



Selecta Biosciences Provides Business Update and Outlook for 2023

January 9, 2023

- Expected topline data for Phase 3 DISSOLVE I & II programs of SEL-212 in chronic refractory gout in Q1 2023 -

- To receive \$10 million upfront for the execution of a license agreement for Xork, the Company's next-generation immunoglobulin G (IgG) protease candidate, to be developed with Astellas Gene Therapies' AT845, an investigational product for the treatment of Pompe disease -*
- Selected an interleukin-2 (IL-2) development candidate to be studied in combination with ImmTOR™ further expanding pipeline in autoimmune disease -*
- Initiated ReiMMAGine, the Phase 1/2 clinical trial for the treatment of methylmalonic acidemia (MMA) with the potential to further validate the ImmTOR™ platform in the field of gene therapy*
- Selected immunoglobulin A (IgA) protease development candidate from IGAN Biosciences for the treatment of IgA nephropathy (IgAN) -*

WATERTOWN, Mass., Jan. 09, 2023 (GLOBE NEWSWIRE) -- Selecta Biosciences, Inc. (NASDAQ: SELB), a biotechnology company leveraging its clinically validated ImmTOR™ platform to develop tolerogenic therapies for autoimmune diseases and gene therapies, today provided a corporate update, including its roadmap for 2023.

Key 2023 Anticipated Milestones

- Report top-line data from Phase 3 DISSOLVE I & II programs of SEL-212 in chronic refractory gout in Q1 2023
- Preliminary Phase 1 SEL-302 data in gene therapy for MMA
- Initiate IND enabling studies with the selected IL-2 candidate to further advance and expand the immune tolerance platform in autoimmune disease
- Begin IND enabling studies with the selected IgA protease candidate from IGAN Biosciences

"In 2022, we delivered on key milestones that further validated the value and breadth of our innovative ImmTOR® and ImmTOR-IL™ immune tolerance platforms, continued to advance our diversified clinical pipeline and established strategic collaborations that will propel our next-generation programs toward multiple IND filings," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Selecta. "Building on the momentum of our recently announced deal with Astellas Gene Therapies' for Xork in Pompe disease, the initiation of the Phase 1/2 trial in methylmalonic acidemia, the identification of an IL-2 candidate and selection of an IgA protease candidate, we also expect joint topline data from the Phase 3 DISSOLVE clinical program investigating SEL-212 in chronic refractory gout in Q1 2023. We are at a pivotal moment in the Company's growth trajectory and as we look ahead, we believe we are well positioned to take a potentially generational leap forward for our precision immune tolerance platform, advance our pipeline in autoimmune disease and continue to explore additional collaborations to maximize the value of our ImmTOR platform and pipeline."

Clinical Development Overview

Tolerogenic Therapies for Autoimmune Disease:

ImmTOR-IL: In December 2022, the Company opted into an agreement for an identified IL-2 candidate and is currently negotiating the terms of the license. The IL-2 candidate will be studied in combination with ImmTOR to further advance and expand the pipeline in autoimmune disease. The combination of ImmTOR and IL-2 (ImmTOR-IL) represents an evolution of the precision immune tolerance platform to further enhance the magnitude and duration of antigen-specific immune tolerance for the treatment of patients with autoimmune diseases.

- The Company plans to initiate IND enabling studies in 2023 while also exploring multiple autoimmune indications that would be suitable for study with ImmTOR-IL.

Gene Therapies:

SEL-302 for Methylmalonic Acidemia (MMA): In December 2022, Selecta initiated ReiMMAGine, the Phase 1/2 clinical trial of SEL-302, an adeno-associated virus (AAV) gene therapy combined with ImmTOR for the treatment of MMA.

- The ReiMMAGine trial is now enrolling patients and aims to evaluate the safety, tolerability and efficacy of SEL-302, a combination of ImmTOR and AAV gene therapy.

SEL-018 IgG Protease (Xork) for Pompe Disease: In January 2023, the Company announced an exclusive licensing and development agreement for IdeXork (Xork), a next-generation immunoglobulin G (IgG) protease, to be developed for use with AT845, Astellas Gene Therapies' investigational AAV-based treatment for Late-Onset Pompe disease (LOPD) in adults.

- Xork has the potential to expand access of life-changing gene therapies to more patients by addressing pre-existing

immunity to AAV. Xork is differentiated by its low cross reactivity to pre-existing antibodies in human serum.

- Under the terms of the agreement, Selecta will receive a \$10M upfront payment and is eligible to receive up to \$340M for certain additional development and commercial milestones plus royalties on commercial sales. Selecta is responsible for the early development activities and manufacturing of Xork and will maintain the rights for the development of additional indications beyond Pompe disease.

Biologic Therapies:

SEL-212 for chronic refractory gout: DISSOLVE, the Phase 3 development program of SEL-212, which has been licensed to Sobi continues to advance. DISSOLVE I & II trials are on track for joint topline data expected in Q1 2023.

ImmTOR with IgA Protease for IgA Nephropathy: In December 2022, the Company selected the next generation Immunoglobulin A (IgA) protease from IGAN Biosciences for the treatment of IgAN.

- Identified a new class of IgA protease from commensal bacteria with a lower level of baseline anti-drug antibodies (ADAs). Combining ImmTOR with this next generation IgA protease candidate has the potential to mitigate the formation of new ADAs and address the underlying pathophysiology of IgAN.

Further Corporate Updates:

In November 2022, Blaine Davis was appointed as Chief Financial Officer. Mr. Davis brings more than 25 years of experience in investor relations, business development, corporate affairs and sales and marketing at life sciences companies, with a particular focus on rare diseases.

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.

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 unique proprietary technology platform of the Company and 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 subsequent Quarterly Reports on Form 10-Q, 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.

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