

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): **December 7, 2016**

SELECTA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-37798
(Commission
File Number)

26-1622110
(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))
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Item 8.01. Other Events.

On December 7, 2016, Selecta Biosciences, Inc. (the “Company”) issued a press release announcing data from the Company’s Phase 1 company-sponsored trial which assessed single ascending dose safety, pharmacokinetic and pharmacodynamics of SEL-212 in patients with elevated uric acid levels.

The Phase 1a trial enrolled 22 U.S. patients with hyperuricemia (uric acid level of >6mg/dL) and evaluated the effect of a single intravenous infusion in a range of 0.1 to 1.2 mg/kg of pegsiticase administered alone. Pegsiticase was generally well tolerated at all tested dose levels. Serum uric acid levels for all patients initially dropped to less than 0.1 mg/dL within approximately 10 hours. However, these levels began rebounding by 14 to 21 days after dosing in a majority of patients. The loss of uric acid level control (defined as uric acid of >6 mg/dL) correlated with the formation of anti-drug antibodies (ADAs). The 0.4 mg/kg dose of pegsiticase was selected as the dose level to carry forward into the Phase 1b trial.

The multicenter Phase 1b trial enrolled 63 U.S. patients. One group received a single intravenous infusion of 0.4 mg/kg of pegsiticase alone. Four groups received either placebo or a single intravenous infusion of SVP-Rapamycin alone in a range of 0.03 to 0.5 mg/kg. As expected, SVP-Rapamycin alone did not significantly affect uric acid levels in these patients. Two serious adverse events (SAEs) of stomatitis were observed at the highest dose level tested (0.5 mg/kg), leading the Company to set 0.3 mg/kg as the maximum tolerated dose of SVP-Rapamycin for the Phase 1b trial. All SAEs resolved completely during the study period.

Four additional groups in the Phase 1b trial received a single fixed dose of 0.4 mg/kg dose of pegsiticase by intravenous infusion in combination with 0.03, 0.1, 0.15 or 0.3 mg/kg of SVP-Rapamycin:

- At the 0.03 mg/kg dose, serum uric acid levels were controlled for at least 21 days in four of the five patients.
- At the 0.1 mg/kg dose, serum uric acid levels were controlled through Day 30 in seven of 10 patients.
- At the 0.15 mg/kg dose, serum uric acid levels were controlled through Day 30 in all five patients.
- At the 0.3 mg/kg dose, serum uric acid levels were controlled through Day 30 in all five patients.

The substantial and sustained reduction in uric acid levels through at least Day 30 was correlated with the prevention of ADAs. These data supported a monthly dosing regimen in the ongoing multi-dose Phase 2 clinical trial.

SEL-212 was generally well tolerated at the clinically active dose levels. One drug-related SAE was reported at the 0.1 mg/kg dose level for a Grade 2 rash which was classified as an SAE due to an emergency room visit. This SAE resolved during the study period without further issues. No SAEs were observed at the 0.03, 0.15 or 0.3 mg/kg dose levels.

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: December 7, 2016

By: /s/ Werner Cautreels, Ph.D.
Werner Cautreels, Ph.D.
President and Chief Executive Officer