NovaSpira Announces FDA Acceptance of IND for NS - 342 in GPC3 Positive Tumors

NovaSpira Biotherapeutics Secures U.S. FDA Acceptance of IND Application for NS 342 in Advanced Hepatocellular Carcinoma and Other GPC3 Expressing Solid Tumors

CHATHAM, NJ, UNITED STATES, October 12, 2026 /EINPresswire.com/ -- NovaSpira Biotherapeutics Inc. today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's Investigational New Drug (IND) application for NS 342, enabling initiation of clinical development in the United States. The IND submission was received on September 8, 2026, and supports the proposed indication of treatment for patients with hepatocellular carcinoma (HCC) and other GPC3 expressing solid tumors.

NS 342 is a next generation GPC3 x 4 1BB bispecific biologic engineered to deliver targeted immune activation within the tumor microenvironment while minimizing systemic toxicity. The molecule is designed to address the urgent unmet need in advanced HCC, a disease with limited effective options and poor long term survival for patients who progress after first line therapy.

"FDA acceptance of the NS 342 IND marks a major milestone for NovaSpira and underscores the potential of our GPC3 directed bispecific platform," said Han Li, Ph.D., CEO of NovaSpira Biotherapeutics. "We are committed to advancing NS 342 rapidly and responsibly for patients with advanced liver cancer and other GPC3 positive tumors who urgently need new treatment options."

The upcoming U.S. Phase 1 study will evaluate safety, tolerability, pharmacokinetics, immune activation, and preliminary antitumor activity.

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 and tumor cell lysis that are strictly 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 (1).

About NovaSpira Biotherapeutics, Inc.
NovaSpira Biotherapeutics is a clinical stage biotechnology company developing next generation immunotherapies for solid tumors with high unmet need. NS 342, the lead candidate, is in Phase 1 clinical development as a bispecific T cell and immune cell activator therapy for GPC3 positive solid tumors, including liver and lung cancers. 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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1. Birgit Bossenmaier, Corinna Schlosser, Rachida-Siham Bel Aiba, Eva-Maria Hansbauer, Thomas Jaquin, Christian Barthels, Janet Peper, Markus Zettl, Benjamin Weiche, Costimulatory T-cell engagement by PRS-342, a GPC3/4-1BB bispecific molecule, leads to activation of T cells and tumor growth inhibition in a HCC humanized mouse model, AACR, 2019

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