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MT-2111 in Phase 2 part of Phase 1/2 Clinical Trial in Diffuse Large B-cell Lymphoma in Japan

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Akihiro Tsujimura; hereinafter, "MTPC"), a member of the Mitsubishi Chemical Group, today announced the initiation of the Phase 2 part of a Phase 1/2 clinical study (MT-2111-A-101, NCT05658562) with MT-2111, ZYNLONTA® (loncastuximab tesirine-lpyl) in patients with relapsed or refractory (r/r) diffuse large B-cell lymphoma (DLBCL) in Japan.

In April 2021, ZYNLONTA® was granted accelerated approval by the U.S. Food and Drug Administration (FDA) as the first and only CD19-targeted antibody drug conjugate (ADC) as a single-agent treatment for adult patients with r/r DLBCL after two or more lines of systemic therapy. In January 2022, MTPC 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. This local study mirrors ADC Therapeutics' global pivotal Phase 2 LOTIS-2 clinical trial of ZYNLONTA®.

"We are proud to have reached this important milestone. Although significant progress has been made in the treatment of DLBCL over the past decades, relapse and refractory nature of the disease continue to remain a significant concern," said Hideki Kuki, Head of Ikuyaku. Integrated Value Development Division of MTPC. "We are excited about MT-2111's potential to make a meaningful difference for patients living with r/r DLBCL in Japan and look forward to advancing this candidate in clinical development."

"We are excited by the progress our partner in Japan has made in the ZYNLONTA® development program," said Ameet Mallik, Chief Executive Officer of ADC Therapeutics. "This is an important part of our global effort to bring this differentiated treatment option to appropriate patients with DLBCL around the world."

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. MTPC conducted the Phase 1 part of this study in Japan and MT-2111 was shown to be safe and well-tolerated in Japanese patients. Therefore, it was decided to proceed to the Phase 2 part of the study which aims to evaluate the efficacy, safety and pharmacokinetics of MT-2111 monotherapy in r/r DLBCL patients.

Leveraging its strengths in drug discovery, MTPC will take on the new challenge of oncology and strive to bring new treatments options to patients suffering from cancer.

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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) 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 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.
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 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. 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 LinkedIn.