PRESS RELEASE

Stockholm, Sweden, 16 September 2022

Loncastuximab tesirine receives positive CHMP opinion for the treatment of relapsed or refractory diffuse large B-cell lymphoma

Sobi® and ADC Therapeutics SA today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has adopted a positive opinion recommending the marketing authorisation of loncastuximab tesirine for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), a debilitating orphan disease in haematology. The positive opinion from the CHMP is now referred to the European Commission for a decision.

“Today’s announcement marks an important step in meeting the critical needs of patients with relapsed and refractory large B-cell lymphoma across the EU,” said Anders Ullman, Head of Research & Development and Chief Medical Officer at Sobi. “We believe Sobi's heritage and strong presence in haematology will provide a competitive platform for bringing loncastuximab tesirine to more patients.”

The opinion is based on data from LOTIS-2, a large (n=145) phase 2 multinational, single-arm clinical study of loncastuximab tesirine as single agent for the treatment of adult patients with relapsed or refractory DLBCL following two or more prior lines of systemic therapy. In April 2021, the US Food and Drug Administration granted accelerated approval to loncastuximab tesirine-lpyl as the first and only CD19-targeted antibody-drug conjugate as a single-agent treatment for adult patients with relapsed or refractory DLBCL after two or more lines of systemic therapy. In September 2021, the European Commission granted orphan designation to loncastuximab tesirine for the treatment of DLBCL.

“The positive CHMP opinion demonstrates significant progress toward bringing loncastuximab tesirine to DLBCL patients in Europe,” said Ameet Mallik, Chief Executive Officer of ADC Therapeutics. “We are committed, along with our partners, to making loncastuximab tesirine available to as many patients as possible worldwide and look forward to the European Commission’s final decision.”

In July 2022, Sobi 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. The license agreement for loncastuximab tesirine aimed at augmenting Sobi's presence in orphan diseases within haematology, one of Sobi's 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 following EU approval.

“The results of the LOTIS-2 study demonstrated significant clinical benefit for patients with recurrent diffuse large B-cell lymphoma, an aggressive subtype of non-Hodgkin lymphoma,” said John Radford, Professor of Medical Oncology at The University of Manchester and Christie NHS Foundation Trust in Manchester, UK. “I am encouraged by the potential of loncastuximab tesirine to help patients in this underserved treatment population. If approved by the European Commission, loncastuximab tesirine will offer a new therapeutic option to patients with this difficult to treat lymphoma and gives hope to them and their families.”

About DLBCL

Diffuse large B-cell lymphoma (DLBCL) is an aggressive, malignant, orphan disease in haematology with an incidence in Europe of approximately 8.8 cases per 100,000 adults per year[1]. 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[2].

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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 internalised 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 US 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 LOTIS-2 study 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 first-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 study.

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 haematologic malignancies and solid tumors.

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 study for relapsed or refractory Hodgkin lymphoma and in a phase 1b clinical study 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.

References
1. The incidence is based on data from Cancer Research UK (Cancer Research UK, 2021) assuming a DLBCL/non-Hodgkin lymphoma proportion of 41% (8.8 per 100,000).
2. R-CHOP resistance in diffuse large B-cell lymphoma: biological and molecular mechanisms: R-CHOP resistance in diffuse large B-cell lymphoma: biological and molecular mechanisms - PMC (nih.gov).

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
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