Innovent Biologics begins patient dosing in phase 3 study of IBI354 for first line treatment of HER2-positive breast cancer

Innovent Biologics, Inc. (Innovent), a world-class biopharmaceutical company that develops, manufactures and commercializes high quality medicines, announces that the first participant has been successfully dosed in the pivotal phase 3 clinical study (HeriCare-Breast01). The trial is evaluating the company's developed IBI354 (HER2 Monoclonal Antibody-Camptothecin Derivative Conjugate, HER2 ADC) as a first-line treatment for patients with unresectable locally advanced or metastatic HER2-positive breast cancer. IBI354 has two pivotal phase 3 trials ongoing (HeriCare-Ovarian01, HeriCare-Breast01), which holds potential to deliver a new generation of ADC therapies characterized by "high potency and low-toxicity".

HeriCare-Breast01 (NCT07377643) is a multicenter, randomized, open-label, active-controlled study designed to evaluate the safety and efficacy of IBI354, with or without pertuzumab, compared with the current standard-of-care, paclitaxel plus trastuzumab and pertuzumab (THP). The primary endpoint is progression-free survival (PFS).

Previously, in a multicenter phase 1/2 study in participants with advanced solid tumours, a total of 88 participants with HER2-positive breast cancer were enrolled(the median prior treatment lines was 4) and were treated with 6-15 mg/kg doses of IBI354.

As of March 24, 2025, the overall confirmed objective response rate (cORR) was 59.1% and the disease control rate (DCR) was 90.9%.

Among them, ORR reached 72.4% and DCR reached 89.7% in 29 breast cancer participants treated with 9mg/kg Q3W.

The median follow-up time of 9mg/kg Q3W dose group was 13.6 months as of the cut-off date, and progression-free survival (PFS) was 14.1 month(95%CI: 8.3, NC). The data were presented at the ASCO 2025[Link].

IBI354 also demonstrated an excellent safety profile in this Phase 1/2 clinical study (n=368).

No DLT was occurred up to 18mg/kg dose group.

The overall incidence of grade 3 or higher treatment-related adverse events (TRAEs) in 9mg/kg Q3W dose group was 21.0%, the incidence of TRAEs leading to dose interruption was 9.9%, the incidence of TRAEs leading to dose reduction was 1.2%, the overall incidence of TRAEs leading to discontinuation was 1.2%, and no TRAE leading to death reported.

The most common TRAEs are white blood cell count decreased, nausea and anemia. The incidence of interstitial lung disease was only 1.2%, all were grade 1.

The Principal Investigator of the HeriCare-Breast01 study, Binghe Xu, academician of the Chinese Academy of Engineering from Cancer Hospital Chinese Academy of Medical Sciences, stated, “We are pleased to complete the first patient enrollment for the HeriCare-Breast01 study at our center. Although first-line treatment for HER2-positive advanced breast cancer has improved substantially—with the THP regimen delivering durable responses for many patients—important clinical challenges remain. These include treatment discontinuation driven by toxicity and limited tolerability of currently available ADCs, particularly among older patients and those with comorbid conditions. As a next-generation HER2-targeted ADC, IBI354 has shown compelling antitumor activity in phase 1/1b studies, achieving class-leading ORR and DCR, alongside a notably favourable safety profile. In particular, IBI354 has demonstrated reduced incidence of key adverse events such as interstitial lung disease (ILD), peripheral neuropathy, and neutropenia. This “high-efficacy, low-toxicity” therapeutic window may allow a broader range of patients to achieve sustained, high-quality treatment outcomes. We look forward to the phase 3 HeriCare-Breast01 study to further validate this potential and advancing IBI354 toward becoming a new standard of care in the first-line treatment for HER2-positive advanced breast cancer. ”

Dr Zhou Hui, chief R&D officer (Oncology) of Innovent, stated, “The initiation of the pivotal phase 3 HeriCare-Breast01 trial in China marks a significant milestone in the clinical translation of Innovent's ADC pipeline. Leveraging the world's leading antibody engineering and differentiated linker-payload technologies, Innovent has established a highly competitive and innovative TOPO1i ADC technology platform SoloTx. IBI354 has demonstrated a compelling safety and efficacy profile in early-stage studies, strongly validating the strengths of our SoloTx ADC platform. IBI354 holds strong potential to offer a new first-line treatment option for patients with HER2-positive advanced breast cancer—one that combines durable antitumor activity with favourable long-term tolerability. Looking ahead, Innovent will continue to advance innovation of next-generation IO+ADC, with a steadfast commitment to delivering improved therapeutic outcomes for cancer patients.”

Breast cancer is one of the most common cancers among women worldwide. Approximately 1.3 million women are diagnosed with breast cancer each year, and about 30% of them develop locally advanced or metastatic breast cancer. The clinical proportion of HER2-positive breast cancer is approximately 20%. Previous studies have demonstrated that overexpression of this HER2 gene plays a significant role in the occurrence and development of invasive breast cancer and is associated with an increased recurrence rate and poor prognosis. At present, no ADC targeting HER2 has been fully approved for first-line treatment of advanced breast cancer in China. There is an urgent need for new drugs to improve the prognosis of patients.

IBI354 is an innovative HER2-targeted antibody–drug conjugate developed using Innovent's proprietary SoloTx ADC platform. Based on this platform, Innovent is promoting clinical trial studies multiple self-developed ADC molecules, which have shown promising safety and efficacy signals.

With a drug-to-antibody ratio (DAR) of 8, IBI354 delivers a high payload of effective drugs to tumours. The highly hydrophilic linker design contributes to its excellent biophysical and pharmacokinetic (PK) properties, while the hydrophobic payload enhances its bystander effect, targeting adjacent antigen-low or negative tumour cells. IBI354 exhibits extremely low exposure of free toxin in circulation and has an ideal safety profile based on pre-clinical and clinical studies. IBI354 has demonstrated remarkable anti-tumour activity in various tumour-bearing mice models, particularly in those resistant to HER2-targeted therapies and in metastatic tumours.

Starting from the urgent clinical needs, in addition to the phase 3 studies (HeriCare-Breast01 and HeriCare-Ovarian01) already initiated in BC and PROC, Innovent will explore IBI354 in multiple solid tumour indications.

Innovent is a leading biopharmaceutical company founded in 2011 with the mission to empower patients worldwide with affordable, high-quality biopharmaceuticals. The company discovers, develops, manufactures and commercializes innovative medicines that target some of the most intractable diseases. Its pioneering therapies treat cancer, cardiovascular and metabolic, autoimmune and eye diseases.

News Source:

https://www.pharmabiz.com/NewsDetails.aspx?aid=184240&sid=2