PRESS RELEASE

Stockholm, Sweden, 20 November 2023

Sobi to present new data at ASH 2023 Annual Meeting

Sobi® will present new data at the 65th Annual Meeting of the American Society of Hematology (ASH) in San Diego from the 9th to the 12th of December 2023. During the meeting several analyses will be presented in patients with haemophilia A, paroxysmal nocturnal hemoglobinuria (PNH), immune thrombocytopenia (ITP), relapsed or refractory diffuse large b-cell lymphoma, myelofibrosis, and haemophagocytic lymphohistiocytosis.

"We take pride in our expanded commitment to individuals affected by rare diseases, which we are pleased to highlight at this year's ASH meeting, with research that spans a range of rare and debilitating conditions. We are continuing our strong legacy of elevating standards of care for haemophilia A with two oral presentations. Additionally, we mark our entry into the myelofibrosis field with several poster presentations," said Lydia Abad-Franch, MD, MBA, Head of Research, Development, and Medical Affairs (RDMA), and Chief Medical Officer at Sobi. "We look forward to collaborating and connecting in person at this year's meeting."

Key data to be presented at ASH 2023

Haemophilia A		
Efanesoctocog Alfa	Once-Weekly Efanesoctocog Alfa Prophylaxis Provided High Sustained Factor VIII Activity Levels, Independent of Blood Group, in Children <12 Years of Age with Severe Hemophilia A	Oral presentation. #506 Session: 322 Sunday, December 10, 2023, 12:00 PM - 1:30 PM Presentation Time: 12:15 PM
	Experiences with Efanesoctocog Alfa: Exit Interviews with Caregivers of Previously Treated Patients with Hemophilia A from the XTEND-Kids Phase 3 Clinical Trial	Oral presentation. #507 Session: 322 Sunday, December 10, 2023, 12:00 PM - 1:30 PM Presentation Time: 12:30 PM
	Experience with Accelerometer Activity Tracking in Patients with Hemophilia A: Results from the XTEND-1 Efanesoctocog Alfa Phase 3 Trial	Poster presentation. #2360 Session: 904 Saturday, December 9, 2023, 5:30 PM - 7:30 PM
	Treatment of Bleeding Episodes with Efanesoctocog Alfa in Children with Severe Hemophilia A in the XTEND-Kids Phase 3 Study	Poster presentation. #3993 Session: 322 Monday, December 11, 2023, 6:00 PM - 8:00 PM

Haemophilia A		
	Real-World Unmet Needs in Patients with Hemophilia A Without Inhibitors in the US: Results from the Picnic Health Database	Poster presentation. #2380 Session: 904 Saturday, December 9, 2023, 5:30 PM - 7:30 PM
	Investigating the Relationship between Endogenous Factor VIII Levels and Annual Bleed Rates and Health-Related Quality of Life in Patients with Hemophilia A Not Treated with Factor VIII Prophylaxis	Poster presentation. #5125 Session: 904 Monday, December 11, 2023, 6:00 PM - 8:00 PM
Paroxysmal Nocturnal Hemoglobinuria		
Empaveli® (pegcetacoplan)	Efficacy and Safety Is Maintained in Adult Patients with Paroxysmal Nocturnal Hemoglobinuria Receiving Pegcetacoplan for up to 3 Years	Oral presentation. #574 Session: 508 Sunday, December 10, 2023, 4:30 PM - 6:00 PM Presentation Time: 5:15 PM
Immune Thrombocytopenia		
Doptelet® (avatrombopag)	Interim Baseline Characteristics of Adult Patients with Immune Thrombocytopenia Enrolled in the Observational Multicenter Phase 4 ADOPT Study to Evaluate the Use and Effectiveness of Avatrombopag	Poster presentation. #1226 Session: 311 Saturday, December 9, 2023, 5:30 PM - 7:30 PM
	Interim Analysis of Platelet Response in a Prospective Phase 4 Study in Adult Immune Thrombocytopenia (ITP) Subjects after Switching from Eltrombopag (ELT) or Romiplostim (ROM) to Avatrombopag (AVA)	Poster presentation. #2577 Session: 311, Sunday, 10 December 2023, 6:00 PM - 8:00 PM
	Interim Analysis of Treatment satisfaction from a Prospective Phase 4 Study in Adult Immune Thrombocytopenia (ITP) Subjects after Switching from Eltrombopag or Romiplostim to Avatrombopag	Poster presentation. #3954 Session: 311 Monday, 11 December 2023, 6:00 PM - 8:00 PM
	Real-World Treatment Patterns and Outcomes in Patients with Immune Thrombocytopenia Treated with Avatrombopag in the United States: REAL-AVA 2.0 Study Design	Poster presentation. #5127 Session: 904 Monday, December 11, 2023, 6:00 PM - 8:00 PM
Relapsed/Refractory Diffuse Large B-Cell Lymphoma		
Zynlonta® (loncastuximab tesirine)	Early and Sustained Circulating Tumor DNA Response Dynamics after Loncastuximab Tesirine for Relapsed/Refractory Diffuse Large B-Cell Lymphoma	Poster presentation. #3133 Session: 627 Sunday, December 10, 2023, 6:00 PM - 8:00 PM

Myelofibrosis		
Vonjo® (pacritinib)	Impact of Symptom Benefit and Transfusion Response on Survival in Myelofibrosis Patients Treated with Pacritinib: PERSIST-2 Landmark Survival Analysis	Poster presentation. #3207 Session: 634 Sunday, December 10, 2023, 6:00 PM - 8:00 PM
	Platelet Response in Pacritinib-Treated Patients with Cytopenic Myelofibrosis: a Retrospective Analysis of PERSIST-2 and PAC203 Studies	Poster presentation. #4554 Session: 634 Monday, 11 December 2023, 6:00 PM -8:00 PM
	Retrospective Analysis of the Relationship between Transfusion Independence and Bone Marrow Fibrosis Reduction in Patients with Myelofibrosis Treated with Pacritinib Versus Ruxolitinib	Poster presentation. #4566 Session: 634 Monday, 11 December 2023, 6:00 PM -8:00 PM
	An Analysis of Ruxolitinib Dosing for Myelofibrosis in Real-World Practice	Poster presentation. #5186 Session: 906 Monday, December 11, 2023, 6:00 PM - 8:00 PM
Haemophagocytic Lymphohistiocytosis		
Gamifant® (emapalumab)	Emapalumab, a Fully Human Anti-Interferon Gamma Monoclonal Antibody, in Pediatric Patients With Primary Hemophagocytic Lymphohistiocytosis: Long-Term Follow-up of a Phase 2/3 Study	Poster presentation. #1174 Session: 203 Saturday, December 9, 2023, 5:30 PM - 7:30 PM
	Real-World Treatment Patterns and Outcomes Among Patients with Primary Hemophagocytic Lymphohistiocytosis with and without Infection at Diagnosis and Treated with Emapalumab: The REAL-HLH Study	Poster presentation. #2534 Session: 201 Sunday, December 10, 2023, 6:00 PM - 8:00 PM
	Real-World Treatment Patterns and Outcomes Among Patients with Secondary Hemophagocytic Lymphohistiocytosis Treated with Emapalumab in the United States: The REAL-HLH Study	Poster presentation. #3909 Session: 201 Monday, December 11, 2023, 6:00 PM - 8:00 PM

About efanesoctocog alfa
Efanesoctocog alfa [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein] (formerly BIVV001) is a novel and investigational recombinant factor VIII therapy with the potential to deliver near-normal factor activity levels for a significant parts of the week, improving bleed protection in a once-weekly dose for people with haemophilia A. Efanesoctocog alfa builds on the innovative Fc fusion technology by adding a region of von Willebrand factor and XTEN® polypeptides to extend its time in circulation. It is the only therapy that has been shown to break through the von Willebrand factor ceiling, which imposes a half-life limitation on current factor VIII therapies. It was approved as ALTUVIIIO™ [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl] by Sanofi in the US in February 2023.

About the Sobi and Sanofi collaboration
Sobi and Sanofi collaborate on the development and commercialisation of Alprolix® and Elocta®/Eloctate®. The companies also collaborate on the development and commercialisation of efanesoctocog alfa, an investigational factor VIII therapy with the potential to provide high sustained factor activity levels with once-weekly dosing for people with haemophilia A. Sobi has final development and commercialisation rights in the Sobi territory (essentially Europe, North Africa, Russia and most Middle Eastern markets). Sanofi has final development and commercialisation rights in North America and all other regions in the world excluding the Sobi territory.

About Aspaveli®/ Empaveli®
Aspaveli/Empaveli (pegcetacoplan) is a targeted C3 therapy designed to regulate excessive activation of the complement cascade, part of the body's immune system, which can lead to the onset and progression of many serious diseases. Pegcetacoplan is approved for the treatment of paroxysmal nocturnal haemoglobinuria (PNH) as EMPAVELI®/ASPAVELI in the United States, European Union, and other countries globally. Aspaveli/Empaveli is also under investigation for several other rare diseases across haematology and nephrology.

About the Sobi and Apellis collaboration
Sobi and Apellis have global co-development rights for systemic pegcetacoplan. Sobi has exclusive ex-US commercialisation rights for systemic pegcetacoplan, and Apellis has exclusive US commercialisation rights for systemic pegcetacoplan and retains worldwide commercial rights for ophthalmological pegcetacoplan, including for geographic atrophy (GA).

About Doptelet®
Doptelet (avatrombopag) 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 in over 30 countries worldwide, including the EU and the US, for the treatment of severe thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure, and for the treatment of thrombocytopenia in adult patients with primary 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 Zynlonta®
Zynlonta (loncastuximab tesirine) is a CD19-directed antibody drug conjugate. Once bound to a CD19-expressing cell, Zynlonta is internalised by the cell, where enzymes release a pyrrolobenzodiazepine payload. The potent payload binds to DNA minor groove with little distortion, remaining less visible to DNA repair mechanisms. This ultimately results in cell cycle arrest and tumour cell death. Zynlonta® is a registered trademark of ADC Therapeutics SA. Zynlonta is currently approved for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy, in the United States, European Union and Great Britain.

About ADC Therapeutics
ADC Therapeutics (NYSE: ADCT) is a commercial-stage biotechnology company improving the lives of those affected by cancer with its next-generation, targeted antibody drug conjugates (ADCs). The Company is advancing its proprietary PBD-based ADC technology to transform the treatment paradigm for patients with hematologic malignancies and solid tumours. ADC Therapeutics is based in Lausanne (Biopôle), Switzerland and has operations in London, the San Francisco Bay Area and New Jersey. For more information, please visit adctherapeutics.com and follow the Company on Twitter and LinkedIn.

1. Lambert et al. Blood 2017.

About Vonjo®
VONJO is approved for the treatment of adults with intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 × 109/L. This indication is approved under FDA accelerated approval based on spleen volume reduction. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). CTI is conducting the Phase 3 PACIFICA study of VONJO in patients with myelofibrosis and severe thrombocytopenia as a post-marketing requirement. For more information, please visit www.ctibiopharma.com.

About Gamifant®
Gamifant (emapalumab) is an anti-interferon gamma (IFNγ) monoclonal antibody that binds to and neutralises IFNγ. In the USA, Gamifant is indicated for the treatment of adult and paediatric (newborn and older) patients with primary haemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy. Primary HLH is a rare syndrome of hyperinflammation that usually occurs within the first year of life and can rapidly become fatal unless diagnosed and treated. The FDA approval is based on data from the phase 2/3 studies (NCT01818492 and NCT02069899). Gamifant is indicated for administration through intravenous infusion over one hour twice per week until haematopoietic stem cell transplantation (HSCT).

Sobi®
Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Providing sustainable access to innovative medicines in the areas of haematology, immunology and specialty care, Sobi has approximately 1,800 employees across Europe, North America, the Middle East and Asia. In 2022, revenue amounted to SEK 18.8 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com, LinkedIn and YouTube.

Contacts
For details on how to contact the Sobi Investor Relations Team, please click here. For Sobi Media contacts, click here.