
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): September 30, 2020

SELECTA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37798
(Commission
File Number)

26-1622110
(IRS Employer
Identification No.)

**65 Grove Street
Watertown, MA 02472**
(Address of principal executive offices) (Zip Code)

(617) 923-1400
Registrant's telephone number, including area code

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	SELB	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

Selecta Biosciences, Inc. (the “Company”) continues to believe that its anticipated cash, cash equivalents and short-term investments of approximately \$145 million as of September 30, 2020 will fund its operating expenses and capital expenditure requirements into the first quarter of 2023. Because the Company’s unaudited financial statements for the quarter ending September 30, 2020 have not yet been prepared, this preliminary estimate of the Company’s cash, cash equivalents and short-term investments as of September 30, 2020 is subject to change, and the Company’s actual cash, cash equivalents and short-term investments as of September 30, 2020 may differ materially from this preliminary estimate. Accordingly, you should not place undue reliance on this preliminary estimate.

The information contained in Item 2.02 of this Current Report on Form 8-K (the “Current Report”) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 7.01. Regulation FD Disclosure.

On September 30, 2020, the Company posted a slide presentation in the “Investors & Media” portion of its website at www.selectabio.com containing topline data for the Phase 2 COMPARE trial comparing the efficacy of SEL-212, a combination of the Company’s ImmTOR immune tolerance platform and a therapeutic uricase enzyme (pegadricase), to pegloticase (KRYSTEXXA®), the currently approved uricase in the United States, for the treatment of chronic refractory gout (the “COMPARE Results”). A copy of the slide presentation is attached as Exhibit 99.1 to this Current Report.

The information contained in Item 7.01 of this Current Report (including Exhibit 99.1 attached hereto) shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly provided by specific reference in such a filing. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

Item 8.01. Other Events.

The Company recently updated its business information as follows:

COMPARE Trial

On September 30, 2020, the Company announced the COMPARE Results.

In accordance with U.S. Food and Drug Administration (FDA) guidance on Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency (June 2020), 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 statistical analysis. This was necessary due to increased protocol deviations in the intention-to-treat (ITT) population observed during the ongoing COVID-19 pandemic. Data are therefore presented per protocol (PP*) and ITT.

Topline results from the Phase 2 COMPARE trial are as follows:

- **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:** SUA < 6 mg/dL for at least 80% of the time during months 3 and 6 combined: 59% SEL-212 versus 46% pegloticase, PP, p=0.056, 53% SEL-212 versus 46% pegloticase, ITT, p=0.181.
 - **Statistically significant higher response rate of SEL-212 during month 3:** SUA < 6 mg/dL for at least 80% of the time during month 3: PP: 70% SEL-212 versus 51% pegloticase, p=0.019, ITT: 70% SEL-212 versus 54% pegloticase, p=0.017.
 - **Numerically higher response rate of SEL-212 during month 6:** SUA < 6 mg/dL for at least 80% of the time during month 6: PP: 61% SEL-212 versus 47% pegloticase, p=0.053, ITT: 54% SEL-212 versus 47% pegloticase, p=0.179.
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- **Statistically significant greater overall reduction in mean SUA levels in SEL-212 versus pegloticase:** Serum uric acid levels were reduced by an average of 6.68 mg/dL (computed by subtracting baseline SUA from mean SUA during the treatment period) for patients treated with SEL-212 versus 4.51 mg/dL for patients treated with pegloticase, p=0.003, during months 3 and 6 combined, PP; ITT: 6.79 mg/dL SEL-212 versus 4.85 mg/dL pegloticase, p=0.003.
- **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:** Approximately 41% of patients in the phase 2 COMPARE trial had visible tophi at baseline. A greater differential on the primary endpoint between SEL-212 versus pegloticase on patients with tophi was observed: PP: 58% SEL-212 versus 39% pegloticase; ITT: 57% SEL-212 versus 41% pegloticase. In these patients, the mean SUA levels were reduced by an average of 7.42 mg/dL for patients treated with SEL-212 versus 4.64 mg/dL for patients treated with pegloticase, p=0.016, during months 3 and 6 combined, PP; ITT: 7.32 mg/dL for SEL-212 versus 4.89 mg/dL for pegloticase, p=0.019, ITT.
- **SEL-212 and pegloticase showed favorable safety results and were well-tolerated:** There were no deaths during the study. There were no notable differences in serious Treatment Emergent Adverse Events (TEAEs), treatment-related serious TEAEs, or infusion reactions between the two groups. A full analysis of safety signals, including gout flare incidence and severity, awaits evaluation of the full data set and will be reported together with the full efficacy analysis at a later medical meeting.

SEL-212 has been licensed to Sobi, with Sobi undertaking development, regulatory and commercial activities in all markets outside of China. Selecta and Sobi recently announced the initiation of two double-blinded, placebo-controlled Phase 3 clinical trials (DISSOLVE I and DISSOLVE II) of SEL-212 for the treatment of chronic refractory gout. Topline data from the DISSOLVE program is expected in the second half of 2022, and a Biologics License Application (BLA) filing is expected in the first quarter of 2023.

Forward-Looking Statements

Any statements in this Current Report about the future expectations, plans and prospects of the Company, including without limitation, statements regarding the clinical development, regulatory, and commercialization activities related to SEL-212 by either the Company or Sobi, the availability and timing of data from the DISSOLVE Phase 3 clinical program, the timing and execution of Company's plans to submit a BLA for SEL-212, upcoming events and presentations, including with respect to the presentation of the Phase 2 COMPARE full data set, the sufficiency of the company's cash, cash equivalents and short-term investments, and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "hypothesize," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials including their uncertain outcomes, the effect of the COVID-19 pandemic on any of the Company's planned or ongoing clinical trials, manufacturing activities, supply chain and operations, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a particular clinical trial will be predictive of the final results of that trial or whether results of early clinical trials will be indicative of the results of later clinical trials, the unproven approach of the Company's ImmTOR technology, undesirable side effects of the Company's product candidates, the Company's reliance on third parties to manufacture its product candidates and to conduct its clinical trials as well as the impact of the COVID-19 pandemic on those third parties and their ability to continue their operations, the Company's inability to maintain its existing or future collaborations, licenses or contractual relationships and the inability of the Company's licensees to make up-front and milestone payments under these collaborations, its inability to protect its proprietary technology and intellectual property, management's ability to perform as expected, potential delays in regulatory approvals, the Company's business development strategy, the availability of funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements, the Company's recurring losses from operations and negative cash flows from operations raise substantial doubt regarding its ability to continue as a going concern, substantial fluctuation in the price of its common stock, and other important factors discussed in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020 filed with the U.S. Securities and Exchange Commission (SEC), and in other filings that the Company makes with the SEC. In addition, any forward-looking statements included in this Current Report represent the Company's views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. The Company specifically disclaims any intention to update any forward-looking statements included in this Current Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	COMPARE Results Slide Presentation of Selecta Biosciences, Inc. dated September 30, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SELECTA BIOSCIENCES, INC.

Date: September 30, 2020

By: /s/ Carsten Brunn, Ph.D.

Carsten Brunn, Ph.D.

President and Chief Executive Officer



Phase 2 COMPARE Trial Topline Data Presentation

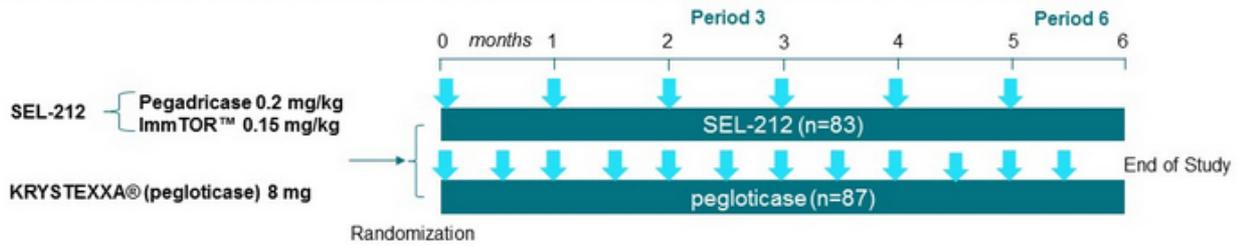
September 30, 2020

Safe Harbor / Disclaimer

Any statements in this presentation about the future expectations, plans and prospects of Selecta Biosciences, Inc. ("the company"), including without limitation, statements regarding the clinical development, regulatory, and commercialization activities related to SEL-212 by either the company or Sobi, including with respect to anticipated geographic markets, the availability and timing of data from the DISSOLVE Phase 3 clinical program, the timing and execution of company's plans to submit a BLA for SEL-212, the potential market opportunity for SEL-212, the potential of SEL-212 to address unmet needs in chronic refractory gout patients including sustained reduction in SUA levels, longer duration of treatment, and elimination of tophi with a convenient monthly treatment, the potential treatment applications and regulatory and clinical development of the company's product candidates utilizing the ImmTOR platform in areas such as enzyme therapy and gene therapy and related timing, the potential of the ImmTOR technology platform generally and the company's ability to grow its strategic collaborations, upcoming events and presentations, including with respect to the presentation of the Phase 2 COMPARE full data set, and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "hypothesize," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials including their uncertain outcomes, the effect of the COVID-19 pandemic on any of the company's planned or ongoing clinical trials, manufacturing activities, supply chain and operations, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a particular clinical trial will be predictive of the final results of that trial or whether results of early clinical trials will be indicative of the results of later clinical trials, the unproven approach of the company's ImmTOR technology, undesirable side effects of the company's product candidates, the company's reliance on third parties to manufacture its product candidates and to conduct its clinical trials as well as the impact of the COVID-19 pandemic on those third parties and their ability to continue their operations, the company's inability to maintain its existing or future collaborations, licenses or contractual relationships and the inability of the company's licensees to make up-front and milestone payments under these collaborations, its inability to protect its proprietary technology and intellectual property, management's ability to perform as expected, potential delays in regulatory approvals, the company's business development strategy, the availability of funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements, the company's recurring losses from operations and negative cash flows from operations raise substantial doubt regarding its ability to continue as a going concern, substantial fluctuation in the price of its common stock, and other important factors discussed in the "Risk Factors" section of the company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020 filed with the U.S. Securities and Exchange Commission (SEC), and in other filings that the company makes with the SEC. In addition, any forward-looking statements included in this presentation represent the company's views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. The company specifically disclaims any intention to update any forward-looking statements included in this presentation.

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

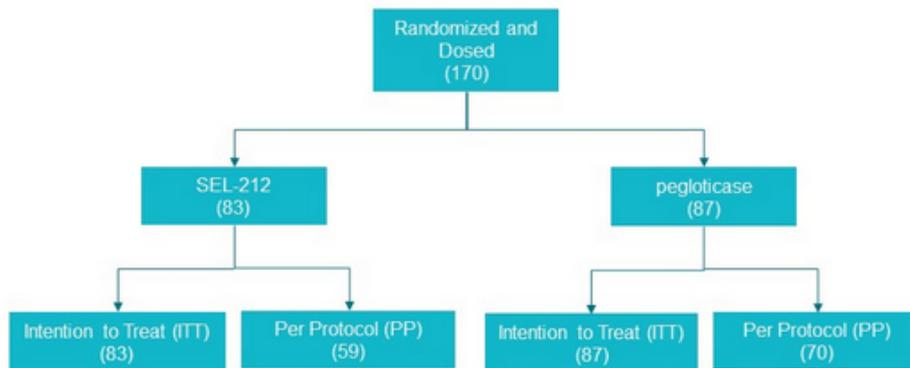
- Chronic refractory gout with serum uric acid (SUA) ≥ 7 mg/dL and one of the following:
 - ≥ 1 tophus **OR** ≥ 3 gout flares in last 18 months **OR** diagnosis of gouty arthritis

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.



(1) Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency: Guidance for Industry, FDA, June 2020.

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

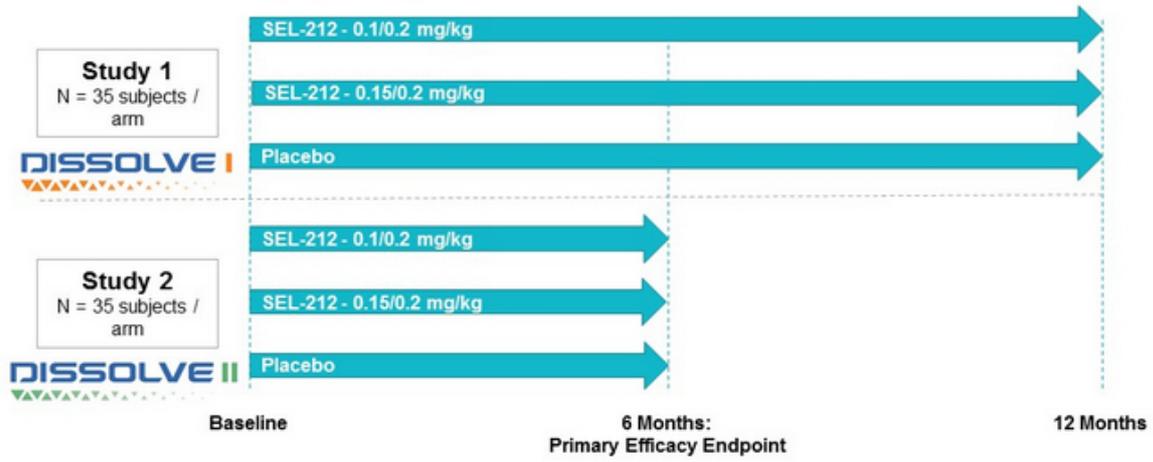
Both SEL-212 and pegloticase were shown to be safe and well-tolerated

- 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