W2	W6	W12	W20	W26
Fosgonimeton -AChEI	CFB	-1.4	-2.1	-1.5	-1.0	0.9
	SD	4.6	5.45	4.03	6.3	6.74
	N	20	20	18	17	18



Modified intent to treat (mITT) population by Wilcoxon analysis

Treatment with fosgonimeton was generally well tolerated with a favorable safety profile

VARIABLE	Placebo (N=24) N (%)	40mg Fosgonimeton (N=27) N (%)	70mg Fosgonimeton (N=26) N (%)	Overall (N=77) N (%)
Treatment Emergent AEs (TEAEs)	17 (70.8%)	24 (88.9%)	26 (100.0%)	67 (87.0%)
Treatment-Related TEAEs	8 (33.3%)	23 (85.2%)	24 (92.3%)	55 (71.4%)
Serious TEAEs	0 (0.0%)	3 (11.1%)	0 (0.0%)	3 (3.9%)
Treatment-Related Serious TEAEs	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Deaths	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TEAEs Leading to Study Drug Withdrawal	0 (0.0%)	4 (14.8%)	5 (19.2%)	9 (11.7%)
TEAEs Leading to Study Drug Interruption	0 (0.0%)	3 (11.1%)	3 (11.5%)	6 (7.8%)



POPULATION	TREATMENT DURATION	ENDPOINTS AND TIMELINE
<p>LIFT-AD: Target N=~420 mild-to-moderate AD dementia subjects (55-85 years; CDR 1 and 2; MMSE 14-24 incl.)</p> <p>Potential Pathways to success:</p> <ul style="list-style-type: none"> • Achieves statistical significance on primary endpoint • Achieves statistical significance on two key secondary endpoints, which may support approval with a single pivotal study 	<p>26-week randomized, double-blind treatment, + optional 18-months OLEX</p> <p>Fosgonimeton (40 mg)</p> <p>Fosgonimeton (70 mg)</p> <p>Placebo</p> <p>Randomization (1:1:1)</p>	<p>PRIMARY ENDPOINT</p> <ul style="list-style-type: none"> • Global Statistical Test (GST) – unbiased composite, fed by data from two key secondaries • Safety <p>SECONDARY ENDPOINTS</p> <ul style="list-style-type: none"> • Cognition: ADAS-Cog11 • Global clinical change: ADCS CGIC - Clinician • Function: ADCS-ADL23 <p>STATUS</p> <ul style="list-style-type: none"> • Enrollment underway • Analysis to inform decision-making



Over 200 completing at least 20 weeks of treatment; ~50% monotherapy

ACT-AD Conclusion

This first small interventional trial with the positive HGF/MET modulator fosgonimeton supports its potential in Alzheimer's disease

- Primary analysis not statistically significant; fosgonimeton suggests potentially beneficial treatment effect as a monotherapy
- By pre-specified analysis, background AChEIs and fosgonimeton both showed positive treatment effects in P300 latency and ADAS-Cog11 as monotherapies, but not in combination
- By post hoc analysis, the parallel P300 latency (-28 ms) and ADAS-Cog11 (-3.3 points) signal appears more pronounced in fosgonimeton monotherapy
- Treatment with fosgonimeton was well tolerated, without typical CNS adverse effects, and safety profile was favorable
- Full analysis is ongoing
- The results will inform the optimization of the parallel Phase 3 LIFT-AD study, with over 200 completing at least 20 weeks of treatment; ~50% monotherapy
- Will seek advice from experts, advisors, and regulators on how to expeditiously analyze and potentially adapt the LIFT-AD study
- Recruitment to LIFT-AD and the transitions to the Open Label Extension study will continue

Conclusion

Mark Litton, Ph.D.
Chief Executive Officer



Closing: Fosgonimeton has potential in Alzheimer's Disease

ACT-AD results to benefit LIFT-AD probability of success

- ACT-AD is the first study to show potential cognitive improvement with ADAS-Cog11 in AD patients by positive modulation of the HGF/MET receptor by fosgonimeton
- ACT-AD outcomes support our conviction that we have a unique opportunity to make a positive difference for patients suffering from neurodegenerative diseases
- ACT-AD results are important data that warrant further evaluation and inform how best to optimize the parallel LIFT-AD study
- Planned near term LIFT-AD analysis will also inform decision-making

Strong balance sheet to support fosgonimeton development program through key inflection points

