PRESS RELEASE

Stockholm, Sweden, January 20 2021

Doptelet® (avatrombopag) approved in the EU for treatment of ITP

Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) today announces that the European Commission (EC) has approved an extension of the indication for Doptelet (avatrombopag) to include the treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins) in all European Union (EU) member states.

Immune thrombocytopenia (ITP) is an autoimmune disorder characterised by low numbers of platelets, leading to bruising and an increased risk of bleeding. It is estimated that up to 100 per million people live with ITP, and the disorder is considered chronic when symptoms last more than 12 months. Currently, no cure is available, and these patients have usually relapsed after various treatments, yet still require treatment to reduce the risk of clinically significant bleeding.

“The European approval of Doptelet for the ITP indication is a milestone for people living with ITP across Europe. There is a large unmet medical need within thrombocytopenia and for us this is a great opportunity to be able to give patients access to a new treatment option”, said Ravi Rao, Chief Medical Officer and Head of Research & Development at Sobi.

In addition to current indications, the new indication reads;
Doptelet is indicated for the treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).

About Doptelet® (avatrombopag)
Doptelet is an orally administered thrombopoietin receptor agonist (TPO-RA) that mimics the biologic effects of TPO in stimulating the development and maturation of megakaryocytes, resulting in increased platelet count. It is approved by both the US Food & Drug Administration (FDA) for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure and by the European Medicines Agency (EMA) for the treatment of severe thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo an invasive procedure. In June 2019, Doptelet was approved by the FDA for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. Chronic ITP is a rare autoimmune bleeding disorder characterised by low number of platelets. The incidence of primary ITP in adults is 3.3/100 000 adults per year with a prevalence of 9.5 per 100 000 adults[1].

About immune thrombocytopenia (ITP)
Immune thrombocytopenia is an autoimmune disorder characterised by low numbers of platelets, leading to bruising and an increased risk of bleeding. The incidence of primary ITP in adults is 3.3 per 100 000 adults per year with a prevalence of 9.5 per 100 000 adults[1]. The disorder is considered chronic when symptoms last more than 12 months. There is no cure for these patients, they have usually relapsed after various treatments, and does still require treatment to reduce the risk of clinically significant bleeding.

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 1,500 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.

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[1] (Lambert et al. Blood 2017)