Mersana Announces FDA Clearance of IND Application for Lead Antibody-Drug Conjugate XMT-1522

October 24, 2016

Cambridge, Mass., October 24, 2016 - Mersana Therapeutics, Inc., a biotechnology company focused on discovering and developing a pipeline of antibody drug conjugates (ADCs) based on its proprietary Fleximer® platform technology, today announced that the U.S. Food and Drug Administration (FDA) cleared the company's Investigational New Drug (IND) application to begin Phase 1 clinical trials for its lead oncology drug candidate XMT-1522. The compound is Mersana's first pipeline product, and defines a new class of HER2-targeted therapies.

The drug is being co-developed with Takeda Pharmaceutical Company Limited (TSE:4502) and as part of that agreement Mersana will receive a $20 million milestone payment based on FDA clearance of this IND. In February, Takeda, through its wholly owned subsidiary Millennium Pharmaceuticals, Inc., entered into a strategic partnership with Mersana to co-develop XMT-1522, and Mersana will lead execution of the Phase 1 trial. Mersana will retain full commercial rights in the United States and Canada while Takeda will have rights in rest of world.

"XMT-1522 represents a promising therapeutic approach for cancer patients with significant unmet medical needs and we are pleased to be in a position to move this therapy into clinical development." said Donald A. Bergstrom, M.D. Ph.D., Chief Medical Officer, Mersana Therapeutics. "We have designed a robust Phase I program that will allow us to better understand the potential of XMT-1522 to address the needs of several patient groups who currently have limited options."

XMT-1522 incorporates a novel, proprietary HER2 antibody, which is conjugated with Mersana's Dolaflexin platform which includes its Fleximer technology and proprietary auristatin payload. XMT-1522 provides a drug load of approximately 12 molecules per antibody, specifically designed to improve potency while simultaneously increasing tolerability. XMT-1522 has the potential to extend HER2-targeted therapy beyond the current "HER2-positive" populations into patients with lower levels of HER2 expression. The Phase 1 protocol will evaluate XMT-1522 in patients with advanced HER2-positive breast and gastric cancer, as well as advanced breast cancer with low HER2 expression and non-small cell lung cancer.

"Our partnership with Mersana exemplifies our approach of uniting Takeda's experience in bringing novel oncology therapies to market with promising drug discovery technology like Mersana's Fleximer to help drive science forward for patients with unmet medical needs," said Phil Rowlands, Interim Head, Oncology Therapeutic Area Unit, Takeda.

About Mersana Therapeutics

Mersana Therapeutics engineers antibody-drug conjugates (ADCs) that maximize the potential of new and established therapeutic classes. Mersana is developing, with select pharmaceutical partners, a portfolio of next-generation Fleximer® ADCs with superior properties not found with current ADC technologies. The company is also advancing its own pipeline of Fleximer-ADCs with best-in-class potential to address unmet needs and improve patient outcomes in multiple oncology indications.

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