# NAYA Biosciences Announces Publication of New Data for its CD38targeted Flex-NK™ Bispecific Antibody in the American Society of Hematology's Blood Journal

- Abstract from 2023 American Society of Hematology (ASH) Meeting
- Data demonstrates differentiated profile from DARZALEX® (daratumumab) with best-inclass potential, supports initiation of clinical trials in 2024
- NAYA expects to close its previously announced merger with INVO Bioscience (NASDAQ: INVO) in the first quarter of 2024

AVENTURA, Fla. and SARASOTA, Fla., Dec. 11, 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, today announced that new data for its CD38-targeted Flex-NK™ Bispecific Antibody (NY-338, formerly CYT-338) for the treatment of Multiple Myeloma (MM) was published as an abstract in the 2023 American Society of Hematology's (ASH) meeting supplement of *Blood*, in the "Multiple Myeloma: Prospective Therapeutic Trials" section.



"NAYA is building a portfolio of differentiated clinical-stage oncology therapeutics, starting with two FLEX-NK™ bispecific antibodies acquired from Cytovia Therapeutics," commented NAYA CEO Dr. Daniel Teper. "We are excited about this new data for our CD38-targeted antibody, which aims to address limitations with the current standard-of-care and offer new options for multiple myeloma patients."

"The synergistic engagement of NK cells through NKp46 greatly enhances the immunotherapeutic effects of FLEX-NK™ bispecific antibodies, reducing NK cell fratricide, maintaining NK cell levels, and enhancing potency including reversal of NK cell dysfunction," added Ola Landgren, MD, PhD, co-author of the abstract and Professor of Medicine, Chief of the Myeloma Division, and Leader of the Experimental Therapeutics Program at the University of Miami's Sylvester Comprehensive Cancer Center. "The data supports initiation of clinical trials to evaluate this promising new therapy and makes it a potential best-in-class anti-CD38 therapeutic for multiple myeloma."

Despite the clinical success of the first anti-CD38 targeted monoclonal antibody, daratumumab, approved for the treatment of multiple myeloma (MM), significant challenges remain such as CD38 antigen loss/internalization and/or natural killer (NK) cell fratricide resulting in resistance to treatment over time. The data presented for NY-338 demonstrates a differentiated profile from daratumumab, with best-in-class potential, and supports the initiation of clinical trials in 2024. Specifically, the conclusions show that the unique NKp46 activation mechanism provided by NY-338 for reducing NK cell fratricide and maintaining NK cell levels together with the enhanced potency including reversal of NK cell dysfunction makes it an attractive best-in-class anti-CD38 therapeutic against MM compared to daratumumab. These results support the development of CYT-338 in both monotherapy and combination with other complementary immunotherapy agents being developed or approved for MM. A first-in-human Phase 1 study targeting patients with relapsed/refractory MM is in development in the U.S.

#### **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.

# **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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