VEGF/DLL4 Bispecific Antibody Meets Primary Endpoint in Phase 2/3 Clinical Trial for Biliary Tract Cancer

The VEGF/DLL4 bispecific antibody (CTX-009/ES104) has successfully achieved its primary endpoint in a Phase 2/3 clinical trial for biliary tract cancer (BTC), showing potential as a new global standard for second-line BTC treatment.

On April 1, 2025, Compass Therapeutics announced promising Phase 2/3 data from their VEGF/DLL4 bispecific antibody Tovecimig (CTX-009) in second-line BTC treatment. The trial demonstrated that Tovecimig combined with paclitaxel significantly improved the objective response rate (ORR) to 17.1%, compared to just 5.3% with paclitaxel monotherapy, meeting its primary clinical endpoint. These compelling results position the Tovecimig combination as a potential new standard of care for second-line BTC treatment worldwide, bringing renewed hope to patients.

Elpiscience holds the Greater China rights to the VEGF/DLL4 bispecific antibody Tovecimig, ES104.

Key data from the trial, which enrolled 168 BTC patients randomized at a 2:1 ratio into either the Tovecimig plus paclitaxel group (n=111) or the paclitaxel-only group (n=57), include:

- **An ORR of 17.1%** in the Tovecimig plus paclitaxel group, including one complete response (CR), versus **5.3% in the paclitaxel-only control**.
- Statistically significant ORR improvement (p=0.031) as confirmed by blinded independent central radiology review.
- **Disease progression rate notably lower in the Tovecimig combination group at 16.2%**, compared with 42.1% in the control group, underscoring the efficacy of Tovecimig in controlling disease progression.
- Tovecimig demonstrated favorable tolerability and safety, consistent with prior studies.

Secondary clinical endpoints, including progression-free survival (PFS) and overall survival (OS), are anticipated to be released in the fourth quarter of 2025.

Significant Market Potential in Greater China for ES104 Amid High BTC Incidence

BTC, a highly aggressive gastrointestinal malignancy, has an incidence rate of approximately 3 per 100,000 worldwide, and this rate continues to rise. Treatment options remain limited, especially given the higher incidence rates observed in China and East Asia compared to Western regions, creating an urgent demand for innovative therapeutic solutions. Key statistics include:

- Annual new BTC cases in China estimated at approximately 55,700, significantly higher than in Western countries.
- Due to challenges in early diagnosis, most patients are diagnosed at advanced stages, resulting in about 85% progressing to second-line treatment after first-line therapy, underscoring the critical need for new, effective treatments.
- Currently limited standard-of-care options for second-line BTC treatment in China highlight the transformative potential of Tovecimig, promising superior therapeutic choices for patients and clinicians.

Elpiscience holds the rights to CTX-009/ES104 in Greater China and plans to leverage the latest clinical data to aggressively advance its development and commercialization in the region, ensuring timely access to cutting-edge treatments for local patients.
Meanwhile, Compass Therapeutics continues to explore the potential of Tovecimig in other prevalent cancers, such as colorectal cancer, aiming to expand indications and bring hope to an even broader population of cancer patients.

[1]Zheng R, Zhang S, Zeng H, et al. Cancer incidence and mortality in China, 2016. J Natl Cancer Cent 2022;2:1-9.

About Elpiscience

Elpiscience is a clinical-stage biopharmaceutical company dedicated to the development of innovative immunotherapies for oncology and autoimmune diseases. By advancing breakthrough biologics and leveraging global strategic partnerships, Elpiscience has built a differentiated pipeline to deliver transformative treatment solutions for patients worldwide. For more information, please visit: www.elpiscience.com.

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