Inhaled AAT Phase II/III Update of Study Results

May 19th, 2015, Denver Colorado, 2015

KAMADA
High Quality Pharmaceuticals

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Introduction Slide

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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.

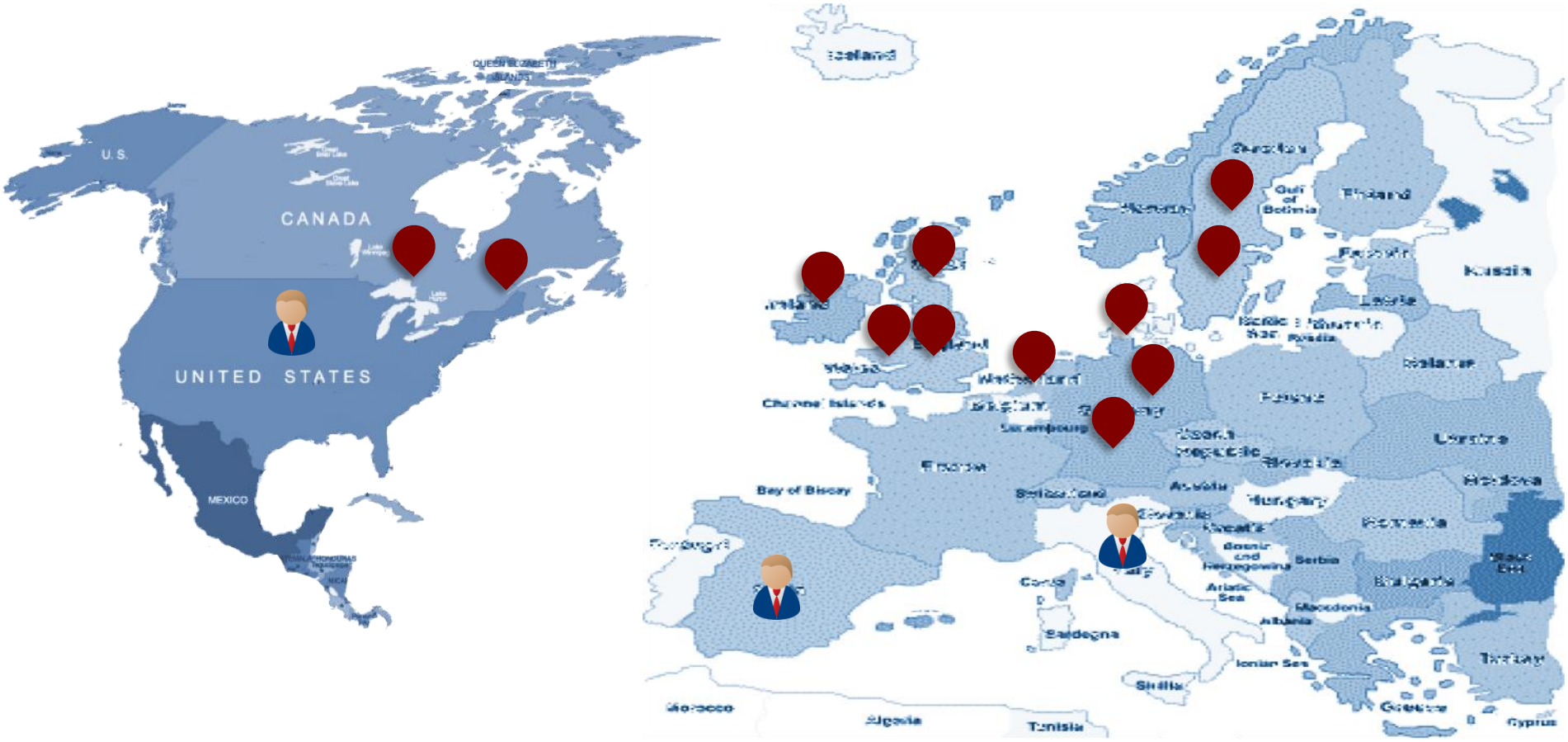
Investigational Product and reference therapy

- 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- Trial designed in accordance with EMA scientific advise/ protocol assistance and EU draft guidance for COPD trials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

Kamada's Inhaled AAT Phase 2-3 EU and Canada Study results. Denver USA 2015

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.

Kamada's Inhaled AAT Phase 2-3 EU and Canada Study results. Denver USA 2015

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

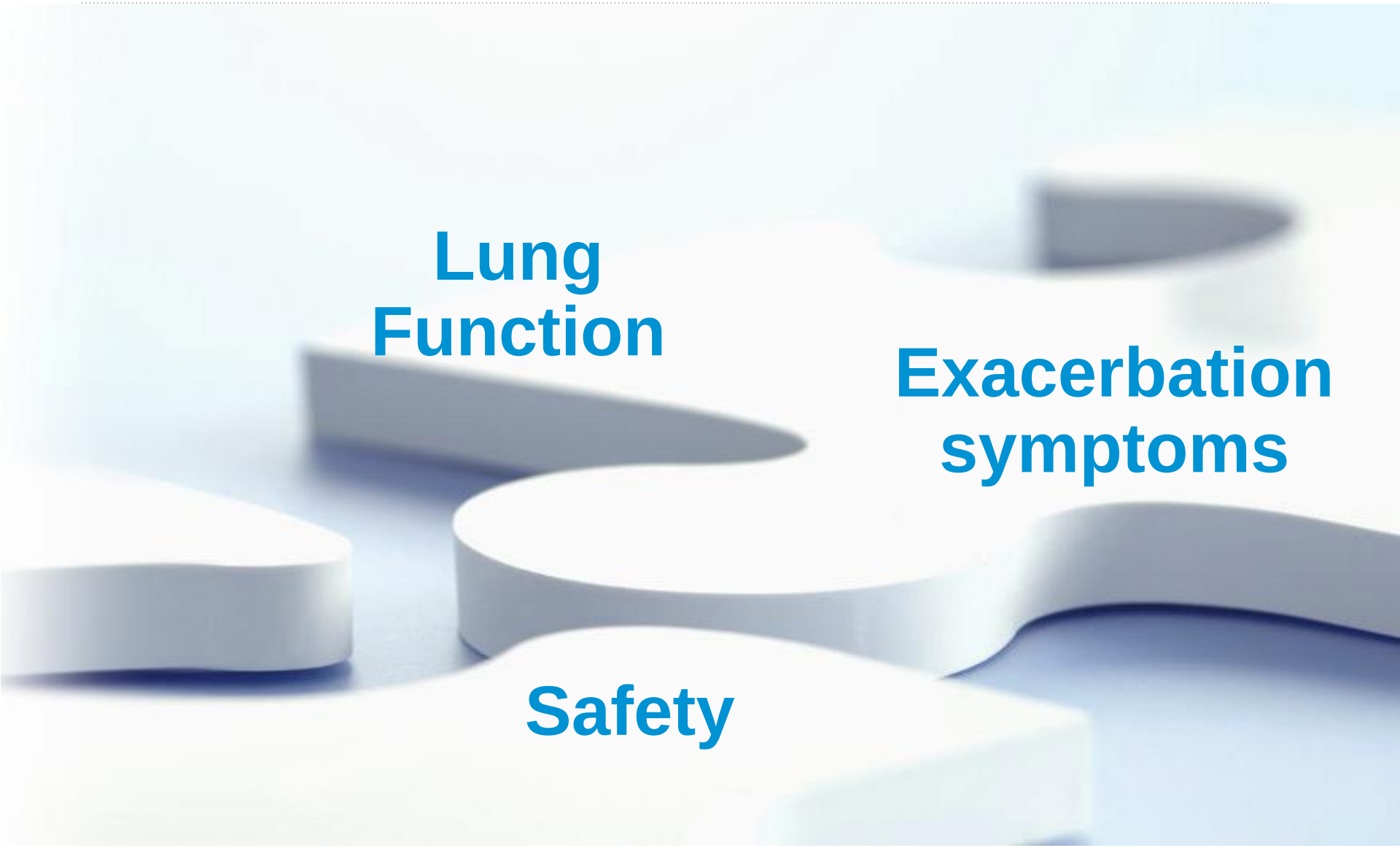
Regulatory guidance as to efficacy indicated:
Importance of secondary endpoint including rate and severity of exacerbation as well as review of totality of the data arising from the trial

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

Kamada's Inhaled AAT Phase 2-3 EU and Canada Study results. Denver USA 2015

Analysis Strategy



Kamada's Inhaled AAT Phase 2-3 EU and Canada Study results. Denver USA 2015

Study Results

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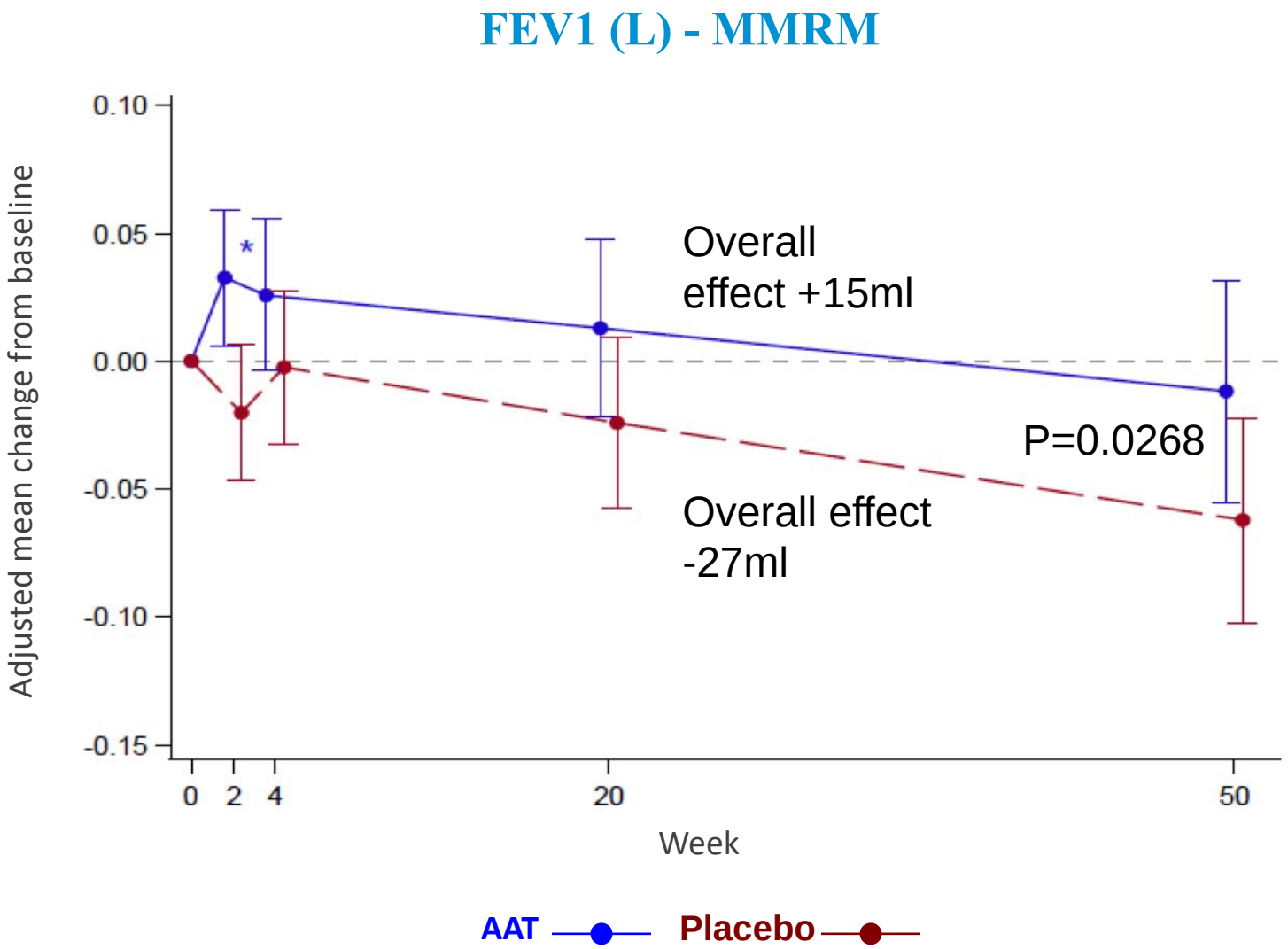
Baseline Characteristics

	AAT (N=85)	Placebo (N=83)
Males Females	51 (60.0%) 34 (40.0%)	49 (59.0%) 34 (41.0%)
Mean age ± SD (years) **Age ≥ 60 years**	56.5 ± 9.9 **38 (44.7%)**	54.4 ± 10.3 **26 (31.3%)**
Race: Caucasian	79 (100%)	75 (100%)
BMI (kg/m^2): mean ± SD **BMI <20**	25.8 ± 4.6 **8 (9.4%)**	26.3 ± 5.5 **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

Kamada's Inhaled AAT Phase 2-3 EU and Canada Study results. Denver USA 2015

Spirometry Measures (MMRM)



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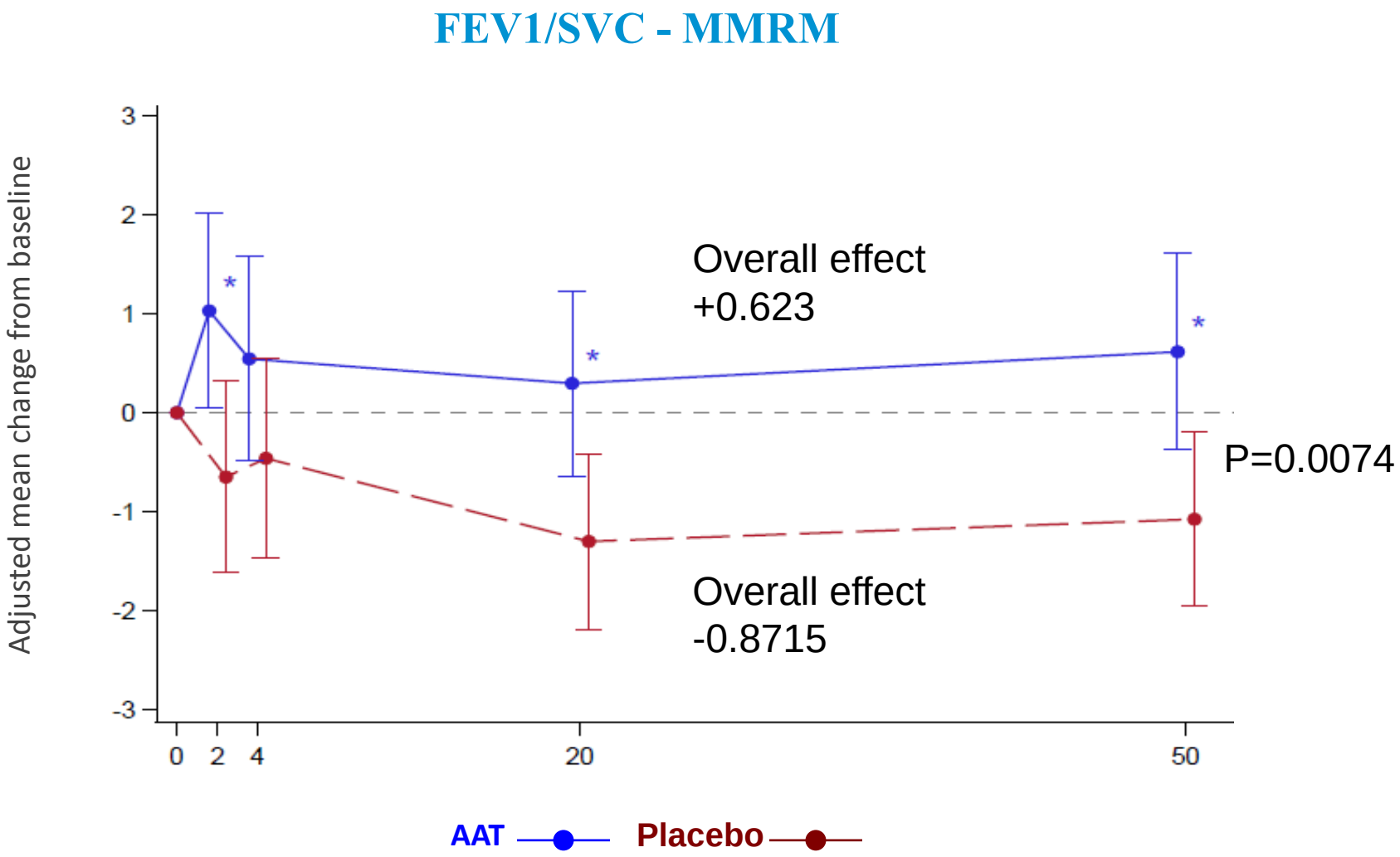
Spirometry Measures (MMRM)



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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)**	
FEV_1 (L)	**-12mL** -0.01183 (0.02196)	**-62mL** -0.06216 (0.02036)	0.0956	**+15mL** 0.01503 (0.01338)	**-27mL** -0.02718 (0.01322)	**0.0268**
FEV_1 (% of predicted)	-0.1323 (0.6649)	-1.6205 (0.6140)	0.1032	0.5404 (0.4451)	-0.6273 (0.4425)	0.0658
FEV_1/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

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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	-0.2011 (0.05585)	-0.1640 (0.05577)	0.6401
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

Kamada's Inhaled AAT Phase 2-3 EU and Canada Study results. Denver USA 2015

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)

Kamada's Inhaled AAT Phase 2-3 EU and Canada Study results. Denver USA 2015

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.

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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)

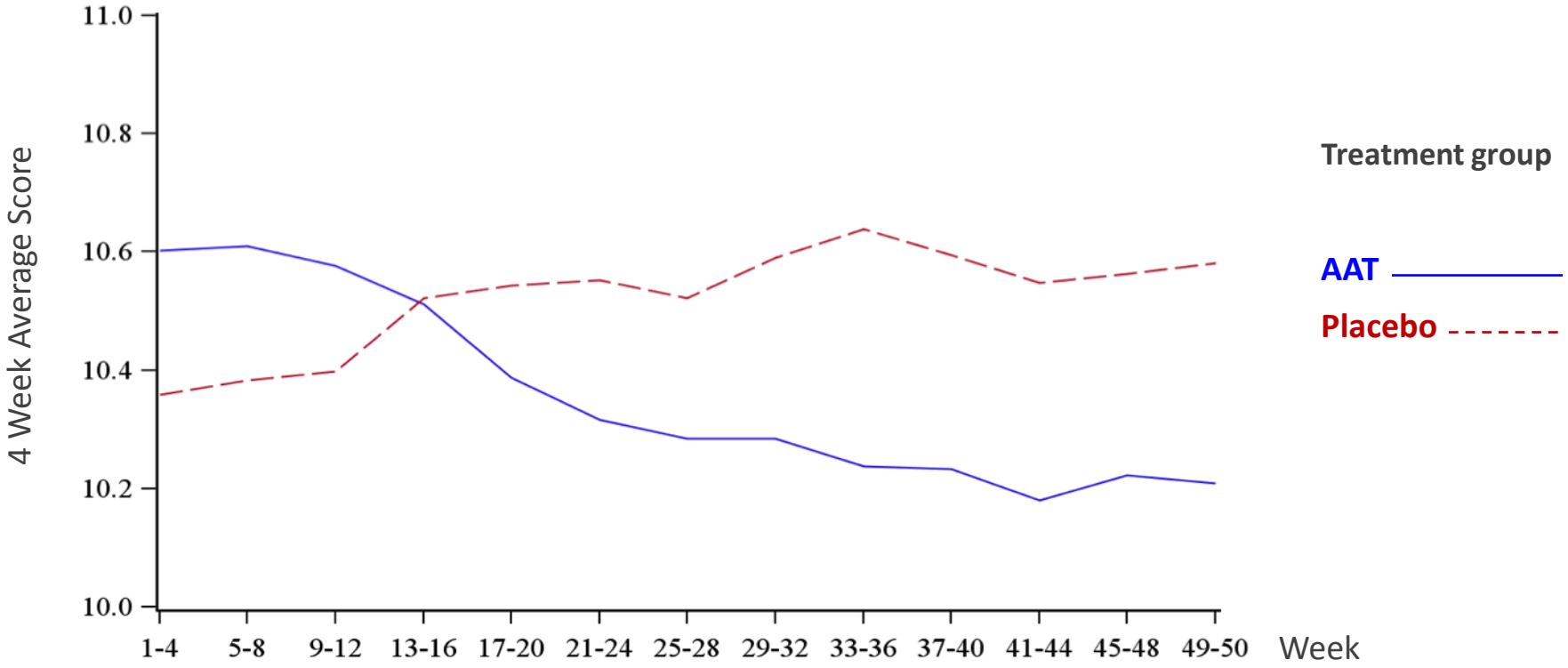
Symptom	Exac. Type	Days	MMRM Least Square Means		P-Value*
			AAT N=73	Placebo N=71	
Dyspnea	All Types (I, II, III)	0-10	11.9464	12.2548	**0.0243**
		0-14	11.5803	11.7832	**0.0817**
Sputum Volume		0-10	1.2748	1.3837	**0.0334**
		0-14	1.2367	1.3206	**0.0595**
Sputum Color		0-10	2.1566	2.0137	**0.0502**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

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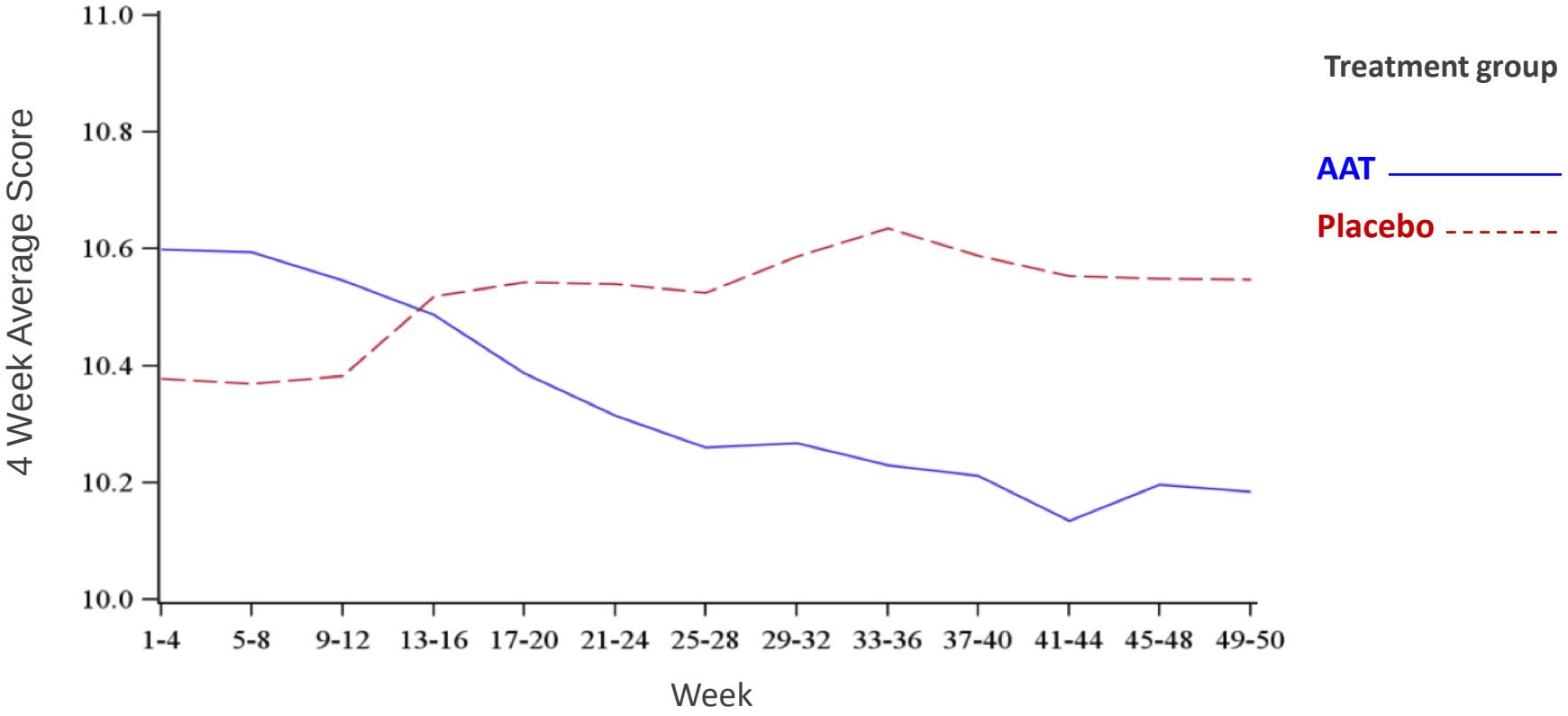
Continuous Symptom Score – Well Being

Well Being 4 Week Moving Average Graphs



Improvement trend in favor of AAT group
No statistical significance

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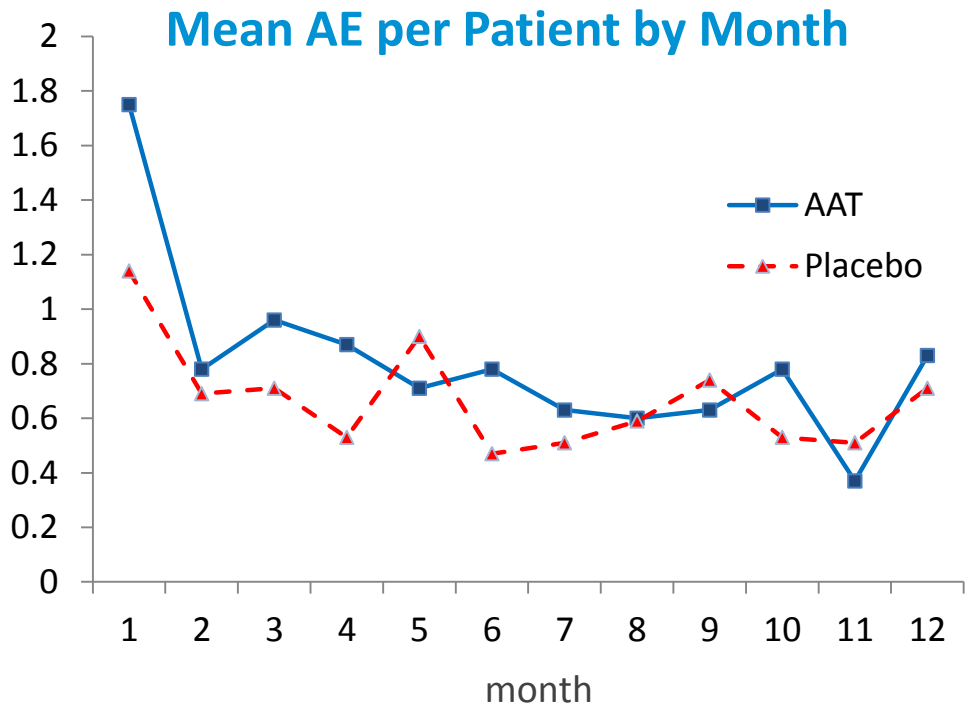
Safety: Mean AE per Patient by Month

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.

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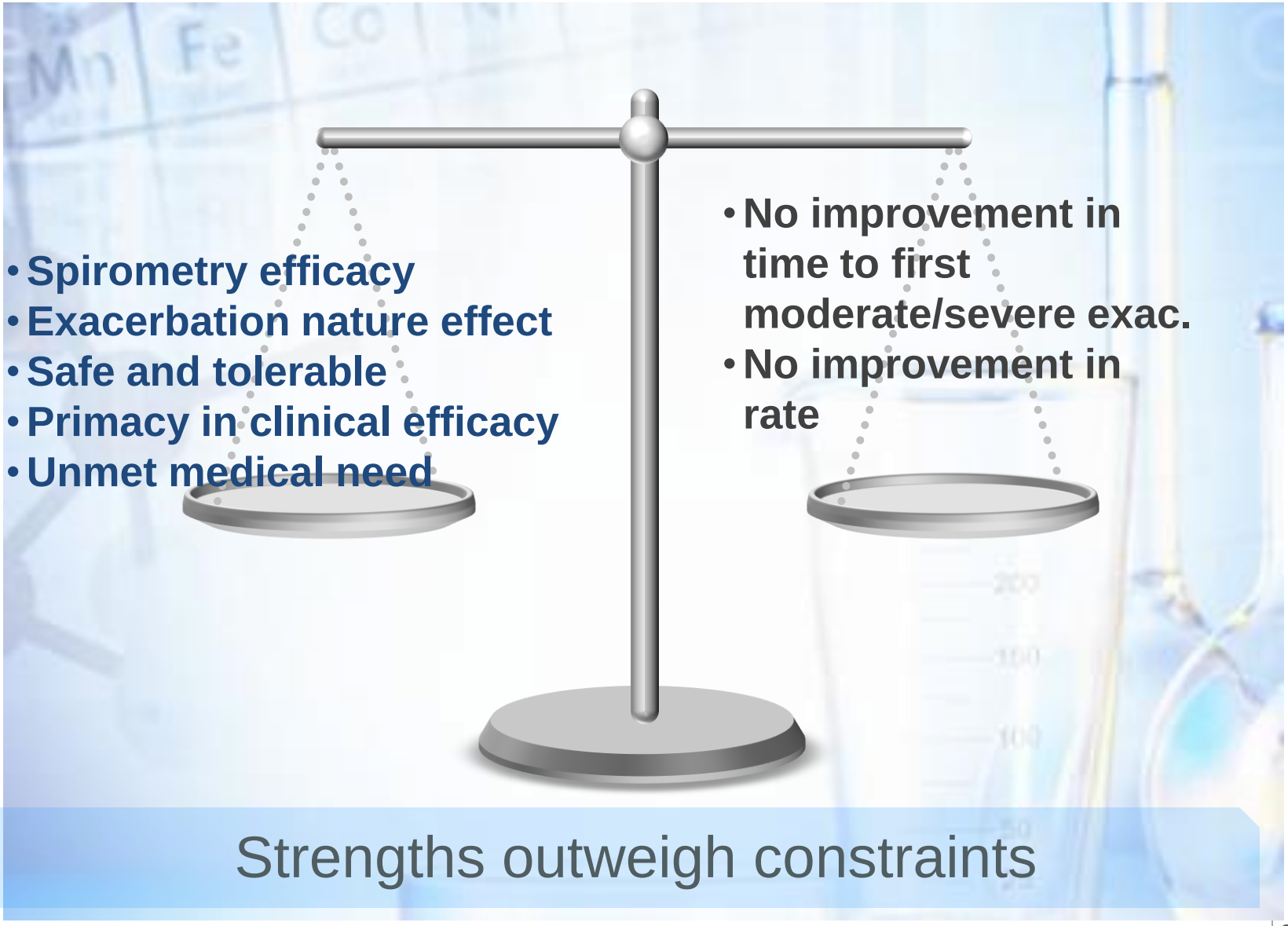
Strengths vs. Constraints



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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 2015to 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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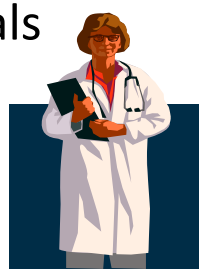

To Dr. Pablo Fernandez,
our Medical advisor

To our DSMB
Dr. Marc Miravitlles
Dr. Maurizio Luisetti
Prof. Victor DeGruttola

To our patients in the study

To our study nurses & coordinators

To our bio- statisticians team

To AIR Group

To the entire Kamada team

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

Thank You

Thank you

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