**Hanmi Pharmaceutical Confirms ‘Complete Remission’ in Phase 1/2 Study of Its Innovative Selective CCR4 Antagonist**

**Hanmi Presents Stage 1 Final Results of Phase 2 Tivumecirnon in combination with** **MSD’s (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) Study at ASCO GI in the US
Tivumecirnon (FLX475) in combination with KEYTRUDA Shows Exceptional Antitumor Efficacy in EBV-Positive Gastric Cancer**

Hanmi Pharmaceutical has showcased the innovative potential of its selective oral CCR4 antagonist, Tivumecirnon (codename: FLX475), in combination with the anti-PD-1 therapy KEYTRUDA® (pembrolizumab). This development stems from a Phase 1/2 study conducted in a clinical collaboration with US-based RAPT Therapeutics and MSD.

On February 17, Hanmi announced its participation in the 2025 ASCO Gastrointestinal Cancers Symposium (American Society of Clinical Oncology GI Cancers Symposium) held in San Francisco, USA, from January 23 to 25. During the event, the company disclosed the final results of the Phase 2 clinical trial of Tivumecirnon—an innovative gastric cancer drug—via a poster presentation.

Tivumecirnon is an oral(small molecule), selective antagonist targeting the CCR4 receptor protein, which facilitates the migration of regulatory T cells (Tregs) into tumors, suppressing immune responses. By blocking this receptor, Tivumecirnon aims to reduce immune suppression signals in the tumor microenvironment (TME), thereby enhancing immune activity to deliver a robust antitumor effect.

This candidate was introduced to the company from the US immunology and oncology-based therapeutics company RAPT Therapeutics in 2019, and the following year, Hanmi signed a clinical collaboration agreement with MSD for combination therapy, including the supply of KEYTRUDA.

At the 2025 ASCO Gastrointestinal Cancers Symposium, Hanmi unveiled the final results of a Phase 2 clinical trial demonstrating the excellent antitumor efficacy and tolerability of Tivumecirnon (FLX475) in combination with KEYTRUDA in patients with Epstein-Barr Virus (EBV)-positive gastric cancer.

The trial was conducted on patients with advanced or metastatic gastric cancer, divided into two cohorts based on their EBV status. Cohort 1 included patients with EBV-negative gastric cancer who had failed at least two prior treatments, while Cohort 2 involved patients with EBV-positive gastric cancer who had failed at least one prior treatment. Importantly, none of the patients had previously been treated with immune checkpoint inhibitors(ICI-naive).

In Cohort 1, which consisted of 10 patients with EBV-negative gastric cancer, no objective response rate (ORR) was observed, although two patients achieved stable disease (SD). By contrast, the results in Cohort 2 were far more promising. Among the 10 patients with EBV-positive gastric cancer, an ORR of 60% was achieved, including one complete response (CR) and five partial responses (PR).

The data further revealed that the median time to response (mTTR) was 2.7 months, while the median duration of response (mDOR) extended to 17.3 months. Additionally, the median progression-free survival (mPFS) for Cohort 2 was confirmed to be 10.4 months.

A safety analysis of all 20 patients enrolled in the trial showed that most treatment-related adverse events were manageable, with no new safety concerns identified.

Commenting on these findings, Professor Do-Youn Oh, of the Department of Hematology and Oncology at Seoul National University Hospital, who served as the principal investigator, stated, “Tivumecirnon in combination with KEYTRUDA demonstrated significant antitumor effects in patients with EBV-positive gastric cancer. The high objective response rate and sustained duration of response highlight new possibilities for cancer immunotherapy. These results represent a critical advancement, underscoring the innovative potential of CCR4 receptor-targeted therapies.”

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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