

NovaSpira Receives MFDS Approval to Start Phase 1 Trial of NS 342 (GPC3x4-1BB Bispecific) in Advanced Solid Tumors

CHATHAM, NJ, UNITED STATES, August 31, 2026 /EINPresswire.com/ -- [NovaSpira Biotherapeutics](#) today announced that the Ministry of Food and Drug Safety (MFDS) of the Republic of Korea has approved the company's updated Phase 1 clinical trial plan for NS-342, enabling the start of its first-in-human study in patients with refractory advanced hepatocellular carcinoma (HCC) and other GPC3-expressing solid tumors.

"The approval of Phase 1 study plan by the MFDS marks an important milestone for NovaSpira and for patients with advanced HCC who urgently need new therapeutic options," said Han Li, Ph.D., CEO of NovaSpira Biotherapeutics. "Refractory HCC remains one of the most challenging solid tumors globally, with limited efficacy from existing systemic therapies and poor long term survival. NS 342 was engineered specifically to address this gap."

NS 342 is a next generation GPC3x4-1BB bispecific designed to improve tumor specificity and safety in difficult to treat solid tumors. The Phase 1 study will evaluate safety, tolerability, pharmacokinetics, and preliminary clinical activity in patients with advanced HCC and other GPC3-expressing malignancies.

About Liver Cancer

Hepatocellular carcinoma (HCC) remains a major global health challenge, ranking as the third leading cause of cancer-related mortality worldwide. According to GLOBOCAN 2024 estimates, there were approximately 843,000 new cases and 732,000 deaths from liver cancer in 2024 (1). Systemic therapy - combinations of PD-1/PD-L1 inhibitors with anti-VEGF agents have improved first-line outcomes, yet nearly all patients ultimately progress, and available subsequent therapies offer limited durable benefit (2,3). Patients with advanced HCC who progress after standard systemic therapy are left with very few effective treatment options.

About NS-342

NS-342 (formerly PRS-342, BOS-342) is a novel GPC3 × 4-1BB bispecific protein. Preclinical data has shown potent T-cell activation that is dependent on the presence of GPC3-positive tumor cells; increased production of IL-2, a pro-inflammatory cytokine associated with anti-tumor immune response; TIL infiltration in tumors in HCC Xenograft mice; and potent anti-tumor activities (4).

About NovaSpira Biotherapeutics, Inc.

NovaSpira Biotherapeutics is a U.S.-based biotech company developing bispecific T-cell &

immune cell activator therapy for GPC3-positive solid tumors, including liver & lung cancers. The lead candidate, NS-342, is currently in Phase 1 clinical development. For more information, visit www.novaspirabio.com

Cautionary Statement Regarding Forward-Looking Statements

Statements in this press release that are not purely historical in nature are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. We use words such as “commitment,” “advancing,” “believe,” “potential,” and similar expressions to identify these forward-looking statements. These forward-looking statements are based on NovaSpira’s current expectations and involve assumptions that may never materialize or may prove to be incorrect; consequently, actual results may differ materially from those expressed or implied due to a number of factors, including risks related to NovaSpira’s ability to grow and advance its pipeline and execute on its business plan; and other risks and uncertainties inherent in drug development. The forward-looking statements included in this press release are made only as of the date of this press release. Except as required by law, NovaSpira assumes no obligation and does not intend to update any forward-looking statements included in this press release.

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