A New Approach to Interstitial Lung Disease

Topline Results for Phase 3 EFZO-FIT™ Study of Efzofitimod in Pulmonary Sarcoidosis

September 15, 2025

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Summary of Key Findings

- Study did not meet primary endpoint in change from baseline in mean daily OCS dose at week 48
- 52.6% of patients treated with 5.0 mg/kg efzofitimod achieved complete steroid withdrawal at week 48 vs 40.2% on placebo (p=0.0919)
- Clinical improvement in KSQ-Lung score at week 48 observed in the 5.0 mg/kg efzofitimod treatment group vs placebo (p=0.0479).
- Greater proportion of patients achieved complete steroid withdrawal at week 48 with a KSQ-Lung score improvement in the 5.0 mg/kg efzofitimod treatment group (29.5%) vs placebo (14.4%) (p=0.0199)
- Lung function as measured by forced vital capacity (FVC) at week 48 was maintained
- Efzofitimod was generally well-tolerated at both the 3.0 mg/kg and 5.0 mg/kg doses, consistent with a previously observed safety profile in all trials conducted to date

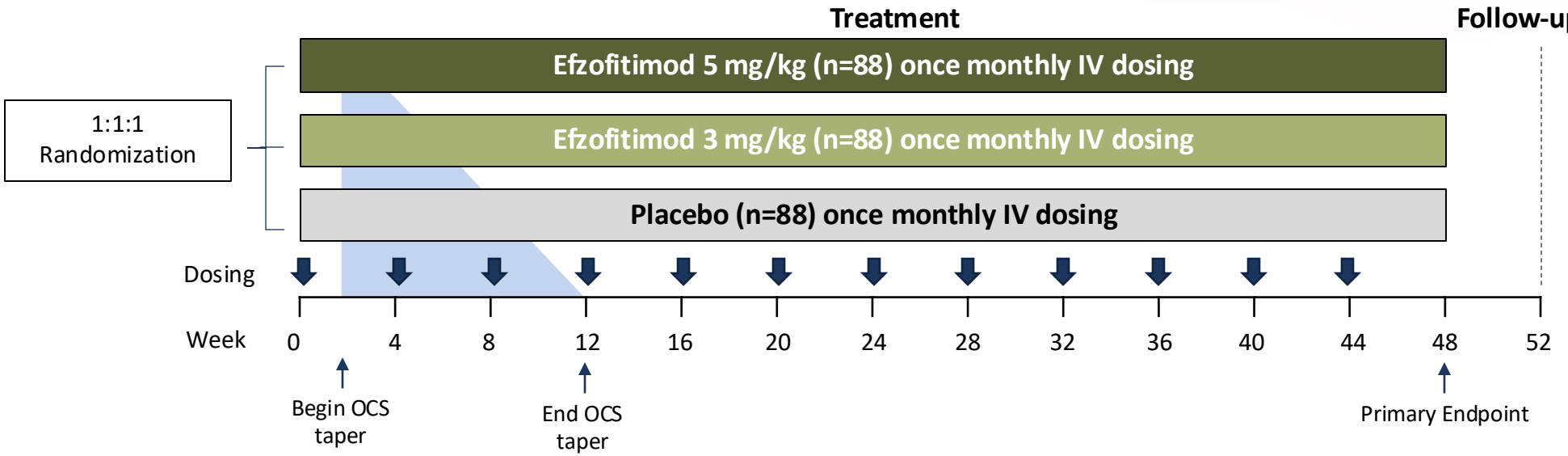
- Findings demonstrate drug activity for efzofitimod across multiple clinically relevant efficacy endpoints
- Company plans to engage with the U.S. FDA to determine the path forward for efzofitimod in pulmonary sarcoidosis

OCS = oral corticosteroids; KSQ = King's Sarcoidosis Questionnaire; FDA = Food and Drug Administration

As the primary endpoint did not achieve statistical significance, p-values for other endpoints should be interpreted as nominal p-values.

Global Phase 3 Trial in Pulmonary Sarcoidosis

Primary objective: Assess the efficacy of efzofitimod in patients with pulmonary sarcoidosis



N = 268 patients in U.S., Europe, Japan and Brazil

Population: moderate to severe pulmonary sarcoidosis

- Diagnosis of pulmonary sarcoidosis for ≥ 6 months
- Stable treatment with ≥ 7.5 and ≤ 25 mg/day OCS
- Extent of fibrosis < 20%
- Symptomatic with KSQ-Lung score ≤ 70

Steroid Taper Protocol Guidelines

- Based on Patients Global Assessment (PGA) **and** Investigator Assessment (IA) conducted every two weeks
- If both PGA **and** IA are stable or improved, patient OCS will need to be **tapered**; If either PGA **or** IA has worsened, patient will be **rescued** with OCS

Individual Patient Expanded Access Program (EAP) is intended to allow access for patients who complete EFZO-FIT™ and wish to receive treatment with efzofitimod outside of the clinical trial

Steroid Reduction

Week 48	Placebo N=90	Efzofitimod 3 mg/kg N=86	Efzofitimod 5 mg/kg N=88
N	81	77	83
LS mean dose at week 48 (mg)	3.5	3.5	2.8
LS mean change from baseline (mg)	-7.1	-7.1	-7.9
Difference in LS mean (95% CI)	-	0.0 (-1.5, 1.5)	-0.7 (-2.2, 0.8)
Nominal p-value	-	*0.9804*	*0.3313*
Steroid free[1]; n (%[2])	36 (40.2)	45 (51.8)	46 (52.6)
Odds ratio (95% CI)	-	1.6 (0.9, 3.0)	1.7 (0.9, 3.1)
Nominal p-value	-	*0.1172*	*0.0919*

- The percent change from baseline was -63.3% for placebo, -67.8% for efzofitimod 3 mg/kg and -73.6% for efzofitimod 5 mg/kg

[1]Missing patients considered non-responders; [2]Adjusted percentage; Tables 14.2.1.2.1, 14.2.2.2.1; rounded to closest first decimal

King's Sarcoidosis Questionnaire (KSQ)-Lung and Composites

Week 48	Placebo N=90	Efzofitimod 3 mg/kg N=86	Efzofitimod 5 mg/kg N=88
N	81	77	83
LS mean week 48 score	57.7	58.8	61.8
LS mean change from baseline	6.2	7.3	10.4
Difference; LS mean (95% CI)	-	1.1 (-3.1, 5.4)	4.2 (0.0, 8.3)
Nominal p-value	-	*0.5932*	***0.0479***
Steroid free and stable[1] KSQ-L[2]; n (%[3])	32 (35.7)	42 (48.3)	41 (46.9)
Odds ratio (95% CI)	-	1.7 (0.9, 3.2)	1.6 (0.9, 3.0)
Nominal p-value	-	*0.0848*	*0.1241*
Steroid free and improved[4] KSQ-L[2]; n (%[5])	13 (14.4)	24 (27.9)	26 (29.5)
Odds ratio (95% CI)	-	2.2 (1.0, 4.7)	2.4 (1.2, 5.1)
Nominal p-value	-	***0.0402***	***0.0199***

[1]stable = >-3; [2]missing patients treated as non-responders; [3]adjusted percentage; [4]improved = ≥8; [5]raw percentage; Source: Tables 14.2.6.3, 14.2.3.1, Draft output for steroid free and improved; rounded to closest first decimal

Forced Vital Capacity (FVC)

Week 48	Placebo N=90	Efzofitimod 3 mg/kg N=86	Efzofitimod 5 mg/kg N=88
N	74	67	74
FVC (mL), LS mean	3380.4	3369.7	3395.4
LS mean change from baseline (mL)	-84.5	-95.1	-69.4
Difference in LS means (mL) (95% CI)	-	-10.6 (-104.7, 83.5)	15.1 (-77.4, 107.6)
Nominal p-value	-	*0.8244*	*0.7485*
FVC % predicted[1]; LS mean	86.7	86.1	87.0
LS mean change from baseline (% predicted)	-2.1	-2.7	-1.8
Difference in LS means (mL) (95% CI)	-	-0.6 (-2.8, 1.6)	0.3 (-1.9, 2.5)
Nominal p-value	-	*0.5855*	*0.7875*

[1]GLI global; Tables 14.2.4.2.1, Draft output for FVC % predicted; rounded to closest first decimal

Safety and Tolerability

- Efzofitimod was generally well-tolerated at both the 3.0 mg/kg and 5.0 mg/kg doses, consistent with a previously observed safety profile in all trials conducted to date
- Adverse events (AEs) were mostly mild or moderate in severity and generally assessed as unrelated to the study drug
- Serious adverse events (SAEs) were limited and balanced between treatment groups
- Proportion of patients with treatment-related SAEs and events leading to discontinuation was small and balanced between treatment groups.
- Proportion of patients who developed antidrug antibodies was small and balanced between treatment groups

Key Takeaways and Next Steps

- Evidence of drug activity observed for 5.0 mg/kg efzofitimod across multiple clinically relevant efficacy endpoints
- Clinical improvement in quality of life as measured by the KSQ-Lung for 5.0 mg/kg efzofitimod vs placebo
- Preservation of lung function with efzofitimod 5.0 mg/kg
- Generally well-tolerated at both the 3.0 mg/kg and 5.0 mg/kg doses, consistent with a previously observed safety profile in all trials conducted to date

Planned Next Steps

- Present EFZO-FIT™ topline results at the European Respiratory Society Congress on September 30, 2025, at 8:44am CEST in Amsterdam, Netherlands
- Engage with the U.S. FDA to determine the path forward for efzofitimod in pulmonary sarcoidosis

KOL Commentary

Robert P. Baughman, M.D.

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- Editor, Sarcoidosis, Vasculitis, and Diffuse Lung Disease
- Editor, Current Opinion in Pulmonary Medicine
- Past President, World Association of Sarcoidosis and Other Granulomatous Disorders (WASOG)
- Member, Trial Steering Committee for the EFZO-FIT™ study

Q&A