

## **NAYA Biosciences and ONK Therapeutics Announce Research Partnership to Advance Combination Therapy of FLEX-NK™ Bispecific Antibodies and Optimally Engineered Off-the-Shelf Natural Killer Cell Therapies**

- NAYA Biosciences and ONK Therapeutics to assess proof-of-concept and establish activity and feasibility of the combination of NAYA's FLEX-NK™ bispecific antibodies and ONK's optimally engineered natural killer (NK) cells for the treatment of cancer
- Partnership may be expanded to joint clinical development following successful completion of the initial research
- Combination therapy expected to improve response rate and address significant unmet medical need in hepatocellular carcinoma (HCC)
- NAYA expects to close its previously announced merger with INVO Bioscience (NASDAQ: INVO) in the first quarter of 2024

AVENTURA, Fla. and SARASOTA, Fla. and GALWAY, Ireland and SAN DIEGO, Dec. 6, 2023 — NAYA Biosciences Inc. ("NAYA"), a company which has recently signed a definitive merger agreement with INVO Bioscience to establish an expanded, publicly-traded life science company dedicated to increasing patient access to breakthrough treatments in fertility, oncology, and regenerative medicine, and ONK Therapeutics ("ONK"), an innovative cell therapy company dedicated to developing the next generation of optimally engineered off-the-shelf natural killer (NK) cell therapies, today announced that they have entered into a research partnership to evaluate combination therapy consisting of NAYA's FLEX-NK™ bispecific antibodies and ONK's optimally engineered natural killer (NK) cells.



Specifically, the partnership will explore the combination of NAYA's GPC3-targeted NY-303 FLEX-NK™ bispecific antibody with ONK's ONKT105, CISH + TGFβR2 double knock-out (KO), SIL-15 knock-in (KI) allogeneic NK cell therapy.

"We are impressed with the data ONK has generated using its differentiated editing of NK cells, which may further enhance the efficacy of our FLEX-NK™ bispecific antibodies," commented NAYA's CEO Dr. Daniel Teper. "The future development of this combination therapy alongside our monotherapy clinical trials will help expand patient options and narrow the gap towards improving the long-term survival of patients with hepatocellular carcinoma."

ONK's CEO Chris Nowers added, "The opportunity to partner with NAYA to evaluate the activity of our optimally gene-edited, non-CAR directed, allogeneic NK cell therapies in combination with its exciting FLEX-NK™ bispecific antibodies offers an opportunity to further improve response rates and durability of NK cell therapy. We believe this therapeutic combination represents a broadly applicable and versatile approach to treat patients with cancer and autoimmune diseases, where additional treatment options are needed."

NAYA and ONK plan to assess several combination therapies in preclinical cancer models in 2024 prior to subsequently exploring initiating clinical trials. The companies' R&D teams will collaboratively evaluate ONK's optimally gene-edited NK cell therapy, ONKT105, with NAYA's NY-303 bispecific antibody before selecting the best candidate for potential clinical development. Both companies will share the costs of manufacturing and preclinical assessments.

NAYA's FLEX-NK™ bispecific antibodies are built on a proprietary tetravalent, multifunctional format with flexible linker, facilitating simultaneous binding to different antigens on one or multiple cells. They redirect and trigger the killing activity of Natural Killer (NK) cells towards their tumor targets using NKP46 activating receptors. NKP46 mediates NK-cell lysis in both autologous and allogeneic cells and shows sustained expression on NK cells in the tumor microenvironment. NY-303 targets GPC3 for the treatment of HCC and other solid tumors and has demonstrated enhanced tumor growth inhibition when combined with NK cells in data presented at leading conferences including the American Association for Cancer Research (AACR) and the Society for Immunotherapy of Cancer (SITC).

ONK Therapeutics employs an innovative gene editing strategy to engineer NK cell therapies that are fit for purpose and optimally engineered, depending on the indication and intent for use alone (CAR NK), or in combination with targeting monoclonal antibody or NK cell engager therapies. All of ONK's allogeneic NK cell therapy products candidates include the foundational CISH KO gene edit, to allow for enhanced metabolic properties and improved *in vivo* persistence. ONK has exclusive, worldwide rights to KO of CISH in NK cells, regardless of the source of the NK cells. Additional gene edits, such as the KO of immunosuppressive checkpoints such as TGFβR2, as well as gene knock-ins (KIs), such as sIL-15, are included to further armor the NK cell therapies for maximal activity within the tumor microenvironment.

**About ONK Therapeutics** - [www.onktherapeutics.com](http://www.onktherapeutics.com)

ONK Therapeutics is an innovative cell therapy company dedicated to developing the next generation of optimally engineered off-the-shelf, natural killer (NK) cell therapies. With a growing pre-clinical pipeline targeting both hematological malignancies and solid tumors, ONK is advancing multiple cell therapy candidates towards the clinic, including its two lead programs, ONKT105, a highly functional, multi gene edited NK cell therapy for use either alone or in combination with monoclonal antibodies or NK cell engagers, and ONKT102, an

optimized affinity CD38 CAR-NK product, intended for the treatment of patients with relapsed/refractory multiple myeloma. Read about the pipeline here.

The company's optimally engineered NK cell therapy platform utilizes a suite of proprietary gene edits and cell modification strategies to optimize NK cell metabolic health, persistence, and anti-tumor effect of NK cells, while reducing the potential for their exhaustion in the tumor microenvironment. These include CISH knockout (KO); the expression of high affinity, membrane bound, TNF-related apoptosis-inducing ligand variants (TRAILv) targeting DR5 or DR4; and the deletion of inhibitory receptors, including extracellular proteins for example CD96, and Siglec-7. Read about the platform here.

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### **About NAYA Biosciences**

NAYA Biosciences is building a group of agile, disruptive, high-growth companies dedicated to increasing patient access to life-transforming treatments in oncology, fertility, and regenerative medicine. NAYA's capabilities in biology, cell and gene therapy, and artificial intelligence (AI) provide a synergistic platform for the accelerated clinical development and commercialization of these breakthrough treatments.

**NAYA Oncology** aims to achieve clinical proof-of-concept for its two bispecific antibodies acquired from Cytovia Therapeutics, with the goal of advancing towards breakthrough outcomes for Hepatocellular Carcinoma and Multiple Myeloma patients. Clinical trials are expected to start in 2024.

**NAYA Fertility** aims to increase accessibility to advanced fertility care through a growing network of INVO-owned and affiliated clinics and the commercialization of INVO's unique FDA-cleared INVOcell® device.

**NAYA Regenerative Medicine** is evaluating the acquisition of clinic-stage assets aiming to restore biological function in patients with damaged tissues and organs.

For more information, please visit [www.nayabiosciences.com](http://www.nayabiosciences.com).

### **About NAYA's Proposed Merger with INVO Bioscience**

NAYA Biosciences and INVO Bioscience have announced a definitive merger agreement to establish an expanded publicly-traded life science company. Under the terms of the October 23rd merger agreement, pending approval of the transaction by INVO's, Cytovia Therapeutic, Inc. 's, and NAYA's stockholders and subject to key closing conditions, INVO will acquire 100% of the outstanding equity interests in NAYA by means of a reverse triangular merger of a wholly owned subsidiary of INVO with and into NAYA, with NAYA surviving as a wholly owned subsidiary of INVO (the "Merger"). In connection with the Merger, INVO will issue to the

stockholders of NAYA newly issued common stock, representing, following such issuance, more than eighty percent (80%) of its issued and outstanding common stock, effectively resulting in a change of control.

Among key closing conditions, INVO must obtain shareholder approval along with certain approvals from existing warrant holders, an estimated \$5 million or more (at NAYA's discretion) in interim private financing in INVO at a premium to INVO's market price at time of financing ("Interim PIPE"), and a private offering by the combined company at a target price of \$5.00, representing a premium to INVO's last offering of \$2.85 per share. The merger target valuation is \$12,373,780 for INVO and \$90,750,000 for NAYA, based on a target stock price of \$5.00 per share. Subject to the Interim PIPE, immediately following the closing of the Merger (but prior to the private offering), the equity holders of NAYA are expected to own approximately 88% of the issued and outstanding common stock of the combined company while the equity holders of INVO are expected to own approximately 12% of the issued and outstanding common stock of the combined company.

The Merger has been unanimously approved by the board of directors of each company and is expected to close in the first quarter (Q1) of 2024.

Glaser Weil Fink Howard Jordan & Shapiro LLP is serving as legal counsel to INVO. Pearl Cohen Zedek Latzer Baratz LLP is serving as legal counsel to NAYA.

### **Additional Information about the Proposed Merger and Where to Find It**

INVO will furnish to the U.S. Securities and Exchange Commission (the "SEC") a Current Report on Form 8-K regarding the Merger, which will include the Merger Agreement as an exhibit thereto. Shareholders and others wishing to obtain additional information regarding the Merger Agreement and the Merger are urged to review these documents, which will be available at the SEC's website (<https://www.sec.gov>).

In connection with the Merger, INVO and NAYA will file relevant materials with the SEC, including a registration statement on Form S-4 filed by INVO that will include a proxy statement of INVO that also constitutes a prospectus of INVO. A definitive proxy statement/prospectus will be distributed to stockholders of NAYA. This communication is not a substitute for the registration statement, proxy statement, or prospectus or any other document that INVO or NAYA (as applicable) may file with the SEC in connection with the proposed Merger. **Before making any voting or investment decision, investors and security holders of INVO and NAYA are urged to read carefully and in their entirety the registration statement, the proxy statement/prospectus, and any other materials filed with or furnished to the SEC when they become available, as well as any amendments or supplements to these documents, as they contain or will contain important information about INVO, NAYA, the Merger Agreement, the Merger, and related matters.** In addition to receiving the proxy statement/prospectus by

mail, shareholders also will be able to obtain the full registration statement and the proxy statement/prospectus and the exhibits thereto, as well as other filings containing information about INVO, the Merger Agreement, the Merger, and related matters, without charge, from the SEC's website (<http://www.sec.gov>), or at the SEC's public reference room at 100 F Street, NE, Room 1580, Washington, D.C. 20549. The information included on, or accessible through, INVO's or NAYA's website is not incorporated by reference to this communication.

INVO, NAYA and certain of their directors, executive officers, and other members of management and employees may, under SEC rules, be deemed to be "participants" in the solicitation of proxies from INVO's shareholders with respect to the Merger. Information about the directors and executive officers of INVO will be set forth in the proxy statement/prospectus and in its Form 10-K for the year ended December 31, 2022, which was filed with the SEC on April 17, 2023. Information about the directors and executive officers of NAYA will be set forth in the joint proxy statement/prospectus.

This announcement is not a solicitation of a proxy, an offer to purchase, or a solicitation of an offer to sell any securities and it is not a substitute for the Schedule 14A, the registration statement on S-4, the proxy statement/prospectus, or other filings that may be made with the SEC in connection with the Merger Agreement and the Merger.

### **No Offer or Solicitation**

This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities, nor a solicitation of any vote or approval with respect to the proposed transaction or otherwise. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended, and otherwise in accordance with applicable law.

### **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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