

PRESS RELEASE

Stockholm, Sweden, 8 July 2022



Sobi to license loncastuximab tesirine from ADC Therapeutics

Agreement augments Sobi's strategic presence in haematology with new orphan medicine

Sobi® today announced an exclusive license agreement with ADC Therapeutics SA to develop and commercialise loncastuximab tesirine for use in haematology and other indications of large unmet medical need in Europe and most international markets. Loncastuximab tesirine is an antibody-drug conjugate (ADC) against CD19, a protein expressed on the surface of B cells. It is currently approved in the US for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy. The medicine has orphan drug designation in the EU and is under regulatory review with a decision anticipated in the first quarter of 2023.

The license agreement for loncastuximab tesirine aims at augmenting Sobi's presence in orphan diseases within haematology, one of Sobi's two main disease areas. The medicine will expand Sobi's offering to patients with debilitating orphan diseases in haematology and is anticipated to be made commercially available alongside other Sobi haematology medicines, including Doptelet®.

Guido Oelkers, CEO of Sobi: "Based on our commitment to provide innovative medicines that transform the lives of people with rare and debilitating diseases as well as our stated capital-allocation priorities, we are pleased to announce the license agreement with ADC Therapeutics for loncastuximab tesirine in Europe and most international markets. We believe Sobi's heritage and strong presence in haematology coupled with new medicines like Doptelet will provide a competitive platform for bringing loncastuximab tesirine to more patients with orphan diseases."

Ameet Mallik, CEO of ADC Therapeutics: "We are thrilled to establish this important partnership with Sobi to continue expanding our global reach to bring loncastuximab tesirine to as many patients as possible worldwide. Sobi has a strong global commercial infrastructure, proven capabilities in the areas of haematology and rare diseases, and importantly, shares our passion for improving the lives of patients."

In the EU, loncastuximab tesirine has orphan drug designation for the treatment of DLBCL and is under regulatory review since October 2021 with a decision anticipated in the first quarter of 2023. In April 2021, the US Food and Drug Administration granted accelerated approval for ZYNLONTA, the US brand name for loncastuximab tesirine, as a single-agent treatment for adult patients with relapsed or refractory DLBCL after two or more lines of systemic therapy.

Financial considerations

Under the terms of the license agreement, Sobi has been granted rights to develop and commercialise loncastuximab tesirine for all hematologic and solid tumour indications outside of the United States, greater China, Singapore and Japan. Sobi will pay USD 55 M in an upfront payment, to be financed by Sobi's cash reserves, and USD 50 M at EU regulatory approval in 3rd-line DLBCL. In addition, Sobi will pay royalties from mid-teens to mid-twenties per cent of net sales and up to approximately USD 330 M in potential regulatory and sales milestones. As loncastuximab tesirine is in development for other indications, Sobi will contribute 25 per cent of the direct development costs up to a cap of USD 10 M per year. ADC Therapeutics is responsible for clinical development and product supply to Sobi.

About DLBCL

Diffuse large B-cell lymphoma (DLBCL) is an aggressive, malignant, orphan disease in haematology with an incidence in Europe of approximately 4 cases per 100,000 adults per year¹. As many as 40 per cent of all patients with DLBCL will need at least a 2nd-line treatment as their disease is relapsing or refractory. For those patients, effective treatment options are limited, representing a critical unmet need.

About loncastuximab tesirine

Loncastuximab tesirine (US brand name ZYNLONTA®) is a CD19-directed antibody drug conjugate (ADC). Once bound to a CD19-expressing cell, ZYNLONTA is internalized by the cell, where enzymes release a pyrrolobenzodiazepine (PBD) 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.

The U.S. Food and Drug Administration (FDA) has approved ZYNLONTA (loncastuximab tesirine-lpyl) for the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, DLBCL arising from low-grade lymphoma and also high-grade B-cell lymphoma. The trial included a broad spectrum of heavily pre-treated patients (median three prior lines of therapy) with difficult-to-treat disease, including patients who did not respond to 1st-line therapy, patients refractory to all prior lines of therapy, patients with double/triple hit genetics and patients who had stem cell transplant and CAR-T therapy prior to their treatment with ZYNLONTA. This indication is approved by the FDA under accelerated approval based on overall response rate and continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

ZYNLONTA is also being evaluated as a therapeutic option in combination studies in other B-cell malignancies and earlier lines of therapy.

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' CD19-directed ADC ZYNLONTA (loncastuximab tesirine-lpyl) is approved by the FDA for the treatment of relapsed or refractory diffuse large b-cell lymphoma after two or more lines of systemic therapy. ZYNLONTA is also in development in combination with other agents. Cami (camidanlumab tesirine) is being evaluated in a pivotal Phase 2 trial for relapsed or refractory Hodgkin lymphoma and in a Phase 1b clinical trial for various advanced solid tumours. In addition to ZYNLONTA and Cami, ADC Therapeutics has multiple ADCs in ongoing clinical and preclinical development.

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 <https://adctherapeutics.com/> and follow the Company on Twitter and LinkedIn.

ZYNLONTA® is a registered trademark of ADC Therapeutics SA.

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 the EU and in 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 adults².

References

1. Sant et al., Blood, 2010.
2. Lambert et al., Blood, 2017.

**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 1,600 employees across Europe, North America, the Middle East and Asia. In 2021, revenue amounted to SEK 15.5 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](#).

This information is information that Sobi is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below, at 08:00 CEST on 8 July 2022.

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