Tanabe Pharma
Creating hope for all facing illness.

Press Release

October 29, 2026

Tanabe Pharma Files for Japanese Approval of loncastuximab tesirine-lpyl (MT-2111) for Relapsed or Refractory Diffuse Large B-cell Lymphoma and Signs Exclusive Sublicense Agreement with Nippon Shinyaku

Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director, CEO: Akihisa Harada; hereinafter, "Tanabe Pharma") today announced that it filed a marketing authorization application with Japan's Ministry of Health, Labour and Welfare on October 29, 2026, for loncastuximab tesirine-lpyl (MT-2111), a CD19-directed antibody drug conjugate (ADC) for the treatment of patients with relapsed or refractory (r/r) diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy. Tanabe Pharma also entered into an exclusive sublicense agreement with Nippon Shinyaku Co., Ltd. (Head office: Minami-ku, Kyoto; President: Toru Nakai; hereinafter "Nippon Shinyaku") on October 22, granting Nippon Shinyaku exclusive rights to commercialize the product in Japan.

ZYNLONTA® (loncastuximab tesirine-lpyl) received accelerated approval from the U.S. Food and Drug Administration (FDA) in April 2021 as the first and only CD19-targeted ADC approved as monotherapy for adults with r/r DLBCL after two or more lines of systemic therapy. In January 2022, Tanabe Pharma entered into an exclusive license agreement with ADC Therapeutics SA (NYSE: ADCT) to develop and commercialize ZYNLONTA® in Japan across all hematologic and solid tumor indications. The marketing authorization application in Japan is based on the results from the MT-2111-A-101 study and studies conducted outside Japan by ADC Therapeutics.

The sublicense agreement with Nippon Shinyaku is intended to maximize the value of MT-2111 in Japan and support a reliable supply of the product to patients following regulatory approval. By drawing on Nippon Shinyaku's expertise and established presence in hematologic malignancies, Tanabe Pharma aims to expand patient access to the treatment. The agreement is also expected to enhance Tanabe Pharma's financial and strategic flexibility.
Tanabe Pharma will remain responsible for obtaining regulatory approval in Japan under the current application.

Guided by our MISSION, "Creating hope for all facing illness," Tanabe Pharma will continue to address unmet medical needs, including rare diseases, through both in-house development and strategic partnerships, delivering innovative medicines to patients.

■About MT-2111, ZYNLONTA® (loncastuximab tesirine-lpyl)

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 tumor cell death.

The U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have 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 diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), 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 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 and in the European Union under conditional 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. Please see full prescribing information including important safety information about ZYNLONTA® at www.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 MT-2111-A-101 Study (Phase 1/2 Study for Japanese Patients with r/r DLBCL)

MT-2111-A-101, a Phase 1/2, multi-center, open-label, single-arm study consists of a Phase 1 and a Phase 2 part.

The Phase 1 part investigated the safety, tolerability, and pharmacokinetics of MT-2111 monotherapy in patients with r/r DLBCL. The Phase 2 part evaluated the efficacy, safety and pharmacokinetics of MT-2111 monotherapy in r/r DLBCL patients. The primary endpoint of the Phase 2 part is ORR (Overall Response Rate) by independent review committee. The key secondary endpoints include CRR (Complete Response Rate), DOR (Duration of Response), PFS (Progression Free Survival), etc. The Phase 2 part enrolled total 43 Japanese patients.

■About Tanabe Pharma

Tanabe Pharma Corporation is a Japan-focused, innovation-driven pharmaceutical company guided by its mission, "Creating hope for all facing illness." Founded in 1678, the company is one of Japan's oldest pharmaceutical companies and is committed to addressing unmet medical needs through R&D, business development, and strategic partnerships with the aim of improving the lives of patients.

For more information, visit https://www.tanabe-pharma.com/en/

■About Nippon Shinyaku

Based on Nippon Shinyaku's business philosophy, "Helping people lead healthier, happier lives," we aim to be an organization trusted by the community through creating unique medicines that will bring hope to patients and families suffering from illness. Please visit our website (https://www.nippon-shinyaku.co.jp/english/) for products or detailed information.

■About ADC Therapeutics

ADC Therapeutics (NYSE: ADCT) is a commercial-stage global leader and pioneer in the field of antibody drug conjugates (ADCs), transforming treatment for patients through our focused portfolio with ZYNLONTA® (loncastuximab tesirine-lpyl).

ADC Therapeutics' CD19-directed ADC ZYNLONTA® received accelerated approval by the FDA and conditional approval from the European Commission 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 and in earlier lines of therapy.

Headquartered in Lausanne (Biopôle), Switzerland, with operations in London and New Jersey, ADC Therapeutics is focused on driving innovation in ADC development with specialized capabilities from clinical to manufacturing and commercialization. Learn more at adctherapeutics.com and follow us on LinkedIn.