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): March 21, 2023

SELECTA BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-37798	26-1622110
(State or other jurisdiction of incorporation)	(Commission File Number)	(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	The Nasdaq Stock Market LLC

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 7.01 Regulation FD Disclosure.

On March 21, 2023, Selecta Biosciences, Inc. (the "Company") issued a press release announcing top-line data from the Phase 3 DISSOLVE I & II placebo controlled randomized clinical trials to determine safety and efficacy of two different dose levels of SEL-212 in adult patients with chronic refractory gout. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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.

As described above, on March 21, 2023, the Company announced top-line data from the Phase 3 DISSOLVE I & II trials. Top-line results include:

- During month six, 56% and 48% of DISSOLVE I patients randomized to receive SEL-212 at the high dose of 0.15 mg/kg of ImmTOR ($p<0.0001$) and the low dose of 0.1 mg/kg of ImmTOR ($p<0.0001$), respectively, reached the primary endpoint of serum urate (SU) levels < 6 mg/dL for 80% of the time in month six, compared to 4% of patients randomized to receive placebo. During month six, 47% and 41% of DISSOLVE II patients randomized to receive SEL-212 at the high dose ($p=0.0002$) and the low dose ($p=0.0015$) of ImmTOR, respectively, reached the primary endpoint, compared to 12% of patients randomized to receive placebo.
- 65% and 47% of DISSOLVE I patients 50 years and older randomized to receive SEL-212 at the high dose ($p<0.0001$) and the low dose ($p<0.0001$) of ImmTOR, respectively, reached the primary endpoint, compared to 5% of patients randomized to receive placebo; 48% and 45% of DISSOLVE II patients 50 years and older randomized to receive SEL-212 the high dose ($p=0.0017$) and the low dose ($p=0.0044$) of ImmTOR, respectively, reached the primary endpoint, compared to 14% of patients randomized to receive placebo.
- In DISSOLVE I, a significant and clinically meaningful overall reduction of 69% in mean SU levels at month six was observed in patients randomized to receive SEL-212 at the high dose, as compared with placebo.
- Adverse events (AEs) identified in the trials were expected, including mild to moderate stomatitis which was observed in 3.4% of the low dose group and 9.2% of the high dose group compared to 0% in placebo across both trials, and a greater number of infusion reactions were observed at 24 hours and 1 hour after drug administration in both treatment groups compared to placebo. Treatment-related serious AEs were observed in six patients, including two cases of anaphylaxis and one gout flare in both the high and low dose treatment groups. Only 4.5% of patients receiving the low dose of SEL-212 and 3.4% at the high dose of SEL-212 had infusion reactions, across both trials, evaluated one hour post-dose. All infusion reactions occurred within the first three infusions, and each occurred during infusions and completely resolved with infusion halt and symptomatic treatment. There was one death in the six-month extension phase of the DISSOLVE I trial, which was caused by a motor vehicle accident unrelated to the study drug. There was no difference in gout flares when both treatment groups were compared to placebo.
- In the six-month extension period for the DISSOLVE I trial, 75% of patients who completed six months of SEL-212 treatment as responders were observed to continue to be successfully treated through 12 months with no infusion reactions or safety signals.

In connection with the announcement of its Phase 3 DISSOLVE I & II trial results, the Company is hosting an investor call to present the data from the trials. A copy of the slide presentation to be presented during the investor call is attached hereto as Exhibit 99.2 and is incorporated into this Item 8.01 by reference. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

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 unique proprietary technology platform of the Company and its partners, the anticipated benefits of the Company's licensing and development agreements, the potential of ImmTOR to enable re-dosing of AAV gene therapy and to mitigate immunogenicity, the potential of ImmTOR and the Company's product pipeline to treat chronic refractory gout, MMA, IgAN, other autoimmune diseases, lysosomal storage disorders, or any other disease, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the anticipated timing or the outcome of the FDA's review of the Company's regulatory filings, the Company's and its partners' ability to conduct its and their clinical trials and preclinical studies, the timing or making of any regulatory filings, the anticipated timing or outcome of selection of developmental product candidates, the potential treatment applications of product candidates utilizing the ImmTOR platform in areas such as gene therapy, gout and autoimmune disease, the ability of the Company and its partners where applicable to develop gene therapy products using ImmTOR, the novelty of treatment paradigms that the Company is able to develop, whether the observations made in non-human study subjects will translate to studies performed with human beings, the potential of any therapies developed by the Company to fulfill unmet medical needs, the Company's plan to apply its ImmTOR technology platform to a range of biologics for rare and orphan genetic diseases, the potential of the Company's technology to enable repeat administration in gene therapy product candidates and products, the ability to re-dose patients and the potential of ImmTOR to allow for re-dosing, the potential to safely re-dose AAV, the ability to restore transgene expression, the potential of the ImmTOR technology platform generally and the Company's ability to grow its strategic partnerships and enrollment in the Company's clinical trials 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 proof of concept trials, including the uncertain outcomes, 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 and whether results of early clinical trials will be indicative of the results of later clinical trials, the ability to predict results of studies performed on human beings based on results of studies performed on non-human subjects, the unproven approach of the Company's ImmTOR technology, potential delays in enrollment of patients, undesirable side effects of the Company's product candidates, its reliance on third parties to manufacture its product candidates and to conduct its clinical trials, the Company's inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, potential delays in regulatory approvals, 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, substantial fluctuation in the price of the Company's common stock, risks related to geopolitical conflicts and pandemics and other important factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K, and in other filings that the Company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this Current Report represent the Company's views only as of the date hereof 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.

EXHIBIT NUMBER	EXHIBIT DESCRIPTION
99.1	Press Release Issued on March 21, 2023
99.2	Slide Presentation of Selecta Biosciences, Inc. dated March 21, 2023
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: March 21, 2023

By: /s/ Carsten Brunn, Ph.D.
Carsten Brunn, Ph.D.
President and Chief Executive Officer

Phase 3 DISSOLVE Program of SEL-212 in Chronic Refractory Gout Meets Primary Endpoint

—Response rate of 56% in patients treated monthly with high dose SEL-212 in DISSOLVE I and 47% in DISSOLVE II

—In patients 50 years and older, response rate with high dose SEL-212 was 65% in DISSOLVE I and 48% in DISSOLVE II

—75% of subjects in the DISSOLVE I extension phase on active treatment were responders through 12 months of therapy with no infusion reactions or new safety signals

—Favorable safety profile with 3.4% of patients with infusion reactions at high dose

—Selecta will host a conference call and webcast today at 8:30 AM ET / 2:30 PM CET

WATERTOWN, Mass./STOCHOLM SWEDEN March 21, 2023 — Selecta Biosciences, Inc. (NASDAQ: SELB) and Sobi®, today announced positive topline results from the Phase 3 DISSOLVE I & II placebo controlled randomized clinical trials to determine safety and efficacy of two different dose levels of SEL-212 in adult patients with chronic refractory gout. The DISSOLVE I (the "US Study") met its primary endpoint, with 56% of patients receiving monthly doses of SEL-212 at 0.15 mg/kg achieving a response (defined as achievement and maintenance of reduction in serum urate (SU) <6mg/dL for at least 80% of the time during month six). The DISSOLVE II (the "Global Study") also met its primary endpoint, with 47% receiving monthly doses of SEL-212 at 0.15 mg/kg achieving a response. SEL-212 is a combination of Selecta's ImmTOR immune tolerance platform and a therapeutic uricase enzyme (pegadricase).

Herbert S. B. Baraf, MD, FACP, MACR, Clinical Professor of Medicine, George Washington University School of Medicine and Health Sciences; Principal Investigator of the DISSOLVE Program said, "Based on these data, I believe SEL-212 has the potential to provide an important new uricase-based treatment option for patients with chronic refractory gout. These patients suffer from chronic pain and endure debilitating functional impairment. The demonstrated profound lowering of the serum uric acid in the DISSOLVE program should meaningfully impact the quality of the lives of these severely afflicted patients. SEL-212's favorable safety profile, coupled with the convenient once monthly treatment regimen, will be welcomed by patients with this challenging form of gout and the physicians who treat them."

Topline results from the Phase 3 DISSOLVE program are as follows:

- **DISSOLVE I had a statistically significant higher response rate of SEL-212 during month six**: 56% and 48% of patients randomized to receive SEL-212 at the high dose of 0.15 mg/kg ($p<0.0001$) and the low dose of 0.1 mg/kg ($p<0.0001$) of ImmTOR, respectively, versus 4% of patients randomized to receive the placebo reached the primary endpoint

- **DISSOLVE II also had a statistically significant higher response rate of SEL-212 during month six**: 47% and 41% of patients randomized to receive SEL-212 at high dose (p=0.0002) and low dose (p=0.0015) of ImmTOR, respectively, versus 12% of patients randomized to receive the placebo reached the primary endpoint
- **Statistically significant higher response rate in patients 50 years and older at the high dose in DISSOLVE I and II:** 65% and 47% of DISSOLVE I patients randomized to receive SEL-212 at the high dose (p<0.0001) and the low dose (p<0.0001) of ImmTOR, respectively, versus 5% of patients randomized to receive the placebo reached the primary endpoint; 48% and 45% of DISSOLVE II patients randomized to receive SEL-212 the high dose (p=0.0017) and low dose (p=0.0044) of ImmTOR, respectively, versus 14% of patients randomized to receive the placebo reached the primary endpoint
- **Significant and clinically meaningful overall reduction of 69% in mean SU levels in patients randomized to receive SEL-212 at 0.15mg/kg in DISSOLVE I, as compared with placebo**: Serum urate levels were reduced by an average of 5.3 mg/dL (computed by subtracting baseline SU from mean SU during the treatment period 6) for patients treated with both doses of SEL-212 (p<0.001) compared to 0.3 mg/dL increase in patients receiving placebo
- **SEL-212 was observed to have a favorable safety profile and was well-tolerated across both doses of ImmTOR:** The adverse events (AEs) identified in the trials were expected, including mild to moderate stomatitis which was seen in 3.4% of the low dose group and 9.2% of the high dose group versus 0% in placeboand a greater number of infusion reactions at 24 hours and 1 hour after drug administration in both treatment groups versus placebo. Treatment-related serious AEs were observed in six patients, including two cases of anaphylaxis and one gout flare in both the high and low dose treatment groups. Only 4.5% of patients receiving the low dose of SEL-212 and 3.4% at the high dose of SEL-212 had infusion reactions, evaluated 1 hour post dose. All infusion reactions occurred within the first three infusions, and each occurred during infusions and completely resolved with infusion halt and symptomatic treatment. There was one death in the six-month extension phase of the trial, which was caused by a motor vehicle accident unrelated to the study drug. There was no difference in gout flares when both treatment groups were compared to placebo.

The six-month extension period in the DISSOLVE I trial, showed that the majority (75%) of patients who completed 6 months of SEL-212 treatment as a responder, continued to be successfully treated through 12 months with no infusion reactions or safety signals.

Peter Traber, M.D., Chief Medical Officer of Selecta, said, “We are very pleased by the robust response rate in the high dose group of SEL-212, especially across older patients (≥50 years)

and the observed durability of response with no infusion reactions or new safety signals through the extension period. We believe the results of SEL-212 observed in these two Phase 3 trials suggest the potential to provide a new treatment solution with convenient once monthly dosing."

Carsten Brunn, Ph.D., President and Chief Executive Officer of Selecta, commented, "The positive readout of the DISSOLVE program is a pivotal milestone for SEL-212, a novel once-monthly treatment option, and for the many patients suffering from chronic refractory gout. We believe the strong efficacy and favorable safety data observed across both doses of ImmTOR in this program positions ImmTOR as the only immune tolerance platform with positive Phase 3 data. We have dosed over 400 patients to date, and plan to continue to leverage our growing safety database to drive forward our clinical pipeline powered by our ImmTOR technology."

Guido Oelkers, Ph.D., President and Chief Executive Officer of Sobi, added, "We are thrilled with the positive results of the DISSOLVE program and the potential to bring this new treatment option to improve the lives of patients with chronic refractory gout. We are poised to move SEL-212 forward towards commercialization and intend to file marketing authorization applications in the U.S. in the first half of 2024."

Anders Ullman, M.D., Ph.D., Head of Research & Development and Medical Affairs, Chief Medical Officer of Sobi, commented, "Altogether, the DISSOLVE program data instils confidence in SEL-212, and we look forward to further exploring its therapeutic potential as we drive forward development on a potential commercial path forward. We remain committed to bringing our therapies to the global patient community as quickly as possible."

Detailed results from the DISSOLVE I and DISSOLVE II trials are expected to be presented at an upcoming medical meeting. Regulatory submission in the U.S. is anticipated in the first half of 2024.

Sobi licensed SEL-212 from Selecta in June 2020 and is responsible for development, regulatory and commercial activities in all markets outside of China. Selecta is responsible for ImmTOR manufacturing. The Phase 3 program for SEL-212 was run by Selecta and funded by Sobi. Under the terms of the agreement with Sobi, Selecta is eligible to receive additional development and regulatory milestone payments totalling $65 million and up to an additional $550 million in commercial milestones. Selecta is also eligible to receive tiered double-digit royalties on sales.

Selecta Conference Call and Webcast Reminder

Selecta management will host a conference call at 8:30 AM ET / 2:30 PM CET today to present the joint topline data from the DISSOLVE clinical program. Investors and the public can access the live webcast here. Individuals may also participate in the live call via telephone by dialing (877) 407-0792 (domestic) or +1 (201) 689-8263 (international). The archived webcast of this call and a copy of the presentation via the Investors & Media section of Selecta's website, www.selectabio.com.

DISSOLVE clinical program

The Phase 3 DISSOLVE clinical program consisted of two double-blind, placebo-controlled studies of SEL-212, titled "A Randomized Double-Blind, Placebo-Controlled Study of SEL-212 in Patients with Gout Refractory to Conventional Therapy," in which SEL-212 was evaluated at two doses of ImmTOR (0.1 mg/kg and 0.15 mg/kg), and one dose of pegadricase (0.2 mg/kg) in both studies. In DISSOLVE I, safety and efficacy were evaluated at six months and with a six-month blinded extension to evaluate safety. DISSOLVE II assessed safety and efficacy at only the six-month time point, with no extension. The primary endpoint in both studies was serum urate (SU) control during month six, a well-validated measure of disease severity in chronic refractory gout. Secondary endpoints include tender and swollen joint counts, tophus burden, patient-reported outcomes of activity limitation and quality of life and gout flare incidence. For more details about the study, visit clinicaltrials.gov (NCT04513366).

SEL-212

SEL-212 is a novel investigational combination medicine designed to reduce serum urate (SU) levels in people with chronic refractory gout, potentially reducing harmful tissue urate deposits which when left untreated can lead to debilitating gout flares and joint deformity. SEL-212 consists of pegadricase, Selecta's proprietary pegylated uricase, co-administered with ImmTOR, designed to mitigate the formation of anti-drug antibodies (ADAs). ADAs develop due to unwanted immune responses to biologic medicines, reducing their efficacy and tolerability, which remains an issue across multiple therapeutic modalities and disease states including chronic refractory gout.

Chronic refractory gout

Gout is the most common form of inflammatory arthritis with more than 8.3 million people in the United States having been diagnosed with gout, which is caused by high levels of uric acid in the body that accumulate around the joints and other tissues and can result in flares that cause intense pain. Approximately 160,000 people in the United States suffer from chronic gout refractory to conventional medicines, a painful and debilitating condition in people with SU levels above 6 mg/dL and therefore have several flares per year and can develop nodular masses of uric acid crystals known as tophi. Elevated SU levels have been associated with diseases of the heart, vascular system, metabolism, kidney and joints.

About Selecta Biosciences, Inc.

Selecta Biosciences Inc. (NASDAQ: SELB) is a clinical stage biotechnology company leveraging its ImmTOR™ platform to develop tolerogenic therapies that selectively mitigate unwanted immune responses. With a proven ability to induce tolerance to highly immunogenic proteins, ImmTOR has the potential to amplify the efficacy of biologic therapies, including redosing of life-saving gene therapies, as well as restore the body's natural self-tolerance in autoimmune

diseases. Selecta has several proprietary and partnered programs in its pipeline focused on enzyme therapies, gene therapies, and autoimmune diseases. Selecta Biosciences is headquartered in the Greater Boston area. For more information, please visit www.selectabio.com.

Sobi®

Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare and debilitating diseases. Providing reliable access to innovative medicines in the areas of haematology, immunology and specialty care, Sobi has approximately 1,600 employees across Europe, North America, the Middle East, Asia and Australia. In 2022, revenue amounted to SEK 18.8 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com, LinkedIn and YouTube.

Selecta Forward-Looking Statements

Any statements in this press release about the future expectations, plans and prospects of Selecta Biosciences, Inc. (the "Company"), including without limitation, statements regarding the Company's cash runway, the unique proprietary technology platform of the Company, and the unique proprietary platform of its partners, the potential of ImmTOR to enable re-dosing of AAV gene therapy and to mitigate immunogenicity, the potential of ImmTOR and the Company's product pipeline to treat chronic refractory gout, MMA, IgAN, other autoimmune diseases, lysosomal storage disorders, or any other disease, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the anticipated timing or the outcome of the FDA's review of the Company's regulatory filings, the Company's and its partners' ability to conduct its and their clinical trials and preclinical studies, the timing or making of any regulatory filings, the anticipated timing or outcome of selection of developmental product candidates, the potential treatment applications of product candidates utilizing the ImmTOR platform in areas such as gene therapy, gout and autoimmune disease, the ability of the Company and its partners where applicable to develop gene therapy products using ImmTOR, the novelty of treatment paradigms that the Company is able to develop, whether the observations made in non-human study subjects will translate to studies performed with human beings, the potential of any therapies developed by the Company to fulfill unmet medical needs, the Company's plan to apply its ImmTOR technology platform to a range of biologics for rare and orphan genetic diseases, the potential of the Company's technology to enable repeat administration in gene therapy product candidates and products, the ability to re-dose patients and the potential of ImmTOR to allow for re-dosing, the potential to safely re-dose AAV, the ability to restore transgene expression, the potential of the ImmTOR technology platform generally and the Company's ability to grow its strategic partnerships and enrollment in the Company's clinical trials 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 proof of concept trials, including the uncertain outcomes, 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 and whether results of early clinical trials will be indicative of the results of later clinical trials, the ability to predict results of studies performed on human beings based on results of studies performed on non-human subjects, the unproven approach of the Company's ImmTOR technology, potential delays in enrollment of patients, undesirable side effects of the Company's product candidates, its reliance on third parties to manufacture its product candidates and to conduct its clinical trials, the Company's inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, potential delays in regulatory approvals, 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, substantial fluctuation in the price of the Company's common stock, risks related to geopolitical conflicts and pandemics and other important factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K, and in other filings that the Company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release 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 press release, except as required by law.

Selecta

For Investors and Media:

Blaine Davis
Chief Financial Officer
609-865-8278
bdavis@selectabio.com

Sobi contacts and other information

For details on how to contact the Sobi Investor Relations Team, please click here. For Sobi Media contacts, click here.

This information is information that Sobi is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below, on 21 March 2023 at 08:30 CET.

Thomas Kudsk Larsen
Head of Communication and Investor Relations

Exhibit 99.2

Nasdaq SELB

DISSOLVE I & II Phase 3 Clinical Trials: Topline Data

For release on March 21, 2023

Forward-looking statements

Any statements in this presentation about the future expectations, plans and prospects of Selecta Biosciences, Inc. (the "Company"), including without limitation, statements regarding the Company's cash runway, the unique proprietary technology platform of the Company, and the unique proprietary platform of its partners, the potential of ImmTOR to enable re-dosing of AAV gene therapy and to mitigate immunogenicity, the potential of ImmTOR and the Company's product pipeline to treat chronic refractory gout, MMA, IgAN, other autoimmune diseases, lysosomal storage disorders, or any other disease, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the anticipated timing or the outcome of the FDA's review of the Company's regulatory filings, the Company's and its partners' ability to conduct its and their clinical trials and preclinical studies, the timing or making of any regulatory filings, the anticipated timing or outcome of selection of developmental product candidates, the potential treatment applications of product candidates utilizing the ImmTOR platform in areas such as gene therapy, gout and autoimmune disease, the ability of the Company and its partners where applicable to develop gene therapy products using ImmTOR, the novelty of treatment paradigms that the Company is able to develop, whether the observations made in non-human study subjects will translate to studies performed with human beings, the potential of any therapies developed by the Company to fulfill unmet medical needs, the Company's plan to apply its ImmTOR technology platform to a range of biologics for rare and orphan genetic diseases, the potential of the Company's technology to enable repeat administration in gene therapy product candidates and products, the ability to re-dose patients and the potential of ImmTOR to allow for re-dosing, the potential to safely re-dose AAV, the ability to restore transgene expression, the potential of the ImmTOR technology platform generally and the Company's ability to grow its strategic partnerships and enrollment in the Company's clinical trials 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 proof of concept trials, including the uncertain outcomes, 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 and whether results of early clinical trials will be indicative of the results of later clinical trials, the ability to predict results of studies performed on human beings based on results of studies performed on non-human subjects, the unproven approach of the Company's ImmTOR technology, potential delays in enrollment of patients, undesirable side effects of the Company's product candidates, its reliance on third parties to manufacture its product candidates and to conduct its clinical trials, the Company's inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, potential delays in regulatory approvals, 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, substantial fluctuation in the price of the Company's common stock, risks related to geopolitical conflicts and pandemics and other important factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K, and in other filings that the Company makes with the Securities and Exchange Commission. 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, except as required by law.

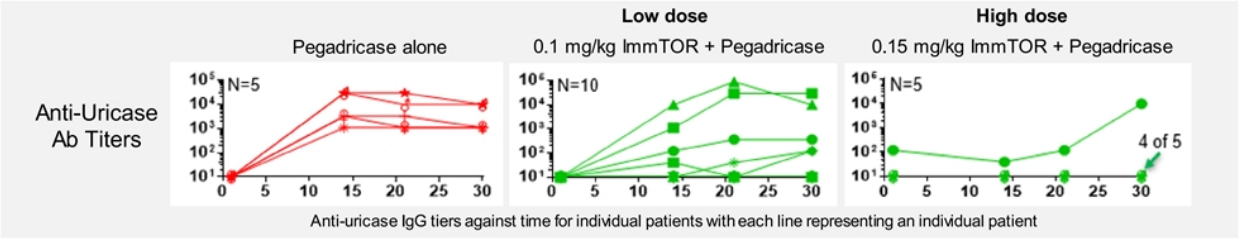
Both Phase 3 Studies and both tested doses met primary efficacy endpoints, achieving a statistically significant response rate with SEL-212 versus placebo

- 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 .

SEL-212 is a combination of pegadricase plus ImmTOR for treatment of chronic refractory gout

- Pegadricase is a novel and potent yeast uricase enzyme that converts serum urate (SU) into a highly water-soluble molecule that is readily excreted in the urine
- While pegadricase markedly reduces SU, it also elicits a vigorous immune response with anti-drug antibodies in all individuals following a single dose
- A single dose of ImmTOR™, an immune-tolerizing nanoencapsulated rapamycin (sirolimus), followed by pegadricase was observed to result in a dose-dependent inhibition of anti-uricase antibodies[1]



Anti-uricase IgG tiers against time for individual patients with each line representing an individual patient

- Phase 2 studies observed that once monthly administration of SEL-212 robustly lowered SU in gout patients over a duration of 6 months
- Based on these findings, the FDA agreed with Selecta Biosciences to evaluate two optimal doses of SEL-212 in Phase 3 clinical trials

[1] Sands et al. Nature Communications 2022. 13:272 – Figure 4

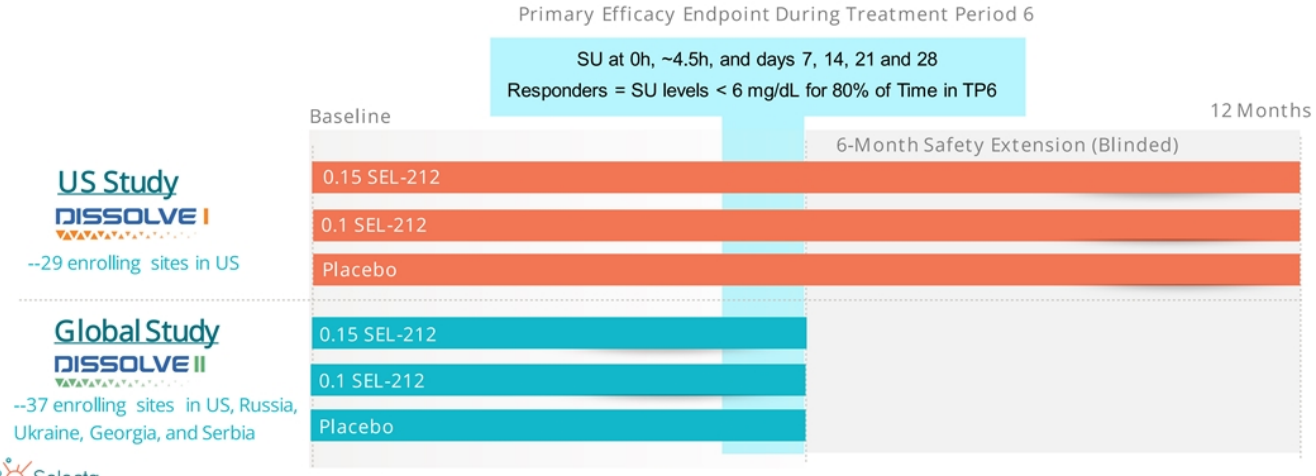
Two randomized double-blind, placebo-controlled Phase 3 studies of SEL-212 in patients with gout refractory to conventional therapy

Both studies have three arms, randomized 1:1:1 to a single dose in each 28-day treatment period (TP):

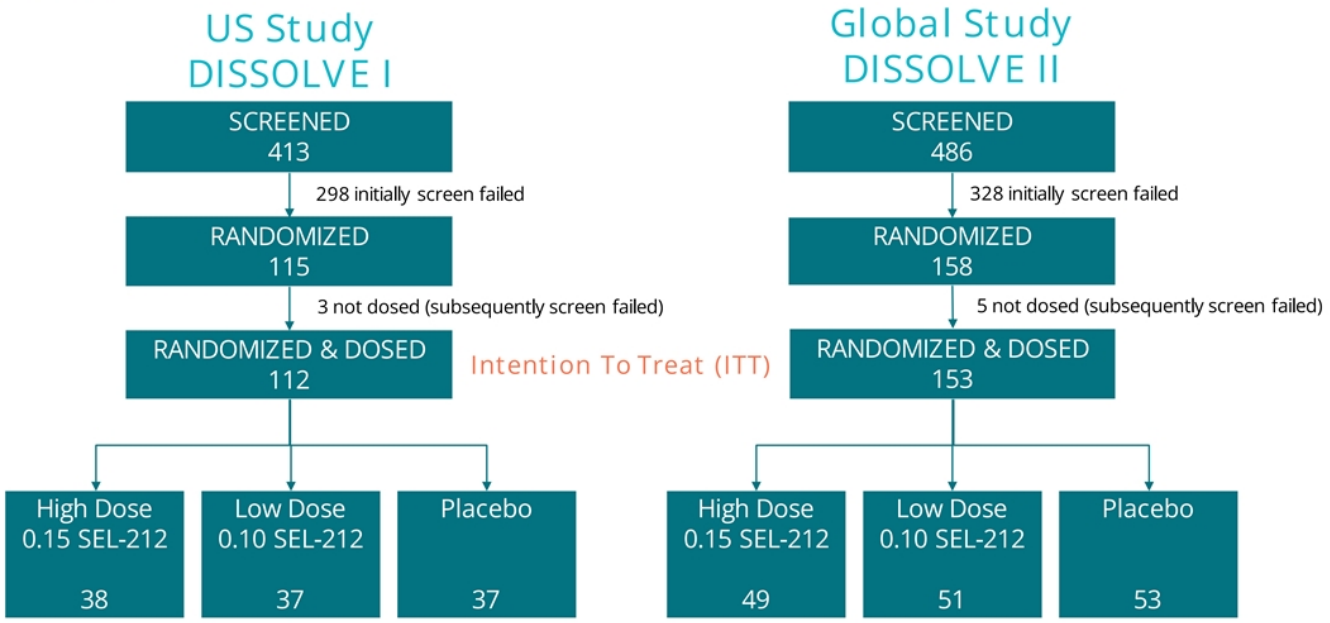
High dose - 0.15 SEL-212
IV infusion of 0.15mg/kg ImmTOR followed by IV infusion of 0.2mg/kg pegadricase

Low dose - 0.1 SEL-212
IV infusion of 0.1mg/kg ImmTOR followed by IV infusion of 0.2mg/kg pegadricase

Placebo
IV infusion of saline followed by IV infusion of saline



Subject flow



Baseline demographic characteristics

Balanced for age, BMI, sex, and race across treatment groups in both studies

	US Study (DISSOLVE I)				Global Study (DISSOLVE II)			
Treatment Group (Number-ITT)	High dose (38)	Low dose (37)	Placebo (37)	Total (112)	High dose (49)	Low dose (51)	Placebo (53)	Total (153)
Age in Years: m (SD)	54 (12)	55 (10.6)	54 (10.6)	54 (11)	56 (9.7)	53 (10.6)	57 (10.1)	55 (10.2)
Age ≥ 50 years: Percent	66	73	60	66	76	61	79	72
BMI: Mean (SD) (kg/m^2)	35 (6.4)	34 (7.5)	33 (6.3)	34 (6.7)	33 (5.2)	32 (6.3)	33 (6.2)	32 (5.9)
Gender: Percent								
Male	92	95	100	96	96	96	98	97
Female	8	5	0	4	4	4	2	3
Race: Percent								
White	71	76	59	69	96	88	83	89
Non-white	29	24	41	31	4	12	17	11
Region: n (Percent)								
United States	38 (100)	37 (100)	37 (100)	112 (100)	14 (29)	18 (35)	24 (45)	56 (37)
Europe [1]					35 (71)	33 (65)	29 (55)	97 (63)
Russia & Ukraine					9 (18)	7 (14)	7 (13)	23 (15)

[1] Russia, Ukraine, Serbia, Georgia

Baseline disease characteristics

- Baseline characteristics were reasonably well balanced across treatment groups in each study
- Gout severity was somewhat greater in the Global Study versus the US Study

	US Study (DISSOLVE I)				Global Study (DISSOLVE II)			
Treatment Group (Number-ITT)	High dose (38)	Low dose (37)	Placebo (37)	Total (112)	High dose (49)	Low dose (51)	Placebo (53)	Total (153)
Gout diag. (yr.): m (SD)	14.3 (10.5)	11.9 (10.0)	12.4 (9.6)	12.9 (10.0)	10.8 (9.0)	11.6 (9.0)	10.5 (7.5)	11.0 (8.5)
Baseline Tophi : n (%)	22 (57.9)	21 (56.8)	21 (56.8)	64 (57.1)	33 (67.3)	34 (66.7)	36 (67.9)	103 (67.3)
SU (mg/dL): m (SD)	8.7 (1.4)	8.2 (1.9)	8.3 (1.5)	8.4 (1.6)	8.4 (1.7)	8.6 (1.5)	9.1 (1.6)	8.7 (1.6)
Tender Joints: m (SD)	1.9 (5.1)	3.5 (6.4)	2.6 (9.9)	2.7 (7.3)	11.6 (11.5)	11.1 (12.8)	10.6 (11.5)	11.1 (11.8)
Swollen Joints: m (SD)	2.0 (4.3)	3.6 (7.5)	1.0 (3.4)	2.2 (5.4)	6.9 (10.4)	4.4 (8.1)	7.0 (9.0)	6.1 (9.2)

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 α = 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.

Key secondary endpoints: Mean and percent reduction in serum urate

- Marked reduction of serum urate in both studies and for both low and high dose groups
- Other secondary endpoints are not yet available

	US Study (DISSOLVE I)			Global Study (DISSOLVE II)		
Key Secondary Endpoint ITT Set	High dose (38)	Low dose (37)	Placebo (37)	High dose (49)	Low dose (51)	Placebo (53)
SU Δ from BL to TP6 (mg/dL, LS mean (SE))[1]	-5.3 (0.6)	-5.3 (0.6)	0.3 (0.6)	-5.0 (0.6)	-4.8 (0.6)	-0.5 (0.5)
LS Mean Difference (SE)	-5.6 (0.8)	-5.6 (0.8)	-	-4.5 (0.8)	-4.2 (0.8)	-
97.5% CI for Difference	[-7.5, -3.8]	[-7.4,-3.7]	-	[-6.1, -2.8]	[-6.0, -2.5]	-
p-value[3]	<0.001	<0.001	-	<0.001	<0.001	-
SU Percent Δ from BL to TP6 (LS mean (SE)[2]	-63.0 (7.1)	-59.6 (7.3)	5.7 (6.6)	-56.1 (6.8)	-58.3 (7.1)	-4.7 (6.1)
LS Mean Difference (SE)	-68.7 (9.8)	-65.3 (9.8)	-	-51.4 (8.9)	-53.5 (9.3)	-
97.5% CI for Difference	[-90.7, -46.8]	[-87.2,-43.4]	-	[-71.4, -31.3]	[-74.3, -32.8]	-
p-value[3]	<0.001	<0.001	-	<0.001	<0.001	-

[1] Reduction of mean sUA as computed by subtracting the Baseline (BL) sUA level from the mean sUA during Treatment Period 6 (TP6) defined as the area under the time curve divided by the corresponding time interval.

[2] Percent reduction mean sUA as computed by subtracting Baseline (BL) sUA level from the mean sUA during TP6 divided by the Baseline and reported as either absolute difference or percent difference.

[3] Analysis using ANCOVA model with reduction or percent reduction of mean SU at TP6 from baseline as dependent variable and randomization stratum and baseline SU as covariates. Missing values of change or percent change from baseline were multiple imputed by using the Recursively Partitioned Mixture Model. The means of treatment groups are pooled estimates after multiple imputation and 2-sided p-values.

All adverse events of special interest (AESI)[1]

- No difference in gout flares between treatment groups and placebo
- Stomatitis in treatment groups (3.4-9.2%), all mild to moderate intensity
- Low incidence of infusion reactions (3.4%-4.5%) in high and low dose groups, respectively

	Pooled Studies at 6-Month Primary Endpoint		
Safety Set	High dose (87) n (%)	Low dose (88) n (%)	Placebo (90) n (%)
≥1 Treatment-emergent AESI	55 (63.2)	60 (68.2)	49 (54.4)
Gout Flares	38 (43.7)	40 (45.5)	39 (43.3)
Infections (including viral)	20 (23.0)	16 (18.2)	15 (16.7)
COVID-19[2]	6 (6.9)	5 (5.7)	6 (6.7)
Infusion-related AEs (24h)	6 (6.9)	6 (6.8)	2 (2.2)
Infusion reactions (1h) incl.anaphylaxis	3 (3.4)	4 (4.5)	0 (0)
Hypertriglyceridemia[3]	7 (8.0)	8 (9.1)	6 (6.7)
Stomatitis[4]	8 (9.2)	3 (3.4)	0 (0)
Proteinuria/renal impairment/↑ creatinine	1 (1.1)	2 (2.3)	3 (3.3)
Thromboembolism	0 (0)	1 (1.1)	0 (0)
Leukopenia	0 (0)	2 (2.3)	0 (0)
Miscellaneous[5]	0 (0)	0 (0)	2 (2.2)

[1] AESIs included in protocol as agreed with FDA; No other TEAEs ≥5% [2] There were no other individual infections >2%
[3] Dyslipidemia/hypertriglyceridemia/hyperlipidemia [4] Stomatitis/oral ulcer/aphthous ulcer; 67% mild, 33% moderate [5] Influenza-like (1), ↑LDL (1)

Serious adverse events (SAEs)

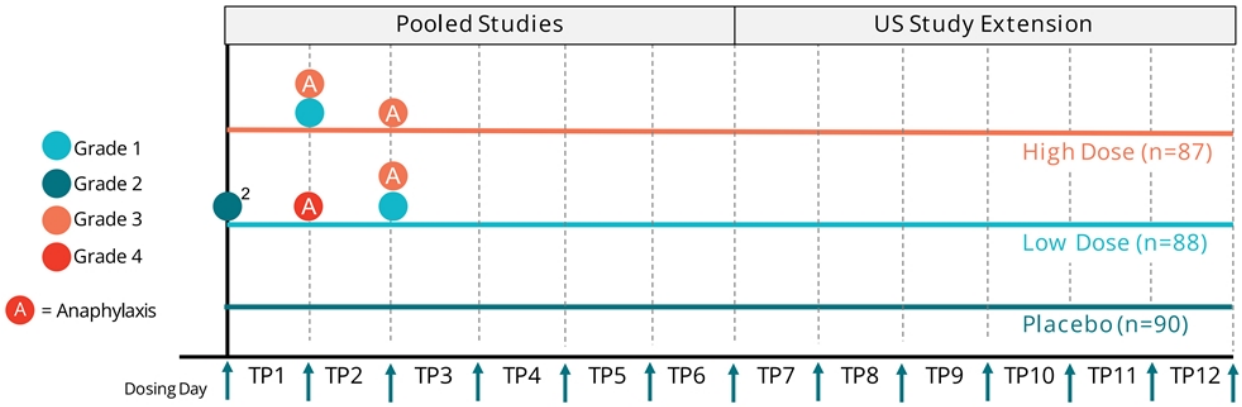
Six subjects (3.4%) in the pooled active treatment groups had an SAE related to treatment

	Pooled Studies at 6-Month Primary Endpoint		
Safety Set	High dose (87) n (%)	Low dose (88) n (%)	Placebo (90) n (%)
Subjects with at least 1 SAE	6 (6.9)	13 (14.8)	2 (2.2)
Subjects with treatment-related SAE	3 (3.4) [1]	3 (3.4) [2]	0 (0)
Total number of SAEs	6 (6.9)	16 (18.2)	2 (2.2)
Primary per Subject			
Infections	0 (0)	4 (4.5) [3]	1 (1.1) [4]
Anaphylaxis	2 (2.3)	2 (2.3)	0 (0)
Gout Flare	1 (1.1)	1 (1.1)	0 (0)
GI, Renal, Liver, & Neuro	2 (2.3) [5]	4 (4.5) [6]	1 (1.1) [7]
Resp, Card, & Vascular	1 (1.1) [8]	2 (2.3) [9]	0 (0)

[1] **US:** Gout flare (1), **Global:** Anaphylaxis (2); [2] **US:** Anaphylaxis (2), Gout Flare (1) [3] **US:** Periodontal infection/cellulitis (1), C. diff colitis (1)
[3] **Global:** Pneumonia/Resp Failure/Sepsis (1); infected tophus (1) [4] **Global:** COVID-19 (1) [5] **US:** GI bleed (1) **Global:** Acute Renal Injury (1)
[6] **US:** Presyncope (1), Cholelithiasis (1), Subarachnoid Hemorrhage (1), **Global:** Enteritis (1) [7] **Global:** Diverticular Hemorrhage (1)
[8] **Global:** Angina Pectoris (1) [9] **Global:** Pulmonary Embolism (1) Acute myocardial infarction (1)

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.

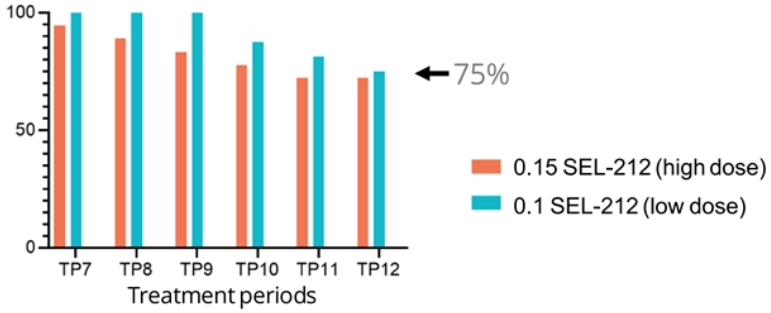
[2] Infusion reaction occurred during the infusion of ImmTOR; pegadricase not administered. All the other infusion reactions occurred during infusion of pegadricase.

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

- 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 .

Phase 3 trials are a massive team effort

Thank you to the entire team

but most importantly

participating patients & their families

clinical sites, principal investigators and clinical staff

Selecta Biosciences — **Clinical team & entire company that contributed to the SEL-212 program**

sobi rare strength — **Our partner in developing SEL-212**

parexel — **Our CRO partner in the conduct of the trials**

Clinical Advisors, Safety Board, and Specialty Vendors