Sobi and Selecta announce strategic licensing agreement for SEL-212, a phase 3-ready novel treatment for Chronic Refractory Gout

- Strategic licensing agreement for SEL-212, a unique phase 3-ready therapy powered by Selecta’s breakthrough immune tolerance platform, ImmTOR™, with the potential to fulfil a significant unmet need for the treatment of chronic refractory gout
- Builds on Sobi’s strategy and expertise to develop and commercialise novel therapies within the area of immunology
- Sobi to take on development, regulatory and commercial activities in all markets outside China while Selecta to run the phase 3 study on behalf of Sobi
- Selecta to receive from Sobi initial payments of USD 100 million, including USD 75 million upfront license fee and USD 25 million for the purchase of Selecta common stock at USD 4.62 per share, and Selecta is eligible to receive potential development, regulatory, and commercial milestone payments of up to USD 630 million, and tiered double-digit royalties on net sales

Stockholm, Sweden and Watertown, Mass June 11, 2020 -- Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) and Selecta Biosciences, Inc. (Nasdaq: SELB) today announced that the companies have entered into a strategic licensing agreement for the product candidate SEL-212. SEL-212 is a combination of Selecta’s tolerogenic ImmTOR immune tolerance platform and a therapeutic uricase enzyme (pegadricase) that is designed to durably control serum uric acid, reduce immunogenicity, and allow for repeated monthly dosing for the treatment of chronic refractory gout.

Gout is an autoinflammatory disease that causes intensely painful flares and debilitating inflammatory arthritis due to deposition of pro-inflammatory monosodium urate (MSU) crystals in synovial fluid and other tissues. Gout is the most common form of inflammatory arthritis in the US and prevalence in both US and Europe is rising. Chronic refractory gout occurs in patients who do not respond to conventional therapies and therefore suffer from high tissue MSU-burden that can cause frequent gout flares and chronic arthritis. The chronic refractory gout market is estimated to be worth at least USD 1 billion in sales in the US alone.

SEL-212 has the potential to reduce serum uric acid and MSU deposits in patients with chronic refractory gout. SEL-212 is a combination therapy comprised of pegadricase, a recombinant enzyme that metabolizes uric acid, and ImmTOR, a platform technology. Recombinant uricas are highly immunogenic in humans, and SEL-212, through Selecta’s proprietary ImmTOR platform, has the potential to mitigate the formation of anti-drug antibodies, thereby enabling convenient once-monthly dosing and improving the efficacy and tolerability of the uricase. The phase 3 programme is expected to commence in 2H 2020.

“SEL-212 is a unique, late-stage product candidate containing a novel enzyme and a potentially ground-breaking immune tolerance platform, which could significantly improve the treatment for patients with chronic refractory gout, a debilitating disease with significant unmet need,” said Guido Oelkers, Chief
Executive Officer of Sobi. “This product candidate is highly differentiated based on the ImmTOR technology and has the potential to become a significant product in our growing Immunology business, and we are excited to become a shareholder and partner of Selecta.”

“This agreement represents an important milestone for Selecta, and for patients with chronic refractory gout, as Sobi is the ideal partner with the commitment, resources, and complementary product portfolio to advance SEL-212 through development and commercialisation,” said Carsten Brunn, Ph.D., President and CEO of Selecta. “This transaction further demonstrates our ability to execute on strategic business development, and provides Selecta with significant non-dilutive capital and cost savings, allowing the company to focus on utilising its pioneering ImmTOR, immune tolerance, platform to potentially improve the efficacy of biologics, enable re-dosing of life-saving gene therapy, and create novel immunotherapies for autoimmune diseases”.

About the transaction
Under the terms of the license agreement, Sobi will assume responsibility for development, regulatory, and commercial activities for SEL-212 in all markets outside of China. Sobi will make initial payments to Selecta of USD 100 million, which include USD 75 million up-front license fee and USD 25 million in a private placement of shares of Selecta common stock. Selecta is eligible to receive potential milestone payments of up to USD 630 million from Sobi, which are dependent upon specific regulatory and development targets having been met, as well as sales thresholds. Additionally, Selecta is eligible to receive tiered double-digit royalties on net sales.

Sobi and Selecta have entered into a share purchase agreement, pursuant to which Sobi will invest USD25 million in a private placement of 5,416,390 shares of Selecta common stock at a purchase price of USD 4.62 per share (representing a 20 per cent premium to the volume weighted average price over the 10 days prior to signing).

The transaction is subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act and other customary closing conditions.

Sobi intends to finance the considerations above by available funds.

Gibson, Dunn & Crutcher LLP is acting as legal advisor to Selecta and Latham & Watkins LLP is acting as legal advisor to Sobi on the transaction.

About Selecta Biosciences, Inc.
Selecta Biosciences, Inc. is a clinical-stage biotechnology company focused on utilizing its pioneering ImmTOR immune tolerance platform for the potential to improve the efficacy of biologics, enable re-dosing of life-saving gene therapy, and create novel immunotherapies for autoimmune diseases. Selecta is based in Watertown, Massachusetts. For more information, please visit www.selectabio.com.

About Sobi
Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Sobi is providing sustainable access to innovative therapies in the areas of haematology, immunology and specialty indications. Today, Sobi employs approximately 1,400 people across Europe, North America, the Middle East, Russia and North Africa. In 2019, Sobi’s revenues amounted to SEK 14.2 billion. Sobi’s share (STO:SOBI) is listed on Nasdaq Stockholm. You can find more information about Sobi at www.sobi.com.

This information is information that Swedish Orphan Biovitrum AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of Linda Holmström, Corporate Communication and Investor Relations, at 23:45 CEST on 11 June 2020.
The shares to be sold in the private placement transaction have not been registered under the Securities Act of 1933, as amended (Securities Act), or any state securities laws, and will be sold in a private placement pursuant to an exemption from the registration requirements of the Securities Act. The securities may not be offered or sold in the United States absent registration or pursuant to an exemption from the registration requirements of the Securities Act and applicable state securities laws. Selecta has agreed, subject to certain terms and conditions, to file one or more registration statements under the Securities Act covering the resale of shares of common stock sold pursuant to the share purchase agreement.

This press release does not constitute an offer to sell or the solicitation of an offer to buy the shares, nor shall there be any sale of the shares in any state in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such state. Any offering of the shares under the resale registration statement will only be by means of a prospectus.

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