



February 14, 2019

**FDA accepted an Investigational New Drug Application for MT-8633, an ADC Targeting cMet Positive Solid Tumors**

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; President & Representative Director: Masayuki Mitsuka, MTPC) announced today that the U.S. Food and Drug Administration (FDA) cleared Tanabe Research Laboratories U.S.A. (TRL)'s first Investigational New Drug (IND) application to initiate a phase 1 for its Antibody Drug Conjugate (ADC) MT-8633/TR1801-ADC in patients with cMet positive solid tumors. TRL is a pharmaceutical research and development subsidiary of MTPC.

MT-8633 is an extremely potent ADC that combines a non-agonizing anti-c-Met antibody developed at TRL, with a pyrrolobenzodiazepine dimer (PBD) toxin, and has demonstrated potent dose dependent anti-tumor activity against Met positive tumors in preclinical models'. The PBDs were developed by TRL's collaborative partner MedImmune Limited (Headquarters: Maryland, U.S.A; Chief Operating Officer: Matt Bell) and licensed to TRL. PBDs are of an order of magnitude more potent than other warheads currently used with other ADCs, and in the case of MT-8633 are linked to the antibody via a site-specific conjugation site.

cMet, also referred to as the hepatic growth factor receptor (HGFR), is a validated target expressed on a variety of tumor types including colorectal, NSCLC, gastric, esophageal, pancreatic, bile duct and many other cancers.

Regarding the oncology domain where MTPC's RD knowledge has not been accumulated yet, TRL chooses the option to utilize open innovation to challenge through a study of MT-8633. MTPC concluded a licensing agreement between Open Innovation Partners (OIP) which was established by DCI partners (Head Office: Chiyoda-ku, Tokyo; President & Representative Director: Hiroki Narita) of the Daiwa Securities group in December, 2017. MTPC and OIP will accelerate the development of MT-8633 in this framework.

MTPC Group will continue challenging to contribute to the patients' health around the world through creating innovative antibody drugs that address unmet medical needs.

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## ◆ Reference ◆

### **Tanabe Research Laboratories U.S.A. Inc. (TRL)**

TRL is an independent subsidiary of MTPC located in San Diego California, whose role is to discover and develop biological drug candidates for therapy. Currently, TRL's efforts are directed towards antibody and antibody-related research to target tumors and other diseases with high unmet needs.

TRL has established collaborative relationships with other companies and academic research organizations to develop Antibody Drug Conjugates (ADCs) and to further its goals of identifying preclinical therapeutic lead compounds for development. <http://trlusa.com>

### **MedImmune Limited**

MedImmune is the global biologics research and development arm of AstraZeneca. MedImmune is pioneering innovative research and exploring novel pathways across key therapeutic areas, including respiratory, inflammation and autoimmunity; cardiovascular and metabolic disease; oncology; neuroscience; and infection and vaccines. The MedImmune headquarters is located in Gaithersburg, MD., one of AstraZeneca's three global R&D centres.

### **Open Innovation Partners (OIP)**

Open Innovation Partners was established by DCI Partners of the Daiwa Securities group to specialize the development of MT-8633. OIP will accelerate the development of MT-8633 by using a fund from Daiwa Taiwan-Japan Biotech Fund Investment Limited Partnership via DCI Partners.