**Hanmi Pharmaceutical and Beijing Hanmi Progress Clinical Trials of Co-developed BH3120 as a Next-Generation Cancer Immunotherapy**

**Hanmi unveils tiral in progress poster on BH3120 at the Society for Immunotherapy of Cancer (SITC) in the U.S.   
Phase 1 trial is progressing smoothly, with no dose-limiting toxicity observed  
Phase 1 trial evaluating the combination of BH3120 and MSD’s anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) underway**

The latest progress in the clinical trial of BH3120, an innovative immunotherapy jointly developed by Hanmi Pharmaceutical and Beijing Hanmi Pharmaceutical, was recently presented at a major global academic conference, drawing significant attention in the field of immunotherapy.

On November 25, Hanmi announced that it presented the research and clinical progress of BH3120 in a poster session at the Society for Immunotherapy of Cancer (SITC) conference, held in Houston, USA, from November 6 to 10.

BH3120 is a novel anticancer drug based on Hanmi’s proprietary dual antibody platform, "Pentambody." This technology enables a single antibody to simultaneously bind to two distinct targets, allowing for a targeted anticancer action by specifically attacking cancer cells while activating immune cells to enhance immunotherapy effects.

BH3120 is designed to target PD-L1 on cancer cells and 4-1BB on immune cells, thereby acting as a “bridge” that facilitates immune cells’ recognition and killing of tumor cells.

While other 4-1BB-targeting antibody candidates have faced anticancer efficacy or safety challenges, BH3120’s preclinical studies reveal robust anticancer efficacy alongside a unique decoupling of immune activity between the tumor microenvironment (TME) and normal tissues. This distinct mechanism highlights BH3120’s potential as a breakthrough in developing an effective and safer anticancer therapy.

During the SITC presentation, Hanmi outlined the background, design, and clinical progress of BH3120. Currently, a global Phase 1 clinical trial is underway in South Korea and the United States, assessing the safety and tolerability of BH3120 as a monotherapy in patients with advanced or metastatic solid tumors.

The Phase 1 clinical trial has progressed smoothly through cohort 3 (1 mg/kg) of the dose escalation phase, with no dose-limiting toxicities (DLT) or grade 3 or higher adverse drug reactions observed to date.

Dr. Dong-wan Kim, director of the Seoul National University Hospital Clinical Trials Center (Hemato-Oncology Department) and lead investigator for the phase 1 clinical trial of BH3120 remarked, “The phase 1 clinical trial of BH3120 is a critical step in verifying the potential of this next-generation immunotherapy. We are optimistic about achieving positive outcomes.” He added, “We hope further research will establish BH3120 as an effective and safe treatment option for various cancer types, reducing the side effects often associated with current immunotherapies.”

In parallel, Hanmi is also conducting a Phase 1 trial to assess the safety and efficacy of BH3120 in combination with MSD’s (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in patients with advanced or metastatic solid tumors.

In September, Hanmi obtained approval from both the Korean Ministry of Food and Drug Safety and the U.S. Food and Drug Administration (FDA) to modify the Phase 1 trial plan to evaluate BH3120 in combination with KEYTRUDA. Full-scale clinical development is expected to commence early next year. Hanmi will serve as the lead sponsor and conduct the clinical trial, while MSD will supply KEYTRUDA for the trial.

Young Su Noh, Director of Hanmi’s ONCO Clinical Team, emphasized, “The BH3120 trial represents a milestone as Hanmi’s first global clinical research project utilizing our proprietary Pentambody dual antibody platform in immuno-oncology, a field at the forefront of cancer treatment innovation.” He continued, “We are committed to advancing a next-generation immunotherapy that overcomes the limitations of existing treatments and enhances therapeutic efficacy.”

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

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