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): October 22, 2018

SELECTA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37798**	**26-1622110**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

480 Arsenal Way
Watertown, MA 02472
(Address of principal executive offices) (Zip Code)

(617) 923-1400
(Registrant's telephone number, include 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))

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 October 22, 2018, Selecta Biosciences, Inc. (the "Company") announced new data from its ongoing Phase 2 Company-sponsored trial of SEL-212, for the treatment of chronic severe gout, which is assessing single ascending dose safety, pharmacokinetics and pharmacodynamics of SEL-212 in patients with elevated uric acid levels.

The Company will present the presentation poster furnished as Exhibit 99.1 to this Current Report on Form 8-K, which contains new data from patients receiving up to 0.15 mg/kg of SVP-Rapamycin with 0.2 or 0.4 mg/kg of pegadricase (formerly known as pegsiticase) from the Phase 2 trial, at the 2018 American College of Rheumatology (ACR)/Association for Rheumatology Health Professionals (ARHP) Annual Meeting in Chicago on October 22, 2018.

The information furnished under this Item 7.01, including Exhibit 99.1 attached hereto, 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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On October 22, 2018, in connection with distribution of the Poster, the Company announced new data from patients in its Phase 2 trial of SEL-212 receiving five monthly combination doses of SEL-212, consisting of up to 0.15 mg/kg of SVP-Rapamycin in combination with 0.2 or 0.4 mg/kg of pegadricase. Pegadricase is the new United States Adopted Name (USAN) for pegsiticase. Approximately 29% of evaluable patients experienced flares during the first month after treatment and continued reduction was observed during months two through five. In addition, 96% of gout flares experienced by patients in the trial were mild or moderate in severity, and no new patient experienced a flare after the second month. Gout flares represented 13% of the total number of treatment-emergent adverse events reported up to October 9, 2018 (708 days of follow up from the start of the study). No gout flares were classified as serious adverse events nor resulted in study discontinuations.

The Company plans to initiate its Phase 3 program for SEL-212 in 2018 with proposed dose regimens based on the Company's Phase 2 data, subject to the Company's end-of-Phase 2 discussion with FDA. The Company also plans to initiate a head-to-head clinical trial of SEL-212 compared to the current FDA-approved uricase therapy in parallel with the Phase 3 program, while accelerating its commercialization plans for SEL-212.

Forward-Looking Statements Disclaimer

This Current Report on Form 8-K (the "Current Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding our expectations surrounding the initiation of our Phase 3 program for SEL-212 and a head-to-head clinical trial of SEL-212 compared to the current FDA-approved uricase therapy, and our expectations surrounding acceleration of our commercialization plans for SEL-212. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials including their uncertain outcomes; the unproven approach of our SVP technology; undesirable side effects of our product candidates; our reliance on third parties to manufacture our product candidates and to conduct our clinical trials; our inability to maintain our existing or future collaborations or licenses; our inability to protect our proprietary technology and intellectual property; potential delays in regulatory approvals; our dependence on our ability to retain key executives and to attract, retain and motivate qualified personnel; and availability of funding sufficient for our foreseeable and unforeseeable operating expenses and capital expenditure requirements. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on August 8, 2018, and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this Current Report. Any such forward-looking statements represent management's estimates as of the date of this Current Report. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this Current Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	2018 American College of Rheumatology (ACR)/Association for Rheumatology Health Professionals (ARHP) Presentation Poster: Initial Phase 2 Clinical Data of SEL-212 in Symptomatic Gout Patients: Monthly Dosing of a Pegylated Uricase (pegadricase) with SVP-Rapamycin Enables Sustained Reduction of Acute Gout Flares

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: October 22, 2018

By: /s/ Werner Cautreels, Ph.D.

Werner Cautreels, Ph.D.
President and Chief Executive Officer

Initial Phase 2 Clinical Data of SEL-212 in Symptomatic Gout Patients: Monthly Dosing of a Pegylated Uricase (Pegadricase) with SVP-Rapamycin Enables Sustained Reduction of Acute Gout Flares

Rehan Azeem[1], Alan Kivitz[2], Wesley DeHaan[1], Lloyd Johnston[1], Takashi K. Kishimoto[1], Justin Park[1], Earl Sands[1]
[1]Selecta Biosciences, Watertown, Massachusetts; [2]Altoona Center for Clinical Research, Altoona, Pennsylvania

Abstract

Background: Pegylated uricases are therapies for treatment of severe chronic gout, particularly for rapid tophi resolution. However, uricases are limited by induction of anti-drug antibodies (ADAs) that can compromise efficacy and safety. SEL-212 is a novel combination product consisting of pegadricase (formerly known as pegsiticase) co-administered with synthetic vaccine particles encapsulating rapamycin (SVP-Rapamycin). We report initial data on gout flares from an ongoing Phase 2 study in symptomatic gout patients.

Gout is caused by the deposition of monosodium urate (MSU) crystals in joints due to chronic hyperuricemia. Long term treatment focuses on reducing serum uric acid (SUA) levels, thus allowing MSU crystals to dissolve. Rapid dissolution of MSU crystals during initial phase of urate-lowering therapy (ULT) is associated with an increased frequency of acute gout flares, which can contribute to poor treatment compliance. During ULT initiation, colchicine, NSAIDs or corticosteroids are used for gout flare prophylaxis.

Methods: Patients with symptomatic gout (≥1 tophus, gout flare within 6 months or gouty arthropathy) and elevated serum uric acid SUA (≥6 mg/dL) were treated with monthly doses of pegadricase (0.2 mg/kg or 0.4 mg/kg) alone or in combination with SVP-Rapamycin (0.05 to 0.15 mg/kg). SEL-212 was infused in 28-day cycles x3 doses followed by challenge with pegadricase alone on 28-day cycles x2 doses, or in 28-day cycles x5 combination doses of SVP-Rapamycin and pegadricase. Safety, tolerability, SUA, and ADAs were monitored.

All randomized patients received colchicine (1.2 mg as loading dose, 0.6 mg QD for the remainder of their participation in the trial) as premedication for gout flare prevention. If colchicine was contraindicated, patients received Ibuprofen 600 mg TID or equivalent dose of a NSAID. If colchicine and NSAIDs were contraindicated, patients did not receive any premedication.

Results: As of 09 Oct 2018, demographics of the 152 treated patients were as follows: 23 - 75 years old (mean 54.8 years), male 90.8%, and white 67.8%. The mean BMI at baseline was 34.6 kg/m^2. 71.7% of patients were obese with mean duration of established or symptomatic gout as 10.8 years.

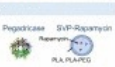
Flare incidence was 32.9% in months 1-3 and 11.1% in months 4-5. In these patients flare frequency was 0.62 flares/patient in months 1-3 and 0.17 flares/patient in months 4-5. Mean duration of the gout flares was 11.6 days, with majority of the gout flares (64.1%) being categorized as mild, 32.0% as moderate and 3.8% (4 cases) as severe in intensity. Adjustments to gout flare prevention medication were not required for 34% of the patients. No gout flares resulted in a patient discontinuation or were reported as a serious adverse event.

Conclusion: SEL-212 has been generally well-tolerated, and, compared to pegylated uricase alone, has mitigated immunogenicity, shown low flare rates, and enabled repeated monthly dosing with sustained control of SUA levels.

Background

SEL-212

- SEL-212 is a combination drug candidate comprised of pegadricase and SVP-Rapamycin
- SVP-Rapamycin is designed to induce the formation of regulatory T cells that mitigate the formation of anti-drug antibodies (ADAs)
- Ongoing Phase 2 clinical trial of SEL-212 has demonstrated low incidence of ADAs resulting in sustained reduction of serum uric acid (SUA) with monthly dosing (see Abstract 2254)



Gout Flares

- Acute gout attacks are characterized by a rapid onset of pain in the affected joint followed by warmth, swelling and pain[1]
- 69% of gout patients describe the pain of an attack as "miserable", 23% of patients compare the pain of a gout attack to shattered glass piercing their skin, 20% to breaking a bone, 24% to a severe burn[2]
- Most people with gout will experience repeated bouts over the years

[1]www.uptodate.com/contents/treatment-of-gout-flares
[2]www.webmd.com/arthritis/news/20130611/gout-is-very-often-times-at-the-pain

Effect of Urate Lowering Therapies on Gout Flares

- Dispersion of MSU crystals during the initial phase of deposit dissolution exposes the patient to an increased rate of acute flares
- Increased gout flare can adversely affect patient compliance[3]
- Pegylated uricase therapy, which rapidly debulks tissue uric acid, has been reported to induce gout flares in 75% of patients in the first months after initiation of therapy[4]

[3]Becker MA et al., Nucleic Acids 2080 27:S85-91
[4]Sundy et al. JAMA, 306 7:711-720

Results

SEL-212201: Ongoing Phase 2 Clinical Trial

Study description

- Evaluate the safety, pharmacokinetics, pharmacodynamics and immunogenicity of repeated monthly IV infusions of SEL-212 in patients with symptomatic gout and elevated SUA levels (≥6 mg/dL)
- Cohorts of patients administered either three q28 day IV infusions of 0.2 or 0.4 mg/kg pegadricase in combination with ascending doses (0.05 – 0.15 mg/kg) of SVP-Rapamycin followed by two q28 day IV infusions of 0.2 or 0.4 mg/kg pegadricase alone, or five q28 day IV infusions of 0.2 mg/kg pegadricase in combination with 0.1 - 0.15 mg/kg doses of SVP-Rapamycin
- Monitored for safety, SUA levels, uricase pharmacodynamic activity, and ADAs
- Male or female subjects aged 21 to 75 inclusive
- Demographics
  - 152 patients with established or symptomatic gout (≥1 tophus, ≥ 1 gout flare in last 6 months, or chronic gouty arthropathy) with hyperuricemia (> 6mg/dL SUA)
  - Average SUA at enrollment/screening: 8.1 mg/dL
  - Average age: 54.8 (range 23-75)
  - Male, 138 (90.8%); Female, 14 (9.2%)
  - Caucasian, 103 (67.8%); African American, 40 (26.3%); Asian 4 (2.6%) and Other 5 (3.3%)
  - Mean BMI at baseline: 34.6 kg/m^2 (71.7% of patients moderately obese)
  - Mean duration of established or symptomatic gout: 8.0 years

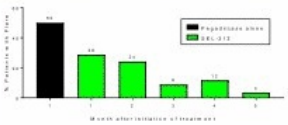
ClinicalTrials.gov NCT02959593

SEL-212 Treatment Cohorts

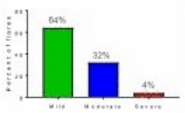
Cohort	Treatment Weeks 0, 4, 8 (months 1, 2, 3)		Treatment Weeks 12 + 16 (months 4, 5)	
	Pegadricase	SVP-Rapamycin	Pegadricase	Status
1	0.2 mg/kg	None	0.2 mg/kg	Dosing completed
2	0.4 mg/kg	None	0.4 mg/kg	Dosing completed
3	0.2 mg/kg	0.05 mg/kg	0.2 mg/kg	Dosing completed
4	0.4 mg/kg	0.05 mg/kg	0.4 mg/kg	Dosing completed
5	0.2 mg/kg	0.08 mg/kg	0.2 mg/kg	Dosing completed
6	0.4 mg/kg	0.08 mg/kg	0.4 mg/kg	Dosing completed
7	0.2 mg/kg	0.1 mg/kg	0.2 mg/kg	Dosing completed
8	0.4 mg/kg	0.1 mg/kg	0.4 mg/kg	Dosing completed
10	0.4 mg/kg	0.125 mg/kg	0.4 mg/kg	Dosing completed
11	0.2 mg/kg	0.15 mg/kg	0.2 mg/kg	Dosing completed
12	0.4 mg/kg	0.15 mg/kg	0.4 mg/kg	Dosing completed

Cohort	Treatment Week 0		Treatment Weeks 4, 8, 12, 16		
	Pegadricase	SVP-Rapamycin	Pegadricase	SVP-Rapamycin	Status
13	0.2 mg/kg	0.15 mg/kg	0.2 mg/kg	0.15 mg/kg	Ongoing
16	0.2 mg/kg	0.15 mg/kg	0.2 mg/kg	0.1 mg/kg	Ongoing
17	0.2 mg/kg	0.1 mg/kg	0.2 mg/kg	0.1 mg/kg	Ongoing

Low Gout Flare Rates with Reduction in Frequency During SEL-212 Therapy



Gout Flare Classification



Summary

- SEL-212 is a monthly combination product candidate being developed as a therapy for the sustained control of SUA leading to removal of urate crystal deposits in patients with chronic severe gout
- The percentage of patients who experienced flares was 29% during the first month after treatment and continued reduction was observed during months 2-5
- 96% of gout flares were mild or moderate in severity, and no new patient experienced a flare after the 2nd month
- Unlike with other urate lowering therapies that typically increase the incidence of flares at the beginning of treatment, the incidence of gout flares substantially decreases after the first and subsequent treatments with SEL-212
- Gout flares represented 13% of the total number of treatment-emergent adverse events (TEAEs) reported up to October 9, 2018 (708 days of follow up from the start of the study)
- No gout flares were classified as SAEs nor resulted in study drug discontinuations

Acknowledgements

We thank all of the patients that participated in the clinical trial. We are very grateful to the clinical trial site investigators, their staff and the entire Selecta SEL-212 project team

Disclosures

Authors are employees and shareholders of Selecta Biosciences

SELECTA Biosciences