NAYA Biosciences Announces Initiation of Phase 1/2a Clinical Trial for its GPC3-targeted NK Engager Bispecific Antibody in Patients with Hepatocellular Carcinoma

SARASOTA, Fla. and MIAMI, Oct. 24, 2024 — NAYA Biosciences ("NAYA") (NASDAQ: NAYA), a life science portfolio company dedicated to bringing breakthrough treatments to patients in oncology, autoimmune diseases, and fertility, today announced an update regarding its clinic trial plans. The Company received regulatory approval from the Israeli Ministry of Health in July 2024 and subsequent institutional review board clearance to initiate patient enrollment in up to 7 academic centers for its clinical trial evaluating the safety and efficacy of NY-303, its GPC3-targeting NK Engager bispecific antibody, as a monotherapy for the treatment of hepatocellular carcinoma in patients not responding to first-line immunotherapy.

"With the completion of the recent merger, we can now begin our focus on planning for the initiation of clinical trials with our lead GPC3-targeting NK engager bispecific antibody, which is a significant milestone for NAYA Biosciences," commented NAYA Biosciences President and NAYA Therapeutics CEO Dr. Daniel Teper. "We are passionate about bringing new options to patients not responding to first line immunotherapy and expect that positive Phase I safety and preliminary efficacy data will support accelerated clinical development in HCC as well as exploration in additional solid and pediatric tumors."

The Phase 1 part of the trial will consist of a dose-escalation where patients responding to treatment will continue weekly administration as long as no disease progression is observed. Key endpoints include safety, pharmacokinetics, activity markers, preliminary clinical efficacy, and time-to-progression. NAYA is planning to start patient recruitment in early 2025 at leading medical centers in Israel including Hadassah Hospital, Sheba Medical Center, and Sourasky Medical Center.

The Phase 2a part of the trial is anticipated to be expanded to the United States and Europe subject to additional regulatory approvals and will evaluate NY-303 at two dose levels selected in Phase I. Key efficacy endpoints will include objective response rate and progression-free survival.

"Hepatocellular carcinoma is a leading cause of cancer death worldwide with a rapidly increasing global trend," commented NAYA Therapeutics Chief Medical Officer Dan Chiche, MD. "Currently, less than 30% of patients treated with current standard of care respond to immunotherapy (confirmed objective response) and mean progression-free survival is less than 7 months. NY-303's dual targeting of NK cells and GPC3 is a unique, novel mechanism of action supported by scientific data showing potential to unlock non-response to checkpoint inhibitors."

About HCC

Hepatocellular carcinoma (HCC) is the most common form of primary liver cancer, often developing in individuals with chronic liver conditions like hepatitis B or C, cirrhosis, and Metabolic Dysfunction-Associated SteatoHepatitis (MASH). HCC is a global health challenge, with over 900,000 new cases annually, making it the sixth most common cancer worldwide. The incidence of HCC in the United States has been steadily rising. Survival rates for HCC are often low due to late detection. The five-year survival rate for liver cancer in the United States is around 20%, but this varies widely depending on the stage at diagnosis. For early-stage HCC, where surgical resection or liver transplantation is possible, survival rates can improve dramatically, while advanced stages have far poorer outcomes. Globally, survival rates are similarly low, with wide variation based on healthcare access and screening programs. Recent advances in immunotherapy such as immune checkpoint inhibitors are offering new hope for patients with advanced HCC but new treatment approaches are still critical for improving survival and quality of life for patients.

About NY-303

NY-303 is a first-in-class therapeutic candidate that leverages the engagement and activation of natural killer (NK) cells using a bispecific antibody targeting both GPC3, an oncofetal protein uniquely expressed on liver cancer cells, and NKp46, a cell surface receptor on natural killer (NK) cells that plays a central role in NK cell activation and the elimination of target cells. The unique mechanism enables NY-303 to turn the tumor form a “cold” into a ‘hot’ stage making liver cancer cells susceptible against immunotherapy to target and destroy cancer cells. This innovative approach is especially promising for patients with liver cancer, such as hepatocellular carcinoma (HCC), who face limited treatment options and poor survival rates but also for other GPC3-expressing tumors like lung squamous cell carcinoma, ovarian cancer, and pediatric cancer.

Currently, liver cancer therapies include surgery, liver transplantation, targeted drugs, and immunotherapies like checkpoint inhibitors, but the prognosis remains grim, especially for advanced-stage disease. With a global five-year survival rate of around 20%, and even lower in more advanced cases, there is a critical need for more effective therapies.

NY-303 represents a new opportunity for liver cancer patients by harnessing the body’s immune system to specifically attack tumor cells and engage NK-cells. Unlike traditional treatments, this therapy is designed to offer potent anti-cancer effects with a potentially safer profile, reducing the side effects often associated with chemotherapy and other conventional treatments and overcoming non-responding tumors against immunotherapies. For patients with HCC, NY-303 could significantly improve outcomes by offering a more precise, targeted approach to eradicating cancer, which is critical given the high recurrence rates and challenges in treating advanced liver cancer. As part of the next generation of immunotherapies, NY-303 may redefine treatment possibilities and offer renewed hope to those facing this difficult diagnosis.

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 fertility. Our 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 and NKp46 targeting bispecific 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 early 2025, NY-338, a CD38 and NKp46 targeting bispecific antibody for the treatment of multiple myeloma and autoimmune diseases with a differentiated safety and efficacy profile, and INVOcell®, an FDA-approved fertility device which has demonstrated comparable success rates to traditional In Vitro Fertilization (IVF).

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.

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