

Press Release

January 29, 2026

MT-2111 (loncastuximab tesirine-lpyl) Achieved Primary Endpoint in Phase 2 part of Japanese Phase 1/2 study for Relapsed or Refractory Diffuse Large B-cell Lymphoma

Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director, CEO: Akihisa Harada; hereinafter, “Tanabe Pharma”) today announced that MT-2111 (ZYNLONTA[®], loncastuximab tesirine-lpyl), a CD19-directed antibody drug conjugate (ADC), achieved the primary endpoint of overall response rate (ORR*) in a Phase 2 part of the Japanese Phase 1/2 study (MT-2111-A-101, NCT05658562) in patients with relapsed or refractory (r/r) diffuse large B-cell lymphoma (DLBCL).

This local study is a bridging study of ADC Therapeutics’ global pivotal Phase 2 LOTIS-2 clinical study of ZYNLONTA[®]. The safety profile was consistent with the overseas studies.

“These encouraging results are the outcome of our research and development efforts and strong collaborations with our partners.” said Yosuke Kimura, PhD, Head of Development and Medical Affairs Division of Tanabe Pharma. “This progress brings new hope to patients and reinforces our mission “creating hope for all facing illness” to deliver innovative therapies that improve lives. We remain committed to conducting rigorous evaluations and working with regulatory body to make this treatment available as swiftly as possible.”

“We congratulate our partners at Tanabe Pharma on completion of the Japanese Phase 1/2 study and are pleased to see these clinical data, further supporting the strength of ZYNLONTA[®] in DLBCL,” said Ameet Mallik, Chief Executive Officer of ADC Therapeutics. “With this latest milestone in the ZYNLONTA[®] development program, together with our partner in Japan, we are now one step closer to bringing this important treatment option to even more relapsed/refractory DLBCL patients in need.”

In April 2021, ZYNLONTA[®] was granted accelerated approval by the U.S. Food and Drug Administration (FDA) as the first and only CD19-targeted ADC as a single-agent treatment for adult patients 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) for the development and commercialization of ZYNLONTA[®] for all hematologic and solid tumor indications in Japan. Tanabe Pharma will file a new drug application in Japan based on the results of MT-2111-A-101 study and overseas studies conducted by ADCT.

Tanabe Pharma will take on the new challenge of oncology and strive to bring new treatments to patients suffering from cancer.

*ORR is defined as the proportion of patients with cancer who have a partial or complete response to the therapy.

<p>Contact: Tanabe Pharma Corporation CEO Office PR Group +81-6-6205-5119</p>
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■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 <https://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 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](#).