



Inhaled AAT Phase II/III Update of Study Results

May 19th, 2015, Denver Colorado, 2015



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Introduction Slide

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Kamada is presenting:



Study Results - Update

Phase II/III, Double-Blind, Randomized, Placebo-Controlled, Multicenter, International Study Evaluating the Safety and Efficacy of Inhaled, Human, Alpha-1 Antitrypsin (AAT) in Alpha-1 Antitrypsin Deficient Patients with Emphysema

Results are presented for the double blind part of the study

Study Information

Study Indication

- Treatment of alpha-1 antitrypsin deficiency in subjects with clinically demonstrable emphysema.

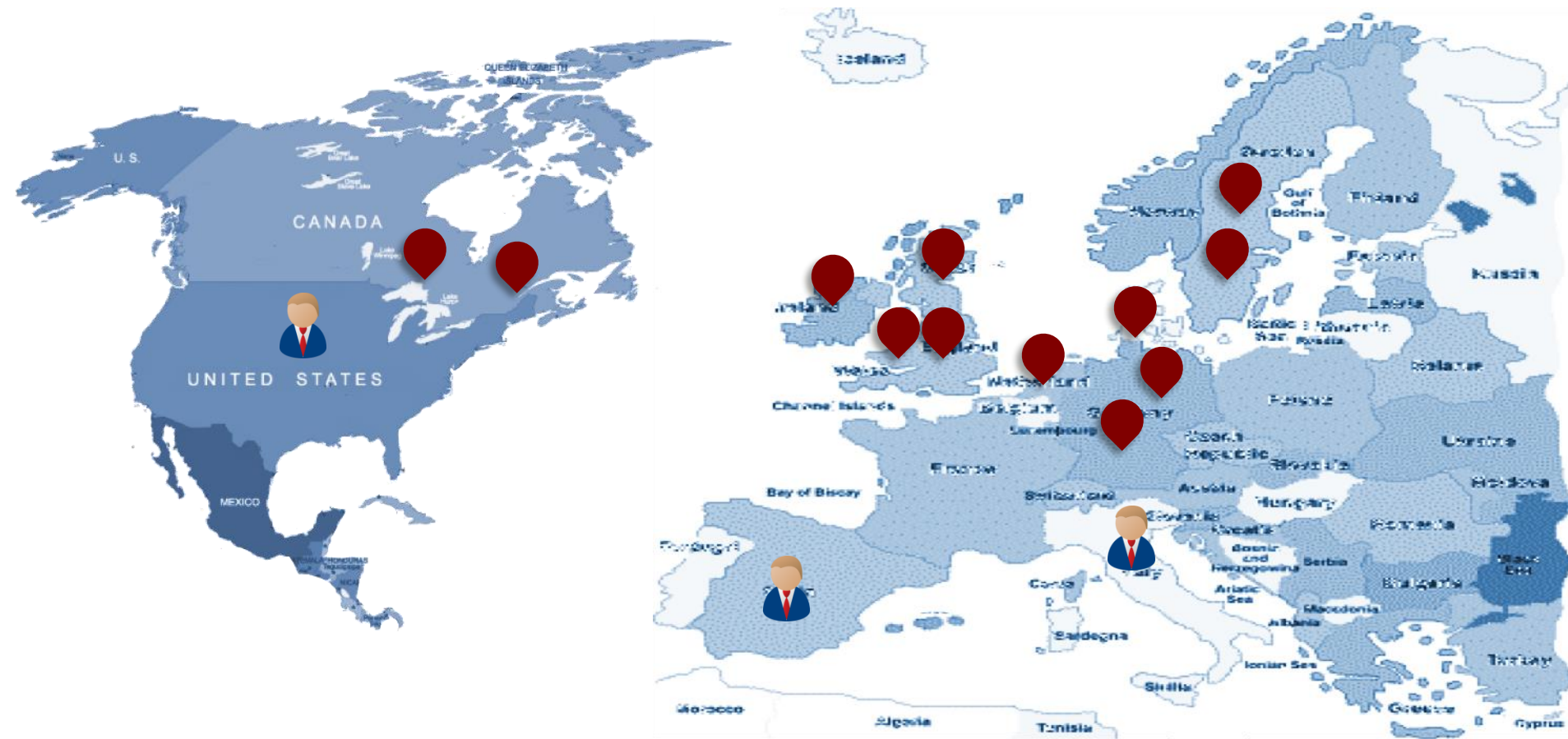
Investigational Product and reference therapy

- Aerosolized (inhaled) human (plasma-derived) AAT at 80 mg, 4ml inhalation X 2/day.
- The placebo comprises the non-active ingredients of the AAT preparation.
- eFlow® inhalation device- PARI Pharma GmbH.

Study Design

- Phase II-III ; Double-blind; Randomized placebo-controlled; Multicenter, intrl' study.
- 168 subjects, Randomized 1:1 AAT; placebo
- 50 weeks double blind ; 50 weeks OLE
- Trial designed in accordance with EMA scientific advise/ protocol assistance and EU draft guidance for COPD trials

Study Information - Sites



Site in study



DSMB members

Sites: UK, SC, IR, SW, DK, CA, NL, GR
DSMB: IT, USA, ES

Primacy

Largest Study

First of its kind,
largest, IH AAT study

E-Diary

Use of e-Diary to
collect robust natural
history and efficacy/
safety data

Efficacy

First controlled
randomized trial to
demonstrate lung
function efficacy



Main Inclusion / Exclusion Criteria

Inclusion

1. Adults with AAT deficiency
2. FEV1/FVC <70% and FEV1 < 80%
3. At least two exacerbations in the last 18 months from screening.
4. AAT deficient subjects who are either naïve (not receiving IV augmentation therapy) or AAT deficient subjects receiving IV augmentation therapy.

Exclusion

1. History of lung transplant; Any lung surgery within the past two years.
2. Active smoking during the last 12 months from screening date.
3. IgA Deficiency
4. History of life threatening allergy, anaphylactic reaction, or systemic response to human plasma derived products.

Study Endpoints



Primary

- The time from randomization to the first event-based exacerbation with a severity of moderate or severe.



Secondary

- Time to first event-based exac. (mild, moderate or severe)
- Severity of the first event-based exac.
- Rate of event-based exac.



Safety

- Adverse Events
- Lung Function
- Vital Signs
- Physical Exam
- ECG
- Laboratory Evaluations

Regulatory guidance as to efficacy indicated:

Importance of secondary endpoint including rate and severity of exacerbation as well as review of totality of the data arising from the trial

What has changed?

1

Analysis of the data revealed:
primary endpoint was not met

2

Lung function analysis and first
exacerbation severity >> statistical
significant changes

3

Kamada approached EMA and
presented the data

4

EMA confirmed for this ODD
review of post-hoc analysis and
totality of the data irrespective
of not meeting primary endpoint

Analysis Strategy

**Lung
Function**

**Exacerbation
symptoms**

Safety



Study Results

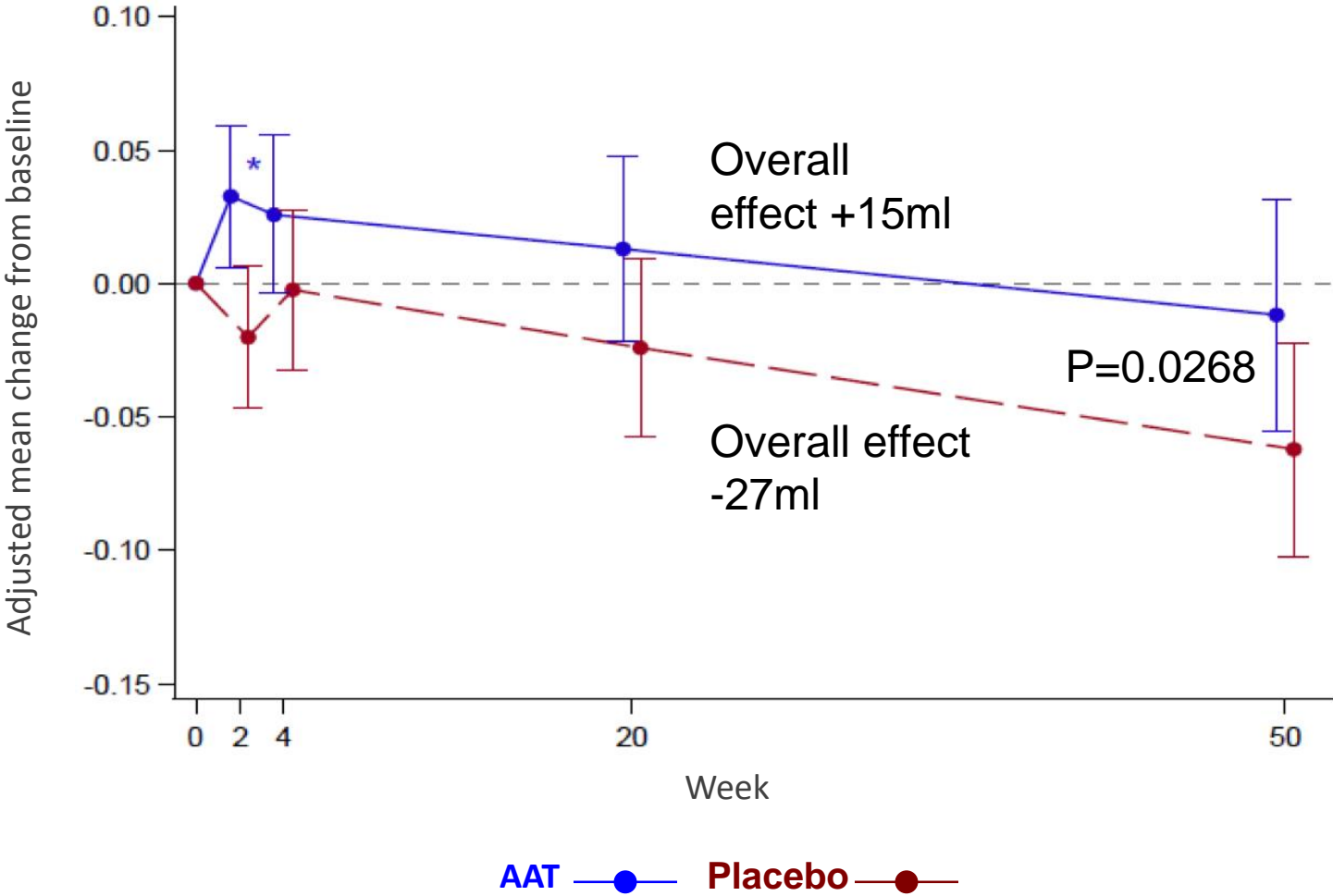


Baseline Characteristics

	AAT (N=85)	Placebo (N=83)
Males	51 (60.0%)	49 (59.0%)
Females	34 (40.0%)	34 (41.0%)
Mean age ± SD (years)	56.5 ± 9.9	54.4 ± 10.3
Age ≥ 60 years	38 (44.7%)	26 (31.3%)
Race: Caucasian	79 (100%)	75 (100%)
BMI (kg/m ²): mean ± SD	25.8 ± 4.6	26.3 ± 5.5
BMI <20	8 (9.4%)	4 (4.8%)
Oxygen users	18 (21.2%)	10 (12.0%)
FEV ₁ (L): mean ± SD	1.32 ± 0.49	1.33 ± 0.53
FEV ₁ % (%): mean ± SD	42.8 ± 14.8	41.8 ± 14.7
DLCO (mMol/min/kPa): mean ± SD	4.23 ± 1.61	4.59 ± 1.96

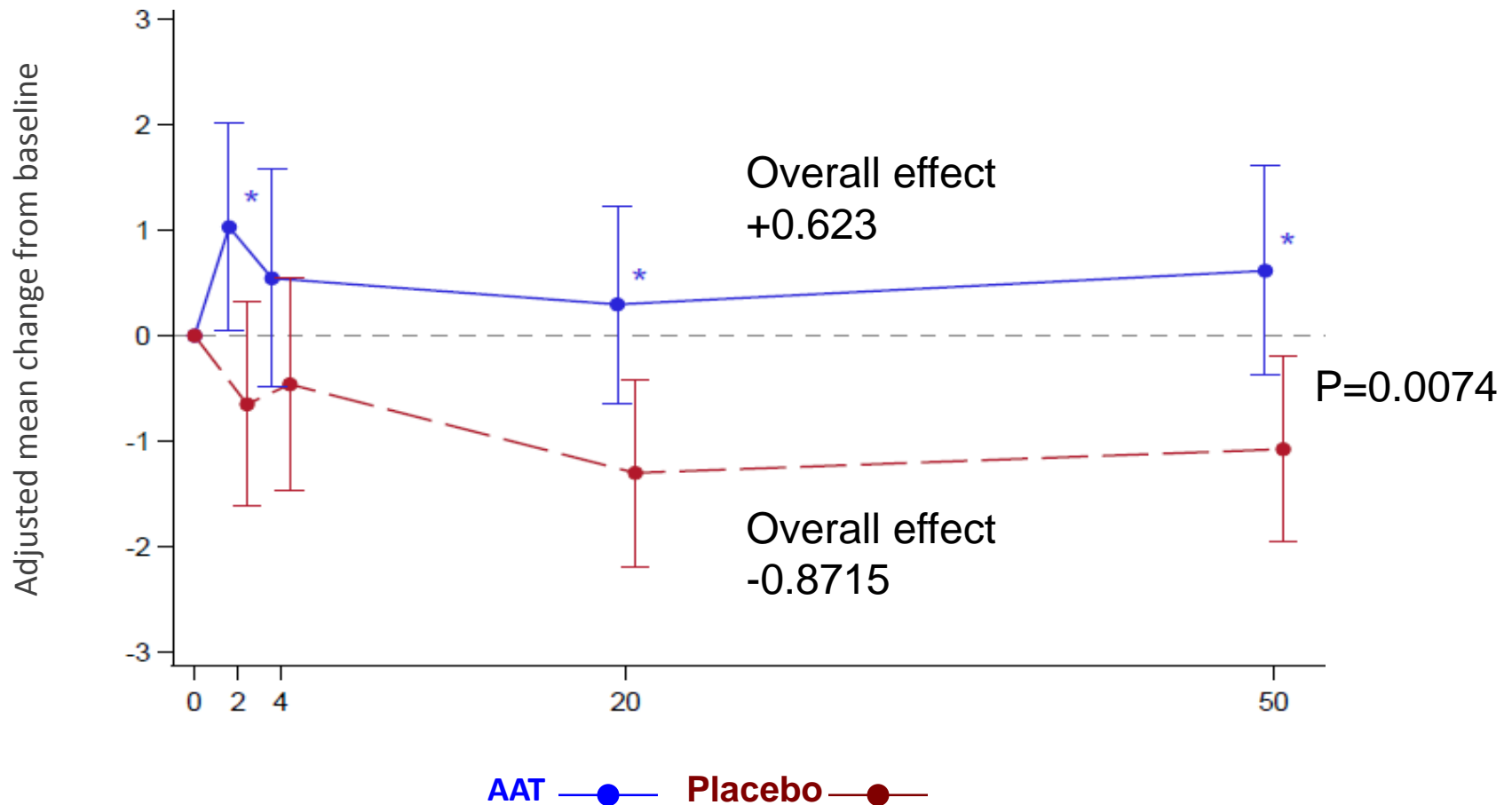
Spirometry Measures (MMRM)

FEV1 (L) - MMRM



Spirometry Measures (MMRM)

FEV1/SVC - MMRM



Spirometry Measures (MMRM)

Lung Function	Least Squares Means (SE) (Changes at Week 50 from Baseline)		P-Value (Changes at Week 50)	Least Squares Means (SE) (overall treatment effect)		P-Value (Overall Effect)
	AAT (N= 84)	Placebo (N= 81)		AAT (N= 84)	Placebo (N= 81)	
	FEV₁ (L)	-12mL -0.01183 (0.02196)		-62mL -0.06216 (0.02036)	0.0956	
FEV₁ (% of predicted)	-0.1323 (0.6649)	-1.6205 (0.6140)	0.1032	0.5404 (0.4451)	-0.6273 (0.4425)	0.0658
FEV₁/SVC (%)	0.6183 (0.5015)	-1.0723 (0.4455)	0.0132	0.6230 (0.3931)	-0.8715 (0.3804)	0.0074

SE in brackets

MMRM = Mixed Model Repeated Measure

Diffusing Capacity (MMRM)

Lung Function	Least Squares Means (SE) (Changes at Week 50 from Baseline)		P-Value (Changes at Week 50)	Least Squares Means (SE) (overall treatment effect)		P-Value (Mixed Linear Model - Overall Treatment Effect)
	AAT (N= 84)	Placebo (N= 81)		AAT (N= 84)	Placebo (N= 81)	
	DLCO	-0.2704 (0.07713)		-0.3054 (0.07182)	0.7407	
DLCO (% of predicted)	-2.9103 (0.9058)	-3.5785 (0.8459)	0.5920	-2.1459 (0.6721)	-1.8723 (0.6734)	0.7748
DLCO/VA	-0.02858 (0.01359)	-0.02464 (0.01299)	0.8349	-0.02672 (0.01061)	-0.00953 (0.01071)	0.2580
DLCO/VA (% of predicted)	-2.1951 (0.9686)	-1.8049 (0.9232)	0.7720	-2.0143 (0.7777)	-0.7094 (0.7851)	0.2415

SE in brackets

No Difference Between Groups

Nature of First Exacerbation

Symptom Based Exacerbation Analysis				
Major Three (3) Exacerbation Symptoms by Severity: Dyspnea; Sputum Volume; Sputum Color				
Exacerbation Type/Category	Classification Rules	Possible Manifestations		
		Dyspnea*	Sputum Volume**	Sputum Color**
Type I	All 3 symptoms at high score	+	+	+
Type II	Two of the 3 symptoms at high score	+	+	
		+		+
			+	+
Type III	One of the 3 symptoms at high score	+		
			+	
				+

Scores (by severity):

*5, 10, 15, 20 for Dyspnea (high severity score ≥10)

** 1, 2, 3, 4 for Sputum volume and Sputum color (high severity score ≥2)

Nature of the First Exacerbation

ITT	N (%)		P Value
	AAT	Placebo	
Type/Category	N=85	N=83	
Type I	16 (18.8%)	26 (31.3%)	0.0614
Type II	23 (27.1%)	12 (14.5%)	0.0444
Type III	34 (40.0%)	33 (39.8%)	0.9746
None	12 (14.1%)	12 (14.5%)	0.9498

AAT may change the nature of the Exacerbation (Potential change from Type I to Type II)

Type I+II → Type I exacerbation stands for 41% within total of type I+ II exacerbations for AAT group vs. 68% for placebo group.

Symptom Score MMRM Analysis of First (Types I+II+III) Exacerbation Severity for each major Symptom

(during 0-10 and 0-14 days of the exacerbation event)

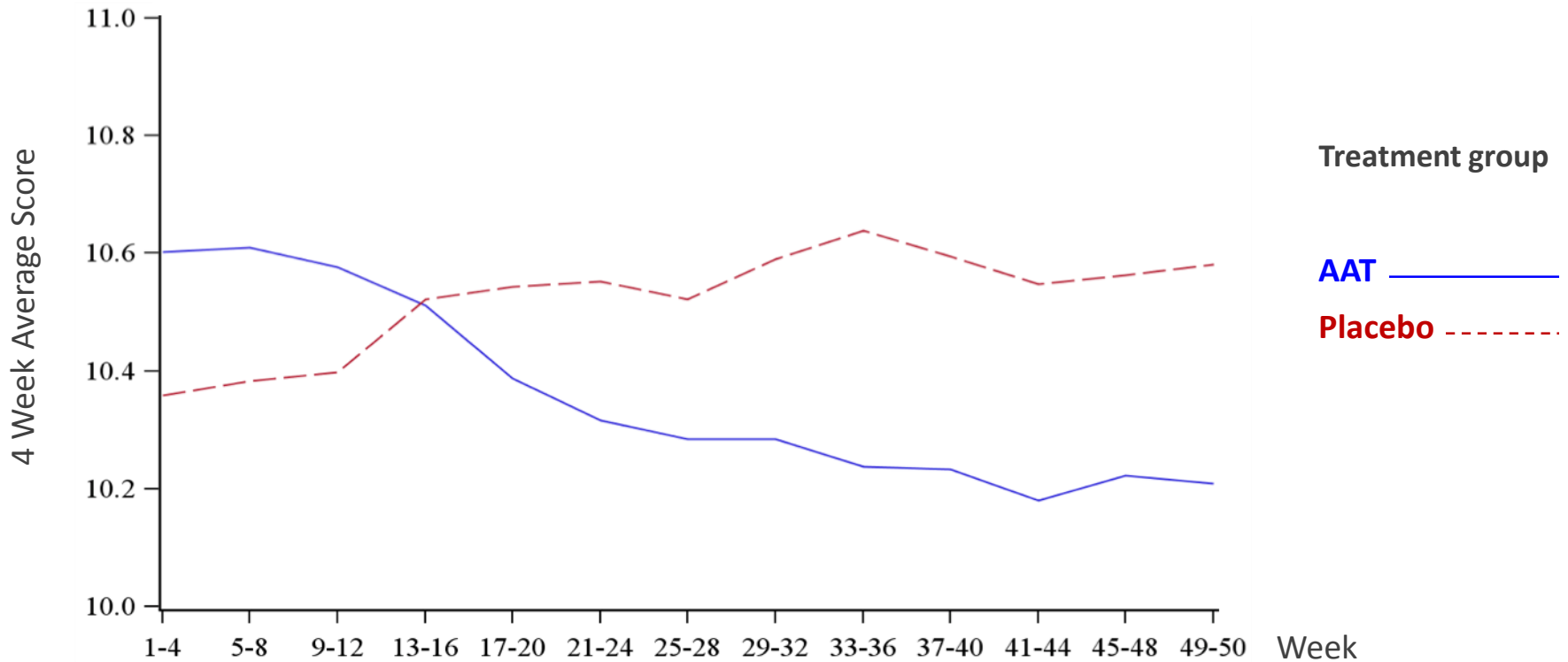
Symptom	Exac. Type	Days	MMRM		P-Value*
			Least Square Means		
			AAT N=73	Placebo N=71	
Dyspnea	All Types (I, II, III)	0-10	11.9464	12.2548	0.0243
		0-14	11.5803	11.7832	0.0817
Sputum Volume		0-10	1.2748	1.3837	0.0334
		0-14	1.2367	1.3206	0.0595
Sputum Color		0-10	2.1566	2.0137	0.0502
		0-14	2.0240	1.8393	0.0032

*Adjustment to age, oxygen, BMI, Country, Treatment Duration

During first Exacerbation, AAT group improves significantly Dyspnea and Sputum volume symptoms

Continuous Symptom Score – Dyspnea

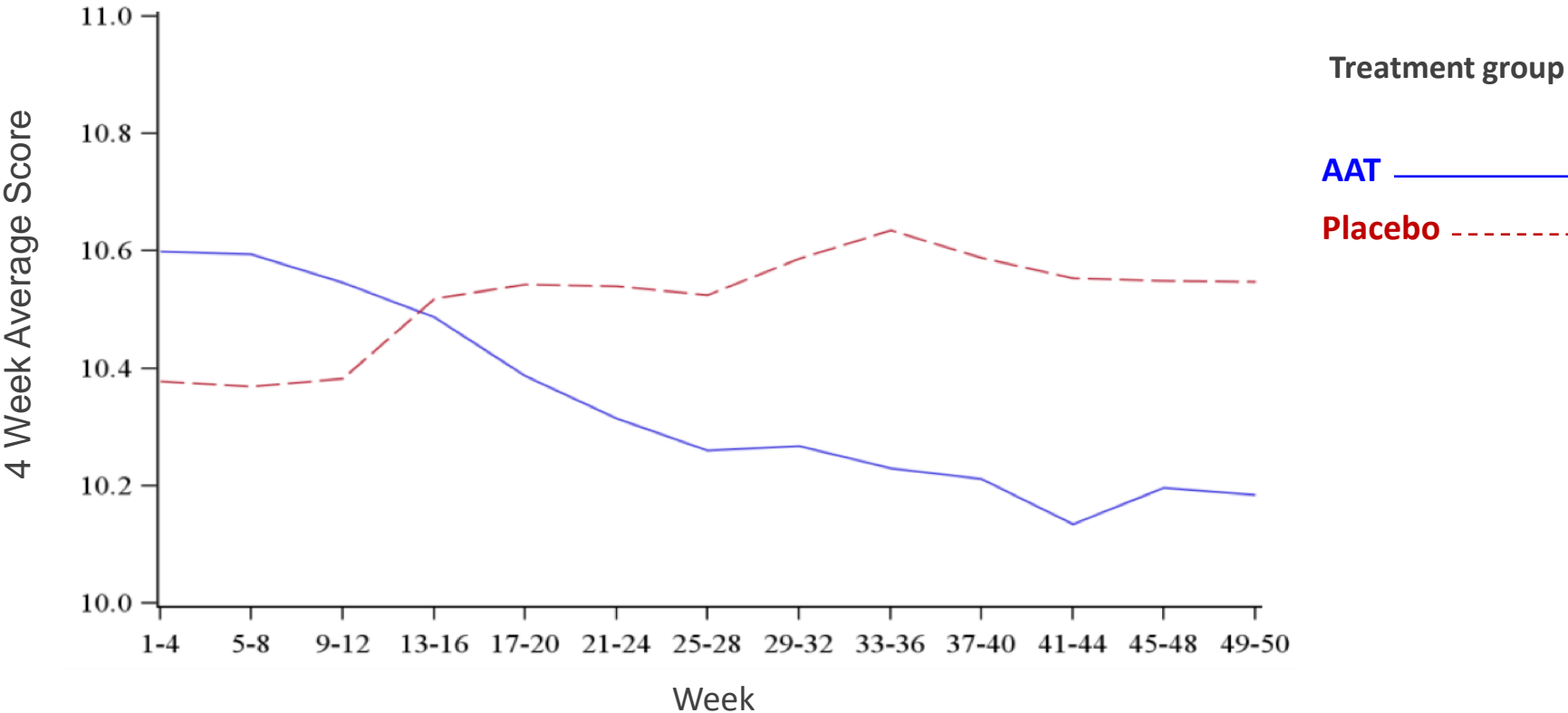
Dyspnea 4 Week Moving Average Graphs



Improvement trend in favor of AAT group
No statistical significance

Continuous Symptom Score – Well Being

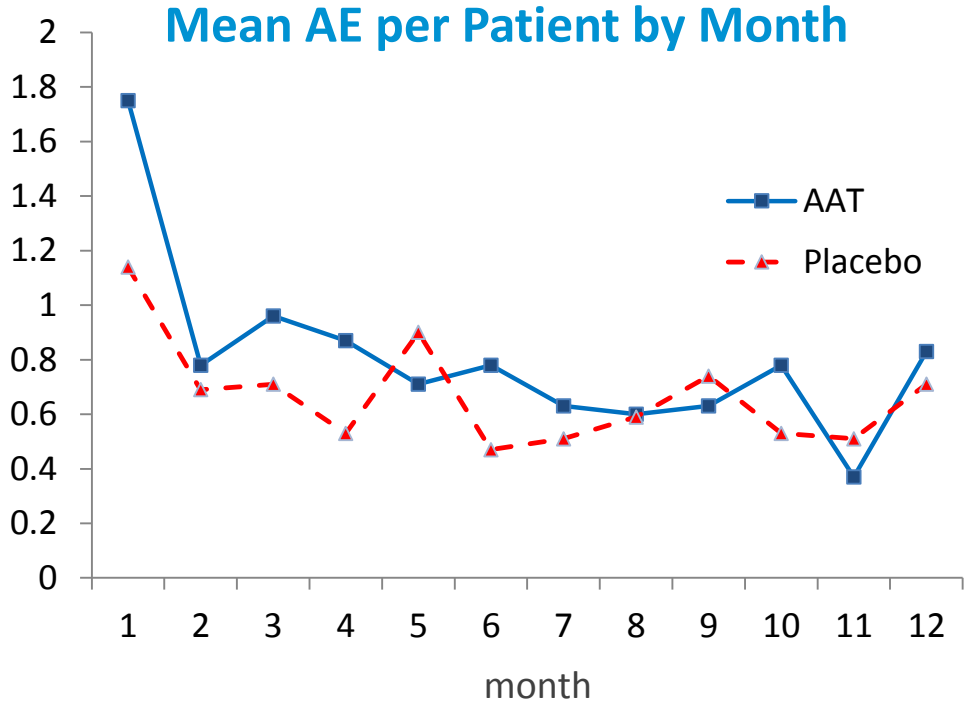
Well Being 4 Week Moving Average Graphs



Improvement trend in favor of AAT group
No statistical significance

Safety: Mean AE per Patient by Month

Month	AAT	Placebo
1	1.75	1.14
2	0.78	0.69
3	0.96	0.71
4	0.87	0.53
5	0.71	0.9
6	0.78	0.47
7	0.63	0.51
8	0.6	0.59
9	0.63	0.74
10	0.78	0.53
11	0.37	0.51
12	0.83	0.71



- There were no AE indicating immunogenicity and/or clinical indication of bronchospasms
- No specific AE pattern
- Most AEs relate to underlying disease
- No Anaphylactic reactions
- Nature of AEs was similar between groups.

Strengths vs. Constraints

- 
- **Spirometry efficacy**
 - **Exacerbation nature effect**
 - **Safe and tolerable**
 - **Primacy in clinical efficacy**
 - **Unmet medical need**

- **No improvement in time to first moderate/severe exac.**
- **No improvement in rate**

Strengths outweigh constraints

In Summary

1. **Efficacy in lung function** (statistically significant)
2. **Change in the nature of exacerbations** (reduction in number of Type 1- exacerbations (trend) and reduction in dyspnea score (statistically significant))
3. **Safe and tolerable** drug
4. **Orphan** designated drug
5. **Unmet patient need** - Clinical primacy in efficacy data for IH AAT and AATD in general



Moving Forward

EMA –EU Front

- Compilation of an MAA dossier
- EMA submission (centralized procedure) end of 2015



EUROPEAN MEDICINES AGENCY

FDA –US Front

- Approach US-FDA with results in H2 2015 to obtain guidance on the clinical/ regulatory pathway for licensing the IH AAT by Kamada in the US.



Kamada is committed to the AATD patient community to bring the IH AAT into the market place and provide an adequate, safe and efficacious answer to current unmet medical need of these orphan patients.

SPECIAL THANKS TO...

To our study investigators

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To our study CRO, QP, labs, logistics and other vendors

Thank You



Thank you