ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: December 19, 2016

ClinicalTrials.gov ID: NCT01014442

Study Identification

Unique Protocol ID: ML22608

Brief Title: A Study of Mycophenolate Mofetil (CellCept) in Lung Transplant Recipients

Official Title: Pharmacokinetics of Mycophenolate Mofetil in de Novo Lung Allograft Recipients

Secondary IDs: 2009-012231-15

Study Status

Record Verification: July 2015

Overall Status: Completed

Study Start: January 2010

Primary Completion: June 2012 [Actual]

Study Completion: June 2012 [Actual]

Sponsor/Collaborators

Sponsor: Hoffmann-La Roche

Responsible Party: Sponsor

Collaborators:

Oversight

FDA Regulated?: No

IND/IDE Protocol?: No

Review Board: Approval Status: Approved
    Approval Number: 10/13/2009
    Board Name: EK Hannover
    Board Affiliation: Medizinische Hochschule Hannover
    Phone: 0049 511 532 3443
    Email: Landowski.Rita@MH-Hannover.de

Data Monitoring?:

Plan to Share IPD?:

Oversight Authorities: Germany: Bundesinstitut für Arzneimittel und Medizinprodukte

Study Description

Brief Summary: This open-label, single center study will assess the pharmacokinetics, efficacy and safety of mycophenolate mofetil in lung allograft recipients. Participants will be split into 2 groups according to the original disease: Group A (cystic fibrosis) and Group B (chronic obstructive pulmonary disease [COPD], emphysema, idiopathic pulmonary fibrosis, alpha-1 antitrypsin deficiency [A1AD]). All participants will receive mycophenolate mofetil orally, 1.5 grams (g) twice daily (BID) from Day 2 to 30 post transplantation, and 1 g BID from Day 31 to 90 post transplantation. Anticipated time on study treatment is 90 days, and target sample size is 50-100 individuals.

Detailed Description:

Conditions

Conditions: Lung Transplantation

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Intervention Model: Parallel Assignment

Number of Arms: 2

Masking: Open Label

Allocation: Non-Randomized

Endpoint Classification: Safety/Efficacy Study

Enrollment: 68 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Mycophenolate Mofetil; Cystic Fibrosis Participants with cystic fibrosis will receive mycophenolate mofetil 1.5 g, orally (PO), BID from Days 2 through 30 post-transplantation, and 1 g, PO, BID from Days 31 through 90 post-transplantation.	Drug: mycophenolate mofetil 1.5 g PO BID from Days 2 to 30 post-transplantation, 1 g PO BID Days 31 to 90 post-transplantation Other Names: • CellCept
Experimental: Mycophenolate Mofetil; Other Participants with COPD, emphysema, idiopathic pulmonary fibrosis, or A1AD will receive mycophenolate mofetil 1.5 g, PO, BID, from Days 2 through 30 post-transplantation, and 1 g, PO, BID from Days 31 through 90 post-transplantation.	Drug: mycophenolate mofetil 1.5 g PO BID from Days 2 to 30 post-transplantation, 1 g PO BID Days 31 to 90 post-transplantation Other Names: • CellCept

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- primary single or bilateral lung allograft
- original disease cystic fibrosis, COPD, emphysema, idiopathic pulmonary fibrosis or A1AD

Exclusion Criteria:

- lung allograft retransplantation
- multiple organ transplantation
- severe gastrointestinal disorder
- malignancies or history of malignancy

Contacts/Locations

Study Officials: Clinical Trials
Study Director
Hoffmann-La Roche

Locations: Germany
Department of Cardiothoracic, Transplantation and Vascular Surgery at Hannover Medical School
Hannover, Germany, 30625

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received mycophenolate mofetil (MMF) capsules at dose of 1.5 grams (g) twice daily (BID) from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with chronic obstructive pulmonary disorder (COPD), emphysema, idiopathic pulmonary fibrosis (IPF), or alpha-1 antitrypsin deficiency (A1AD) having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Overall Study

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Started	33	35
Completed	26	16
Not Completed	7	19

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Adverse Event	0	8
Withdrawal by Subject	4	4
Protocol Violation	2	5
Lack of Compliance	0	1
Unspecified Reason	1	1

Baseline Characteristics

Baseline Analysis Population Description
The safety population included all participants who received at least one dose of study drug and a safety follow-up, whether withdrawn prematurely or not.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Baseline Measures

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD	Total
Overall Number of Participants		33	35	68
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	33 participants	35 participants	68 participants
		31.3 (7.42)	54.3 (7.93)	43.1 (13.86)

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD	Total
Gender, Male/ Female Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	33 participants	35 participants	68 participants
	Female	13 39.39%	14 40%	27 39.71%
	Male	20 60.61%	21 60%	41 60.29%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Maximum Concentration (Cmax) of Mycophenolic Acid (MPA), Mycophenolic Acid Glucuronide (MPAG) and Acyl Glucuronide Metabolite of Mycophenolic Acid (AcMPAG) at Day 4
Measure Description	Cmax was expressed in milligrams per liter (mg/L).
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 4 after transplantation
Safety Issue?	No

Analysis Population Description

Per Protocol (PP) Population: Intent-to treat (ITT) population (received at least one dose of study drug and where the primary variable was measured at least once under study drug) excluding participants with major protocol violations (total 46 participants). Number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	21	24

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Maximum Concentration (Cmax) of Mycophenolic Acid (MPA), Mycophenolic Acid Glucuronide (MPAG) and Acyl Glucuronide Metabolite of Mycophenolic Acid (AcMPAG) at Day 4 Mean (Standard Deviation) Unit of measure: mg/L		
MPA	7.914 (5.46450)	5.608 (2.5591)
MPAG	117.210 (58.9632)	91.207 (26.3876)
AcMPAG	1.583 (0.9697)	1.810 (0.8306)

Statistical Analysis 1 for Maximum Concentration (Cmax) of Mycophenolic Acid (MPA), Mycophenolic Acid Glucuronide (MPAG) and Acyl Glucuronide Metabolite of Mycophenolic Acid (AcMPAG) at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of MPA at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2649
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	1.305
	Confidence Interval	(2-Sided) 95% -0.8300 to 4.2500
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Maximum Concentration (Cmax) of Mycophenolic Acid (MPA), Mycophenolic Acid Glucuronide (MPAG) and Acyl Glucuronide Metabolite of Mycophenolic Acid (AcMPAG) at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of MPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3113
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	11.405
	Confidence Interval	(2-Sided) 95% -10.2000 to 42.7800
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Maximum Concentration (Cmax) of Mycophenolic Acid (MPA), Mycophenolic Acid Glucuronide (MPAG) and Acyl Glucuronide Metabolite of Mycophenolic Acid (AcMPAG) at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of AcMPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2953
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]

Comments		[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.305
	Confidence Interval	(2-Sided) 95% -0.8100 to 0.1900
	Estimation Comments	[Not specified]

2. Primary Outcome Measure:

Measure Title	Cmax of MPA, MPAG and AcMPAG at Day 8
Measure Description	Cmax was expressed in mg/L.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 8 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	20	22
Cmax of MPA, MPAG and AcMPAG at Day 8 Mean (Standard Deviation) Unit of measure: mg/L		
MPA	5.124 (4.2748)	6.106 (3.3663)
MPAG	100.127 (54.0215)	100.128 (25.1228)
AcMPAG	1.007 (0.5914)	1.361 (0.9163)

Statistical Analysis 1 for Cmax of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of MPA at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1308
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-1.29
	Confidence Interval	(2-Sided) 95% -2.9900 to 0.4100
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Cmax of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of MPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4886
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-10.845
	Confidence Interval	(2-Sided) 95% -31.5000 to 20.7900
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Cmax of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of AcMPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2218
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.2
	Confidence Interval	(2-Sided) 95% -0.6000 to 0.1900
	Estimation Comments	[Not specified]

3. Primary Outcome Measure:

Measure Title	Cmax of MPA, MPAG and AcMPAG at Day 20
Measure Description	Cmax was expressed in mg/L.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 20 post-transplantation
Safety Issue?	No

Analysis Population Description

PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	17	21
Cmax of MPA, MPAG and AcMPAG at Day 20 Mean (Standard Deviation) Unit of measure: mg/L		
MPA	5.284 (3.8472)	6.762 (3.7405)
MPAG	93.882 (37.6112)	124.450 (45.0613)
AcMPAG	0.624 (0.3895)	1.434 (1.0501)

Statistical Analysis 1 for Cmax of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of MPA at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0886
	Comments	[Not specified]

	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-1.87
	Confidence Interval	(2-Sided) 95% -3.7900 to 0.2800
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Cmax of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of MPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0220
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-30.76
	Confidence Interval	(2-Sided) 95% -54.9700 to -6.3600
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Cmax of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of AcMPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0008
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.56
	Confidence Interval	(2-Sided) 95% -1.0200 to -0.2700
	Estimation Comments	[Not specified]

4. Primary Outcome Measure:

Measure Title	Cmax of MPA, MPAG and AcMPAG at Day 90
Measure Description	Cmax was expressed in mg/L.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	15	12

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD

Cmax of MPA, MPAG and AcMPAG at Day 90
    Mean (Standard Deviation)
    Unit of measure: mg/L		

MPA	12.915 (9.2479)	7.294 (3.1817)
MPAG	104.938 (44.6135)	113.453 (48.2935)
AcMPAG	1.375 (0.6514)	1.163 (0.6856)

Statistical Analysis 1 for Cmax of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of MPA at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0318
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	3.945
	Confidence Interval	(2-Sided) 95% 0.2500 to 8.2300
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Cmax of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD

	Comments	Cmax of MPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.7144
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-7.59
	Confidence Interval	(2-Sided) 95% -51.1900 to 30.7000
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Cmax of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of AcMPA at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3930
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.27

Confidence Interval	(2-Sided) 95% -0.3100 to 0.8800	
Estimation Comments	[Not specified]	

5. Primary Outcome Measure:

Measure Title	Cmax of Free MPA at Day 4
Measure Description	Cmax was expressed in micrograms per liter (mcg/L).
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 4 post-transplantation
Safety Issue?	No

Analysis Population Description

    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	19	23

Cmax of Free MPA at Day 4
    Mean (Standard Deviation)
 	
    Unit of measure: mcg/L
	135.275 (133.2231)	84.014 (57.8348)

Statistical Analysis 1 for Cmax of Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of Free MPA at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3002
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	17.08
	Confidence Interval	(2-Sided) 95% -16.5000 to 74.3200
	Estimation Comments	[Not specified]

6. Primary Outcome Measure:

Measure Title	Cmax of Free MPA at Day 8
Measure Description	Cmax was expressed in mcg/L.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 8 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	18	21

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Cmax of Free MPA at Day 8 Mean (Standard Deviation) Unit of measure: mcg/L	59.571 (35.1104)	95.553 (62.6051)

Statistical Analysis 1 for Cmax of Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of Free MPA at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0334
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-25.24
	Confidence Interval	(2-Sided) 95% -53.2500 to -2.2900
	Estimation Comments	[Not specified]

7. Primary Outcome Measure:

Measure Title	Cmax of Free MPA at Day 20
Measure Description	Cmax was expressed in mcg/L.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 20 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	16	20
Cmax of Free MPA at Day 20 Mean (Standard Deviation) Unit of measure: mcg/L	51.822 (39.9533)	100.094 (120.8269)

Statistical Analysis 1 for Cmax of Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of Free MPA at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.1151
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-23.805

Confidence Interval	(2-Sided) 95% -52.2700 to 5.9700	
Estimation Comments	[Not specified]	

8. Primary Outcome Measure:

Measure Title	Cmax of Free MPA at Day 90
Measure Description	Cmax was expressed in mcg/L.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description
   PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	11	10
Cmax of Free MPA at Day 90 Mean (Standard Deviation) Unit of measure: mcg/L	87.293 (97.6509)	101.472 (93.9834)

Statistical Analysis 1 for Cmax of Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmax of Free MPA at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.5974
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-15.63
	Confidence Interval	(2-Sided) 95% -63.8800 to 30.5600
	Estimation Comments	[Not specified]

9. Primary Outcome Measure:

Measure Title	Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 4
Measure Description	Dose-normalized Cmax was determined (in 1 per liter [1/L]) by dividing the Cmax by the actual dose taken.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 4 post-transplantation
Safety Issue?	No

Analysis Population Description
PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		21	24
Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 4 Mean (Standard Deviation) Unit of measure: 1/L			
MPA	Number Analyzed	21 participants	24 participants
		0.00557 (0.003907)	0.00422 (0.001924)
MPAG	Number Analyzed	21 participants	24 participants
		0.08286 (0.037461)	0.06749 (0.017478)
AcMPAG	Number Analyzed	21 participants	24 participants
		0.001122 (0.0006350)	0.001388 (0.0007160)
Free MPA	Number Analyzed	19 participants	23 participants
		0.0000929 (0.00008796)	0.0000625 (0.00003907)

Statistical Analysis 1 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of MPA at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5466
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.0005
	Confidence Interval	(2-Sided) 95% -0.00103 to 0.00259
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of MPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3223
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.00728
	Confidence Interval	(2-Sided) 95% -0.00707 to 0.03161
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of AcMPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2108
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.00026
	Confidence Interval	(2-Sided) 95% -0.00070 to 0.00012
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of Free MPA at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called a Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4334
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.0000112
	Confidence Interval	(2-Sided) 95% -0.0000140 to 0.0000462
	Estimation Comments	[Not specified]

10. Primary Outcome Measure:

Measure Title	Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 8
Measure Description	Dose-normalized Cmax was determined (in 1/L) by dividing the Cmax by the actual dose taken.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 8 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		20	22
Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 8 Mean (Standard Deviation) Unit of measure: 1/L			
MPA	Number Analyzed	20 participants	22 participants
		0.00356 (0.002769)	0.00435 (0.002522)
MPAG	Number Analyzed	20 participants	22 participants
		0.06980 (0.033524)	0.07070 (0.017856)
AcMPA	Number Analyzed	20 participants	22 participants
		0.000702 (0.0003736)	0.000967 (0.0006297)
Free MPA	Number Analyzed	18 participants	21 participants
		0.0000409 (0.00002274)	0.0000663 (0.00004075)

Statistical Analysis 1 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of MPA at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1511
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.00081
	Confidence Interval	(2-Sided) 95% -0.00216 to 0.00030
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of MPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4131
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.00695
	Confidence Interval	(2-Sided) 95% -0.02050 to 0.01103
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of AcMPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2677
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.00017
	Confidence Interval	(2-Sided) 95% -0.00046 to 0.00013
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of Free MPA at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0173
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.0000185
	Confidence Interval	(2-Sided) 95% -0.0000394 to -0.0000050
	Estimation Comments	[Not specified]

11. Primary Outcome Measure:

Measure Title	Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 20
Measure Description	Dose-normalized Cmax was determined (in 1/L) by dividing the Cmax by the actual dose taken.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 20 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	17	21
Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 20 Mean (Standard Deviation) Unit of measure: 1/L		

			MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
MPA	Number Analyzed		17 participants	21 participants
			0.00395 (0.002619)	0.00456 (0.002462)
MPAG	Number Analyzed		17 participants	21 participants
			0.07044 (0.029284)	0.08430 (0.029430)
AcMPAG	Number Analyzed		17 participants	21 participants
			0.000482 (0.0003487)	0.000969 (0.0006947)
Free MP	Number Analyzed		16 participants	20 participants
			0.0000439 (0.00004750)	0.0000666 (0.00008052)

Statistical Analysis 1 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis
	Comments	Dose-Normalized Cmax of MPA at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3784
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.00063
	Confidence Interval	(2-Sided) 95% -0.00230 to 0.00084
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of MPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0942
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.01602
	Confidence Interval	(2-Sided) 95% -0.03229 to 0.00297
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of AcMPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0032
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.00037
	Confidence Interval	(2-Sided) 95% -0.00062 to -0.00015
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of Free MPA at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1760
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.0000126
	Confidence Interval	(2-Sided) 95% -0.0000328 to -0.0000091
	Estimation Comments	[Not specified]

12. Primary Outcome Measure:

Measure Title	Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 90
Measure Description	Dose-normalized Cmax was determined (in 1/L) by dividing the Cmax by the actual dose taken.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description
  PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		16	12
Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 90 Mean (Standard Deviation) Unit of measure: 1/L			
MPA	Number Analyzed	15 participants	12 participants
		0.01261 (0.007644)	0.00742 (0.003631)
MPAG	Number Analyzed	15 participants	12 participants
		0.10671 (0.037035)	0.10948 (0.030395)
AcMPAG	Number Analyzed	16 participants	12 participants
		0.001377 (0.0006935)	0.001134 (0.0005100)
Free MPA	Number Analyzed	11 participants	10 participants
		0.0000945 (0.00009640)	0.0001043 (0.00009208)

Statistical Analysis 1 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of MPA at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0509
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.0043
	Confidence Interval	(2-Sided) 95% -0.00027 to 0.00833
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of MPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.8262
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]

	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.00567
	Confidence Interval	(2-Sided) 95% -0.03414 to 0.02671
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of AcMPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.4345
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.00023
	Confidence Interval	(2-Sided) 95% -0.00030 to 0.00070
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Dose-Normalized Cmax of MPA, MPAG, AcMPAG and Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized Cmax of Free MPA at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.6472
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.00001
	Confidence Interval	(2-Sided) 95% -0.0000586 to 0.0000364
	Estimation Comments	[Not specified]

13. Primary Outcome Measure:

Measure Title	Time to Maximum Concentration (Tmax) of MPA, MPAG, AcMPAG and Free MPA at Day 4
Measure Description	
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 4 post-transplantation
Safety Issue?	No

Analysis Population Description
   PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		21	24
Time to Maximum Concentration (Tmax) of MPA, MPAG, AcMPAG and Free MPA at Day 4 Mean (Standard Deviation) Unit of measure: hour			
MPA	Number Analyzed	21 participants	24 participants
		1.823 (1.1626)	2.892 (2.9202)
MPAG	Number Analyzed	21 participants	24 participants
		3.713 (2.4167)	4.891 (2.6546)
AcMPAG	Number Analyzed	21 participants	24 participants
		2.379 (1.2344)	3.405 (1.9162)
Free MPA	Number Analyzed	19 participants	23 participants
		1.472 (0.3758)	1.405 (0.4644)

Statistical Analysis 1 for Time to Maximum Concentration (Tmax) of MPA, MPAG, AcMPAG and Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of MPA at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5745
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.0333
	Confidence Interval	(2-Sided) 95% -1.9500 to 0.5000
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Time to Maximum Concentration (Tmax) of MPA, MPAG, AcMPAG and Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of MPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2003
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-1.8
	Confidence Interval	(2-Sided) 95% -2.3333 to 0.0833
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Time to Maximum Concentration (Tmax) of MPA, MPAG, AcMPAG and Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of AcMPA at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0929
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.5
	Confidence Interval	(2-Sided) 95% -2.0833 to 0.0000
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Time to Maximum Concentration (Tmax) of MPA, MPAG, AcMPAG and Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of Free MPA at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0823
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0
	Confidence Interval	(2-Sided) 95% 0.0000 to 0.0667
	Estimation Comments	[Not specified]

14. Primary Outcome Measure:

Measure Title	Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 8
Measure Description	
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 8 post-transplantation
Safety Issue?	No

Analysis Population Description
PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		20	22
Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 8 Mean (Standard Deviation) Unit of measure: hour			
MPA	Number Analyzed	20 participants	22 participants
		2.138 (1.4976)	1.659 (0.9530)
MPAG	Number Analyzed	20 participants	22 participants
		3.669 (1.4773)	3.647 (1.4555)
AcMPAG	Number Analyzed	20 participants	22 participants
		2.802 (1.2418)	2.546 (1.1508)
Free MPA	Number Analyzed	18 participants	21 participants
		1.272 (0.5982)	1.446 (0.3638)

Statistical Analysis 1 for Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of MPA at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.8106
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.0417
	Confidence Interval	(2-Sided) 95% -0.5000 to 1.7333
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of MPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	1.0000
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0
	Confidence Interval	(2-Sided) 95% -0.1667 to 0.1667
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of AcMPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6311
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.0667
	Confidence Interval	(2-Sided) 95% -0.3333 to 1.4667
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of Free MPA at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.

	Non-Inferiority or Equivalence Analysis?	No	
	Comments	[Not specified]	
Statistical Test of Hypothesis	P-Value	0.4330	
	Comments	[Not specified]	
	Method	Other [Wilcoxon rank sum test]	
	Comments	[Not specified]	
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]	
	Estimated Value	0	
	Confidence Interval	(2-Sided) 95% -0.1667 to 0.0167	
	Estimation Comments	[Not specified]	

15. Primary Outcome Measure:

Measure Title	Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 20
Measure Description	
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 20 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		17	21
Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 20 Mean (Standard Deviation) Unit of measure: hour			
MPA	Number Analyzed	17 participants	21 participants
		2.293 (1.9048)	2.463 (1.8928)
MPAG	Number Analyzed	17 participants	21 participants
		3.762 (2.2954)	4.907 (2.8568)
AcMPAG	Number Analyzed	17 participants	21 participants
		2.842 (1.7915)	3.411 (1.8799)
Free MPA	Number Analyzed	16 participants	20 participants
		1.236 (0.6144)	1.366 (0.4692)

Statistical Analysis 1 for Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of MPA at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	1.0000
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0
	Confidence Interval	(2-Sided) 95% -1.1667 to 0.5833
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of MPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4947
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.0833
	Confidence Interval	(2-Sided) 95% -2.0000 to 0.0833
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of AcMPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4425
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.1667
	Confidence Interval	(2-Sided) 95% -1.9667 to 0.2000
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of Free MPA at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9720
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0
	Confidence Interval	(2-Sided) 95% -0.0500 to 0.0333
	Estimation Comments	[Not specified]

16. Primary Outcome Measure:

Measure Title	Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 90
Measure Description	
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description

PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		15	12
Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 90 Mean (Standard Deviation) Unit of measure: hour			
MPA	Number Analyzed	15 participants	12 participants
		1.450 (0.5251)	2.143 (2.2487)
MPAG	Number Analyzed	15 participants	12 participants
		3.095 (1.7884)	4.420 (1.9078)
AcMPAG	Number Analyzed	15 participants	12 participants
		2.234 (1.0899)	3.564 (2.3686)
Free MPA	Number Analyzed	11 participants	10 participants
		1.490 (0.0666)	1.485 (0.5282)

Statistical Analysis 1 for Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of MPA at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.8834
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.0333
	Confidence Interval	(2-Sided) 95% -1.1667 to 0.7000
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of MPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0386
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-1.8333
	Confidence Interval	(2-Sided) 95% -2.2000 to 0.0000
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of AcMPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0558
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.525
	Confidence Interval	(2-Sided) 95% -2.6167 to 0.0000
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Tmax of MPA, MPAG, AcMPAG and Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Tmax of Free MPA at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0082
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.15
	Confidence Interval	(2-Sided) 95% -0.2333 to -0.0667
	Estimation Comments	[Not specified]

17. Primary Outcome Measure:

Measure Title	Minimum Concentration (Cmin) of MPA, MPAG and AcMPAG at Day 4
Measure Description	Cmin was expressed in mg/L.
Time Frame	Predose (0 hour) on Day 4 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	21	25
Minimum Concentration (Cmin) of MPA, MPAG and AcMPAG at Day 4 Mean (Standard Deviation) Unit of measure: mg/L		

			MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
	MPA	Number Analyzed	21 participants	25 participants
			1.267 (1.0082)	1.094 (0.8473)
	MPAG	Number Analyzed	21 participants	25 participants
			66.917 (41.3384)	47.493 (17.9747)
	AcMPAG	Number Analyzed	21 participants	24 participants
			0.602 (0.5628)	0.733 (0.4686)

Statistical Analysis 1 for Minimum Concentration (Cmin) of MPA, MPAG and AcMPAG at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmin of MPA at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5224
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.13

	Confidence Interval	(2-Sided) 95% -0.2600 to 0.5000
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Minimum Concentration (Cmin) of MPA, MPAG and AcMPAG at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmin of MPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.2088
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	11.16
	Confidence Interval	(2-Sided) 95% -5.2900 to 30.2900
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Minimum Concentration (Cmin) of MPA, MPAG and AcMPAG at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmin of AcMPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1794
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.165
	Confidence Interval	(2-Sided) 95% -0.4500 to 0.0800
	Estimation Comments	[Not specified]

18. Primary Outcome Measure:

Measure Title	Cmin of MPA, MPAG and AcMPAG at Day 8
Measure Description	Cmin was expressed in mg/L.
Time Frame	Predose (0 hour) on Day 8 post-transplantation
Safety Issue?	No

Analysis Population Description

PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	20	24

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Cmin of MPA, MPAG and AcMPAG at Day 8 Mean (Standard Deviation) Unit of measure: mg/L			
MPA	Number Analyzed	20 participants	24 participants
		0.750 (0.6136)	0.772 (0.3482)
MPAG	Number Analyzed	20 participants	24 participants
		54.566 (51.2379)	57.189 (20.8518)
AcMPAG	Number Analyzed	17 participants	22 participants
		0.386 (0.4870)	0.517 (0.2623)

Statistical Analysis 1 for Cmin of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmin of MPA at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4027
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.125
	Confidence Interval	(2-Sided) 95% -0.3800 to 0.1900
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Cmin of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmin of MPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0875
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-16.09
	Confidence Interval	(2-Sided) 95% -29.3500 to 6.3900
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Cmin of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmin of AcMPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0112
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.2
	Confidence Interval	(2-Sided) 95% -0.3500 to -0.0500
	Estimation Comments	[Not specified]

19. Primary Outcome Measure:

Measure Title	Cmin of MPA, MPAG and AcMPAG at Day 20
Measure Description	Cmin was expressed in mg/L.
Time Frame	Predose (0 hour) on Day 20 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		18	22

Cmin of MPA, MPAG and AcMPAG at Day 20
  Mean (Standard Deviation)
    Unit of measure: mg/L			

MPA	Number Analyzed	18 participants	22 participants
		0.782 (0.5945)	1.234 (0.9971)

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
MPAG	Number Analyzed	18 participants	22 participants
		58.484 (29.5576)	69.023 (25.6603)
AcMPAG	Number Analyzed	13 participants	22 participants
		0.261 (0.1662)	0.528 (0.3977)

Statistical Analysis 1 for Cmin of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmin of MPA at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0818
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.215
	Confidence Interval	(2-Sided) 95% -0.5600 to 0.0500
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Cmin of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmin of MPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0945
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-14.03
	Confidence Interval	(2-Sided) 95% -26.9000 to 2.9400
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Cmin of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmin of AcMPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0081
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.19
	Confidence Interval	(2-Sided) 95% -0.4100 to -0.0400
	Estimation Comments	[Not specified]

20. Primary Outcome Measure:

Measure Title	Cmin of MPA, MPAG and AcMPAG at Day 90
Measure Description	Cmin was expressed in mg/L.
Time Frame	Predose (0 hour) on Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		15	12

Cmin of MPA, MPAG and AcMPAG at Day 90
  Mean (Standard Deviation)
  Unit of   mg/L
  measure:			

MPA	Number Analyzed	15 participants	12 participants
		1.103 (0.7446)	1.570 (1.0282)
MPAG	Number Analyzed	15 participants	12 participants
		57.957 (32.6863)	80.488 (37.2631)
AcMPAG	Number Analyzed	13 participants	12 participants
		0.449 (0.3552)	0.466 (0.3096)

Statistical Analysis 1 for Cmin of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmin of MPA at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3289
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.36
	Confidence Interval	(2-Sided) 95% -1.1400 to 0.2800
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Cmin of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmin of MPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1243
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-20.3
	Confidence Interval	(2-Sided) 95% -49.3900 to 4.7100
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Cmin of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Cmin of AcMPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.8704
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.03
	Confidence Interval	(2-Sided) 95% -0.2800 to 0.2300
	Estimation Comments	[Not specified]

21. Primary Outcome Measure:

Measure Title	Cmin of Free MPA at Day 4
Measure Description	Cmin was expressed in mcg/L.
Time Frame	Predose (0 hour) on Day 4 post-transplantation
Safety Issue?	No

Analysis Population Description

PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	19	23
Cmin of Free MPA at Day 4 Mean (Standard Deviation) Unit of measure: mcg/L	40.188 (37.9357)	23.711 (14.6991)

Statistical Analysis 1 for Cmin of Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4043
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	5.22

	Confidence Interval	(2-Sided) 95% -5.0100 to 24.4900
	Estimation Comments	[Not specified]

22. Primary Outcome Measure:

Measure Title	Cmin of Free MPA at Day 8
Measure Description	Cmin was expressed in mcg/L.
Time Frame	Predose (0 hour) on Day 8 post-transplantation
Safety Issue?	No

Analysis Population Description

    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	19	24

Cmin of Free MPA at Day 8
    Mean (Standard Deviation)
 	
    Unit of measure: mcg/L
	18.161 (16.3831)	15.669 (9.6168)

Statistical Analysis 1 for Cmin of Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.8930
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.44
	Confidence Interval	(2-Sided) 95% -6.0700 to 8.0100
	Estimation Comments	[Not specified]

23. Primary Outcome Measure:

Measure Title	Cmin of Free MPA at Day 20
Measure Description	Cmin was expressed in mcg/L.
Time Frame	Predose (0 hour) on Day 20 post-transplantation
Safety Issue?	No

Analysis Population Description
   PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	18	20

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD

Cmin of Free MPA at Day 20
 	
    Mean (Standard
    Deviation)
 	
    Unit of measure: mcg/L
	12.193 (9.1443)	20.237 (16.2117)

Statistical Analysis 1 for Cmin of Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0819
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-4.935
	Confidence Interval	(2-Sided) 95% -14.3100 to 1.1100
	Estimation Comments	[Not specified]

24. Primary Outcome Measure:

Measure Title	Cmin of Free MPA at Day 90
Measure Description	Cmin was expressed in mcg/L.
Time Frame	Predose (0 hour) on Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	13	12
Cmin of Free MPA at Day 90 Mean (Standard Deviation) Unit of measure: mcg/L	8.102 (3.3201)	18.831 (12.6155)

Statistical Analysis 1 for Cmin of Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0414
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-8.205
	Confidence Interval	(2-Sided) 95% -19.2700 to -0.0700

	Estimation Comments	[Not specified]

25. Primary Outcome Measure:

Measure Title	Volume of Distribution (Vz) of MPA, MPAG and AcMPAG at Day 4
Measure Description	Vz is defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired blood concentration of a drug.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 4 post-transplantation
Safety Issue?	No

Analysis Population Description
PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		21	23
Volume of Distribution (Vz) of MPA, MPAG and AcMPAG at Day 4 Mean (Standard Deviation) Unit of measure: Liter			
MPA	Number Analyzed	21 participants	22 participants
		345.46 (182.247)	287.74 (237.295)
MPAG	Number Analyzed	20 participants	22 participants
		11.681 (4.7587)	12.062 (3.7316)
AcMPAG	Number Analyzed	20 participants	23 participants

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
	1065.02 (611.137)	705.38 (502.996)

Statistical Analysis 1 for Volume of Distribution (Vz) of MPA, MPAG and AcMPAG at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Vz of MPA at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.1552
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	69.7186
	Confidence Interval	(2-Sided) 95% -23.4659 to 162.9545
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Volume of Distribution (Vz) of MPA, MPAG and AcMPAG at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Vz of MPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6057
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.7836
	Confidence Interval	(2-Sided) 95% -3.2675 to 2.5529
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Volume of Distribution (Vz) of MPA, MPAG and AcMPAG at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Vz of AcMPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0188
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	299.1021
	Confidence Interval	(2-Sided) 95% 79.5869 to 695.1789
	Estimation Comments	[Not specified]

26. Primary Outcome Measure:

Measure Title	Vz of MPA, MPAG and AcMPAG at Day 8

Measure Description	Vz is defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired blood concentration of a drug.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 8 post-transplantation
Safety Issue?	No

Analysis Population Description
PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		20	21
Vz of MPA, MPAG and AcMPAG at Day 8 Mean (Standard Deviation) Unit of measure: Liter			
MPA	Number Analyzed	20 participants	21 participants
		465.45 (260.837)	331.51 (150.037)
MPAG	Number Analyzed	20 participants	21 participants
		12.168 (5.1048)	12.740 (5.2593)
AcMPAG	Number Analyzed	19 participants	20 participants
		1432.88 (919.423)	1173.38 (708.767)

Statistical Analysis 1 for Vz of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Vz of MPA at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0659
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	88.959
	Confidence Interval	(2-Sided) 95% -5.7876 to 209.0183
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Vz of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Vz of MPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.7842
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.4456
	Confidence Interval	(2-Sided) 95% -3.1366 to 2.2920
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Vz of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Vz of AcMPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4072
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	121.3737
	Confidence Interval	(2-Sided) 95% -233.6483 to 560.0069
	Estimation Comments	[Not specified]

27. Primary Outcome Measure:

Measure Title	Vz of MPA, MPAG and AcMPAG at Day 20
Measure Description	Vz is defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired blood concentration of a drug.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 20 post-transplantation
Safety Issue?	No

Analysis Population Description
　　PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		17	21
Vz of MPA, MPAG and AcMPAG at Day 20 　Mean (Standard Deviation) 　Unit of measure: Liter			
MPA	Number Analyzed	17 participants	21 participants
		476.06 (267.025)	257.57 (126.679)
MPAG	Number Analyzed	16 participants	17 participants
		12.798 (5.1535)	9.533 (3.1984)
AcMPAG	Number Analyzed	13 participants	21 participants
		3006.18 (2570.205)	1571.93 (1944.621)

Statistical Analysis 1 for Vz of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Vz of MPA at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0040
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	207.9933
	Confidence Interval	(2-Sided) 95% 71.2442 to 355.1739
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Vz of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Vz of MPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0689
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	2.6186
	Confidence Interval	(2-Sided) 95% -0.1999 to 6.7766
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Vz of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Vz of AcMPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0306
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	635.7812
	Confidence Interval	(2-Sided) 95% 49.4696 to 2793.7642
	Estimation Comments	[Not specified]

28. Primary Outcome Measure:

Measure Title	Vz of MPA, MPAG and AcMPAG at Day 90
Measure Description	Vz is defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired blood concentration of a drug.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description
PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		15	12
Vz of MPA, MPAG and AcMPAG at Day 90 Mean (Standard Deviation) Unit of measure: Liter			
MPA	Number Analyzed	15 participants	12 participants
		139.48 (78.679)	192.53 (226.826)
MPAG	Number Analyzed	12 participants	8 participants
		9.254 (4.6738)	9.201 (4.4274)
AcMPAG	Number Analyzed	12 participants	9 participants
		811.15 (404.733)	980.49 (473.444)

Statistical Analysis 1 for Vz of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Vz of MPA at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9029
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	4.7477
	Confidence Interval	(2-Sided) 95% -73.5212 to 59.8304
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Vz of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Vz of MPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9692
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.0077
	Confidence Interval	(2-Sided) 95% -3.6739 to 3.9521
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Vz of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Vz of AcMPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3744
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-149.7962
	Confidence Interval	(2-Sided) 95% -644.4526 to 311.9735
	Estimation Comments	[Not specified]

29. Primary Outcome Measure:

Measure Title	Clearance (CL) of MPA, MPAG and AcMPAG at Day 4
Measure Description	CL is a quantitative measure of the rate at which a drug substance is removed from the body and expressed in liters per hour (L/hour).
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 4 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

	Description
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	21	24
Clearance (CL) of MPA, MPAG and AcMPAG at Day 4 Mean (Standard Deviation) Unit of measure: L/hours		
MPA	68.471 (32.7611)	56.709 (22.3503)
MPAG	1.6754 (0.81910)	1.7615 (0.46573)
AcMPAG	206.60 (151.301)	140.96 (110.400)

Statistical Analysis 1 for Clearance (CL) of MPA, MPAG and AcMPAG at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	CL of MPA at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1362
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	7.8422

	Confidence Interval	(2-Sided) 95% -3.9110 to 18.4444
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Clearance (CL) of MPA, MPAG and AcMPAG at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	CL of MPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4325
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.1609
	Confidence Interval	(2-Sided) 95% -0.5693 to 0.2710
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Clearance (CL) of MPA, MPAG and AcMPAG at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	CL of AcMPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0316
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	47.2686
	Confidence Interval	(2-Sided) 95% 4.1970 to 112.7806
	Estimation Comments	[Not specified]

30. Primary Outcome Measure:

Measure Title	CL of MPA, MPAG and AcMPAG at Day 8
Measure Description	CL is a quantitative measure of the rate at which a drug substance is removed from the body and expressed in L/hour.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 8 post-transplantation
Safety Issue?	No

Analysis Population Description
 PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	20	22

CL of MPA, MPAG and AcMPAG at Day 8
    Mean (Standard Deviation)
    Unit of measure: L/hour		

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
MPA	90.921 (33.7184)	81.578 (63.7936)
MPAG	2.3235 (1.55336)	1.7847 (0.75624)
AcMPAG	410.86 (448.947)	253.81 (237.283)

Statistical Analysis 1 for CL of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	CL of MPA at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0572
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estmator]
	Estimated Value	19.0536
	Confidence Interval	(2-Sided) 95% -0.4250 to 35.3852
	Estimation Comments	[Not specified]

Statistical Analysis 2 for CL of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	CL of MPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3198
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.3541
	Confidence Interval	(2-Sided) 95% -0.2524 to 1.1097
	Estimation Comments	[Not specified]

Statistical Analysis 3 for CL of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	CL of AcMPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0845
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	54.0322
	Confidence Interval	(2-Sided) 95% -6.7706 to 160.3469
	Estimation Comments	[Not specified]

31. Primary Outcome Measure:

Measure Title	CL of MPA, MPAG and AcMPAG at Day 20
Measure Description	CL is a quantitative measure of the rate at which a drug substance is removed from the body and expressed in L/hour.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 20 post-transplantation
Safety Issue?	No

Analysis Population Description
  PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	17	21
CL of MPA, MPAG and AcMPAG at Day 20 Mean (Standard Deviation) Unit of measure: L/hour		
MPA	83.068 (27.7321)	58.295 (19.5800)
MPAG	1.9338 (0.69979)	1.4788 (0.44488)
AcMPAG	680.68 (614.970)	232.34 (179.449)

Statistical Analysis 1 for CL of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	CL of MPA at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0048
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	25.0037
	Confidence Interval	(2-Sided) 95% 8.2373 to 43.5102
	Estimation Comments	[Not specified]

Statistical Analysis 2 for CL of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	CL of MPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0277
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.4297
	Confidence Interval	(2-Sided) 95% 0.0340 to 0.9925
	Estimation Comments	[Not specified]

Statistical Analysis 3 for CL of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	CL of AcMPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0002
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	318.5455
	Confidence Interval	(2-Sided) 95% 154.1902 to 526.1716
	Estimation Comments	[Not specified]

32. Primary Outcome Measure:

Measure Title	CL of MPA, MPAG and AcMPAG at Day 90
Measure Description	CL is a quantitative measure of the rate at which a drug substance is removed from the body and expressed in L/hour.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description

PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		15	12
CL of MPA, MPAG and AcMPAG at Day 90 Mean (Standard Deviation) Unit of measure: L/hour			
MPA	Number Analyzed	15 participants	12 participants
		38.091 (20.9125)	36.922 (15.2129)
MPAG	Number Analyzed	15 participants	12 participants
		1.5701 (0.99265)	1.2433 (0.53337)
AcMPAG	Number Analyzed	14 participants	12 participants
		231.28 (218.455)	223.56 (191.887)

Statistical Analysis 1 for CL of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	CL of MPA at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9417
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.579
	Confidence Interval	(2-Sided) 95% -14.5052 to 11.6346
	Estimation Comments	[Not specified]

Statistical Analysis 2 for CL of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	CL of MPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2941
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.1817
	Confidence Interval	(2-Sided) 95% -0.1954 to 0.6246
	Estimation Comments	[Not specified]

Statistical Analysis 3 for CL of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	CL of AcMPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.8170
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-4.9076
	Confidence Interval	(2-Sided) 95% -84.8234 to 109.9321
	Estimation Comments	[Not specified]

33. Primary Outcome Measure:

Measure Title	Area Under the Curve From Time 0 to 12 Hours (AUC0-12) of MPA, MPAG and AcMPAG at Day 4
Measure Description	AUC0-12 is a measure of the serum concentration of the drug from time 0 to 12 hours and expressed in hours time milligrams per liter (hours*[mg/L]).
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 4 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

	Description
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	21	24
Area Under the Curve From Time 0 to 12 Hours (AUC0-12) of MPA, MPAG and AcMPAG at Day 4 Mean (Standard Deviation) Unit of measure: hours*(mg/L)		
MPA	23.460 (7.8103)	27.174 (10.4909)
MPAG	1095.98 (659.211)	829.14 (281.878)
AcMPAG	10.414 (7.5535)	13.672 (6.6349)

Statistical Analysis 1 for Area Under the Curve From Time 0 to 12 Hours (AUC0-12) of MPA, MPAG and AcMPAG at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	AUC0-12 of MPA at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2798
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-2.4102

	Confidence Interval	(2-Sided) 95% -8.5642 to 3.0044
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Area Under the Curve From Time 0 to 12 Hours (AUC0-12) of MPA, MPAG and AcMPAG at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	AUC0-12 of MPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4063
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	72.7203
	Confidence Interval	(2-Sided) 95% -107.1596 to 393.5295
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Area Under the Curve From Time 0 to 12 Hours (AUC0-12) of MPA, MPAG and AcMPAG at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	AUC0-12 of AcMPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0441
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-3.6042
	Confidence Interval	(2-Sided) 95% -8.1854 to -0.1887
	Estimation Comments	[Not specified]

34. Primary Outcome Measure:

Measure Title	AUC0-12 of MPA, MPAG and AcMPAG at Day 8
Measure Description	AUC0-12 is a measure of the serum concentration of the drug from time 0 to 12 hours and expressed in hours*(mg/L).
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 8 post-transplantation
Safety Issue?	No

Analysis Population Description
   PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	20	22

AUC0-12 of MPA, MPAG and AcMPAG at Day 8
     Mean (Standard Deviation)
     Unit of measure: hours*(mg/L)		

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
MPA	17.841 (8.2077)	23.352 (10.7853)
MPAG	881.50 (634.587)	888.96 (277.565)
AcMPAG	6.064 (4.2591)	9.081 (6.5063)

Statistical Analysis 1 for AUC0-12 of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	AUC0-12 of MPA at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0510
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-5.8077
	Confidence Interval	(2-Sided) 95% -11.7302 to 0.0033
	Estimation Comments	[Not specified]

Statistical Analysis 2 for AUC0-12 of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	AUC0-12 of MPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2733
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-171.159
	Confidence Interval	(2-Sided) 95% -361.4437 to 171.9652
	Estimation Comments	[Not specified]

Statistical Analysis 3 for AUC0-12 of MPA, MPAG and AcMPAG at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	AUC0-12 of AcMPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0718
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-1.9621
	Confidence Interval	(2-Sided) 95% -4.8456 to 0.2067
	Estimation Comments	[Not specified]

35. Primary Outcome Measure:

Measure Title	AUC0-12 of MPA, MPAG and AcMPAG at Day 20
Measure Description	AUC0-12 is a measure of the serum concentration of the drug from time 0 to 12 hours and expressed in hours*(mg/L).
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 20 post-transplantation
Safety Issue?	No

Analysis Population Description

PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	17	21
AUC0-12 of MPA, MPAG and AcMPAG at Day 20 Mean (Standard Deviation) Unit of measure: hours*(mg/L)		
MPA	18.925 (10.7674)	28.290 (10.5485)
MPAG	812.65 (391.881)	1095.37 (391.620)
AcMPAG	3.252 (2.2066)	9.482 (6.6815)

Statistical Analysis 1 for AUC0-12 of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	AUC0-12 of MPA at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis		
	P-Value	0.0002
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation		
	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-8.6964
	Confidence Interval	(2-Sided) 95% -13.7713 to -4.6498
	Estimation Comments	[Not specified]

Statistical Analysis 2 for AUC0-12 of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview		
	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	AUC0-12 of MPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis		
	P-Value	0.0058
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation		
	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-268.9537
	Confidence Interval	(2-Sided) 95% -506.7782 to -77.3970
	Estimation Comments	[Not specified]

Statistical Analysis 3 for AUC0-12 of MPA, MPAG and AcMPAG at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	AUC0-12 of AcMPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-4.828
	Confidence Interval	(2-Sided) 95% -7.1455 to -2.6133
	Estimation Comments	[Not specified]

36. Primary Outcome Measure:

Measure Title	AUC0-12 of MPA, MPAG and AcMPAG at Day 90
Measure Description	AUC0-12 is a measure of the serum concentration of the drug from time 0 to 12 hours and expressed in hours*(mg/L).
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		15	12
AUC0-12 of MPA, MPAG and AcMPAG at Day 90 Mean (Standard Deviation) Unit of measure: hours*(mg/L)			
MPA	Number Analyzed	15 participants	12 participants
		32.365 (16.4658)	31.864 (15.5442)
MPAG	Number Analyzed	15 participants	12 participants
		776.28 (385.310)	972.69 (530.667)
AcMPAG	Number Analyzed	14 participants	12 participants
		7.776 (5.0791)	7.219 (5.2217)

Statistical Analysis 1 for AUC0-12 of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	AUC0-12 of MPA at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.7144
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	1.7477
	Confidence Interval	(2-Sided) 95% -12.1010 to 14.6563
	Estimation Comments	[Not specified]

Statistical Analysis 2 for AUC0-12 of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	AUC0-12 of MPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3413
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-156.3255
	Confidence Interval	(2-Sided) 95% -526.0765 to 195.8348
	Estimation Comments	[Not specified]

Statistical Analysis 3 for AUC0-12 of MPA, MPAG and AcMPAG at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	AUC0-12 of AcMPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6251
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.888
	Confidence Interval	(2-Sided) 95% -3.0288 to 4.2273
	Estimation Comments	[Not specified]

37. Primary Outcome Measure:

Measure Title	AUC0-12 of Free MPA at Day 4
Measure Description	AUC0-12 is a measure of the serum concentration of the drug from time 0 to 12 hours and expressed in hours times micrograms per liter (hours*[mcg/L]).
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 4 post-transplantation
Safety Issue?	No

Analysis Population Description
   PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

	Description
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	19	22
AUC0-12 of Free MPA at Day 4 Mean (Standard Deviation) Unit of measure: hours*mcg/L	135.703 (120.4152)	80.272 (45.9523)

Statistical Analysis 1 for AUC0-12 of Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2342
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	24.315
	Confidence Interval	(2-Sided) 95% -16.0292 to 79.3650
	Estimation Comments	[Not specified]

38. Primary Outcome Measure:

Measure Title	AUC0-12 of Free MPA at Day 8
Measure Description	AUC0-12 is a measure of the serum concentration of the drug from time 0 to 12 hours and expressed in hours*(mcg/L).
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 8 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	17	21
AUC0-12 of Free MPA at Day 8 Mean (Standard Deviation) Unit of measure: hours*mcg/L	61.155 (26.0913)	83.683 (51.4228)

Statistical Analysis 1 for AUC0-12 of Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1964
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-13.5592
	Confidence Interval	(2-Sided) 95% -37.3950 to 5.4825
	Estimation Comments	[Not specified]

39. Primary Outcome Measure:

Measure Title	AUC0-12 of Free MPA at Day 20
Measure Description	AUC0-12 is a measure of the serum concentration of the drug from time 0 to 12 hours and expressed in hours*(mcg/L).
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 20 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	16	20
AUC0-12 of Free MPA at Day 20 Mean (Standard Deviation) Unit of measure: hours*mcg/L	48.530 (30.3408)	89.315 (90.3819)

Statistical Analysis 1 for AUC0-12 of Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0672
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-22.7878
	Confidence Interval	(2-Sided) 95% -44.8217 to 3.7573
	Estimation Comments	[Not specified]

40. Primary Outcome Measure:

Measure Title	AUC0-12 of Free MPA at Day 90
Measure Description	AUC0-12 is a measure of the serum concentration of the drug from time 0 to 12 hours and expressed in hours*(mcg/L).
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

	Description
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	11	10
AUC0-12 of Free MPA at Day 90 Mean (Standard Deviation) Unit of measure: hours*mcg/L	68.874 (64.6536)	99.212 (81.0812)

Statistical Analysis 1 for AUC0-12 of Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2453
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-21.4737
	Confidence Interval	(2-Sided) 95% -64.1567 to 8.5708
	Estimation Comments	[Not specified]

41. Primary Outcome Measure:

Measure Title	Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 4
Measure Description	AUC0-12 is a measure of the serum concentration of the drug from time 0 to 12 hours. Dose-normalized AUC0-12 was determined (in hours/L) by dividing the AUC0-12 by the actual dose taken.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 4 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		21	24
Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 4 Mean (Standard Deviation) Unit of measure: hours/L			
MPA	Number Analyzed	21 participants	24 participants
		0.01652 (0.004684)	0.02016 (0.007383)
MPAG	Number Analyzed	21 participants	24 participants
		0.7720 (0.42519)	0.6165 (0.20281)
AcMPAG	Number Analyzed	21 participants	24 participants
		0.00739 (0.005002)	0.01056 (0.005828)

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Free MPA	Number Analyzed	19 participants	22 participants
		0.0000943 (0.00008029)	0.0000594 (0.00003237)

Statistical Analysis 1 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 of MPA at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1362
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.00237
	Confidence Interval	(2-Sided) 95% -0.00734 to 0.00106
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 MPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4325
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.04797
	Confidence Interval	(2-Sided) 95% -0.08467 to 0.26322
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 of AcMPAG at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0316
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.00311
	Confidence Interval	(2-Sided) 95% -0.00645 to -0.00029
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 of Free MPA at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3269
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.0000158
	Confidence Interval	(2-Sided) 95% -0.0000134 to 0.0000552
	Estimation Comments	[Not specified]

42. Primary Outcome Measure:

Measure Title	Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 8
Measure Description	AUC0-12 is a measure of the serum concentration of the drug from time 0 to 12 hours. Dose-normalized AUC0-12 was determined (in hours/L) by dividing the AUC0-12 by the actual dose taken.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 8 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		20	22
Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 8 Mean (Standard Deviation) Unit of measure: hours/L			
MPA	Number Analyzed	20 participants	22 participants
		0.01256 (0.005018)	0.01624 (0.007077)
MPAG	Number Analyzed	20 participants	22 participants
		0.6157 (0.40835)	0.6270 (0.18884)
AcMPAG	Number Analyzed	20 participants	22 participants
		0.00426 (0.002733)	0.00644 (0.004471)
Free MPA	Number Analyzed	17 participants	21 participants
		0.0000428 (0.00001807)	0.0000580 (0.00003330)

Statistical Analysis 1 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 of MPA at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0572
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.00383
	Confidence Interval	(2-Sided) 95% -0.00761 to 0.00010
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 of MPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.3198
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.09626
	Confidence Interval	(2-Sided) 95% -0.25269 to 0.11464
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 of AcMPAG at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0845
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.00131
	Confidence Interval	(2-Sided) 95% -0.00352 to 0.00013
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 of Free MPA at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1769
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.00001
	Confidence Interval	(2-Sided) 95% -0.0000250 to 0.0000043
	Estimation Comments	[Not specified]

43. Primary Outcome Measure:

Measure Title	Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 20
Measure Description	AUC0-12 is a measure of the serum concentration of the drug from time 0 to 12 hours. Dose-normalized AUC0-12 was determined (in hours/L) by dividing the AUC0-12 by the actual dose taken.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 20 post-transplantation
Safety Issue?	No

Analysis Population Description
   PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	17	21
Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 20 Mean (Standard Deviation) Unit of measure: hours/L		

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
MPA	Number Analyzed	17 participants	21 participants
		0.01402 (0.007208)	0.01923 (0.007029)
MPAG	Number Analyzed	17 participants	21 participants
		0.6059 (0.28149)	0.7440 (0.26032)
AcMPAG	Number Analyzed	17 participants	21 participants
		0.00239 (0.001707)	0.00642 (0.004432)
Free MPA	Number Analyzed	16 participants	20 participants
		0.0000399 (0.00003632)	0.0000597 (0.00006020)

Statistical Analysis 1 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 of MPA at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0048
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.0049
	Confidence Interval	(2-Sided) 95% -0.00876 to -0.00148
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 of MPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0277
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.14764
	Confidence Interval	(2-Sided) 95% -0.31026 to -0.01067
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 of AcMPAG at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0002
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.0035
	Confidence Interval	(2-Sided) 95% -0.00476 to 0.00168
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 of Free MPA at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1661
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.0000138
	Confidence Interval	(2-Sided) 95% -0.0000295 to 0.0000047
	Estimation Comments	[Not specified]

44. Primary Outcome Measure:

Measure Title	Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 90
Measure Description	AUC0-12 is a measure of the serum concentration of the drug from time 0 to 12 hours. Dose-normalized AUC0-12 was determined (in hours/L) by dividing the AUC0-12 by the actual dose taken.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description
PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure. Number of participants with available data for specified category are provided against individual category.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		15	12
Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 90 Mean (Standard Deviation) Unit of measure: hours/L			
MPA	Number Analyzed	15 participants	12 participants
		0.03126 (0.011529)	0.03172 (0.012879)
MPAG	Number Analyzed	15 participants	12 participants
		0.7887 (0.31007)	0.9190 (0.31896)
AcMPAG	Number Analyzed	14 participants	12 participants
		0.00748 (0.004735)	0.00700 (0.004084)
Free MPA	Number Analyzed	11 participants	10 participants
		0.0000752 (0.00006364)	0.00001023 (0.00007888)

Statistical Analysis 1 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD

	Comments	Dose-Normalized AUC0-12 of MPA at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9417
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.00054
	Confidence Interval	(2-Sided) 95% -0.01037 to 0.01042
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 of MPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2941
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.1461

	Confidence Interval	(2-Sided) 95% -0.39951 to 0.12988
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 of AcMPAG at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.8170
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.00033
	Confidence Interval	(2-Sided) 95% -0.00361 to 0.00421
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Dose-Normalized AUC0-12 of MPA, MPAG, AcMPAG and Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Dose-Normalized AUC0-12 of Free MPA at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1927
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodge-Lehmann estimator]
	Estimated Value	-0.0000239
	Confidence Interval	(2-Sided) 95% -0.0000594 to 0.0000154
	Estimation Comments	[Not specified]

45. Primary Outcome Measure:

Measure Title	Free Fraction of Free MPA at Day 4
Measure Description	MPA Free fraction (in percent [%]) was calculated by dividing free MPA AUC0-12 by total MPA AUC0-12 times 100%.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 4 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	19	22
Free Fraction of Free MPA at Day 4 Mean (Standard Deviation) Unit of measure: percentage of free fraction	0.5789 (0.42113)	0.3208 (0.16486)

Statistical Analysis 1 for Free Fraction of Free MPA at Day 4

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Free Fraction of Free MPA at Day 4. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.0821
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.1616
	Confidence Interval	(2-Sided) 95% -0.0121 to 0.4188
	Estimation Comments	[Not specified]

46. Primary Outcome Measure:

Measure Title	Free Fraction of Free MPA at Day 8
Measure Description	MPA Free fraction (in %) was calculated by dividing free MPA AUC0-12 by total MPA AUC0-12 times 100%.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 8 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	17	21
Free Fraction of Free MPA at Day 8 Mean (Standard Deviation) Unit of measure: percentage of free fraction	0.3595 (0.13517)	0.3594 (0.20504)

Statistical Analysis 1 for Free Fraction of Free MPA at Day 8

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Free Fraction of Free MPA at Day 8. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.3628
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.0427
	Confidence Interval	(2-Sided) 95% -0.0455 to 0.1221

Estimation Comments	[Not specified]

47. Primary Outcome Measure:

Measure Title	Free Fraction of Free MPA at Day 20
Measure Description	MPA Free fraction (in %) was calculated by dividing free MPA AUC0-12 by total MPA AUC0-12 times 100%.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 20 post-transplantation
Safety Issue?	No

Analysis Population Description
   PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	16	20
Free Fraction of Free MPA at Day 20 Mean (Standard Deviation) Unit of measure: percentage of free fraction	0.2922 (0.19811)	0.3052 (0.22218)

Statistical Analysis 1 for Free Fraction of Free MPA at Day 20

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Free Fraction of Free MPA at Day 20. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9873
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	0.0010
	Confidence Interval	(2-Sided) 95% -0.1152 to 0.1173
	Estimation Comments	[Not specified]

48. Primary Outcome Measure:

Measure Title	Free Fraction of Free MPA at Day 90
Measure Description	MPA Free fraction (in %) was calculated by dividing free MPA AUC0-12 by total MPA AUC0-12 times 100%.
Time Frame	Predose (0 hour), 0.5, 1, 1.5, 2, 4, 8, 10, and 12 hours post-dose on Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description
    PP Population. Here, number of participants analyzed=participants who were evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	11	10

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Free Fraction of Free MPA at Day 90 Mean (Standard Deviation) Unit of measure: percentage of free fraction	0.2270 (0.14614)	0.3020 (0.13446)

Statistical Analysis 1 for Free Fraction of Free MPA at Day 90

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	Free Fraction of Free MPA at Day 90. Analysis was performed using Wilcoxon rank sum test; corresponding p-value and point estimate (Hodges-Lehmann estimator) were calculated. The point estimator derived by sending the confidence level to zero is called as Hodges-Lehmann estimator.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2178
	Comments	[Not specified]
	Method	Other [Wilcoxon rank sum test]
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Hodges-Lehmann estimator]
	Estimated Value	-0.0857
	Confidence Interval	(2-Sided) 95% -0.1870 to 0.0265
	Estimation Comments	[Not specified]

49. Secondary Outcome Measure:

Measure Title	Forced Expiratory Volume in 1 Second (FEV1) at Day 90 Post-Transplantation
Measure Description	FEV1 is the amount of air which can be forcibly exhaled from the lungs in the first second of a forced exhalation.
Time Frame	Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description
    ITT Population (total 64 participants). Here, Number of participants analyzed = participants evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	26	16
Forced Expiratory Volume in 1 Second (FEV1) at Day 90 Post-Transplantation Mean (Standard Deviation) Unit of measure: L	3.087 (0.9335)	2.834 (0.6912)

50. Secondary Outcome Measure:

Measure Title	Percent of Predicted FEV1 at Day 90 Post-Transplantation
Measure Description	FEV1 is the amount of air which can be forcibly exhaled from the lungs in the first second of a forced exhalation. Percent predicted FEV1 [%] = (FEV1 [L] / Predicted normal value FEV1 [L]) * 100%
Time Frame	Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description
    ITT Population. Here, Number of participants analyzed = participants evaluable for this outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.

	Description
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 and then at 1 g BID from Day 31 to Day 90.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	26	15

Percent of Predicted FEV1 at Day 90 Post-Transplantation
 	
  Mean (Standard Deviation)
 	
  Unit of measure: percentage of predicted FEV1
	81.75 (19.743)	90.17 (20.176)

51. Secondary Outcome Measure:

Measure Title	Forced Vital Capacity (FVC) at Day 90 Post-Transplantation
Measure Description	FVC at Day 90 post-transplantation is reported.
Time Frame	Day 90 post-transplantation
Safety Issue?	No

Analysis Population Description
    ITT Population. Here, Number of participants analyzed = participants evaluable for the outcome measure.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 and then at 1 g BID from Day 31 to Day 90.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	26	16

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Forced Vital Capacity (FVC) at Day 90 Post-Transplantation Mean (Standard Deviation) Unit of measure: L	3.445 (0.9499)	3.619 (1.0388)

52. Secondary Outcome Measure:

Measure Title	Change From Baseline in Intracellular Adenosine-Tri-Phosphate (iATP) Levels
Measure Description	iATP was expressed in ng/mL.
Time Frame	Baseline, Days 4, 8, 20 and 90 post-transplantation
Safety Issue?	No

Analysis Population Description
ITT Population. Here, number of participants analyzed = participants who were evaluable for this outcome measure. Here "n"= participants who were evaluable for each category, for respective arm groups.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 and then at 1 g BID from Day 31 to Day 90.

Measured Values

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed		20	18
Change From Baseline in Intracellular Adenosine-Tri-Phosphate (iATP) Levels Mean (Standard Deviation) Unit of measure: ng/mL			
Day 4	Number Analyzed	19 participants	18 participants

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
		24.0 (223.32)	85.4 (215.78)
Day 8	Number Analyzed	20 participants	17 participants
		162.9 (294.53)	144.9 (286.23)
Day 20	Number Analyzed	15 participants	15 participants
		-42.4 (382.87)	-45.9 (199.20)
Day 90	Number Analyzed	16 participants	6 participants
		-164.6 (312.98)	-114.7 (138.99)

53. Secondary Outcome Measure:

Measure Title	Change From Baseline in T-Cell Phenotype
Measure Description	Reported values are change in the T-cell phenotype status from baseline to Day 20 and 90 for cluster of differentiation (CD) 3, CD19, CD4, CD4CD25, CD28, CD45RA, CD45RO, CD69, CD127, and CD152.
Time Frame	Baseline, Days 20 and 90 post-transplantation
Safety Issue?	No

Analysis Population Description
    ITT Population. Here, number of participants analyzed = participants who were evaluable for this outcome measure. Here "n"= participants who were evaluable for each category, for respective arm groups.

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 and then at 1 g BID from Day 31 to Day 90.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	19	16

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Change From Baseline in T-Cell Phenotype Mean (Standard Deviation) Unit of measure: percentage of lymphocytes			
CD3: Change at Day 20	Number Analyzed	19 participants	16 participants
		-1.34 (13.012)	-3.01 (13.075)
CD3: Change at Day 90	Number Analyzed	11 participants	8 participants
		1.74 (11.433)	-2.81 (6.995)
CD19: Change at Day 20	Number Analyzed	19 participants	16 participants
		3.29 (10.554)	1.88 (8.046)
CD19: Change at Day 90	Number Analyzed	10 participants	7 participants
		0.59 (5.322)	0.61 (6.000)
CD4: Change at Day 20	Number Analyzed	19 participants	16 participants
		13.29 (15.626)	-14.71 (24.467)
CD4: Change at Day 90	Number Analyzed	10 participants	8 participants
		9.00 (26.054)	-1.93 (13.415)
CD4CD25: Change at Day 20	Number Analyzed	19 participants	16 participants
		2.72 (6.877)	-0.53 (0.940)
CD4CD25: Change at Day 90	Number Analyzed	10 participants	8 participants
		0.89 (1.354)	-0.10 (0.941)
CD28: Change at Day 20	Number Analyzed	18 participants	16 participants
		4.54 (10.105)	-4.44 (7.635)
CD28: Change at Day 90	Number Analyzed	10 participants	8 participants
		10.15 (25.362)	-1.04 (6.176)
CD45RA: Change at Day 20	Number Analyzed	19 participants	16 participants
		5.35 (15.802)	-5.11 (17.327)
CD45RA: Change at Day 90	Number Analyzed	11 participants	8 participants
		-1.57 (12.498)	-4.88 (13.342)

		MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
CD45RO: Change at Day 20	Number Analyzed	19 participants	16 participants
		-0.08 (4.199)	-2.83 (3.285)
CD45RO: Change at Day 90	Number Analyzed	12 participants	8 participants
		-1.92 (7.564)	-0.43 (7.574)
CD69: Change at Day 20	Number Analyzed	19 participants	16 participants
		5.68 (10.031)	0.01 (0.328)
CD69: Change at Day 90	Number Analyzed	10 participants	7 participants
		-0.46 (10.040)	-0.04 (0.237)
CD127: Change at Day 20	Number Analyzed	19 participants	16 participants
		-1.36 (13.566)	-3.90 (7.227)
CD127: Change at Day 90	Number Analyzed	10 participants	7 participants
		-0.19 (14.603)	-2.03 (12.509)
CD152: Change at Day 20	Number Analyzed	19 participants	16 participants
		-3.78 (17.562)	-10.97 (17.935)
CD152: Change at Day 90	Number Analyzed	11 participants	8 participants
		-0.28 (2.624)	-15.59 (29.715)

54. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Opportunistic Infections
Measure Description	Opportunistic infections included all infections which occurred due to aspergillus, candida, pneumocystis, cryptococcus, listeria, herpes zoster, herpes simplex, cytomegalovirus pathogens.
Time Frame	Up to Day 90
Safety Issue?	Yes

Analysis Population Description
    Safety Population

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF at dose of 1.5 g BID from Day 2 to Day 30 and then at 1 g BID from Day 31 to Day 90.

Measured Values

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
Number of Participants Analyzed	33	35
Percentage of Participants With Opportunistic Infections Measure Type: Number Unit of measure: percentage of participants	18.2	20.0

Statistical Analysis 1 for Percentage of Participants With Opportunistic Infections

Statistical Analysis Overview	Comparison Groups	MMF - Cystic Fibrosis, MMF - COPD, Emphysema, IPF, or A1AD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	1.0000
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in rates]
	Estimated Value	-1.8
	Confidence Interval	(2-Sided) 95% -24.9 to 22.1
	Estimation Comments	[Not specified]

Reported Adverse Events

Time Frame	From baseline up to Day 90
Additional Description	[Not specified]

Reporting Groups

	Description
MMF - Cystic Fibrosis	Participants with cystic fibrosis having transplantation at Day 0, received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 post-transplantation and then at 1 g BID from Day 31 to Day 90 post-transplantation.
MMF - COPD, Emphysema, IPF, or A1AD	Participants with COPD, emphysema, IPF or A1AD, having transplantation at Day 0 received MMF capsules at dose of 1.5 g BID from Day 2 to Day 30 and then at 1 g BID from Day 31 to Day 90.

Serious Adverse Events

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
	Affected/At Risk (%)	Affected/At Risk (%)
Total	13/33 (39.39%)	14/35 (40%)
Blood and lymphatic system disorders		
Leukopenia A *	1/33 (3.03%)	0/35 (0%)
Cardiac disorders		
Atrial tachycardia A *	1/33 (3.03%)	0/35 (0%)
Tachyarrhythmia A *	0/33 (0%)	1/35 (2.86%)
Ear and labyrinth disorders		
Deafness A *	1/33 (3.03%)	0/35 (0%)
Gastrointestinal disorders		
Distal intestinal obstruction syndrome A *	1/33 (3.03%)	0/35 (0%)
Ileus A *	2/33 (6.06%)	0/35 (0%)
Pancreatitis A *	1/33 (3.03%)	0/35 (0%)
Volvulus A *	0/33 (0%)	1/35 (2.86%)
General disorders		
Pyrexia A *	0/33 (0%)	1/35 (2.86%)

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
	Affected/At Risk (%)	Affected/At Risk (%)
Sudden cardiac death A *	0/33 (0%)	1/35 (2.86%)
Hepatobiliary disorders		
Cholangitis sclerosing A *	0/33 (0%)	1/35 (2.86%)
Hepatic failure A *	0/33 (0%)	1/35 (2.86%)
Infections and infestations		
Bacterial infection A *	1/33 (3.03%)	0/35 (0%)
Bronchopneumonia A *	1/33 (3.03%)	0/35 (0%)
Pneumonia A *	1/33 (3.03%)	1/35 (2.86%)
Viral infection A *	0/33 (0%)	1/35 (2.86%)
Wound infection A *	1/33 (3.03%)	0/35 (0%)
Injury, poisoning and procedural complications		
Graft dysfunction A *	0/33 (0%)	1/35 (2.86%)
Investigations		
Antibiotic resistant Staphylococcus test positive A *	0/33 (0%)	1/35 (2.86%)
Nervous system disorders		
Convulsion A *	1/33 (3.03%)	0/35 (0%)
Renal and urinary disorders		
Renal failure acute A *	0/33 (0%)	1/35 (2.86%)
Respiratory, thoracic and mediastinal disorders		
Acute respiratory failure A *	0/33 (0%)	1/35 (2.86%)
Bronchial haemorrhage A *	0/33 (0%)	1/35 (2.86%)
Haemothorax A *	0/33 (0%)	1/35 (2.86%)
Hydropneumorthorax A *	0/33 (0%)	1/35 (2.86%)

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
	Affected/At Risk (%)	Affected/At Risk (%)
Pleural effusion A *	1/33 (3.03%)	0/35 (0%)
Pneumothorax A *	2/33 (6.06%)	0/35 (0%)
Pulmonary embolism A *	0/33 (0%)	3/35 (8.57%)
Pulmonary oedema A *	0/33 (0%)	1/35 (2.86%)
Respiratory failure A *	0/33 (0%)	2/35 (5.71%)
Vascular disorders		
Haematoma A *	1/33 (3.03%)	0/35 (0%)

*   Indicates events were collected by non-systematic methods.

A   Term from vocabulary, MedDRA (14.1)

Other Adverse Events

    Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
	Affected/At Risk (%)	Affected/At Risk (%)
Total	27/33 (81.82%)	29/35 (82.86%)
Blood and lymphatic system disorders		
Anaemia A *	3/33 (9.09%)	8/35 (22.86%)
Hyperchromic anaemia A *	3/33 (9.09%)	0/35 (0%)
Leukopenia A *	8/33 (24.24%)	3/35 (8.57%)
Normochromic normocytic anaemia A *	1/33 (3.03%)	2/35 (5.71%)
Thrombocytopenia A *	2/33 (6.06%)	1/35 (2.86%)
Cardiac disorders		
Atrial fibrillation A *	1/33 (3.03%)	12/35 (34.29%)
Ear and labyrinth disorders		
Tinnitus A *	3/33 (9.09%)	0/35 (0%)

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
	Affected/At Risk (%)	Affected/At Risk (%)
Eye disorders		
Visual impairment A *	1/33 (3.03%)	2/35 (5.71%)
Gastrointestinal disorders		
Abdominal pain A *	0/33 (0%)	2/35 (5.71%)
Abdominal pain upper A *	0/33 (0%)	3/35 (8.57%)
Constipation A *	0/33 (0%)	2/35 (5.71%)
Diarrhoea A *	3/33 (9.09%)	4/35 (11.43%)
Gastrointestinal motility disorder A *	0/33 (0%)	2/35 (5.71%)
Nausea A *	5/33 (15.15%)	3/35 (8.57%)
Vomiting A *	4/33 (12.12%)	4/35 (11.43%)
General disorders		
Oedema peripheral A *	0/33 (0%)	3/35 (8.57%)
Infections and infestations		
Bacterial infection A *	3/33 (9.09%)	4/35 (11.43%)
Clostridium difficile colitis A *	3/33 (9.09%)	0/35 (0%)
Enterococcal infection A *	0/33 (0%)	2/35 (5.71%)
Febrile infection A *	1/33 (3.03%)	2/35 (5.71%)
Gastroenteritis norovirus A *	0/33 (0%)	2/35 (5.71%)
Infection A *	0/33 (0%)	2/35 (5.71%)
Pseudomonas infection A *	0/33 (0%)	3/35 (8.57%)
Injury, poisoning and procedural complications		
Anastomotic complication A *	3/33 (9.09%)	1/35 (2.86%)
Investigations		

	MMF - Cystic Fibrosis	MMF - COPD, Emphysema, IPF, or A1AD
	Affected/At Risk (%)	Affected/At Risk (%)
Antibody test positive A *	0/33 (0%)	2/35 (5.71%)
C-reactive protein increased A *	1/33 (3.03%)	2/35 (5.71%)
Klebsiella test positive A *	0/33 (0%)	2/35 (5.71%)
Liver function test abnormal A *	3/33 (9.09%)	1/35 (2.86%)
Metabolism and nutrition disorders		
Hyperlipidaemia A *	2/33 (6.06%)	0/35 (0%)
Hyperuricaemia A *	2/33 (6.06%)	1/35 (2.86%)
Hypokalaemia A *	1/33 (3.03%)	3/35 (8.57%)
Psychiatric disorders		
Sleep disorder A *	0/33 (0%)	6/35 (17.14%)
Respiratory, thoracic and mediastinal disorders		
Bronchial polyp A *	5/33 (15.15%)	2/35 (5.71%)
Bronchostenosis A *	5/33 (15.15%)	1/35 (2.86%)
Cough A *	2/33 (6.06%)	0/35 (0%)
Fibrinous bronchitis A *	5/33 (15.15%)	6/35 (17.14%)
Pleural effusion A *	1/33 (3.03%)	4/35 (11.43%)
Skin and subcutaneous tissue disorders		
Subcutaneous emphysema A *	2/33 (6.06%)	4/35 (11.43%)
Vascular disorders		
Circulatory collapse A *	0/33 (0%)	2/35 (5.71%)
Hypertension A *	5/33 (15.15%)	1/35 (2.86%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (14.1)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:
Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The Study being conducted under this Agreement is part of the Overall Study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the Study, but only after the first publication or presentation that involves the Overall Study. The Sponsor may request that Confidential Information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights.

Results Point of Contact:
Name/Official Title: Medical Communications
Organization: Hoffmann-LaRoche
Phone: 800-821-8590
Email: genentech@druginfo.com