Both Phase 3 Studies and both tested doses met primary efficacy endpoints, achieving a statistically significant response rate with SEL-212 versus placebo

- The response rate in the high dose group was **56% in DISSOLVE I (the "US Study")** and **47% in DISSOLVE II (the "Global Study")**
- The response rate in the high dose group **for patients ≥50 years old was 65% and 48%** in the US and Global Studies, respectively
- **Majority (75%)** of those who entered the 6-month extension phase on active treatment were responders at 12 months with no new safety signals
- Infusion reaction[1] incidence was **3.4% in the high dose group**
- There was **no increase in gout flare adverse events** in SEL-212-treated groups versus placebo
- We believe the observations of **efficacy and safety of SEL-212** in these two Phase 3 trials suggest the potential to provide a new treatment solution with once monthly dosing

[1] Defined by Rheumatology Common Toxicity Criteria, ver. 2.0. occurring during or 1 hour after completion of study drug infusion .

Both studies and tested doses met primary efficacy endpoints

- Percent responders in the high dose group was 56% and 47% for US & Global Studies, respectively
- Percent responders in the low dose group was 48% and 41% for US & Global Studies, respectively
- Results are consistent across multiple modified ITT and per protocol population groups

		US Study (DISSOLVE I)			Global Study (DISSOLVE II)		
	ITT Set	High dose (38)	Low dose (37)	Placebo (37)	High dose (49)	Low dose (51)	Placebo (53)
Responders [1]	% [97.5% CI]	56 [55, 57]	48 [47,48]	4 [3,4]	47 [46, 48]	41 [40, 41]	12 [11,13]
	Risk Difference	53	44	-	35	28	-
	97.5% CI [2]	[32, 73]	[23, 64]	-	[14, 56]	[8, 48]	-
	p-value [3]	<0.0001	<0.0001	-	0.0002	0.0015	-

1 Responders were defined as subjects with SU levels < 6mg/mL for at least 80% of time during month 6 of therapy (TP6). Subjects who dropped from study due to stopping rule, AE, and COVID were considered non-responders. Percentages shown are averaged over multiple imputed datasets for missing SU for withdrawal of consent, lost to follow-up, and other as per FDA guidance.

2 Confidence interval of the risk difference

3 p-value versus placebo group for each treatment group. Mantel-Haenszel test was used for a pooled estimate derived after multiple imputation. Risk difference considered randomization stratum of tophus presence (Y/N) with a two-sided type 1 error rate of $\alpha = 2.5\%$ to adjust for the two comparisons of study drug against placebo.

Responders in patients ≥ 50 years old

- Pre-determined endpoint for largest age group population[1]
- Percent responders in the high dose group was 65% and 48% for US & Global Studies, respectively

		US Study (DISSOLVE I)			Global Study (DISSOLVE II)		
	ITT Set	High dose (25)	Low dose (27)	Placebo (22)	High dose (37)	Low dose (31)	Placebo (42)
Responders [2]	% [97.5% CI]	65 [64, 66]	47 [46, 48]	5 [5,6]	48 [47, 49]	45 [44, 45]	14 [13, 15]
	Risk Difference	51	43	-	33	31	-
	97.5% CI [3]	[22, 79]	[19, 67]	-	[10, 57]	[7, 55]	-
	p-value [4]	<0.0001	<0.0001	-	0.0017	0.0044	-

1 Topline data suggest consistent results in other key subgroups of interest

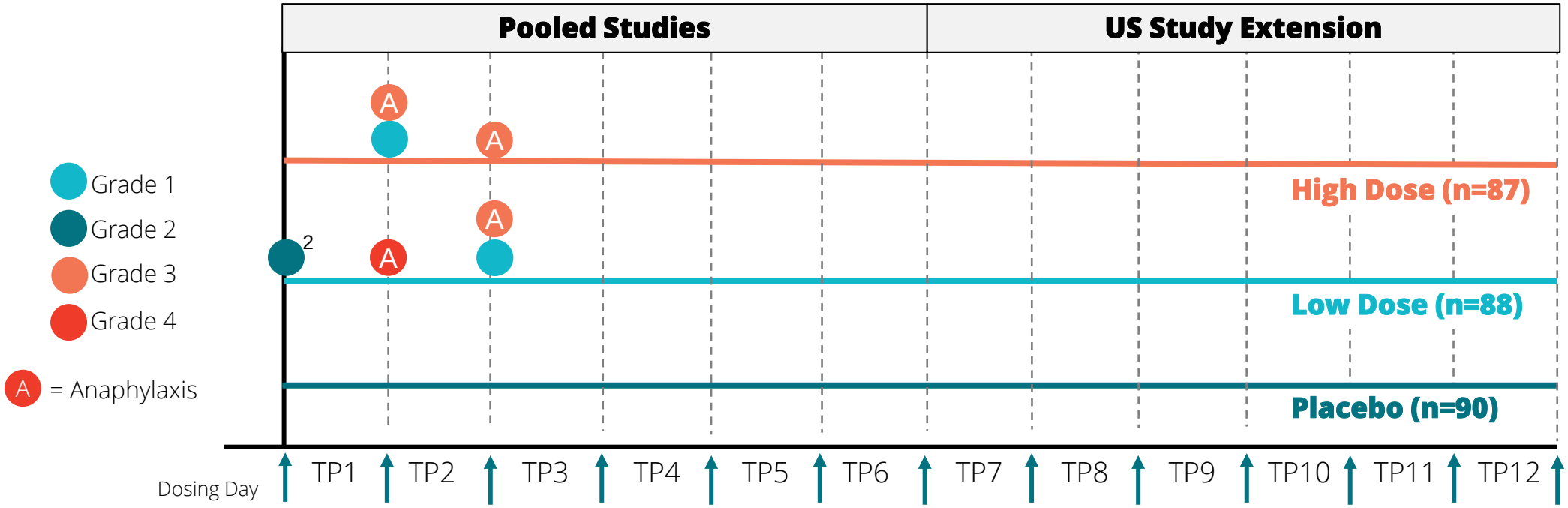
2 Responders were defined as subjects with SU levels < 6mg/mL for at least 80% of time during month 6 of therapy (TP6). Subjects who dropped from study due to stopping rule, AE, and COVID were considered non-responders. Percentages shown are averaged over multiple imputed datasets for missing SU for withdrawal of consent, lost to follow-up, and other as per FDA guidance.

3 Confidence interval of the risk difference

4 p-value versus placebo group for each treatment group. Mantel-Haenszel test was used for a pooled estimate derived after multiple imputation. Risk difference considered randomization stratum of tophus presence (Y/N) with a two-sided type 1 error rate of α = 2.5% to adjust for the two comparisons of study drug against placebo.

Low incidence of infusion reactions (IRs) [1]

- IRs occurred in 3.4% of high dose group and in 4.5% of low dose group
- All IRs occurred within the first three infusions
- All occurred during infusion and completely resolved with stopping infusion and symptomatic treatment



[1] Infusion reaction defined as a study drug-related AE that occurs during or after completion of study drug infusion (Rheumatology Common Toxicity Criteria, ver. 2.0.). The observation time was defined as 1 h following completion of the second (pegadricase) infusion.

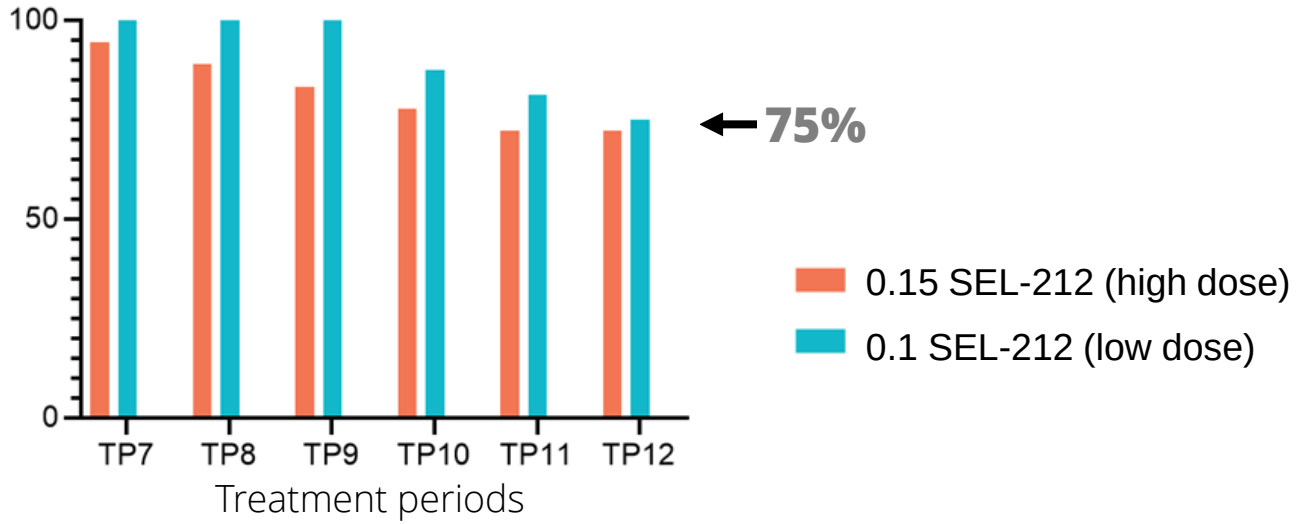
[2] Infusion reaction occurred during the infusion of ImmTOR; pegadricase not administered. All the other infusion reactions occurred during infusion of pegadricase.

Table 14.3.1.1.1.

Majority (75%) of those who entered the 6-month extension phase on active treatment were responders at 12 months with no new safety signals

100% of patients who received dose 12 of active drug were responders in TP12

Percent of subjects on active treatment entering TP7 (both dose groups) who have a mean SU <6 mg/dL in subsequent TPs



No new safety signals in the 6-month extension phase

- No Infusion Reactions, new AESIs, or additional safety signals
- 9 SAE events reported in 7 subjects with none related to study drug (see below table)

High Dose (0.15 SEL-212)	Low Dose (0.1 SEL-212)	Placebo
Motor vehicle accident--death	COVID-19	COVID-19 Pneumonia
Sepsis	Pulmonary embolism/pneumonia/sepsis (3 events)	Deep venous thrombosis
Pneumonia		

Both Phase 3 Studies and both tested doses met primary efficacy endpoints, achieving a statistically significant response rate with SEL-212 versus placebo

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[1] Defined by Rheumatology Common Toxicity Criteria, ver. 2.0. occurring during or 1 hour after completion of study drug infusion .