NAYA Biosciences Announces Development of NY-500, a Novel AI-Optimized PD-1 x VEGF Bifunctional Antibody

PD-1 x VEGF antibodies show potential to surpass checkpoint inhibitors as standard-of-care in multiple oncology indications

NAYA aiming to initiate clinical trials in early 2026

SARASOTA, Fla. and MIAMI, Jan. 06, 2025 (GLOBE NEWSWIRE) — NAYA Biosciences ("NAYA") (NASDAQ: NAYA), a life science portfolio company dedicated to bringing breakthrough treatments to patients in oncology, autoimmune diseases, and women's health, today announced that it is expanding its bifunctional antibody pipeline to include a novel PD-1 x VEGF tetravalent bifunctional antibody for the treatment of hepatocellular carcinoma (HCC) and other solid tumors.

NAYA is leveraging its proprietary FLEX antibody platform and further optimizing its design through a partnership with MabSilico, an artificial intelligence & deep technology-focused company, to accelerate the development of new best-in-class candidates for validated therapeutic targets.

"We are excited to add a novel, AI-optimized PD-1 x VEGF therapeutic candidate to our pipeline of best-in-class bifunctional antibodies," commented NAYA Biosciences President Dr. Daniel Teper. "NAYA's bifunctional format has demonstrated the ability for synergistic dual-targeting activity, resulting in the potential to unlock clinical response in solid tumors. NY-500, our PD-1 x VEGF antibody, will target hepatocellular carcinoma (HCC) and other solid tumors with high unmet medical needs. Recent clinical data with *ivonescimab*, the most advanced PD-1 x VEGF antibody, has shown superiority in non-small-cell lung cancer (NSCLC) compared to Keytruda®, the leading first-line immunotherapy standard-of-care in multiple solid tumors, paving the way for a new generation of PD-(L)1 therapeutic candidates."

NAYA is also developing a GPC3-targeting bifunctional antibody (NY-303) in a phase 1/2 clinical trial for HCC patients not responding to PD-1 +/- VEGF therapy. NAYA has recently presented data for NY-303 at the Society for Immunotherapy of Cancer (SITC) demonstrating the ability to reverse resistance to PD-1 checkpoint blockage and turn tumors from a "cold" into a "hot" status, making the tumors susceptible to immunotherapy again. Initiation of monotherapy Phase 1/2a clinical trials has been cleared by regulatory authorities and leading academic centers and is expected to start in 2025.

About NY-500 (PD-1 x VEGF Bifunctional Antibody)

NY-500 is a tetravalent bifunctional antibody targeting PD-1, a key immune checkpoint targeted by pembrolizumab (Keytruda®, Merck & Co), and VEGF, a vascular endothelial growth factor targeted by bevacizumab (Avastin®, Genentech Roche) which regulates the

production of new blood vessels (angiogenesis). Synergistic effects of simultaneously targeting PD-1 & VEGF have been shown to improve T-cell infiltration into tumors and enhance immune response while disrupting tumor vasculature. Ivonescimab, a PD-1 x VEGF antibody from Summit Therapeutics, recently outperformed pembrolizumab in a head-to-head lung cancer clinical trials. NY-500 has a differentiated molecular design, leveraging both NAYA's proprietary FLEX format and AI-optimization, and is expected to enter monotherapy phase 1/2a clinical trials in early 2026 for the treatment of hepatocellular carcinoma (HCC) & other solid tumors. According to IQVIA, the PD(L)1 market is expected to exceed $50 billion in 2025.

About NAYA Biosciences

NAYA Biosciences (NASDAQ: NAYA) is a life science portfolio company dedicated to bringing breakthrough treatments to patients in oncology, autoimmune diseases, and women's health. Our proven hub & spoke model harnesses the shared resources of a parent company and agility of lean strategic franchises, enabling efficient acquisition, development, and partnering of assets and allowing for optimized return on investment by combining scalable, profitable commercial revenues with the upside of innovative clinical-stage therapeutics.

NAYA's expanding portfolio of assets currently includes NY-303, a GPC3 x NKp46 bifunctional antibody for the treatment of hepatocellular carcinoma (HCC) with a unique mode of action targeting non-responders to the current immunotherapy standard of care (approximately 70% of the current treatable market) cleared to enroll patients in a Phase 1/2a monotherapy trial in 2025, NY-338, a CD38 x NKp46 bifunctional antibody for the treatment of multiple myeloma and autoimmune diseases with a differentiated safety and efficacy profile, NY-500, a PD-1 x VEGF bifunctional antibody for the treatment of HCC and other solid tumors, and NY-600 a PSMA x NKp46 bifunctional antibody for the treatment of metastatic Castration Resistant Prostate Cancer (mCRPC).

Safe Harbor Statement

This release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The Company invokes the protections of the Private Securities Litigation Reform Act of 1995. All statements regarding our expected future financial position, results of operations, cash flows, financing plans, business strategies, products and services, competitive positions, growth opportunities, plans and objectives of management for future operations, as well as statements that include words such as "anticipate," "if," "believe," "plan," "estimate," "expect," "intend," "may," "could," "should," "will," and other similar expressions are forward-looking statements. All forward-looking statements involve risks, uncertainties, and contingencies, many of which are beyond our control, which may cause actual results, performance, or achievements to differ materially from anticipated results, performance, or achievements. Factors that may cause actual results to differ materially from

those in the forward-looking statements include those set forth in our filings at www.sec.gov. We are under no obligation to (and expressly disclaim any such obligation to) update or alter our forward-looking statements, whether as a result of new information, future events or otherwise.

NAYA Investor & Media Contact
Anna Baran-Djokovic
SVP, Investor Relations
+1-305-615-9162
anna@nayabiosciences.com