



**Corporate Presentation** 

April 2020



### Safe harbor/disclaimer

Any statements in this presentation about the future expectations, plans and prospects of Selecta Biosciences, Inc. ("the company"), including without limitation, statements regarding the progress of the clinical development of SEL-212, the anticipated timing of the head-to-head trial comparing SEL-212 and Krystexxa® and related data readouts, whether the head-to-head trial with Krystexxa will demonstrate superiority, provide rapid results or de-risk the Phase 3 trials for SEL-212, the company's ability to enroll patients in its clinical trials, the potential of ImmTOR<sup>TM</sup> to reduce AAV vector immunogenicity and enable re-dosing of AAV gene therapy without neutralizing antibody formation or loss of therapy expression, the anticipated timing of preclinical toxicology studies in AAV gene therapy and initiation of a clinical trial related thereto, the potential of SEL-212 to serve unmet needs in chronic refractory gout patients including sustained sUA reduction, reduced flares, and once monthly dosing, the anticipated timing for advancing into Phase 3 if at all, the anticipated timing of the company's plans to meet with the U.S. Food and Drug Administration, the ability of the company's ImmTOR technology to induce immune tolerance and mitigate antigen-specific neutralizing antibody formation, the scalability of the company's manufacturing processes, the potential of ImmTOR to enable sustained therapeutic activity of biologic therapies. whether current evaluable SEL-212 patients will be predictive of future evaluable SEL-212 patients, whether maintained SUA level reduction correlates with low and/or negative drug- specific antibody titers, the potential of SEL-212 to significantly reduce tophi/heavy urate burden and/or rapidly eliminate tissue urate burden, whether SEL-212 has the ability to reduce gout flares frequency initially and over time during SEL-212 therapy, anticipated achievement of key milestones for the company's chronic refractory gout and gene therapy programs, the company's ability to execute on its strategic priorities, advance its ImmTOR platform, and grow its strategic partnerships, the potential of the company's partnership with Asklepios BioPharmaceutical, Inc. to address unmet medical need in patients with rare diseases, the amount of upfront and milestone payments that Selecta is eligible to receive pursuant to its license agreement with Asklepios BioPharmaceutical, Inc., the company's expected cash position and runway, the billion dollar market potential of the chronic refractory gout market, the ability of the company's ImmTOR platform to unlock the full potential of biologic therapies, the potential of SEL-212 to enable sustained efficacy in chronic refractory gout patients and resolve their symptoms, the potential treatment applications for products utilizing the ImmTOR platform in areas such as enzyme therapy and gene therapy, the potential of AAV gene therapy to transform the future in a variety of inherited and acquired diseases, the potential of the ImmTOR platform generally, and other statements containing the words "anticipate." 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### Selecta well-positioned for success

- o Tolerogenic platform Selecta's immune tolerance platform, ImmTOR™, could unlock the full potential of biologic therapies by mitigating Neutralizing Antibody (Nab) formation
  - Pipeline focused on therapeutic biologics/enzymes and AAV genetherapies
- Lead program SEL-212, addressing a \$1B+ chronic refractory gout market with high unmet need
  - COMPARE trial ongoing to evaluate efficacy and safety of SEL-212 vs. pegloticase, which is marketed as KRYSTEXXA®
    - Announced completion of enrollment in December 2019, with approximately 150 patients enrolled (approximately 75 patients per arm)
    - o Top-line data to be reported in 3Q 2020
  - Phase 3 pivotal program against placebo to commence in 2H 2020

#### • *Pipeline* – gene therapy program to enter the clinic in 2020

- Preclinical results suggest high relevance to diseases which may require re-dosing gene therapies to maintain efficacy
- Several collaborations & licensing agreements with leading gene therapy players
  - o 50/50 collaboration agreement with AskBio
  - o License agreement with AskBio for Pompe disease
  - o License agreement with Spark for HemophiliaA

#### • Appointed Carrie S. Cox as Chairman of the Company's Board of Directors in November 2019

## ImmTOR

Immune Tolerance Platform

# Biologic therapies may trigger NAbs that negate their therapeutic benefit



# ImmTOR has the potential ability to enable sustained therapeutic activity of biologic therapies and unlock their potential



### **SEL-212** (ImmTOR+pegadricase) for Chronic Refractory Gout

# Chronic refractory gout is a severe form of inflammatory arthritis with a significant impact on patients

23%

piercing skin

Glass

7 to 14

days

28%

Breaking

a bone

How chronic refractory gout patients describe their flare pain

How long chronic refractory gout flares can last

Annual lost productivity (pts<65)

~25 days

34%

Severe

burn

Estimated # of patients diagnosed in US with chronic refractory gout

~160,000

Chronic disease can lead to sequelae including: • Bone erosions • Tophi • Chronic pain • Joint deformities • Loss of function • Disability





# Significant need for effective new therapies in chronic refractory gout

- Improved efficacy, allowing patients to complete full 6-month therapy cycle
  - Persistent reduction in Serum Uric Acid (SUA) levels
  - Elimination of tophi
- Monthly dosing
- Gout flare reduction
- Avoidance of "off-label" and global immunosuppressive therapies

SEL-212 has the potential to address these unmet needs and holds \$1B+ market potential



Sustained reduction of SUA with monthly dosing of SEL-212 was observed in Phase 2 dose ranging study

Phase 2 results after 20 weeks of once-monthly SEL-212 treatment:



66% of evaluable patients completed the 20-week period with an SUAlevel <6 mg/dL



\*Week 20 Evaluable patients = patients who received a full first dose and did not discontinue due to any measure other than drug effectiveness or drug related safety

Dual energy computed tomography (DECT) scan images show reduction of tissue urate burden in Phase 2 dose ranging study



DECT uses a computer algorithm to produce color-coded images that render uric acid green, cortical bone blue, and trabecular bone purple



https://selectabio.com/wp-content/uploads/2018/10/ACR-poster-DECT-2018-FINAL-.pdf

# Phase 2 dose ranging data showed reduced frequency and severity of flares during SEL-212 therapy

### Percent of SEL-212 patients who had flares





#### **Severity of flares**

- Majority of flares occurred in months 1 & 2, with no new patients who flared after month 2
- 96% of flares were mild or moderate in severity
- No gout flares were classified as SAEs nor resulted in study drug discontinuations



# SEL-212 generally well-tolerated in the Phase 2 dose ranging study

SEL-212 was generally well tolerated at clinically active doses following >470 administrations during the Phase 2 trial

### 23 SAEs reported in the Phase 2 trial

- 14 were reported not to be or unlikely to be related to study drug
- 9 were infusion reactions which decreased in incidence with increasing doses of ImmTOR

## All SAEs were successfully treated without further issues

### **Serious infusion reactions (%)**





Head-to-Head (COMPARE) study: Comparing the efficacy of SEL-212 to pegloticase in gout patients refractory to conventional therapy



#### Head-to-head trial is designed to provide objective, comparative results

- SUA level reduction, a robust primary endpoint for approval, can be seen soon after dosing
  - Easy to measure
  - Maintenance strongly correlated with low/negative drug-specific antibody titers
- Adult patient population with two active arms
- Opportunity to test revised stopping rules and de-risk Phase 3 program

### ImmTOR in Gene Therapy

## The ability to re-dose AAV gene therapy is a key goal to unlocking the full therapeutic potential

#### **Dose titration**

- Potential to increase proportion of patients who achieve therapeutic benefit without risk of overdosing
- Goal of improving enrollment in clinical trials

#### **Multiple vector administrations**

 Provide potential to target systemic diseases in which multiple vector administrations are likely needed to achieve full therapeutic efficacy

#### **Rescue of expression**

- Allows for potential rescue in patients with organ damage
- Potential to restore therapeutic expression in pediatric patients as they grow





# In preclinical studies, ImmTOR induced antigen-specific immune tolerance



sciences

## ImmTOR provided AAV-specific immune tolerance

- NAbs did not develop in mice treated with ImmTOR+AAV vector
- Mice treated with empty nanoparticle (NP) + AAV vector developed significant IgG response
- When challenged with a different AAV vector, both arms mounted an immune response, suggesting antigen-specific immune tolerance rather than broad immunosuppression was achieved

### Preclinical data indicates potential of ImmTOR-powered re-dosing in gene therapy



Meliani et al., Nature Communications, In Oct. 2018

## First dose benefit of ImmTOR on liver-directed transgene expression



First dose benefit is immediate and independent of effect on adaptive immune response Cumulative benefit of first dose and repeat dose provides up to 4-fold increase in transgene expression



### Opportunities for clinical POC in gene therapy

### Collaboration

#### o AskBio

- Development pipeline and human trials planned for repeat dosing of AAV-based gene therapies to address the unmet medical need for patients with rare and orphan genetic diseases
- Lead indication is MMA (Methylmalonic Acidemia)
- Expect to enter the clinic under this collaboration in 2020

### **Proprietary Program**

• OTC (Ornithine Transcarbamylase deficiency)

### **License Agreements**

- AskBio
  - Licensed ImmTOR for pompe disease in December 2019;
    Selecta received upfront payments of \$7 million and is eligible for clinical and sales milestone payments of \$237 million

#### • Spark Therapeutics

- Licensed ImmTOR for hemophilia A



### Financial Overview and Projected Milestones

### **Financial snapshot**

	For the Year Ended
(In thousands)	December 31, 2019
Research & Development Expenses	\$42,743
General & Administrative Expenses	\$16,389
Total Operating Expenses	\$59,132
Cash used in Operations	\$51,435
	As of
(In thousands, except shares outstanding)	December 31, 2019
Cash, Cash Equivalents, Marketable Securities, Restricted Cash	\$91,551
Basic Shares Outstanding	86,325,547

Cash runway into 2021



### **Projected upcoming milestones**

**O**SEL-212

- Report top-line data in head-to-head (COMPARE) trial of SEL-212 against pegloticase in chronic refractory gout (3Q 2020)
- Commence Phase 3 clinical program against placebo (2H 2020)

• Gene Therapy Program

- Commence human POC trial under AskBio collaboration (2H2020)





Relentlessly committed to overcoming IMMUNOGENICITY with our pioneering ImmTOR immune tolerance platform to transform the lives of patients and their families