PRESS RELEASE

Stockholm, Sweden, 21 December 2022

Zynlonta® (loncastuximab tesirine) approved in the EU for the treatment of relapsed or refractory diffuse large B-cell lymphoma

Sobi® and ADC Therapeutics SA today announced that the European Commission (EC) has granted conditional marketing authorisation for the use of Zynlonta® (loncastuximab tesirine) for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL). The approval follows a positive opinion issued in September by the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA).

“We are delighted by the European Commission’s approval of Zynlonta” said Anders Ullman, Head of Research & Development and Medical Affairs, Chief Medical Officer at Sobi. “We look forward to making Zynlonta available as a new treatment option to patients in the EU impacted by diffuse large B-cell lymphoma, a debilitating disease in haematology.”

The approval is based on data from LOTIS-2, a large (n=145) phase 2 multinational, single-arm clinical study of Zynlonta 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 of Zynlonta as the first 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 July, Sobi announced an exclusive license agreement with ADC Therapeutics to develop and commercialise Zynlonta for use in haematology and other indications of large unmet medical need in Europe and most international markets. The license agreement aimed at augmenting Sobi's presence in haematology, one of Sobi's two main disease areas. Zynlonta will be made commercially available alongside other Sobi haematology medicines.

“This approval marks a major milestone in our pursuit to expand the global reach of Zynlonta,” said Ameet Mallik, Chief Executive Officer of ADC Therapeutics. “We are thrilled that Zynlonta will be available to help fill a critical unmet need for patients with DLBCL across Europe.”

The EC decision is valid in all European Union member states, Iceland, Norway and Liechtenstein. As a routine part of the marketing authorisation process, the EMA's Committee for Orphan Medicinal Products reviewed the orphan designation and decided not to uphold it.

Financial considerations

Under the terms of the license agreement and as previously communicated, Sobi will pay USD 50 M to ADC Therapeutics as a result of the EU approval in DLBCL. ADC Therapeutics is responsible for clinical development and product supply to Sobi. For more details on the financial considerations, please visit sobi.com.

About DLBCL

Diffuse large B-cell lymphoma (DLBCL) is an aggressive and malignant 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 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.

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 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. Please see full prescribing information including important safety information about Zynlonta at zynlonta.com.

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. In addition to Zynlonta, 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 - 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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