UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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): December 9, 2016

Biogen Inc.

(Exact name of registrant as specified in its charter)

Delaware	**0-19311**	**33-0112644**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

225 Binney Street, Cambridge, Massachusetts 02142
(Address of principal executive offices; Zip Code)

Registrant's telephone number, including area code: **(617) 679-2000**

Not Applicable
(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:

☐ 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))

Item 7.01 Regulation FD Disclosure

Attached as Exhibit 99.1 and Exhibit 99.2 to this Current Report on Form 8-K are slides from presentations that Biogen Inc. made on December 9, 2016 at the 9th Clinical Trials on Alzheimer's Disease (CTAD) meeting in San Diego, California.

Limitation on Incorporation by Reference. The information furnished in this Item 7.01 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as expressly set forth by specific reference in such a filing.

Cautionary Note Regarding Forward-Looking Statements. The presentations may contain forward-looking statements, including statements about additional results from the Phase 1b study, and the potential clinical effects and safety of aducanumab. These statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will" and similar expressions, and are based on our current beliefs and expectations. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. Factors which could cause actual results to differ materially from our current expectations include the risk that we may not fully enroll our clinical trials or enrollment will take longer than expected, unexpected concerns may arise from additional data, analysis or results obtained during our clinical trials, regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of our drug candidates, or we may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with our drug development and commercialization activities, please review the Risk Factors section of our most recent annual or quarterly report filed with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of the presentations and we assume no obligation to update any forward-looking statements.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Aducanumab Titration Dosing Regimen Presentation slides from CTAD dated December 9, 2016
99.2	Aducanumab 24 Month Data from Prime Presentation slides from CTAD dated December 9, 2016

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.

Biogen Inc.

By: /s/ Steven N. Avruch
Steven N. Avruch
Chief Corporation Counsel and Assistant Secretary

Date: December 9, 2016

EXHIBIT INDEX

Exhibit Number	Description
99.1	Aducanumab Titration Dosing Regimen Presentation slides from CTAD dated December 9, 2016
99.2	Aducanumab 24 Month Data from Prime Presentation slides from CTAD dated December 9, 2016

Interim analysis presented at CTAD 2016

Aducanumab Titration Dosing Regimen: 12-Month Interim Analysis from PRIME, a Randomized, Double-Blind, Placebo-Controlled Phase 1b Study in Patients With Prodromal or Mild Alzheimer's Disease

Vissia Viglietta,[1] John O'Gorman,[1] Leslie Williams,[1] Tianle Chen,[1] Ahmed Enayetallah,[1] Ping Chiao,[1] Christoph Hock,[2] Roger M. Nitsch,[2] Samantha Budd Haeberlein,[1] Alfred Sandrock[1]

[1]Biogen, Cambridge, MA, USA; [2]Neurimmune, Schlieren-Zurich, and University of Zurich, Switzerland

Disclosures

This study is funded by Biogen[a]

- VV, JO, LW, TC, AE, PC, SBH, and AS are employees and shareholders of Biogen
- CH and RMN are employees and shareholders of Neurimmune

[a]Medical writing support for this presentation was provided by Erin Bekes, PhD, of Complete Medical Communications and funded by Biogen.

Introduction

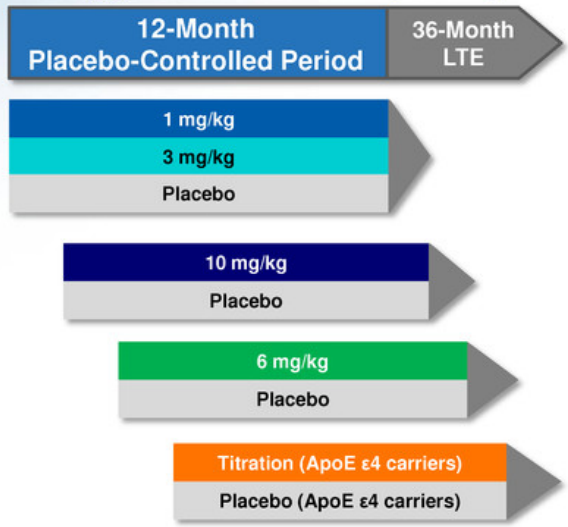
- Aducanumab is a human monoclonal antibody selective for aggregated forms of Aβ, including soluble oligomers and insoluble fibrils
- PRIME is an ongoing Phase 1b study assessing the safety, tolerability, PK and PD of aducanumab in patients with prodromal or mild Alzheimer's disease
- Results from a 12-month interim analysis from fixed-dose cohorts have been previously published[1]
- Here we present 12-month interim data for both fixed-dose and titrated aducanumab in PRIME

1. Sevigny et al. *Nature* 2016;537:50-56
PD, pharmacodynamics; PK, pharmacokinetics

Interim analysis presented at CTAD 2016

PRIME Study Design: Placebo-Controlled and LTE Periods

Staggered Parallel-Group Design



Population

- Prodromal or mild AD
- MMSE ≥20
- Stable concomitant medications
- Positive amyloid PET scan

Endpoints

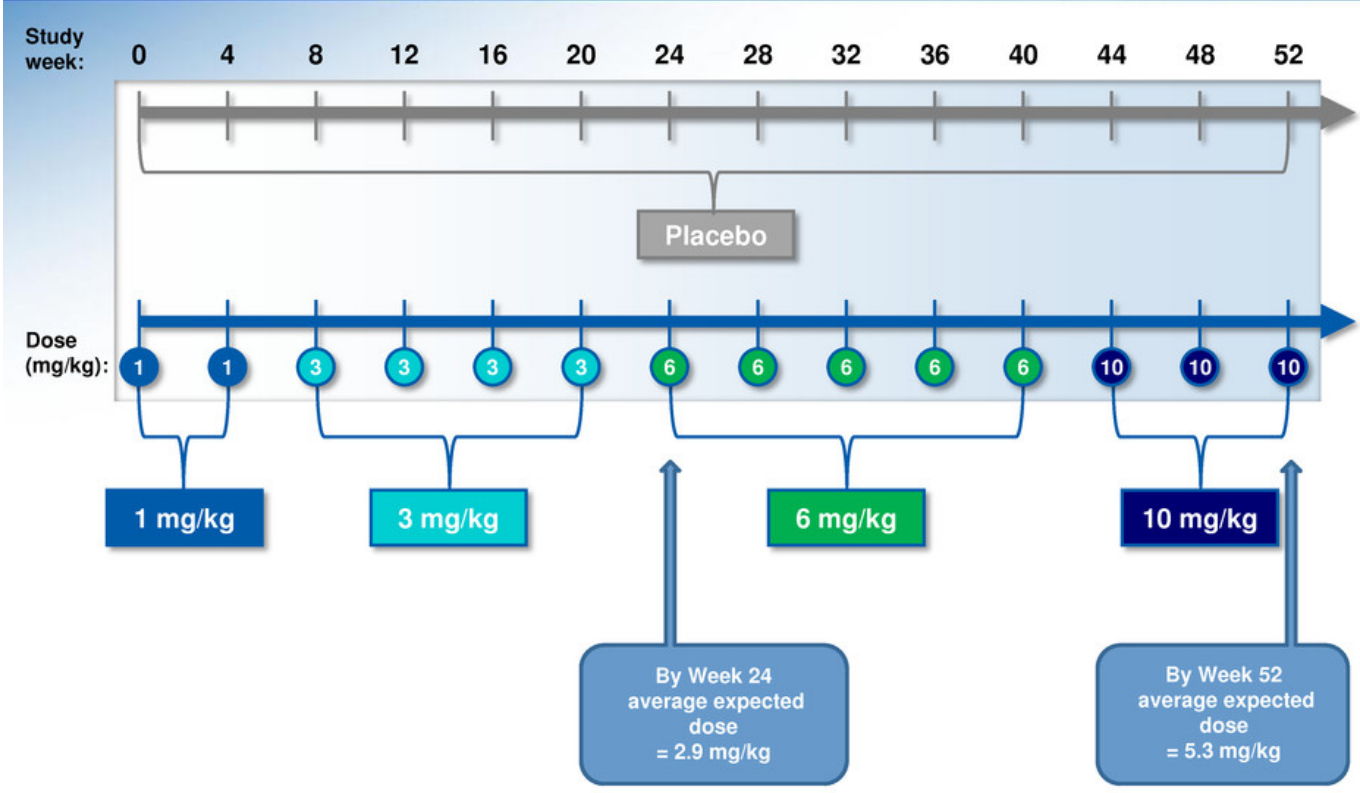
- **Primary endpoint**: safety and tolerability
- **Secondary endpoints**: serum PK, immunogenicity, change in amyloid PET (Week 26)
- **Exploratory endpoints** included CDR–SB, MMSE, change in amyloid PET (Week 54)

- **Randomization**: 3:1 active: placebo within cohorts, fixed-dose cohorts stratified by ApoE ε4 status
- **Planned sample size**: 188 patients
- **Titration cohort** of ApoE ε4 carriers added after enrollment into fixed-dose arms was complete (planned sample size: 21 aducanumab: 7 placebo)

CDR–SB, Clinical Dementia Rating–Sum of Boxes; LTE, long-term extension; MMSE, Mini-Mental State Examination; PET, positron emission tomography

Interim analysis presented at CTAD 2016

Titration Dosing Regimen in the 12-Month Placebo-Controlled Period



Patient Disposition at 12 Months

197 randomized (by cohort)

	Pooled placebo	1 mg/kg	3 mg/kg	6 mg/kg	10 mg/kg	Titration
Randomized	48	31	33	30	32	23
Dosed	48	31	32	30	32	23
Discontinued treatment	10	7	6	5	12	4
AE	3	3	2	3	10	2
Lost to follow-up	0	0	1	0	0	0
Disease progression	0	0	0	1	0	0
Consent withdrawn	0	2	1	1	1	0
Investigator decision	1	0	0	0	1	0
Death	1	0	0	0	0	0
Other	5	2	2	0	0	2

AE, adverse event
Analysis of data from all cohorts up to Week 54

Baseline Disease Characteristics

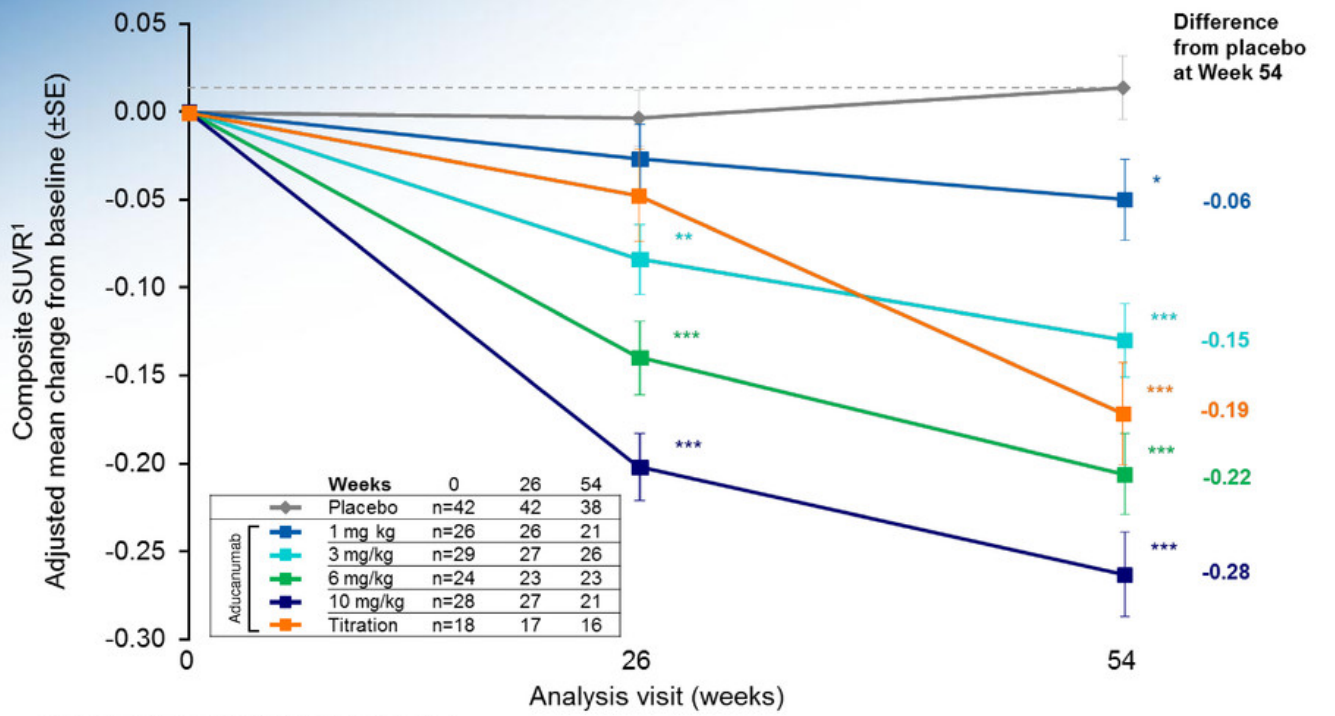
	Placebo (n=48)	Aducanumab 1 mg/kg (n=31)	Aducanumab 3 mg/kg (n=32)	Aducanumab 6 mg/kg (n=30)	Aducanumab 10 mg/kg (n=32)	Aducanumab Titration (n=23)
Age in years, mean ± SD	73.3 ± 6.8	72.6 ± 7.8	70.5 ± 8.2	73.3 ± 9.3	73.7 ± 8.3	73.1 ± 7.8
ApoE ε4, n (%)						
Carriers	34 (71)	19 (61)	21 (66)	21 (70)	20 (63)	23 (100)
Non-carriers	14 (29)	12 (39)	11 (34)	9 (30)	12 (38)	0
Clinical stage, n (%)						
Prodromal	22 (46)	10 (32)	14 (44)	12 (40)	13 (41)	13 (57)
Mild	26 (54)	21 (68)	18 (56)	18 (60)	19 (59)	10 (43)
MMSE, mean ± SD	24.7 ± 3.6	23.6 ± 3.3	23.2 ± 4.2	24.4 ± 2.9	24.8 ± 3.1	24.7 ± 3.0
CDR Global Score, n (%)						
0.5	40 (83)	22 (71)	22 (69)	25 (83)	24 (75)	18 (78)
1	8 (17)	9 (29)	10 (31)	5 (17)	8 (25)	5 (22)
CDR-SB, mean ± SD	2.69 ± 1.54	3.40 ± 1.76	3.50 ± 2.06	3.32 ± 1.54	3.14 ± 1.71	3.24 ± 1.84
PET SUVR, mean composite	1.435	1.441	1.464	1.429	1.441	1.325
AD medications used,[a] n (%)	30 (63)	21 (68)	28 (88)	20 (67)	17 (53)	12 (52)

AD, Alzheimer's disease; SD, standard deviation; SUVR, standardized uptake value ratio
[a]Cholinesterase inhibitors and/or memantine.

PET AMYLOID IMAGING

Interim analysis presented at CTAD 2016

Aducanumab Reduces Amyloid Plaques



Nominal p values: * $P<0.05$; ** $P<0.01$; *** $P<0.001$ vs placebo.

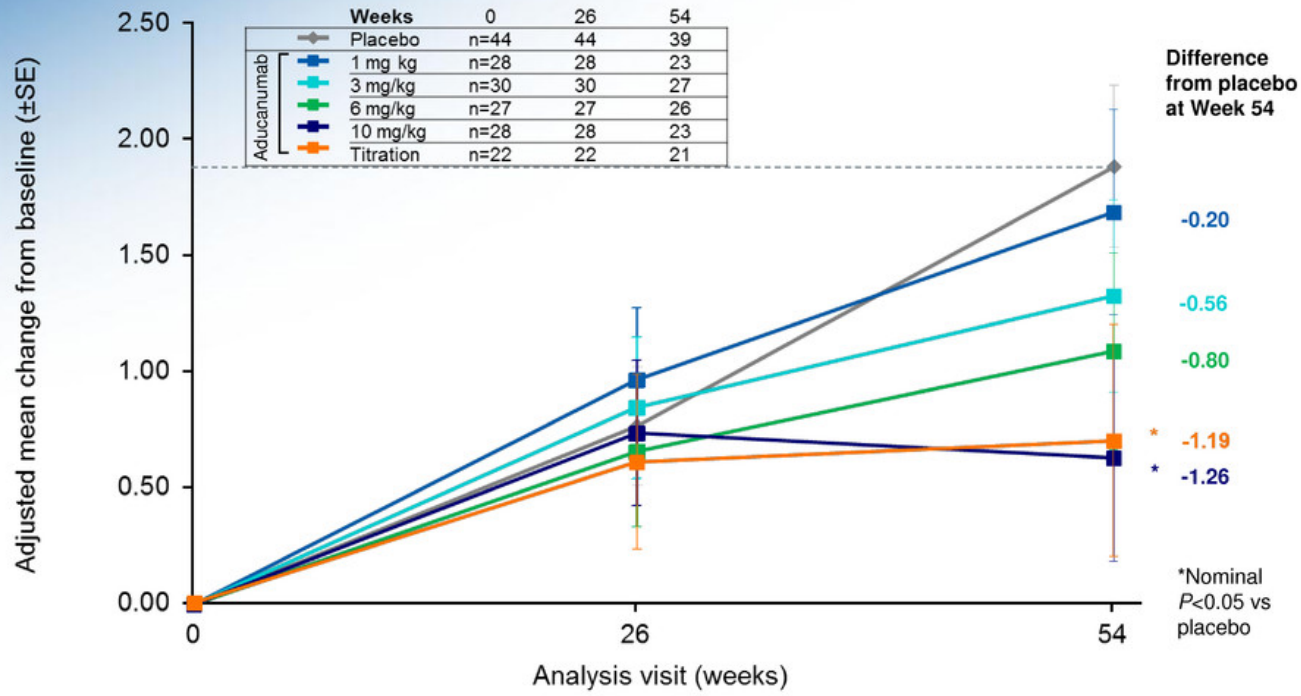
1. Ostrowitzki et al. Arch Neurol 2012

Analyses based on observed data. ANCOVA for change from baseline with factors of treatment, laboratory ApoE ε4 status (carrier and non-carrier), and baseline composite SUVR. PD analysis population is defined as all randomized patients who received at least 1 dose of study medication and had at least 1 post-baseline assessment of the parameter. ANCOVA, analysis of covariance; SE, standard error

CLINICAL ENDPOINTS

Interim analysis presented at CTAD 2016

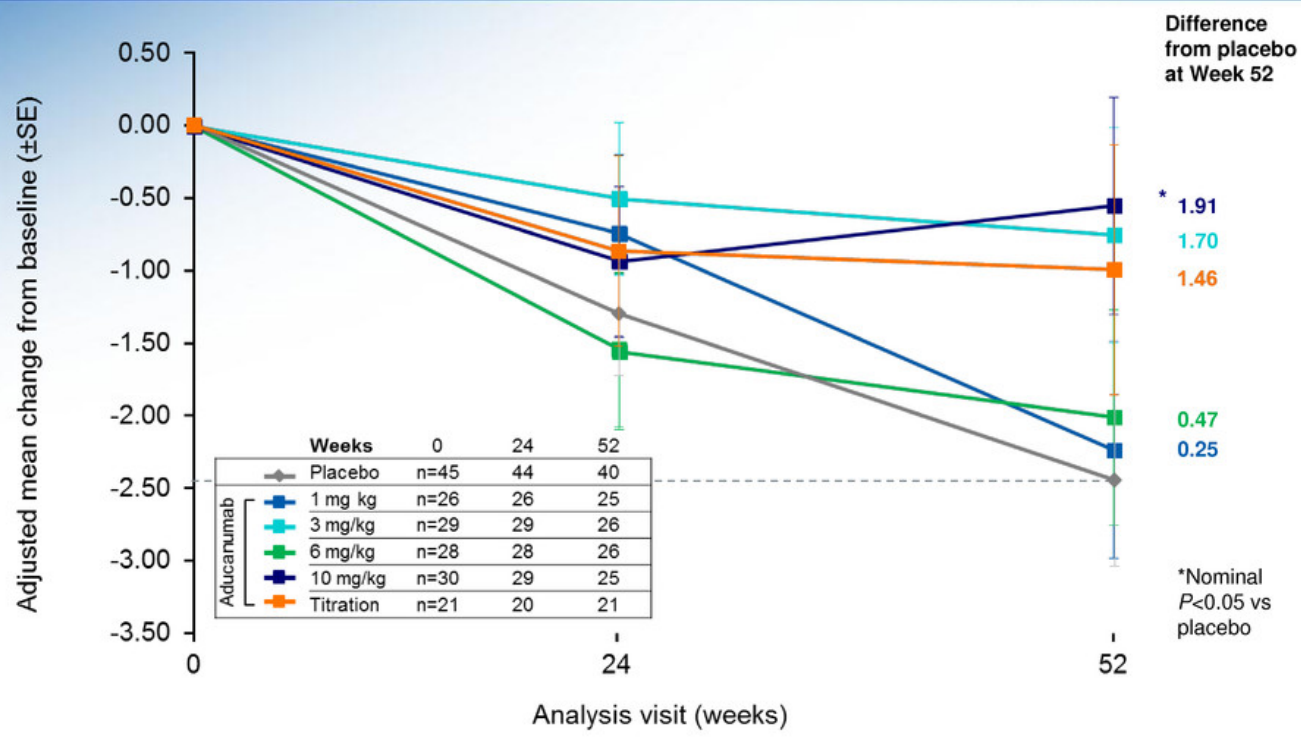
Effect of Aducanumab on Clinical Decline as Measured by CDR–SB (exploratory endpoint)



CDR-SB is an exploratory endpoint. Analyses based on observed data. ANCOVA for change from baseline with factors of treatment, laboratory ApoE ε4 status (carrier and non-carrier), and baseline CDR-SB. Efficacy analysis population is defined as all randomized subjects who received at least 1 dose of study medication and had at least 1 post-baseline questionnaire assessment

Interim analysis presented at CTAD 2016

Effect of Aducanumab on Clinical Decline as Measured by MMSE (exploratory endpoint)



MMSE is an exploratory endpoint. Analyses based on observed data. ANCOVA for change from baseline with factors of treatment, laboratory ApoE ε4 status (carrier and non-carrier), and baseline MMSE. Efficacy analysis population is defined as all randomized patients who received at least 1 dose of study medication and had at least 1 post-baseline questionnaire assessment.

SAFETY AND TOLERABILITY

No New Safety Signals Identified in Titration Cohort During 12-Month Placebo-Controlled Period

		Aducanumab				
	Placebo (N=48)	1 mg/kg (N=31)	3 mg/kg (N=32)	6 mg/kg (N=30)	10 mg/kg (N=32)	Titration (N=23)
Number with an AE (%)	47 (98)	28 (90)	27 (84)	28 (93)	29 (91)	21 (91)
Number with an SAE (%)	16 (33)	4 (13)	4 (13)	4 (13)	12 (38)	5 (22)
Number discontinuing treatment due to AE (%)	4 (8)	3 (10)	2 (6)	3 (10)	10 (31)	2 (9)

- No new safety signals were identified in the titration cohort
- As previously presented for the fixed-dose cohorts:
  - The most common AE/SAE was ARIA
  - Other AEs/SAEs were consistent with the patient population
    - Three deaths; none considered treatment-related; two in placebo and one in 10 mg/kg arm (two occurred after study discontinuation)
  - No significant changes in chemistry, hematology, urinalysis, ECGs, or vital signs

ARIA, amyloid-related imaging abnormalities; ECG, electrocardiogram; SAE, serious adverse event

Dose Titration Slightly Attenuated Incidence of ARIA-E Versus Higher Fixed Doses

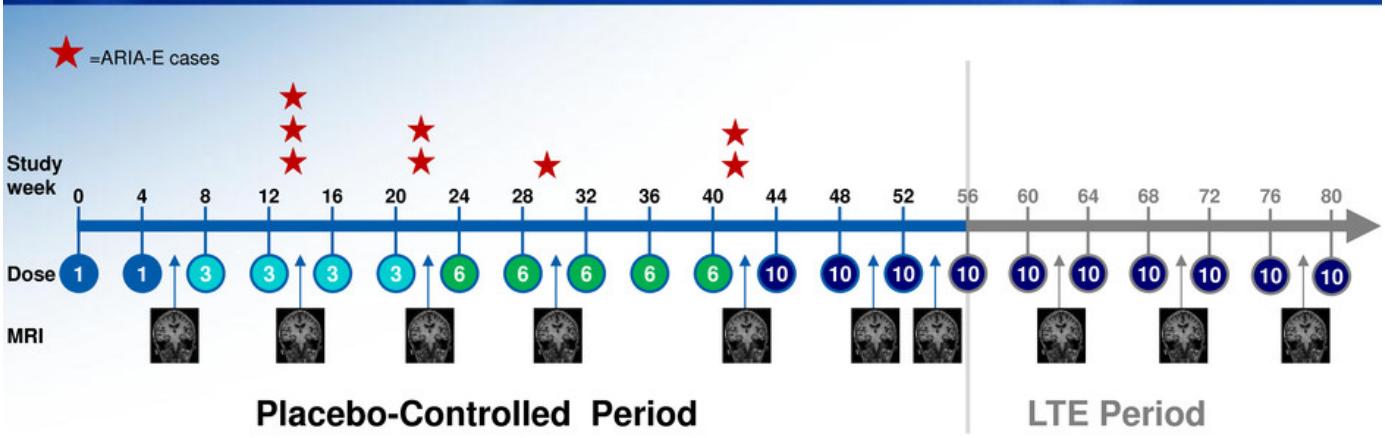
		Aducanumab				
	Placebo	1 mg/kg	3 mg/kg	6 mg/kg	10 mg/kg	Titration
Patients with at least 1 post-baseline MRI	46	31	32	30	32	23
ARIA-E,[a] n (%)	0/46	1/31 (3)	2/32 (6)	11/30 (37)	13/32 (41)	8/23 (35)
ApoE ε4 carrier	0/32	1/19 (5)	1/21 (5)	9/21 (43)	11/20 (55)	8/23 (35)
ApoE ε4 non-carrier	0/14	0/12	1/11 (9)	2/9 (22)	2/12 (17)	--
Isolated ARIA-H, n (%)	3/46 (7)	2/31 (6)	3/32 (9)	0/30	2/32 (6)	0/23

[a]ARIA-E with or without ARIA-H.

Incidence of ARIA based on MRI.
ARIA-E, ARIA–vasogenic edema; ARIA-H, ARIA–microhemorrhages, macrohemorrhages, or superficial siderosis; MRI, magnetic resonance imaging

Interim analysis presented at CTAD 2016

Timing of ARIA-E in the Titration Cohort



- 8 subjects had ARIA-E in 3 or 6 mg/kg stage.
- 13 subjects reached 10 mg/kg without ARIA-E
  - Currently 12 of the 13 subjects are active in the study
    - All 12 have received ≥10 doses of 10 mg/kg

Most Titration Patients with ARIA-E Continued Treatment

	Aducanumab				
	1 mg/kg	3 mg/kg	6 mg/kg	10 mg/kg	Titration
ApoE ε4 carriers with at least 1 post-baseline MRI	19	21	21	20	23
ARIA-E, n (%)	1 (5)	1 (5)	9 (43)	11 (55)	8 (35)
Continued treatment, n (%)	0	1 (5)	7 (33)	4 (20)	6 (26)
Same dose	0	0	1	0	0
Reduced dose	0	1	6	4	6
Discontinued treatment, n (%)	1 (5)	0	2 (10)	7 (35)	2 (9)

Among ApoE ε4 carriers with ARIA-E,

- 4/11 (36%) in the 10 mg/kg group continued treatment
- 7/9 (78%) in the 6 mg/kg group continued treatment
- 6/8 (75%) in the titration group continued treatment

ARIA-E Characteristics in the Titration Cohort

- Majority of cases occurred within the first 5 months of treatment
- 75% of events were asymptomatic
- 2 patients (25%) had mild symptoms that resolved
- MRI findings typically resolved within 4–12 weeks

Summary

- Both titration and fixed doses of aducanumab significantly reduced amyloid plaque burden following 12 months of treatment versus placebo
- Clinical effects with titrated aducanumab were generally consistent with findings in the fixed-dose cohorts
  - Slowing of decline as measured by the CDR–SB and MMSE was observed in the titration and fixed-dose cohorts
- Titration up to 10 mg/kg may reduce incidence of ARIA-E compared with higher fixed dosing based on the ApoE ε4 cohort studied
- PRIME results support the study design of the ENGAGE and EMERGE Phase 3 trials, which are investigating the clinical efficacy and safety of aducanumab in patients with early AD
- 24-month data with fixed doses of aducanumab from PRIME will also be presented at CTAD 2016 (Fri Dec 9, 9:15 AM)

Acknowledgments

We thank all the patients and their family members participating in the aducanumab studies, as well as the investigators and their staff conducting these studies.

Interim analysis presented at CTAD 2016

Aducanumab 24-Month Data From PRIME: A Randomized Double-Blind, Placebo-Controlled Phase 1b Study in Patients With Prodromal or Mild Alzheimer's Disease

Vissia Viglietta,[1] John O'Gorman,[1] Leslie Williams,[1] Tianle Chen,[1] Ahmed Enayetallah,[1] Ping Chiao,[1] Christoph Hock,[2] Roger M. Nitsch,[2] Samantha Budd Haeberlein,[1] Alfred Sandrock[1]

[1]Biogen, Cambridge, MA, USA; [2]Neurimmune, Schlieren-Zurich, and University of Zurich, Switzerland

Disclosures

This study was funded by Biogen[a]

- VV, JO, LW, TC, AE, PC, SBH, and AS are employees and shareholders of Biogen
- CH and RMN are employees and shareholders of Neurimmune

[a]Medical writing support for this presentation was provided by Erin Bekes, PhD, of Complete Medical Communications and funded by Biogen.

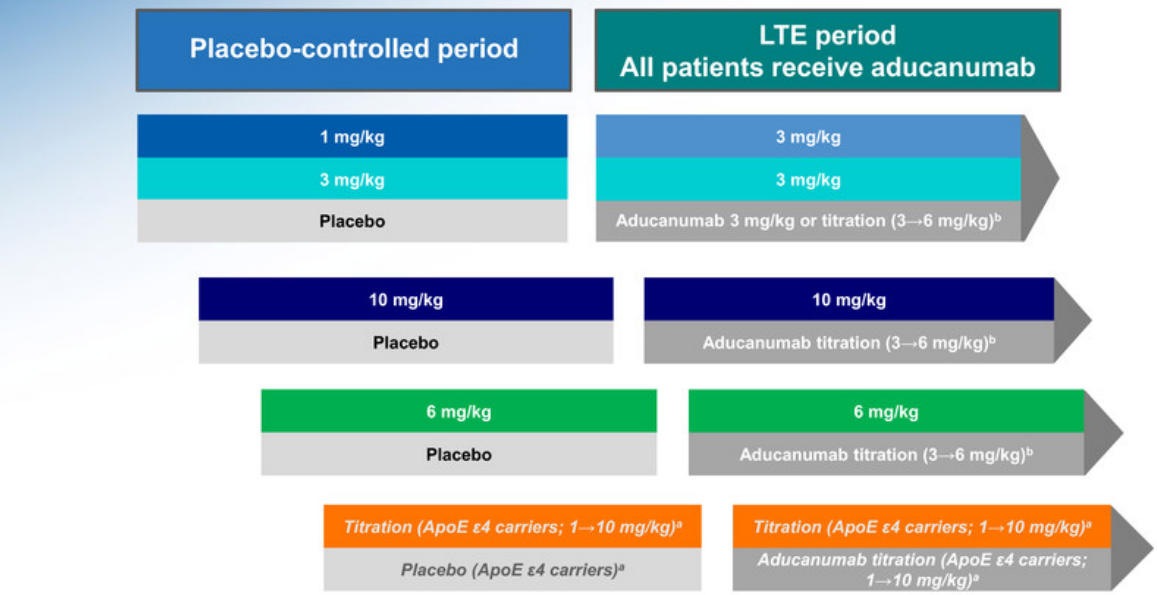
Overview

- Aducanumab is a human monoclonal antibody selective for aggregated forms of Aβ, including soluble oligomers and insoluble fibrils
- PRIME is an ongoing Phase 1b study assessing the safety, tolerability, PK and PD of aducanumab in patients with prodromal or mild Alzheimer's disease
- Here we present 24-month data from the 12-month placebo-controlled period and the first 12 months of the LTE period of PRIME
  - Data from the titration cohort are not reported because 24-month data are not yet available for this cohort
- Primary endpoint in the LTE was safety/tolerability
- Exploratory endpoints included:
  - Changes in amyloid PET
  - Measures of clinical decline on the CDR–SB and MMSE

CDR-SB, Clinical Dementia Rating-Sum of Boxes; MMSE, Mini-Mental State Examination; PD, pharmacodynamics; PET, positron emission tomography; PK, pharmacokinetics; LTE, long-term extension

Interim analysis presented at CTAD 2016

PRIME Study Design: Placebo-Controlled and LTE Periods

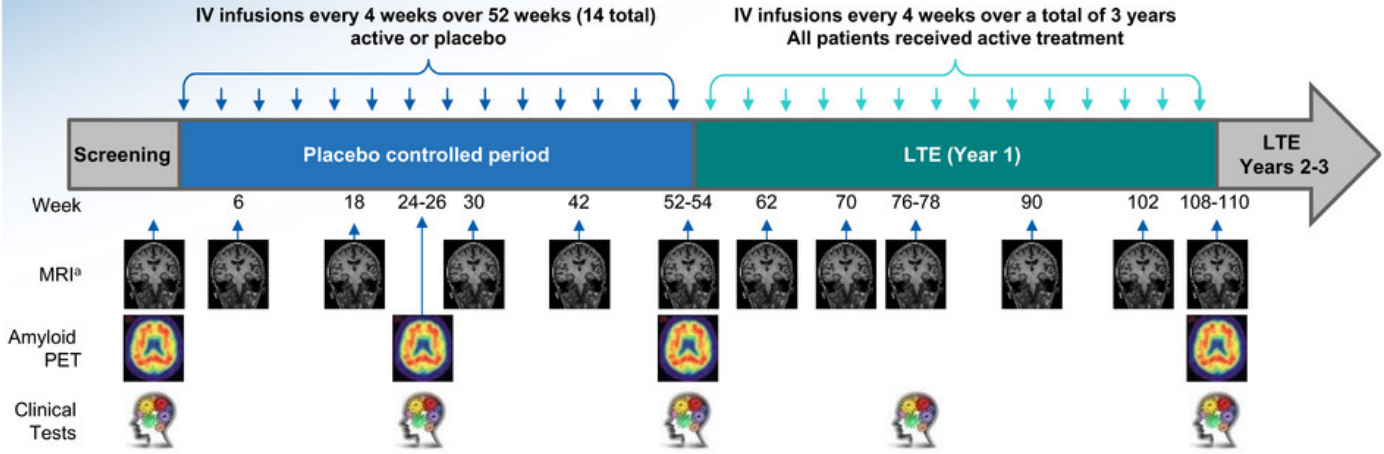


- **Randomization**: 3:1 active: placebo within cohorts, fixed-dose cohorts stratified by ApoE ε4 status
- Patients randomized to placebo or aducanumab 1 mg/kg in the placebo-controlled period were switched to aducanumab 3 mg/kg or titration in the LTE ("**switchers**"). Patients randomized to aducanumab 3, 6, or 10 mg/kg or titration in the placebo-controlled period were assigned to continue in the same dose group in the LTE ("**continuers**")

[a]Data from the titration cohort are not included in this analysis as 24-month data from this cohort are not yet available. [b]For patients switched from placebo to titration in the LTE, titration denotes 2 doses of 3 mg/kg followed by subsequent doses of 6 mg/kg.

Interim analysis presented at CTAD 2016

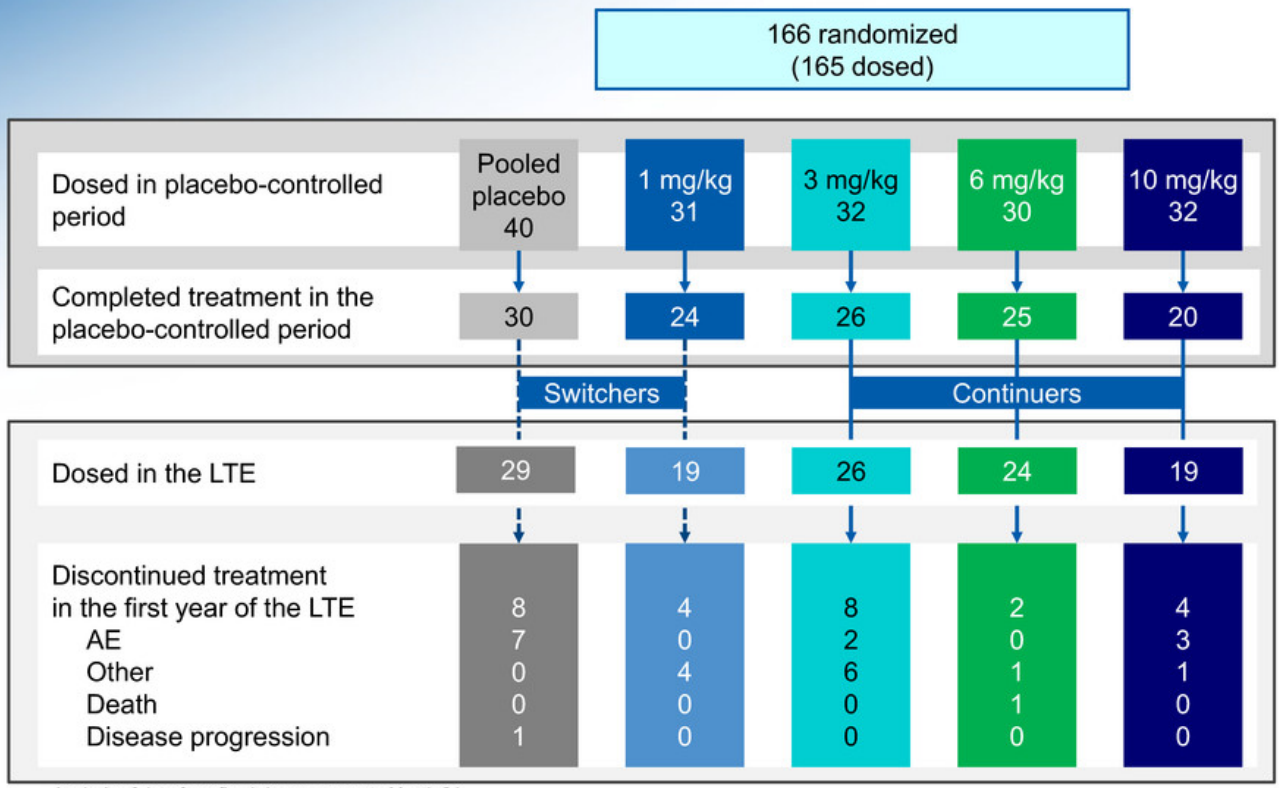
Timeline of Dose Administration and Key Assessments in PRIME



[a]Schedule of brain MRIs for fixed-dose cohorts (Arms 1-7)
MRI, magnetic resonance imaging

Interim analysis presented at CTAD 2016

Patient Disposition at 24 Months



Analysis of data from fixed-dose arms up to Month 24.

Interim analysis presented at CTAD 2016

Baseline Disease Characteristics: Placebo-Controlled Period

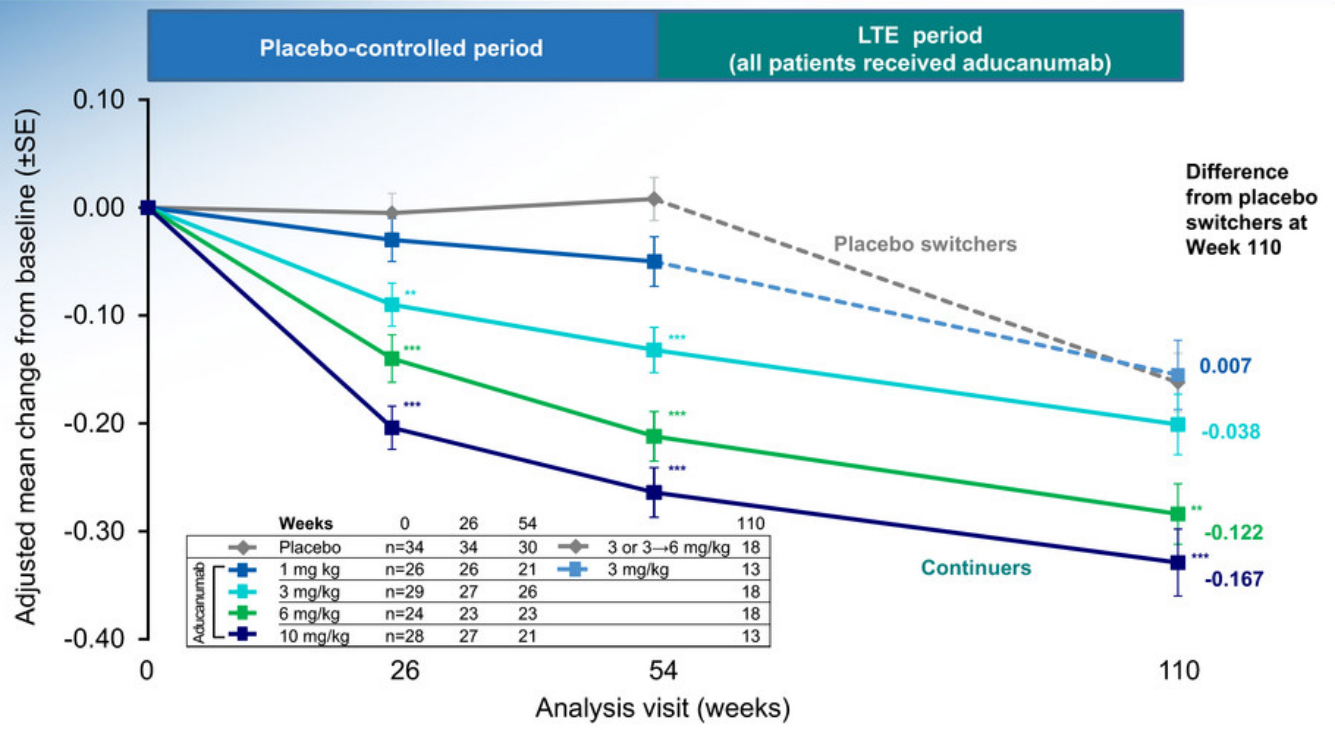
	Placebo (n=40)	Aducanumab 1 mg/kg (n=31)	Aducanumab 3 mg/kg (n=32)	Aducanumab 6 mg/kg (n=30)	Aducanumab 10 mg/kg (n=32)
Age years, mean ± SD	72.8 ± 7.2	72.6 ± 7.8	70.5 ± 8.2	73.3 ± 9.3	73.7 ± 8.3
ApoE ε4, n (%)					
Carriers	26 (65)	19 (61)	21 (66)	21 (70)	20 (63)
Non-carriers	14 (35)	12 (39)	11 (34)	9 (30)	12 (38)
Clinical stage, n (%)					
Prodromal	19 (48)	10 (32)	14 (44)	12 (40)	13 (41)
Mild	21 (53)	21 (68)	18 (56)	18 (60)	19 (59)
MMSE, mean ± SD	24.7 ± 3.6	23.6 ± 3.3	23.2 ± 4.2	24.4 ± 2.9	24.8 ± 3.1
CDR Global Score, n (%)					
0.5	34 (85)	22 (71)	22 (69)	25 (83)	24 (75)
1	6 (15)	9 (29)	10 (31)	5 (17)	8 (25)
CDR-SB, mean ± SD	2.66 ± 1.50	3.40 ± 1.76	3.50 ± 2.06	3.32 ± 1.54	3.14 ± 1.71
PET SUVR, mean composite	1.441	1.441	1.464	1.429	1.441
AD medications use,[a] n (%)	24 (60)	21 (68)	28 (88)	20 (67)	17 (53)

SUVR, standardized uptake value ratio
[a]Cholinesterase inhibitors and/or memantine

Interim analysis presented at CTAD 2016

PET AMYLOID IMAGING

Aducanumab Reduced Amyloid Plaque Burden Over 24 Months

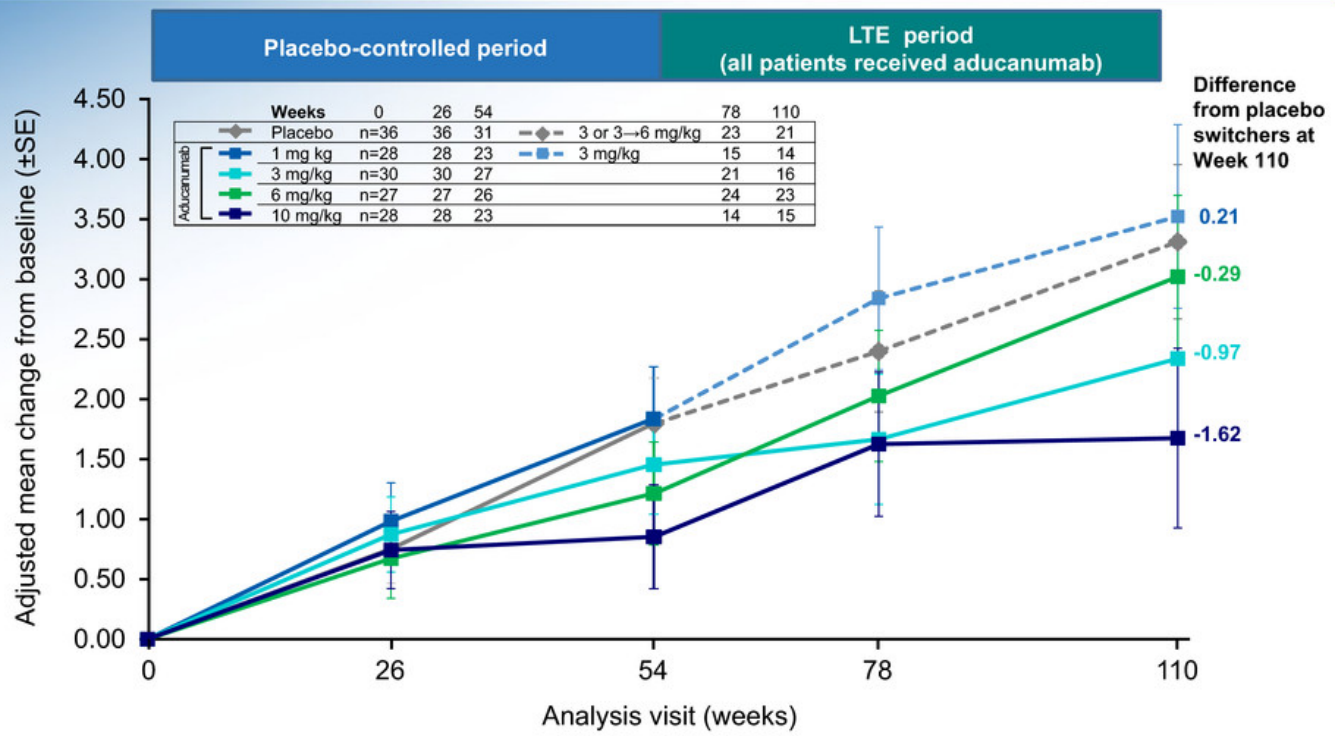


** Nominal *P*<0.01; *** Nominal *P*<0.001 vs placebo in the placebo-controlled period and vs placebo switchers in the LTE period.
Results based on MMRM, fitted with change from baseline as a dependent variable, and included fixed effects for categorical treatment, categorical visit and treatment-by-visit interaction, continuous baseline value, and laboratory ApoE ε4 status (carrier and non-carrier).
MMRM, mixed model for repeated measures

CLINICAL ENDPOINTS

Interim analysis presented at CTAD 2016

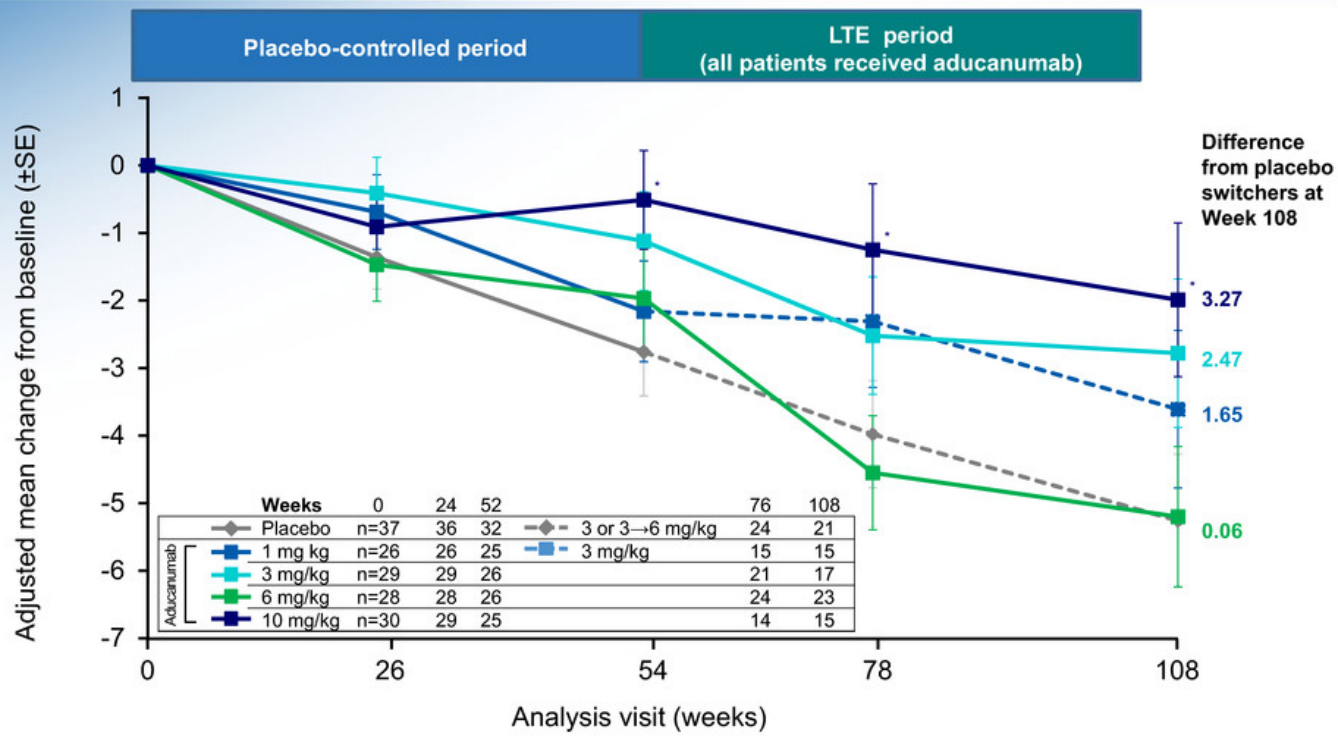
Continued Slowing of Decline on CDR-SB Over 24 Months



CDR–SB is an exploratory endpoint. Results based on MMRM, fitted with change from baseline as a dependent variable, and included fixed effects for categorical treatment, categorical visit and treatment-by-visit interaction, continuous baseline value, and laboratory ApoE ε4 status (carrier and non-carrier). MMRM, mixed model for repeated measures.

Interim analysis presented at CTAD 2016

Continued Slowing of Decline on MMSE Over 24 Months



*Nominal *P*<0.05 (vs placebo [Week 52] or placebo switchers [Weeks 76 and 108])
MMSE is an exploratory endpoint. Results based on MMRM, fitted with change from baseline as a dependent variable, and included fixed effects for categorical treatment, categorical visit and treatment-by-visit interaction, continuous baseline value, and laboratory ApoE ε4 status (carrier and non-carrier). MMRM, mixed model for repeated measures.

SAFETY AND TOLERABILITY

No New Safety Signals Identified with Aducanumab in the First Year of the LTE

	Placebo Switchers[a] (N=29)	1 mg/kg → 3 mg/kg (N=19)	Continuers[b]		
			3 mg/kg (N=26)	6 mg/kg (N=24)	10 mg/kg (N=19)
Number with an AE (%)	27 (93)	15 (79)	18 (69)	22 (92)	15 (79)
Number with an SAE (%)	13 (45)	2 (11)	2 (8)	6 (25)	3 (16)
Number discontinuing treatment due to AE (%)	7 (24)	0	2 (8)	0	3 (16)

- The most common AEs in the LTE were fall, headache, and ARIA[c]
- Treatment-related SAEs occurring in 2 or more patients in the LTE were ARIA[c] (n=5), including one subject with a concurrent SAE of seizure and loss of pulse
  - Other AEs/SAEs were consistent with the patient population
  - There were two deaths (none considered treatment-related), one in the 6 mg/kg arm and one in the 10 mg/kg arm, in the first year of the LTE (one occurred after study discontinuation)

[a]Placebo switchers received aducanumab 3 mg/kg or titration (2 doses of 3 mg/kg followed by subsequent doses of 6 mg/kg) in the LTE. [b]Patients who were randomized to receive 3, 6, and 10 mg/kg were scheduled to receive the same dose throughout the LTE. Patients who received a dose reduction during the placebo-controlled period due to ARIA would remain on the reduced dose throughout the LTE. [c]Based on incidence reporting by preferred term.
AE, adverse event; ARIA, amyloid-related imaging abnormality; SAE, serious AE

Interim analysis presented at CTAD 2016

No Continuers Developed ARIA-E During the First Year of the LTE

	Placebo Switchers[c]	1 mg/kg → 3 mg/kg	Continuers[b]		
			3 mg/kg	6 mg/kg	10 mg/kg
Patients with ≥1 post-baseline MRI	29	17	23	24	19
ARIA-E,[a] n (%)	5/29 (17)	3/17 (18)	0/23	0/24	0/19
ApoE ε4 carrier	4/17 (24)	3/11 (27)	0/16	0/17	0/12
ApoE ε4 non-carrier	1/12 (8)	0/6	0/7	0/7	0/7
Isolated ARIA-H, n (%)	2/29 (7)	0/17	3/23 (13)	2/24 (8)	1/19 (5)

[a]ARIA-E with or without ARIA-H

- No new ARIA-E cases or recurrence were observed among aducanumab continuers

[b]Patients who were randomized to receive 3, 6, and 10 mg/kg were scheduled to receive the same dose throughout the LTE. Patients who received a dose reduction during the placebo-controlled period due to ARIA would remain on the reduced dose throughout the LTE. [c]Placebo switchers received aducanumab 3 mg/kg or titration (2 doses of 3 mg/kg followed by subsequent doses of 6 mg/kg) in the LTE.
ARIA-E, ARIA–vasogenic edema; ARIA-H, ARIA–microhemorrhages, macrohemorrhages, or superficial siderosis

Interim analysis presented at CTAD 2016

Discontinuations due to ARIA-E During the First Year of the LTE

	Placebo Switchers[c]	1 mg/kg → 3 mg/kg	Continuers[b]		
			3 mg/kg	6 mg/kg	10 mg/kg
Patients with ≥1 post-baseline MRI	29	17	23	24	19
ARIA-E[a], n (%)	5 (17)	3 (18)	0	0	0
Continued treatment, n (%)	1 (3)	3 (18)	0	0	0
Same dose	0	2	0	0	0
Reduced dose	1	1	0	0	0
Discontinued treatment, n (%)	4 (14)	0	0	0	0
ApoE ε4 carriers	3	0	0	0	0
ApoE ε4 non-carriers	1	0	0	0	0

[a]ARIA-E with or without ARIA-H

[b]Patients who were randomized to receive 3, 6, and 10 mg/kg were scheduled to receive the same dose throughout the LTE. Patients who received a dose reduction during the placebo-controlled period due to ARIA would remain on the reduced dose throughout the LTE. [c]Placebo switchers received aducanumab 3 mg/kg or titration (2 doses of 3 mg/kg followed by subsequent doses of 6 mg/kg) in the LTE.

Summary

- At 24 months, brain amyloid plaque burden continued to decrease in aducanumab continuers
  - This decrease was dose- and time-dependent
- CDR–SB and MMSE data suggest a clinical benefit in patients continuing aducanumab over 24 months
- No new ARIA-E cases or recurrence among aducanumab continuers
  - ARIA-E incidence in aducanumab switchers was consistent with that observed in the placebo-controlled portion of the study
- These data continue to support further investigation of the clinical efficacy and safety of aducanumab in patients with early AD in the ENGAGE and EMERGE Phase 3 trials

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