Number of subjects planned : 585

Number of subjects included: 534

Demographic characteristics are shown in Table I. The largest proportion of patients were female 478 (89.5%) and white skin color 286 (53.6%) predominated. The median age was 58 ± 14 years, ranging from 19 to 89 years. The median weight was 66 ± 19 kg, ranging from 31 to 147 kg, the median height was 159 ± 9 cm, ranging from 121 to 188 cm, for a median BMI of 26.0 ± 6.5 kg/m^2, ranging from 13.9 to 49.1 kg/m^2.

Table I. Distribution of patients according to demographic characteristics

Demographic characteristics		**Total**	
		N	**%**
Total		**534**	**100.0**
Age (years)	Mean ± SD	58 ± 11	
	Median ± RQ	58 ± 14	
	Minimum; Maximum	19; 89	
Height (cm)	Mean ± SD	160 ± 8	
	Median ± RQ	159 ± 9	
	Minimum; Maximum	121;188	
Body weight (kg)	Mean ± SD	68 ± 14.7	
	Median ± RQ	66 ± 19	
	Minimum; Maximum	31; 147	
Body mass index (BMI) (kg/m^2)	Mean ± SD	26.6 ± 5.3	
	Median ± RQ	26.0 ± 6.5	
	Minimum; Maximum	13.9; 49.1	
Gender	Female	478	89.5
	Male	56	10.5
Skin color	White	286	53.6
	Mixed-blood	164	30.7
	Black	81	15.2
	Yellow	3	0.6

1. Safety Results:

The most frequent adverse events were burning and pain at the administration site; classified as mild and related to the product, which resolved without the need for treatment. Several patients reported increased appetite. These events had already been reported in previous studies.
Two patients experienced adverse events due to falls caused by a car accident and a domestic accident, resulting in a metatarsal fracture and a tibial plateau fissure, respectively.

Other non-serious and isolated adverse events not related to product use were also reported: flushing, dysphonia, vasculitis, headache, joint pain, metallic taste, and dry mouth.
Additionally, during protocol-defined evaluations, some patients showed clinically significant deviations in complementary test results, which were classified as adverse events. After analysis by the site investigation teams, it was determined that in all cases these alterations were not related to the investigational product but rather to the patients' medical history. All cases coincided with patients not continuing their baseline treatments, leading to decompensation. These included increases in blood glucose, creatinine, proteins, and triglycerides. One case of anemia was identified in a patient with a history of recurrent anemia. Arterial hypertension was also reported in 3 patients, linked to their medical history.

2. Therapeutic Effect Results:

Clinical Response According to DAS28: All patients began treatment with moderate or severe disease activity. DAS28 scores decreased during treatment. Table II shows clinical response results using the DAS28 scale at three evaluation points, classifying treatment response as remission, mild, moderate, or severe.

- Week 16: 119 patients (23.6%) achieved remission, 99 (19.6%) had mild activity, 240 (47.6%) moderate activity, and 46 (9.1%) severe activity.
- Week 28: 191 (39.1%) remission, 123 (25.2%) mild, 157 (32.1%) moderate, and 18 (3.7%) severe.

Table II. Clinical Response According to DAS28

	Week0		**Week16**		**Week28**	
	N	%	N	%	N	%
Total = 534	534	100.0	504	94.4	489	91.6
Remission	0	0.0	119	23.6	191	39.1
Mild	0	0.0	99	19.6	123	25.2
Moderate	120	22.5	240	47.6	157	32.1
Severe	414	77.5	46	9.1	18	3.7

Clinical Response According to ACR: Table III shows clinical response to treatment based on ACR criteria at weeks 16 and 28. According to this criterion, 451 patients (89.0%) showed an ACR response at

week 16, distributed as follows: ACR20 in 196 patients (38.7%), ACR50 in 144 patients (28.4%), and ACR70 in 111 patients (21.9%).

Analyzing the 95% confidence interval (CI) for the proportion of patients with an ACR response, we can expect with 95% confidence that between 86% and 91% of subjects treated with Jusvinza under the study protocol will achieve an ACR response.

A hypothesis test for proportions was conducted to evaluate the study hypothesis (expecting that ≥70% of patients treated with 0.5 mg of Jusvinza would achieve an ACR20 response at week 16). The result was p = 0.000 (<0.05), confirming the study hypothesis.

At week 28, 471 patients (95.7%) achieved an ACR response, distributed as follows: ACR20 in 63 patients (12.8%), ACR50 in 113 patients (23.0%), and ACR70 in 295 patients (60.0%).

Table III. Clinical Response According to ACR

ACR Response	**Week 16**		**Week 28**	
	N	%	N	%
Total = 534	507	94.9	492	92.1
No	56	11.0	21	4.3
Yes	451	89.0	471	95.7
CI (95%)	86.1 – 91.8	93.8 – 97.6		
p*	0.000	--		
ACR20	196	38.7	63	12.8
ACR50	144	28.4	113	23.0
ACR70	111	21.9	295	60.0