



Phase 2 COMPARE Trial Topline Data Presentation

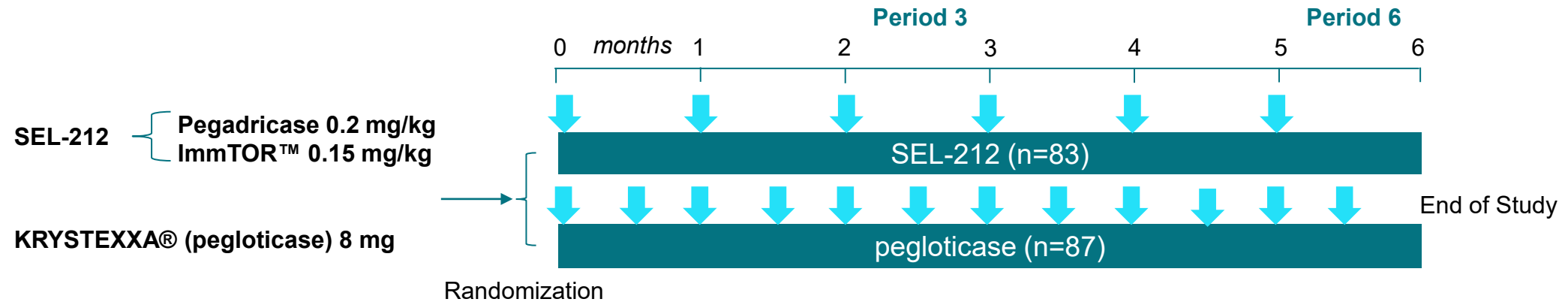
September 30, 2020

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Phase 2 COMPARE Study Design

Once-monthly doses of SEL-212 were compared to bi-weekly doses of pegloticase for six months



Patient Inclusion Criteria

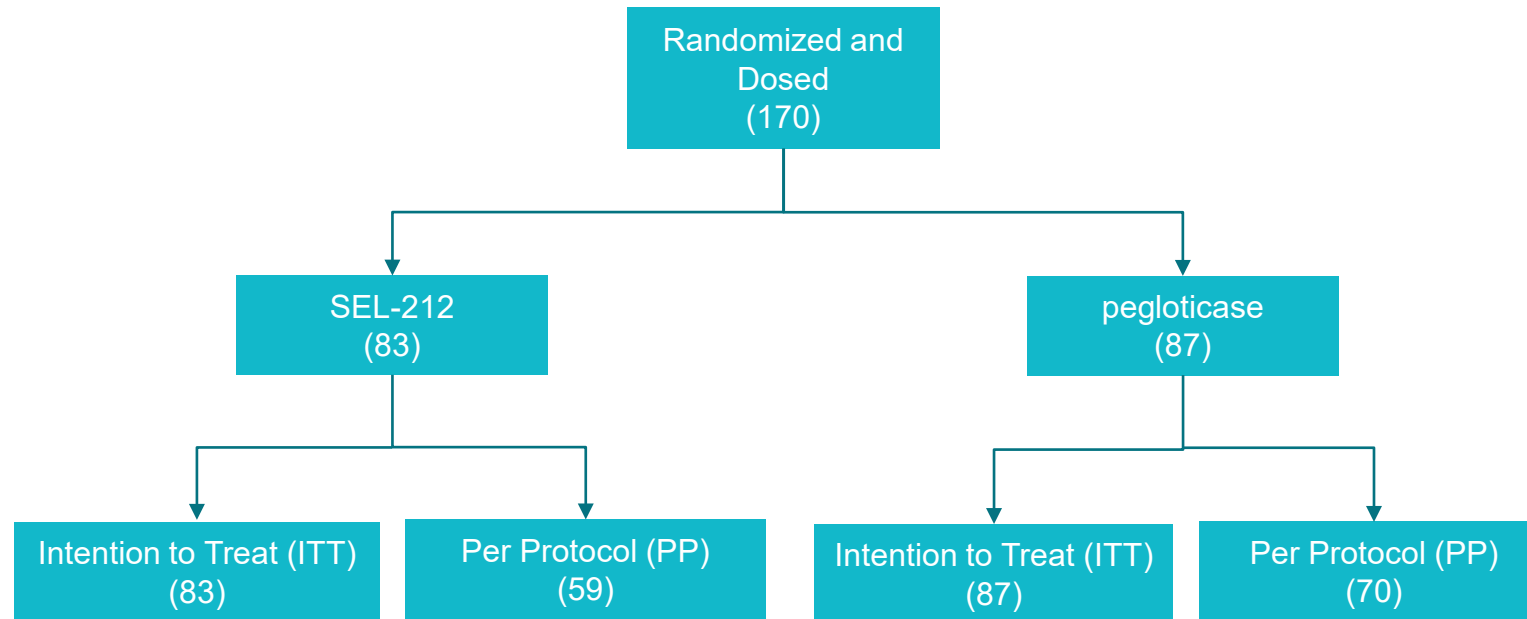
- Chronic refractory gout with serum uric acid (SUA) ≥ 7 mg/dL and one of the following:
 - ≥ 1 tophus **OR** ≥ 3 gout flares in last 18 months **OR** diagnosis of gouty arthritis

Endpoints

- *Primary Endpoint:* Comparison of the percentage of patients on SEL-212 vs. pegloticase who achieve and maintain reduction of SUA < 6 mg/dL for at least 80% of the time during months 3 and 6 combined
- *Key Secondary Endpoints:*
 - Comparison of the percentage of patients on SEL 212 vs. pegloticase who achieve and maintain reduction of SUA < 6 mg/dL for at least 80% of the time during months 3 and 6 individually
 - Reduction of mean SUA levels during months 3 and 6 combined
- Safety and tolerability

Phase 2 COMPARE Subject Disposition and Analysis Sets

170 patients were randomized and dosed in the phase 2 COMPARE trial



Per Protocol Analysis Set:

Defined as patients who were administered any amount of study medication and have completed at least 65% of the study dosing **unless**:

- Early termination from the study occurred after study drug withdrawal due to meeting stopping rules or due to an adverse event
- Early termination due to investigator discretion
- Major protocol deviations affecting the primary efficacy assessment

Impact of COVID-19 Pandemic

Per FDA guidance, the statistical analysis plan was modified and submitted to FDA prior to database lock to address the potential impact of the COVID-19 pandemic on the trial

- One patient in the pegloticase arm of the trial had a confirmed COVID-19 infection, and this led to discontinuation; no patients in the SEL-212 arm had a COVID-19 infection
- Increased protocol deviations in the intention-to-treat (ITT) population were observed during the ongoing COVID-19 pandemic
- The COMPARE trial statistical analysis plan (SAP) was modified and submitted to the U.S. Food and Drug Administration (FDA) prior to database lock in compliance with FDA guidance ⁽¹⁾ to account for the potential impact of the COVID-19 pandemic on statistical analysis
- The company is pleased we completed the trial during the COVID-19 pandemic. Trials conducted and completed during the pandemic may heighten the importance of the per protocol data set more than usual in analysis of the data. After receipt of the full data set, the impact of COVID-19 will be more deeply explored.

Baseline Characteristics and Demographics

Approximately 41% of patients had visible tophi at baseline in the phase 2 COMPARE trial

Parameter		Stats	Intention-to-Treat			Per Protocol		
			SEL-212 (n=83)	pegloticase (n=87)	Total (n=170)	SEL-212 (n=59)	pegloticase (n=70)	Total (n=129)
Age		Mean (SD)	52.6 (11.47)	52.0 (10.43)	52.3 (10.92)	52.3 (11.86)	51.3 (10.89)	51.8 (11.31)
Tophus Presence	Yes	n (%)	35 (42.2)	34 (39.1)	69 (40.6)	26 (44.1)	26 (37.7)	52 (40.3)
	No	n (%)	48 (57.8)	53 (60.9)	101 (59.4)	33 (55.9)	44 (62.9)	77 (59.7)
Gender	Male	n (%)	78 (94.0)	85 (97.7)	163 (95.9)	56 (94.9)	68 (97.1)	124 (96.1)
	Female	n (%)	5 (6.0)	2 (2.3)	7 (4.1)	3 (5.1)	2 (2.90)	5 (3.9)
BMI		n (SD)	34.8 (6.73)	35.4 (7.18)	35.1 (6.95)	34.8 (6.60)	35.8 (7.43)	35.3 (7.05)
Race	White	n (%)	62 (74.7)	69 (79.3)	131 (77.1)	45 (76.3)	57 (81.4)	102 (79.1)
	AA	n (%)	16 (19.3)	16 (18.4)	32 (18.8)	10 (16.9)	11 (15.7)	21 (16.3)
	Other	n (%)	5 (6)	2 (2.3)	7 (4.1)	4 (6.8)	2 (2.8)	6 (4.7)
Ethnicity	Hispanic	n (%)	15 (18.1)	21 (24.1)	36 (21.2)	9 (15.3)	16 (22.9)	25 (19.4)
	Not Hispanic	n (%)	68 (81.9)	66 (75.9)	134 (78.8)	50 (84.7)	54 (77.1)	104 (80.6)

Patients Who Achieved and Maintained Reduction of Serum Uric Acid (SUA) < 6 mg/dL for at least 80% of the Time During the Evaluation Period

SEL-212 demonstrated statistically significant higher response rate during month 3 and numerically higher response rate during month 6, and during months 3 and 6 combined, but did not meet the primary endpoint of statistical superiority during months 3 and 6 combined

Evaluation Period (Month)	Data Set	SEL-212		pegloticase		Treatment Difference		p****
		n*	Responder Percent**	n*	Responder Percent**	Absolute**	Relative***	
Month 3	PP	59	70%	70	51%	18%	37%	0.019
	ITT	83	70%	87	54%	16%	30%	0.017
Month 6	PP	59	61%	70	47%	14%	30%	0.053
	ITT	83	54%	87	47%	7%	15%	0.179
Months 3 and 6 combined (primary endpoint)	PP	59	59%	70	46%	14%	28%	0.056
	ITT	83	53%	87	46%	7%	15%	0.181

* Number of patients with Responder Assessment

** Absolute Treatment difference = SEL-212 percent responders – pegloticase percent responders. Percent values are rounded to nearest integer

*** Relative Treatment difference = (SEL-212 percent responders – pegloticase percent responders) / pegloticase percent responders*100. Percent values are rounded to nearest integer

**** One-sided p-value (SEL-212 > pegloticase) Based on stratified Cochran-Mantel-Haenszel (CMH) test. Stratification factor is tophus presence at randomization (Yes/No)

Reduction in Mean Serum Uric Acid (SUA) During Months 3 and 6 Combined

Statistically significant 48% overall reduction in mean SUA for SEL-212 versus pegloticase

- Treatment with SEL-212 demonstrated a statistically significant greater reduction in mean SUA levels than pegloticase during months 3 plus 6 combined in both PP and ITT data sets
- Baseline SUA levels were not statistically different between SEL-212 and pegloticase

Evaluation Period (Month)	Data Set	Treatment Group	Baseline SUA (mg/dL)	n*	Mean Reduction (mg/dL)**	% reduction of SEL-212 versus pegloticase***	p****
Months 3 and 6 combined	PP	SEL-212	9.00	49	-6.68	-48%	0.003
		pegloticase	8.52	61	-4.51		
	ITT	SEL-212	9.12	64	-6.79	-40%	0.003
		pegloticase	8.47	72	-4.85		

* Number of patients with SUA assessments

** Reduction in SUA computed by subtracting baseline SUA from mean during treatment period as determined by the area under the SUA time curve divided by the corresponding time interval (mg/dL). Rounded to two decimal points.

*** Computed by (pegloticase – SEL-212) / pegloticase * 100 (rounded to nearest integer)

**** p-value is based on ANOVA with fixed factor for treatment and tophus presence at randomization (Yes/No)

Patients With Tophi at Baseline Who Achieved and Maintained Reduction of Serum Uric Acid (SUA) < 6 mg/dL for at least 80% of the Time During the Evaluation Period

A delta of 19 percentage points was observed on SEL-212 versus pegloticase for patients with visible tophi at baseline

Evaluation Period (Month)	Data Set	SEL-212		pegloticase		Treatment Difference*		p****
		n*	Responder Percent**	n*	Responder Percent**	Absolute**	Relative***	
Month 3 and 6 combined	PP	26	58%	26	39%	19%	49%	0.085
	ITT	35	57%	34	41%	16%	39%	0.094

* Number of patients with Responder Assessment

** Absolute Treatment difference = SEL-212 percent responders – pegloticase percent responders. Percent values are rounded to nearest integer

*** Relative Treatment difference = (SEL-212 percent responders – pegloticase percent responders) / pegloticase percent responders*100. Percent values are rounded to nearest integer

**** One-sided p-value (SEL-212 > pegloticase) Based on stratified Cochran-Mantel-Haenszel (CMH) test. Stratification factor is tophus presence at randomization (Yes/No)

Reduction in Mean Serum Uric Acid (SUA) During Months 3 and 6 Combined in Patients with Tophi at Baseline

SEL-212 demonstrated a statistically significant 60% overall reduction versus pegloticase in mean SUA levels for patients with visible tophi at baseline

- Treatment with SEL-212 demonstrated a statistically significant greater reduction in mean SUA levels than pegloticase during months 3 and 6 combined in both PP and ITT Data Sets
- Baseline SUA levels were not statistically different between SEL-212 and pegloticase

Evaluation Period (Month)	Data Set	Treatment Group	Baseline SUA (mg/dL)	n*	Mean Reduction (mg/dL)**	% reduction of SEL-212 versus pegloticase***	p****
Months 3 and 6 combined	PP	SEL-212	9.48	19	-7.42	-60%	0.016
		pegloticase	8.58	19	-4.64		
	ITT	SEL-212	9.42	26	-7.32	-50%	0.019
		pegloticase	8.28	24	-4.89		

* Number of patients with SUA assessments

** Reduction in SUA computed by subtracting baseline SUA from mean during treatment period as determined by the area under the SUA time curve divided by the corresponding time interval (mg/dL). Rounded to two decimal points.

*** Computed by $(\text{pegloticase} - \text{SEL-212}) / \text{pegloticase} * 100$ (rounded to nearest integer)

**** p-value is based on ANOVA with fixed factor for treatment and tophus presence at randomization (Yes/No)

Safety Summary

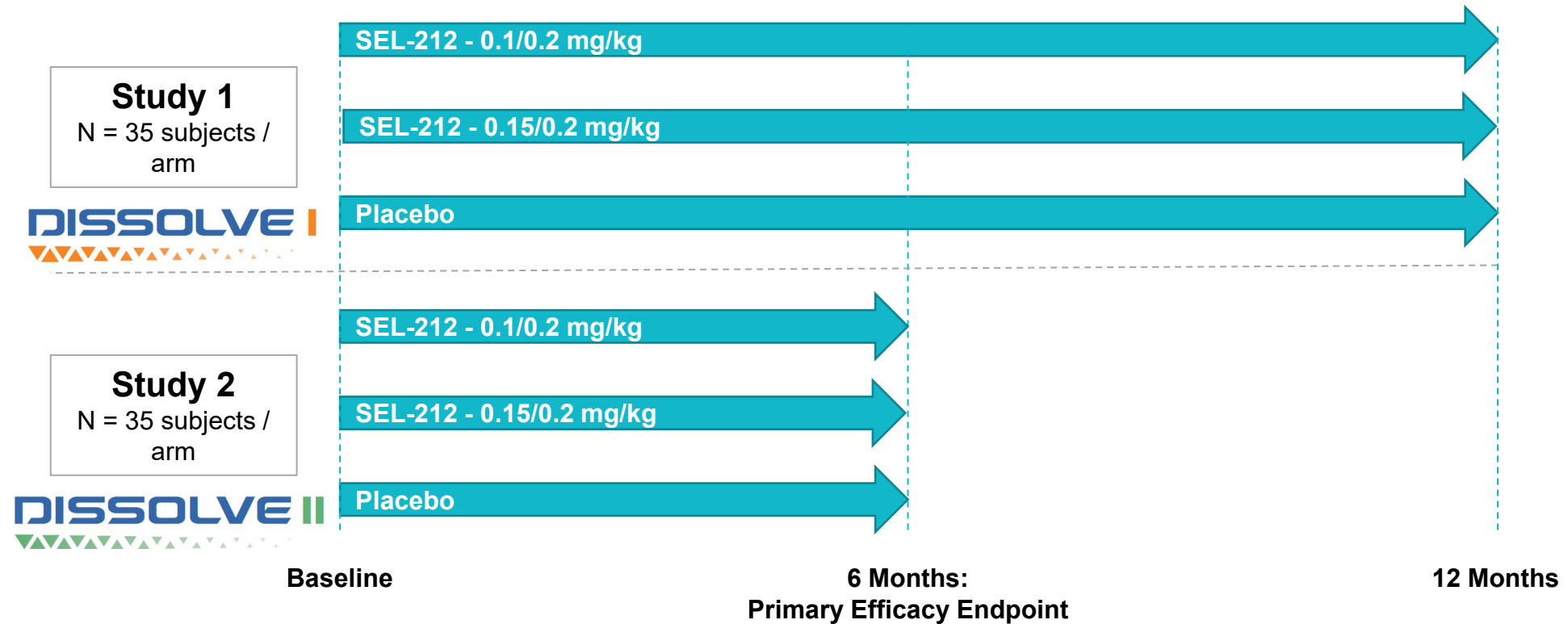
Both SEL-212 and pegloticase were shown to be safe and well-tolerated

- Topline data suggests that both SEL-212 and pegloticase were generally well-tolerated
- There were no deaths during the study
- There were no differences in serious TEAEs, treatment-related serious TEAEs, or infusion reactions between the two groups
- Full analysis of safety signals, including gout flare incidence and severity, awaits evaluation of the full data set and will be reported along with full efficacy analysis at a future medical meeting

SEL-212 Phase 3 DISSOLVE Program Design

SEL-212 is being evaluated in a pivotal phase 3 program versus placebo, with topline data expected in 2H 2022

- 2 double blinded placebo-controlled trials of SEL-212 (0.1 mg/kg & 0.15 mg/kg ImmTOR)
- Randomized 1:1:1 against Placebo with a total of 210 Treated Subjects
- First patient randomized and dosed in September 2020
- Topline data from the DISSOLVE program is expected in 2H 2022



Summary of Data From COMPARE Clinical Trial

All data consistent with stronger performance of SEL-212 versus pegloticase

- SEL-212 showed a numerically higher response rate on the primary endpoint during months 3 and 6 combined, but did not meet the primary endpoint of statistical superiority during months 3 and 6 combined
- Statistically significant higher response rate of SEL-212 during month 3
- Numerically higher response rate of SEL-212 during month 6
- Statistically significant greater overall reduction in mean SUA levels in SEL-212 versus pegloticase
- In patients with tophi at baseline, substantially higher responder rates for SEL-212 compared to pegloticase on the primary endpoint, and statistically significant reduction in mean SUA
- SEL-212 and pegloticase showed favorable safety results and were well-tolerated