### **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): June 21, 2017

### SELECTA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter) 001-37798

(Commission File Number) **26-1622110** (I.R.S. Employer Identification No.)

(State or other jurisdiction of incorporation or organization)

Delaware

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

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

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. x

#### Item 7.01. Regulation FD Disclosure.

On June 15, 2017, Selecta Biosciences, Inc. (the "Company") furnished a corporate slide presentation (the "June 15 Presentation") providing additional data from the Company's ongoing, open-label Phase 2 company-sponsored trial, which is assessing the safety, tolerability, pharmacokinetic and pharmacodynamics of SEL-212 in patients with elevated uric acid levels and symptomatic gout (the "Phase 2 Trial").

The Company is now furnishing an updated corporate presentation (the "Updated Presentation"), which is attached to this Current Report on Form 8-K as Exhibit 99.1. In addition to incorporating information from the June 15 Presentation, the Updated Presentation includes, among other things, data with respect to Cohort 7 of the Phase 2 Trial, which were not contained in the June 15 Presentation.

The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

The information in Item 7.01 of this Form 8-K, 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.

The Updated Presentation amends (i) the number of patients enrolled in the Phase 2 Trial as of June 12, 2017 from 60 to 62 and (ii) the percentage of patients reporting a gout flare in the first month of treatment from 15% to 14% as a result of the increase in the number of patients.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.

Description

99.1

Corporate presentation of Selecta Biosciences, Inc. dated June 21, 2017

### 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: June 21, 2017

By:

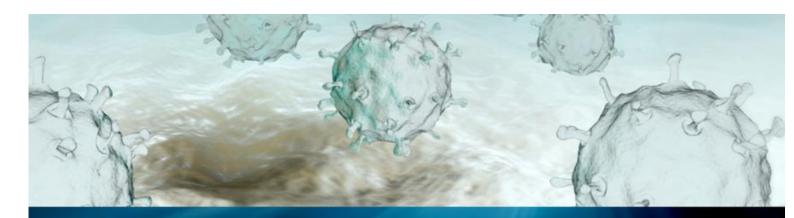
/s/ Werner Cautreels, Ph.D. Werner Cautreels, Ph.D.

President and Chief Executive Officer

Description

99.1

Corporate presentation of Selecta Biosciences, Inc. dated June 21, 2017



**Corporate Overview** 



June 21, 2017

## Safe Harbor / Disclaimer

Any statements in this presentation about the future expectations, plans and prospects of Selecta Biosciences, Inc. ("the company"), including without limitation, the progress of the Phase 1/2 clinical program of SEL-212, the potential of SEL-212 to treat severe gout patients and resolve their debilitating symptoms, the ability of SVP-Rapamycin to induce immune tolerance against pegsiticase, the ability of SEL-212 to improve acute symptoms during a short induction cycle, the ability of SEL-212 to be re-administered if severe gout symptoms recur, whether the company will determine an appropriate dose of SEL-212 for a Phase 3, whether the company will advance to a Phase 3 for SEL-212 at all, the ability of the company's SVP platform, including SVP-Rapamycin, to mitigate immune response and create better therapeutic outcomes, the potential treatment applications for products utilizing the SVP platform in areas such as enzyme therapy, gene therapy, oncology therapy, vaccines and treatments for allergies and autoimmune diseases, the potential of the company's two gene therapy product candidates to enable repeat administration, whether the company submits an IND for its lead gene therapy program, MMA, in the first half of 2018, the company's expectations about receiving additional payments from Spark Therapeutics, Inc. under the license agreement and/or the stock purchase agreement, the sufficiency of the company's cash, cash equivalents, investments, and restricted cash 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 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 SVP 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 or licenses, 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, substantial fluctuation in the price of its common stock, a significant portion of the company's total outstanding shares have recently become eligible to be sold into the market, and other important factors discussed in the "Risk Factors" section of the company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on May 11, 2017, 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 obligation to update any forward-looking statements included in this presentation.



## Immunogenicity is Now Recognized as a Serious Challenge for Biologic Therapies

### IMMUNOGENICITY'S IMPACT —

COMPROMISED EFFICACY

Anti-drug antibodies (ADAs) neutralize therapeutic benefit

SAFETY RISK Hypersensitivity reactions can impact patients UNPREDICTABLE RESPONSE Changed PK/PD through

drug-ADA interaction

# The New York Times

## When the Immune System Thwarts Lifesaving Drugs

Patients often produce antibodies to the very treatments keeping them alive, sometimes to disastrous effect.

By GINA KOLATA May 15, 2017

"Prophylactic immune tolerance induction should be strongly considered in patients who are at risk of developing immune responses to ERT."

- Amy Rosenberg, MD, Director, Division of Biotechnology Products Review and Research, FDA



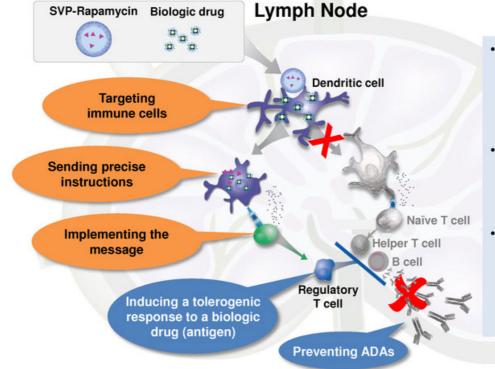


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# IMAGINE IF WE COULD...

- 1. Effectively treat many more patients with existing biologics
- 2. Enable a new generation of novel non-immunogenic biologics for rare and serious diseases

## The Key: Mitigate Anti-Drug Antibodies by Inducing Regulatory T Cells

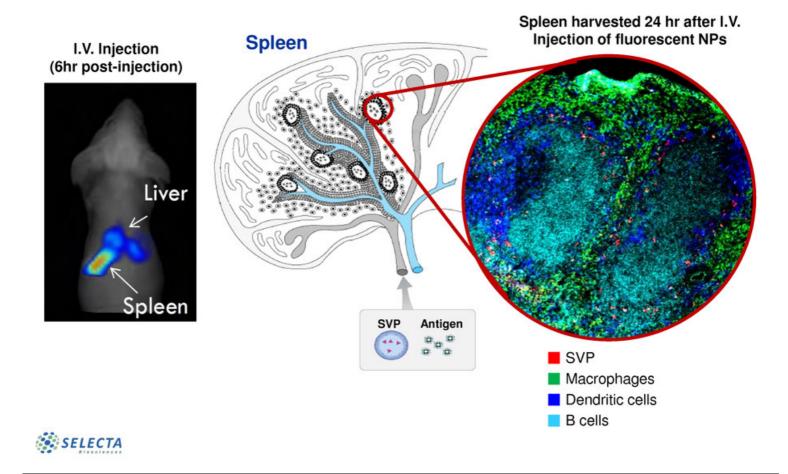


- By dosing "free biologic" separate from SVP-Rapamycin, it distributes broadly to desired sites of action
- Some of the biologic colocalizes with dendritic cells that have taken up SVP-Rapamycin
- The dendritic cells then induce regulatory T cells that circulate throughout the body and suppress immune responses against the biologic (i.e. ADAs)

## Potential to enable new therapies and improve efficacy/safety of existing biologics

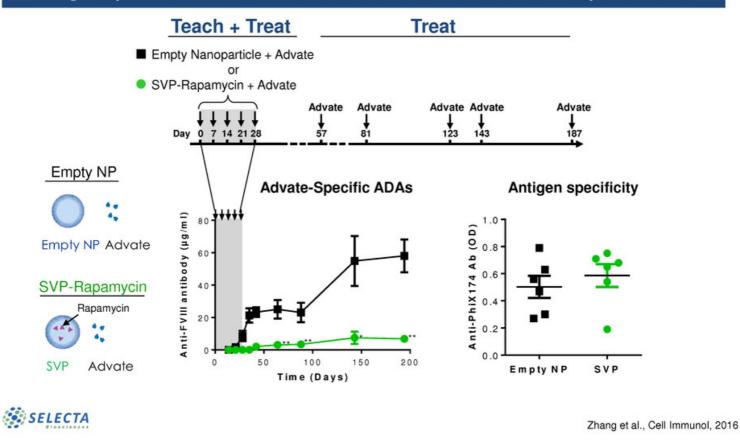


## Leveraging Nanoparticles to Deliver Instructions to the Immune System

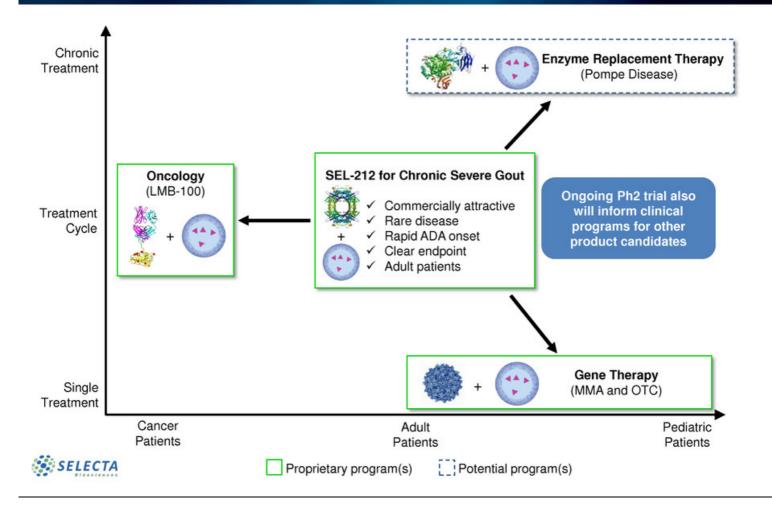


## **Example of Immune System Education**

## Antigen-Specific Tolerance Maintained for Over Five Months in Hemophilia A Mice



## Plan for SVP Immune Tolerance Platform Expansion





SELECTA

## Selecta's Lead Product Candidate: SEL-212





## **Ownership**

In-licensed pegsiticase in 2014; combined with SVP-Rapamycin to form SEL-212

### **Rare and Serious Disease**

- ~160,000 adults with chronic severe gout treated by U.S. rheumatologists
- Debilitating flares and joint-damaging arthritis caused by uric acid deposits; risk of renal and cardiovascular disease



### Immunogenicity Barrier

- Uricase is highly effective in breaking down uric acid deposits, but is foreign to the human immune system, causing immunogenicity
- Two approved products (Krystexxa and Elitek) cause inhibitory antibodies in ~60% of patients and carry risk for anaphylaxis



SELECTA

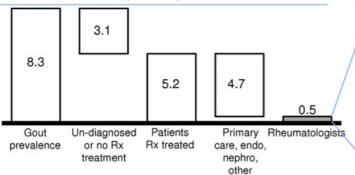
## **Clear Clinical Path**

- Krystexxa approved with less than 500 patients dosed from phase 1-3
- Primary endpoint: serum uric acid level reduction a robust FDA/EMA-approved endpoint – can be seen rapidly upon dosing, easy to measure, maintenance strongly correlated with low/negative ADA titers
- Adult patient population with rapid enrollment potential

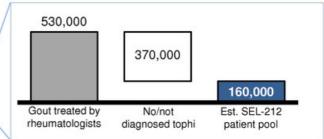
## Substantial Unmet Need for Chronic Severe Gout Patients

### U.S. Gout Patients (million)1

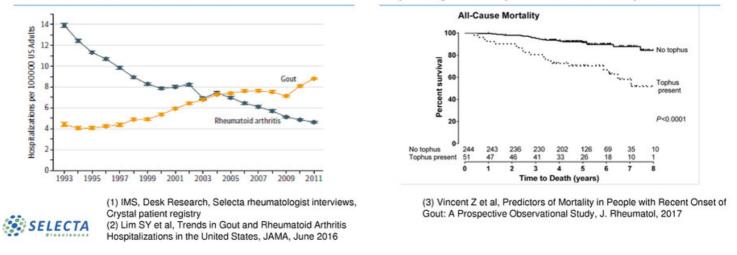
Gout Admissions Now Exceed RA<sup>2</sup>



### Estimated SEL-212 Target Patient Population<sup>1</sup>



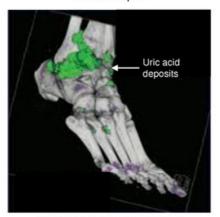
### Tophi Significantly Increase Mortality Risk<sup>3</sup>



## What is Chronic Severe Gout?



Visible tophi



Hidden uric acid deposits

- SELECTA
- (1) IMS, Desk Research

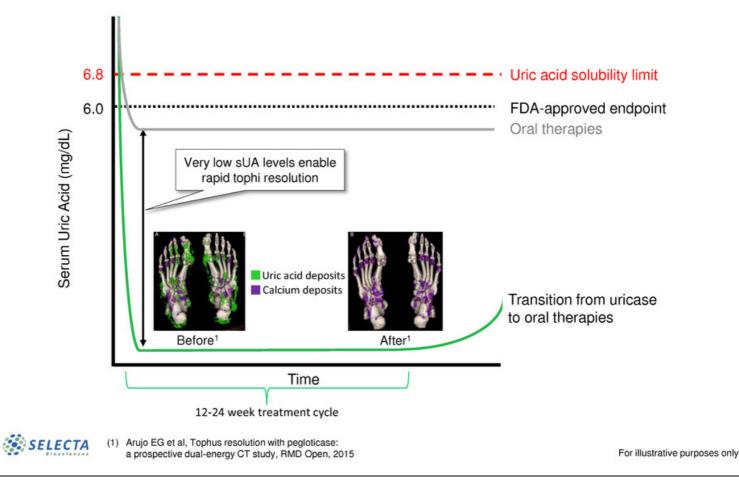
(2) Selecta rheumatologist interviews, Crystal patient registry

(3) Choi HK et al, Tophaceous Gout and the Risk of Mortality: A General

Population-Based Study, ACR, Sept. 2016

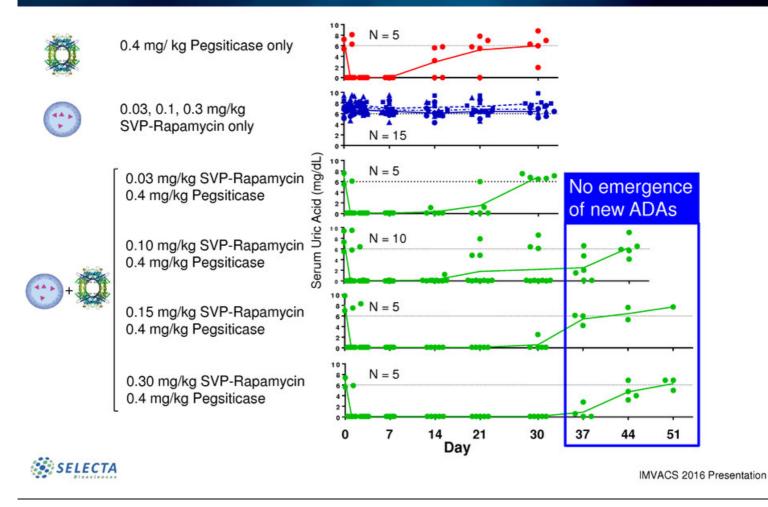
- ~50,000 U.S. gout patients are refractory to standard therapies and most have existing "tophi"<sup>1</sup>
- Over 100,000 additional patients have tophaceous gout and remain symptomatic<sup>2</sup>
- Tophi are hidden or disfiguring inflammatory nodules of crystallized uric acid that form in severe gout patients
  - Tend to form primarily in joints and tissues
  - Source of recurrent flares and debilitating pain that cannot be treated effectively by simply lowering sUA to <6 mg/dL</li>
  - Shown to significantly increase morbidity and mortality if left untreated<sup>3,4</sup>
    - (4) Zhu Y, et al, Comorbidities of gout and hyperuricemia in the US general population: NHANES 2007-2008, Am J Med, July 2012

# Resolving Tophi and Uric Acid Deposits with Monthly Uricase Treatments

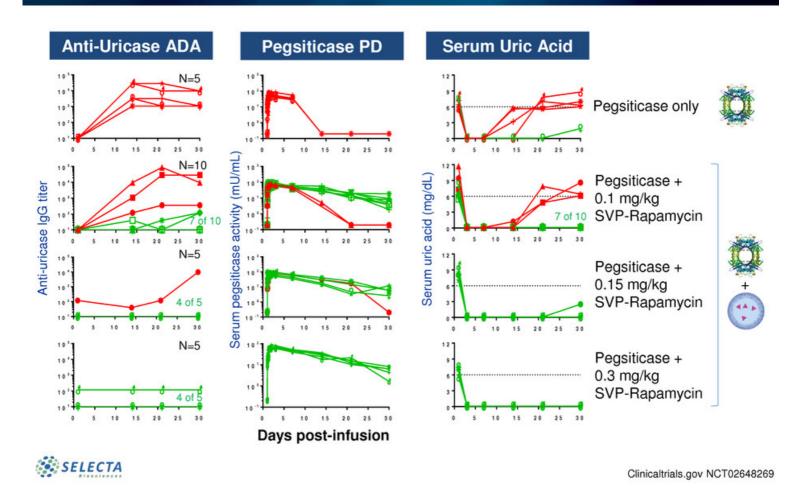


## Phase 1b Demonstrates SEL-212's Clinical Activity for ≥30 Days

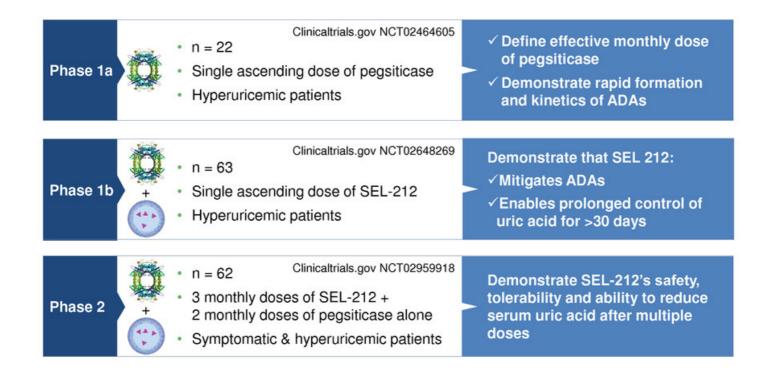




# Phase 1b Trial Shows Correlation Between ADA Titers, Pegsiticase Activity and sUA



## **Clinical Objectives of SEL-212 Program**



### Nearly 100 patients now dosed with SEL-212



Unaudited data as of June 12, 2017; amended following on-site reviews Clinicaltrials.gov NCT02959918 Phase 2 Trial Overview

Enrollment Criteria	<ul> <li>Patients with symptomatic gout and serum uric acid levels &gt;6 mg/dL</li> </ul>
Primary/Secondary Endpoints	<ul> <li>Safety, tolerability and pharmacokinetics of multiple doses of SEL-212 and pegsiticase alone</li> <li>Reduction of serum uric acid levels</li> <li>Reduction of ADA levels</li> </ul>
Design	Multiple ascending dose cohorts
Dosing	<ul> <li>Control cohorts: pegsiticase alone every 28 days for up to five doses</li> <li>All other cohorts: SEL-212 every 28 days for three doses followed by two doses of pegsiticase alone</li> </ul>
Stopping Rules	Dosing stopped upon loss of sUA control at Days 21 after a dose
Trial Completion	Expected by the end of 2017
As of June 12	62 patients dosed at 11 active U.S. clinical sites
SELECTA	Unaudited data as of June 12, 2017; amended following on-site review Clinicaltrials.gov NCT0295991

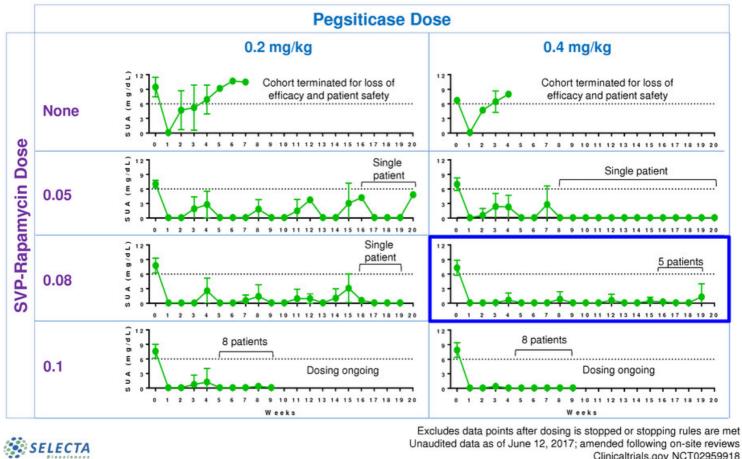
## **Status of Phase 2 Trial Cohorts**

	Treatmer	Treatment Weeks 0, 4, 8 Treatment Weeks 12 + 16		
Cohort	Pegsiticase	SVP-Rapamycin	Pegsiticase	Status
1	0.2 mg/kg	None	0.2 mg/kg	Enrollment terminated
2	0.4 mg/kg	None	0.4 mg/kg	Enrollment terminated
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	Ongoing
7	0.2 mg/kg	0.1 mg/kg	0.2 mg/kg	Ongoing
8	0.4 mg/kg	0.1 mg/kg	0.4 mg/kg	Ongoing
9+		Under desig	ŋn	Planned



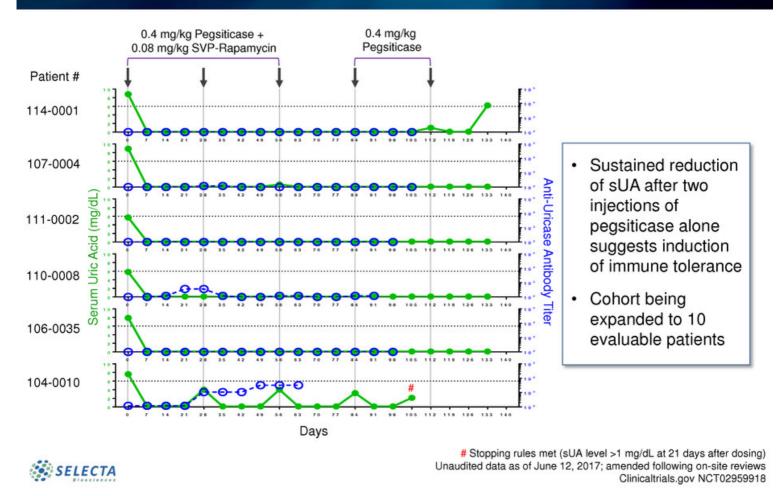
Unaudited data as of June 12, 2017; amended following on-site reviews Clinicaltrials.gov NCT02959918

# Minimal Effective Dose of SEL-212 Now Defined

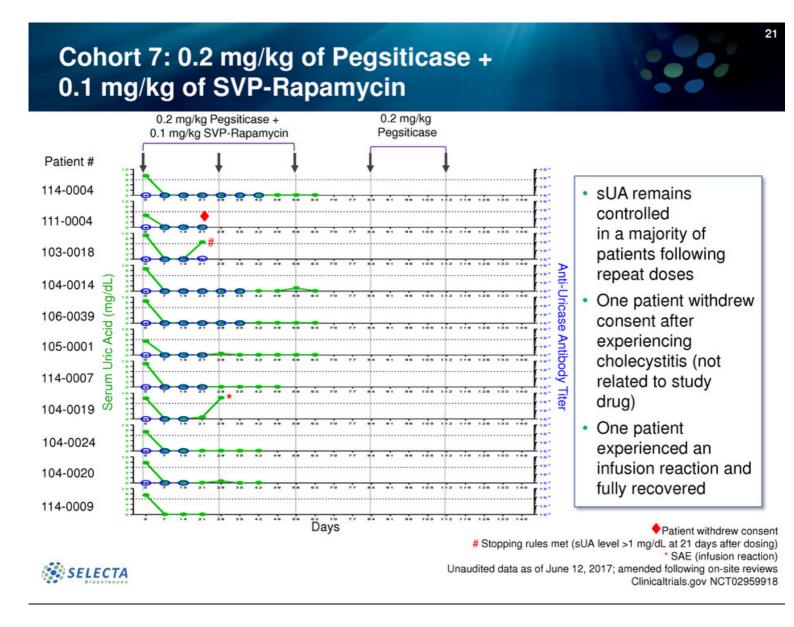


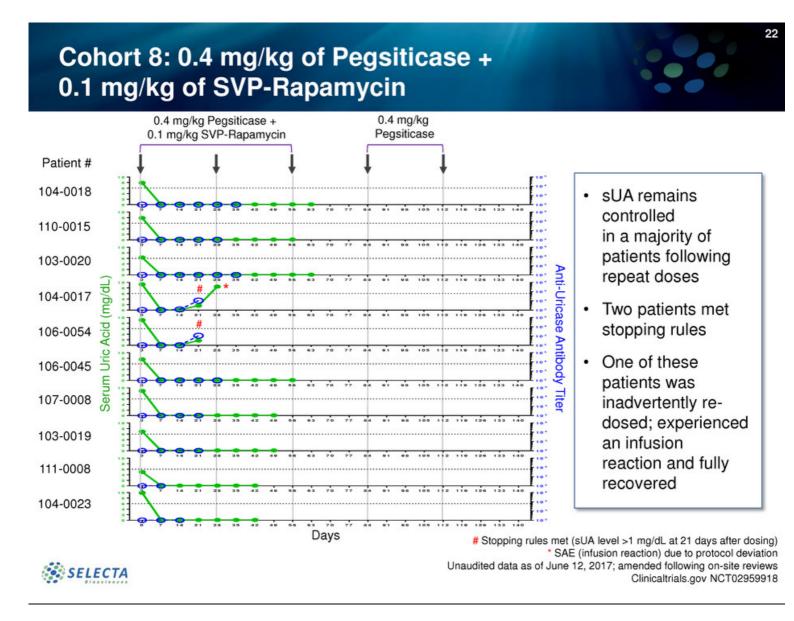
Clinicaltrials.gov NCT02959918

## **Cohort 6: Minimal Effective Dose of SEL-212**

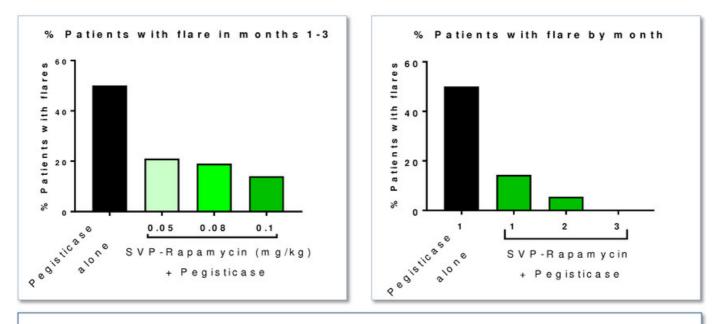


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## Results to Date Suggest Reduction in Flare Frequency During SEL-212 Therapy



- Urate lowering therapies typically increase the incidence of flares at the beginning of therapy
- Data indicate SEL-212 lowers flares compared to pegsiticase alone



Unaudited data as of June 12, 2017; amended following on-site reviews Clinicaltrials.gov NCT02959918

## **Phase 2 Safety Overview**

- SEL-212 has been generally well tolerated at clinically active doses following repeated administrations
- Eight SAEs reported to date in the trial:
  - Seven infusion reactions, four of which were in cohorts receiving pegsiticase alone or pegsiticase in combination with the lowest dose of SVP-Rapamycin, as expected, and two of which were due to protocol deviations related to dosing errors
  - One was for a patient with history of gall stones who experienced cholecystitis (inflammation of gall bladder caused by impacted gall stones), which was determined not to be related to study drug
- All SAEs were successfully treated and resolved without further issues



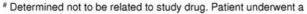
Unaudited data as of June 12, 2017; amended following on-site reviews Clinicaltrials.gov NCT02959918

## **Phase 2 Adverse Events**

Cohort	Entire Study	1	2	3	4	5	6	7	8
N(%)	62	3	3	9	10	6	10	11	10
≥ 1TEAE	50(80.1)	3	2	8	7	5	8	8	9
≥ SAE	8	1	1	2	0	0	1*	1#, 1	1*
Death	0	0	0	0	0	0	0	0	0
Discontinuation due to TEAE	9	1	1	2	0	0	1*, 1	1#, 1	1*

### Specific TEAEs

Infusion reaction	8(12.9)	1	1	2	0	0	1*, 1	1	1*
Gout flare	13(21.0)	3	0	2	2	1	2	1	2
Hyperglycemia <sup>1</sup>	7(11.3)	0	0	2	0	2	1	1	1
Hypertriglyceridemia <sup>1</sup>	7(11.3)	0	0	1	0	3	1	1	1
Infection <sup>1</sup>	11(17.7)	0	1	5	1	0	1	1	2
Tachycardia1	3(4.8)	0	0	2	0	0	1	0	0
Headache <sup>1</sup>	8(12.9)	0	0	0	3	0	1	2	2
Hypophosphatemia <sup>1</sup>	4(6.5)	0	0	4	0	0	0	0	0
Stomatitis or oral lesion <sup>1</sup>	3(4.8)	0	0	0	0	1	0	0	2
Leukopenia <sup>1</sup>	8(12.9)	0	0	2	0	2	1	1	2





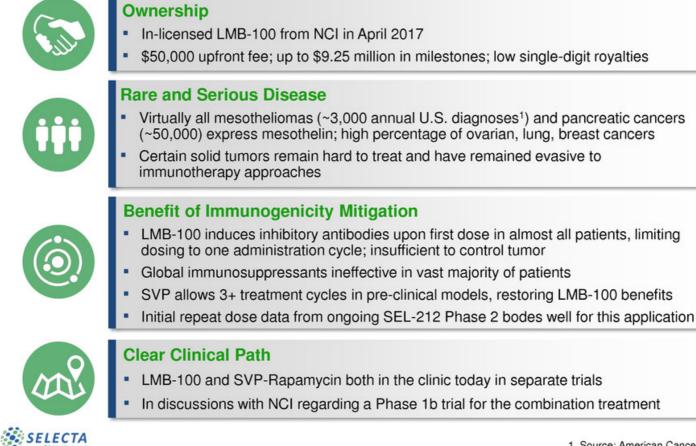
moderate

Unaudited data as of June 12, 2017; amended following on-site reviews

cholecystectomy \*Patient incorrectly dosed; protocol deviation (1) Observed at single data points, transient in nature and mild or Clinicaltrials.gov NCT02959918



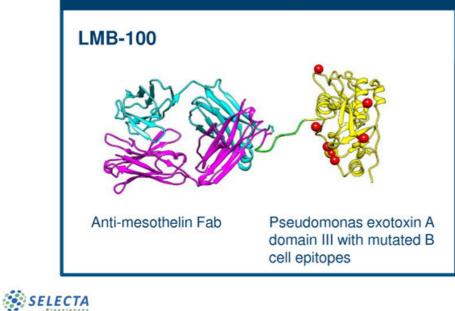
## Developing a Highly Potent Recombinant Pseudomonas Immunotoxin Targeting Mesothelin



1. Source: American Cancer Society

## Immunotoxin LMB-100

- LMB-100: Pseudomonas exotoxin A linked to antibody Fab targeting mesothelin
- · Currently in Phase 1 clinical trials
- Efficacy is limited by immunogenicity after one or two cycles in most patients





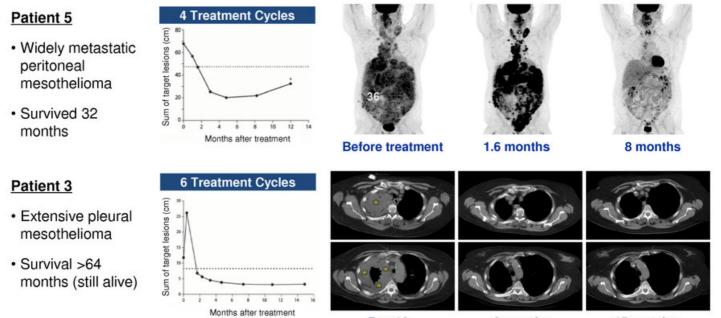
Ira Pastan, M.D. Head, Molecular Biology Section National Cancer Institute

## Mesothelin is overexpressed on many solid tumors

- Mesothelioma (~100%)
- Pancreatic cancer (~100%)
- Ovarian cancer (70%)
- Lung cancer (50%)
- Breast cancer (34%)
- Gastric cancer

## Clinical Activity of LMB-100 Precursor in Mesothelioma

## The patients able to receive 4 or more cycles showed major anti-tumor response



Day 12

3 months

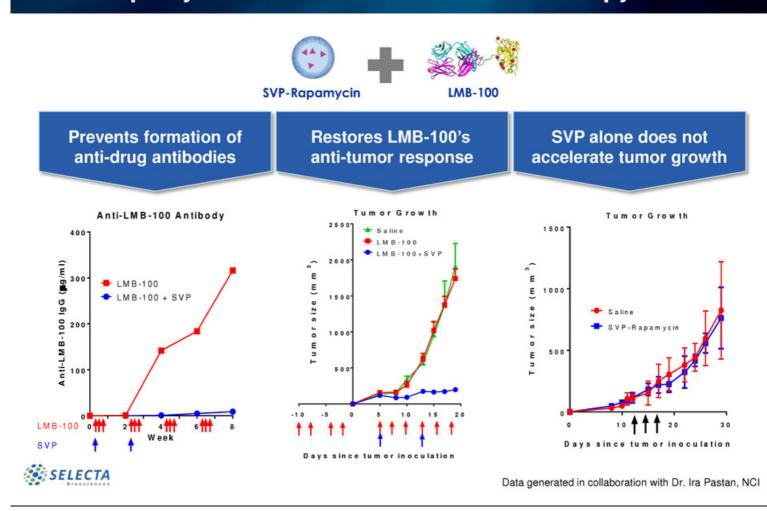
15 months

# However, immunogenicity limited treatment to 1 or 2 cycles for most patients despite concomitant use of immunosuppressive therapy



Hassan, Pastan et al. Cancer Research (2014)

## Preclinical Data Supports the Benefits of SVP-Rapamycin + LMB-100 Combination Therapy





## Selecta's Proprietary Gene Therapy Programs



## Ownership

Two proprietary gene therapies utilizing AAV and Anc80 + SVP-Rapamycin

### **Rare and Serious Diseases**

- Two inborn error of metabolism: Methylmalonic Acidemia (MMA) and Ornithine Transcarbamylase (OTC) Deficiency
- MMA affects 1 in 25,000-48,000<sup>1</sup>; OTC deficiency affects 1 in 15,000-60,000 worldwide<sup>1</sup>
- Onset in early infancy; significantly reduces life expectancy

### **Immunogenicity Barrier**

- Infants require treatment prior to metabolic crisis to avoid CNS effects; retreatment likely needed as patients grow
- Repeat gene therapy dosing impossible due to neutralizing antibodies to viral capsid
- Cellular immune responses to the liver are an additional potential barrier

### **Clear Clinical Path**

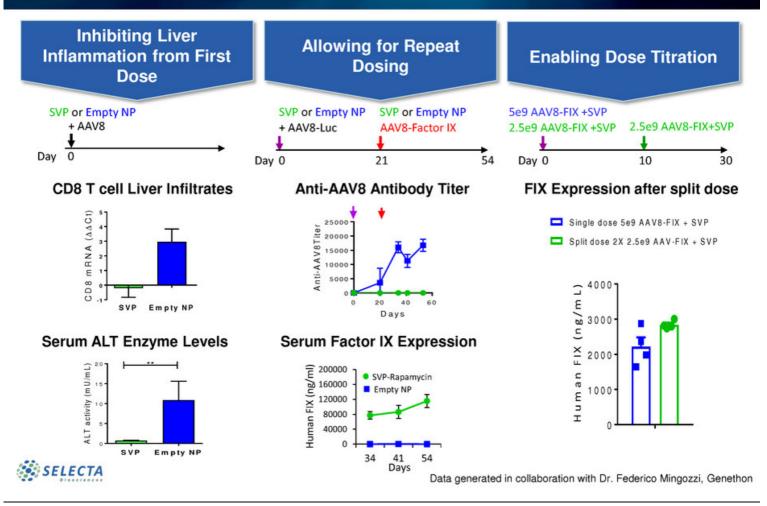
- Targeting IND for lead gene therapy program, MMA, in the first half of 2018
- Collaboration with NIH and Mass Eye & Ear: Access to validated animal models, gene therapy development expertise and patients
- Clinical endpoints include: Methylmalonyl-CoA mutase and MMA levels



SELECTA

1. Source: NIH

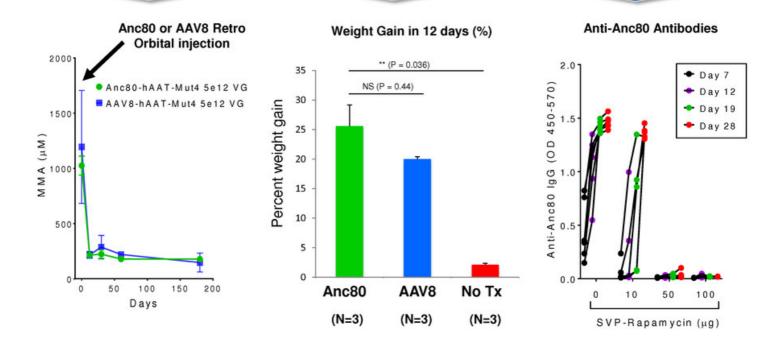
## **Benefits of ADA Avoidance in Gene Therapy**



## Anc80/synMUT Proof of Concept in Mouse Model of MMA at ASGCT 2017

Reducing MMA Levels With Anc80 and AAV8

Increasing Weight Gain Following Treatment Preventing Anti-Anc80 Antibodies with SVP-Rapamycin



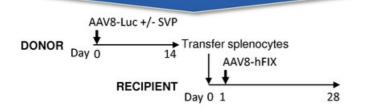
SELECTA

Data generated in collaboration with Dr. Charles Venditti, NIH, and Dr. Luk Vandenberghe, Mass Eye & Ear

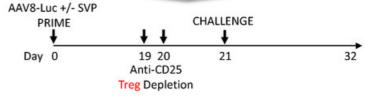
## **Demonstration of the Role of Regulatory T Cells**

### Effect can be Transferred to a Recipient

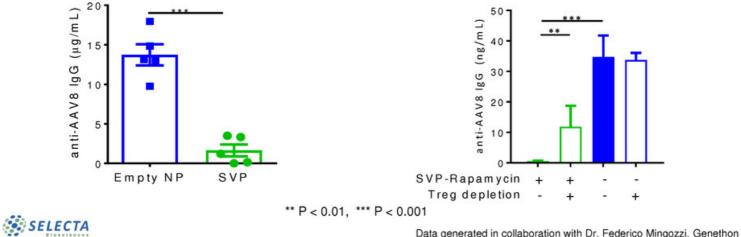




### Anti-AAV8 IgG levels in recipient mice (Day +14)



### Anti-AAV8 IgG levels (Day 32)



Data generated in collaboration with Dr. Federico Mingozzi, Genethon

Indication	Description	Preclinical	Phase 1	Phase 2
Proprietary ADA Mitigatio	n Programs			
Chronic Severe Gout	SVP-Rapamycin co-administered with pegsiticase (SEL-212)			
Mesothelioma & Pancreatic Cancer*	SVP-Rapamycin co-administered with LMB-100			
Methylmalonic Acidemia (MMA)	SVP-Rapamycin co-administered with Anc80 vector			
Ornithine Transcarbamylase Deficiency (OTC)	SVP-Rapamycin co-administered with AAV vector			
ADA Mitigation Program L	icense			
Hemophilia A	SVP-Rapamycin licensed for FVIII gene therapy	5	Spark 🧶	

\* LMB-100 is currently being investigated in two Phase 1 clinical trials at the National Cancer Institute (NCI): one of LMB-100 alone in Mesothelioma and one of LMB-100 in combination with nab-paclitaxel in Pancreatic Cancer. Selecta and NCI are currently in discussions regarding a planned Phase 1b clinical trial to evaluate multiple cycles of LMB-100 in combination with SVP-Rapamycin.



## Q1 Financial Overview

	For the Quarter Ended		
(In thousands, except share and per share data)	March 31, 2017	March 31, 2016	
Grant & Collaboration Revenue	\$137	\$2,088	
Research & Development Expenses	11,044	6,648	
General & Administrative Expenses	3,875	2,381	
Net Loss Attributable to Common Stockholders	(\$15,134)	(\$9,832)	
Net Loss Per Basic Share	(\$0.82)	(\$4.52)	
Wtd. Avg. Common Shares Outstanding – Basic & Diluted	18,474,227	2,175,037	

	As of		
(In thousands)	March 31, 2017	December 31, 2016	
Cash, Cash Equivalents, Marketable Securities, Restricted Cash	\$68,919	\$84,535	



