

# NantKwest, ImmunityBio Announce Positive Interim Data on Survival Rates in Metastatic Pancreatic Cancer Trials

January 13, 2021

Pivotal QUILT 88 trial based on combination immunotherapy of "Cancer Moonshot" strategy; early indications of increased survival rate for pancreatic cancer patients with no other approved treatment options

- In initial Cancer Moonshot QUILT trials of haNK and avelumab (PD-L1 checkpoint inhibitor) completed in 2019, median overall survival rate more than doubled compared to historical controls (eight months versus three months)
- A complete remission was achieved when replacing haNK and PD-L1 checkpoint inhibitor avelumab with PD-L1 t-haNK and four out of five patients are alive 8-16 months since beginning treatment on these expanded protocols
- Based on this encouraging early data, a single-arm Phase 2 study (QUILT 88, Cohort C) was initiated in October 2020, for which the primary endpoint is overall survival and 15 out of 18 (83%) of patients enrolled with second-line or greater pancreatic cancer remain alive to date
- Randomized trials in first- and second-line pancreatic cancer are actively recruiting at three sites with more than 50 patients enrolled or being evaluated in QUILT 88 to date

EL SEGUNDO & CULVER CITY, Calif .-- (BUSINESS WIRE)-- Jan. 13, 2021--

NantKwest, Inc. (NASDAQ: NK), a clinical-stage, natural killer cell-based therapeutics company, and ImmunityBio, Inc., a privately-held immunotherapy company, today announced early interim results of its PD-L1 t-haNK protocols showing median survival rates more than doubled that of the historic rate in patients with advanced metastatic pancreatic cancer for which no other FDA-approved treatment exists. These trials, which were based on the original Cancer Moonshot hypothesis and exploratory QUILT trials initiated in 2017, appear to validate the theory that by orchestrating natural killer and T-cell therapy, survival rates could be improved without high-dose chemotherapy.

The early collaborative Cancer Moonshot trials involved the combination of cell therapy and immunotherapeutics from multiple biotech and pharmaceutical companies, including NantKwest, ImmunityBio, Celgene, and Pfizer. These trials explored the hypothesis that by activating the patient's own immune system, a paradigm change in cancer therapy could evolve to eradicate cancer cells without high-dose chemotherapy. From 2017 to 2020, multiple QUILT clinical trials exploring this combination of cell therapy, immunomodulating antibodies, adenovirus-based cancer vaccines, and low-dose chemotherapy provided preliminary results showing the median survival rate can be more than doubled and a complete remission can be achieved in patients with metastatic pancreatic cancer for which there are no other FDA-approved treatment options. Based on the data from these trials, ImmunityBio is conducting a pivotal, three-cohort pivotal trial (QUILT 88) in metastatic pancreatic cancer.

## **Interim Study Results**

- In the Cancer Moonshot QUILT trials of haNK combined with PD-L1 inhibitor avelumab, which were completed in 2019, the median overall survival rate more than doubled (three months historic control versus 8 months in the treatment arm) in the 12-patient study. See related press release here for details.
- A complete remission was achieved when replacing haNK and PD-L1 inhibitor avelumab with PD-L1 t-haNK and four out
  of five patients who had not yet reached median survival time (three months) are alive 8-16 months since beginning
  treatment on these expanded protocols
- A single-arm Phase 2 study (QUILT 88, Cohort C) was initiated in October 2020, for which the primary endpoint is overall survival and 15 out of 18 (83%) of patients enrolled with second-line or greater pancreatic cancer remain alive to date.
- A randomized Phase 2 study (QUILT 88, Cohorts A and B) for first- and second-line metastatic pancreatic cancer is actively enrolling at three sites.

"The goal of the Cancer Moonshot program was to explore the hypothesis that by orchestrating natural killer cells and T cells, a paradigm change for the treatment of cancer could evolve. The initial results of these Cancer Moonshot trials combining immunotherapy molecules—including Abraxane from Celgene, haNK from NantKwest, Anktiva from ImmunityBio, and a PD-L1 inhibitor Avelumab from Pfizer—provided promising early data that a doubling of median overall survival rate in patients with advanced metastatic disease across multiple tumor types was possible," said Patrick Soon-Shiong, M.D., Chairman, and CEO of ImmunityBio.

"For five patients for whom no other treatment was available, we replaced haNK and avelumab with the investigational NK cell therapy PD-L1 t-haNK and were pleased to observe a complete remission in the first patient to receive this combo therapeutic," continued Soon-Shiong. "To date, four out of five of these patients remain alive since beginning treatment. These observations confirmed the promise of our hypothesis that activating the patient's own immune system with low-dose chemo immunomodulation therapy could improve outcomes. On the basis of our initial studies, we initiated our QUILT 88 randomized trials in metastatic pancreatic cancer and are pleased to present today those findings, including Cohort C survival rates. While this data is still early, a doubling of the survival rate is encouraging and warrants further confirmation through QUILT 88."

This Phase 2, randomized, three-cohort, open-label study will evaluate the comparative efficacy and overall safety of standard-of-care chemotherapy versus standard-of-care chemotherapy in combination with PD-L1 t-haNK, Anktiva (N-803), and aldoxorubicin in subjects with locally advanced or metastatic pancreatic cancer (QUILT 88, NCT04390399). Each treatment setting, as well as each first- and second-line or later maintenance treatment, will be evaluated independently as Cohort A, Cohort B, and Cohort C, respectively, with cohorts A and B having independent experimental and control arms. The study will initially enroll 298 subjects across all three cohorts. The primary objective of Cohorts A and B is progression-free survival (PFS) and the objective of Cohort C is overall survival (OS) per RECIST V1.1. Secondary objectives include initial safety and additional efficacy measures, including overall response rate (ORR), complete response (CR) rate, durability of response (DoR), disease control rate (DCR), and overall survival (OS).

Cancer Moonshot QUILT trial numbers include QUILT 3.039, 3.060, 3.070, and 3.080.

### **QUILT 88 Trial Sites and Enrollment**

Currently, three trial sites have been activated: Hoag Memorial Hospital Presbyterian in Orange County, Calif.; The Chan Soon-Shiong Institute for Medicine in Los Angeles County, Calif.; and Avera McKennan Hospital and University Health Center in Sioux Falls, South Dakota, which will serve patients in the tri-state area (Iowa, Nebraska, and South Dakota). More than 50 patients are currently enrolled in or being evaluated for the trial.

Pancreatic cancer is the fourth leading cause of cancer-related death in the U.S., with an estimated 47,050 deaths and 57,600 new cases expected in 2020. It is the 12th most common cancer worldwide, with around 338,000 new cases diagnosed in 2012 (2% of all cancer diagnoses). Pancreatic cancer continues to increase today with no standard of care available for patients beyond second line. A clear unmet medical need exists in these patients with short expected survival time and high levels of existing comorbidities.

## **NantKwest Transaction**

As previously announced, on December 21, 2020, ImmunityBio entered into an agreement to combine in a stock-for-stock transaction with NantKwest. The combination, which is expected to close in the first half of 2021, would create a leading immunotherapy and cell therapy company focused on oncology and infectious disease.

## **About ImmunityBio**

ImmunityBio, Inc. is a late-clinical-stage immunotherapy company developing next-generation therapies that drive immunogenic mechanisms for defeating cancers and infectious diseases. The company's immunotherapy platform activates both the innate (natural killer cell and macrophage) and adaptive (T-cell) immune systems to create long-term "immunological memory." This novel approach is designed to eliminate the need for high-dose chemotherapy, improve upon the outcomes of current CAR T-cell therapies, and extend beyond checkpoint inhibitors.

ImmunityBio's platform is based on the foundation of three separate modalities: antibody cytokine fusion proteins, synthetic immunomodulators, and second-generation human adenovirus (hAd5) vaccine technologies.

Anktiva<sup>TM</sup> (ImmunityBio's lead cytokine infusion protein) is a novel interleukin-15 (IL-15) superagonist complex and has received Breakthrough Therapy and Fast Track Designations from the U.S. Food and Drug Administration (FDA) for BCG-unresponsive CIS non-muscle invasive bladder cancer (NMIBC). The company is also in Phase 2 or 3 trials for indications such as first- and second-line lung cancer, triple-negative breast cancer, metastatic pancreatic cancer, recurrent glioblastoma, and soft tissue sarcoma in combination with the company's synthetic immune modulator (aldoxorubicin).

ImmunityBio is also developing therapies, including vaccines, for the prevention and treatment of HIV, influenza, and the coronavirus SARS-CoV-2 with its second-generation human adenovirus (hAd5) vaccine technologies.

## About NantKwest

NantKwest (NASDAQ: NK) is an innovative, clinical-stage, immunotherapy company focused on harnessing the power of the innate immune system to treat cancer and infectious diseases. NantKwest is the leading producer of clinical dose forms of off-the-shelf natural killer (NK) cell therapies. The activated NK cell platform is designed to destroy cancer and virally-infected cells. The safety of these optimized, activated NK cells—as well as their activity against a broad range of cancers—has been tested in Phase 1 clinical trials irCanada and Europe, as well as in multiple Phase 1 and 2 clinical trials in the United States. By leveraging an integrated and extensive genomics and transcriptomics discovery and development engine, together with a pipeline of multiple, clinical-stage, immuno-oncology programs, NantKwest's goal is to transform medicine by bringing novel NK cell-based therapies to routine clinical care. NantKwest is a member of the NantWorks ecosystem of companies. For more information, please visit www.nantkwest.com.

# **Forward-Looking Statements**

This presentation contains forward-looking statements relating to the proposed transaction involving NantKwest, Inc. ("NantKwest") and ImmunityBio, Inc. ("ImmunityBio"), including financial estimates and statements as to the expected timing, completion and effects of the proposed transaction and statements relating to NantKwest and ImmunityBio's future success in improving the treatment of various diseases and illnesses, including, but not limited to COVID-19 and cancer. Statements in this communication that are not statements of historical fact are considered forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are usually identified by the use of words such as "anticipates," "believes," "continues", "could", "estimates," "expects," "intends," "may," "plans," "potential", "predicts", "projects," "seeks," "should," "will," and variations of such words or similar expressions. These forward-looking statements are neither forecasts, promises nor guarantees, and are based on the current beliefs of NantKwest's management and ImmunityBio's management as well as assumptions made by and information currently available to NantKwest and ImmunityBio. Such statements reflect the current views of NantKwest and ImmunityBio with respect to future events and are subject to known and unknown risks, including business, regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about NantKwest and ImmunityBio, including, without limitation, (i) inability to complete the proposed transaction because, among other reasons, conditions to the closing of the proposed transaction may not be satisfied or waived, (ii) uncertainty as to the timing of completion of the proposed transaction, (iv) potential adverse effects or changes to relationships with employees, suppliers or other parties resulting from the announcement or completion of the pr

ImmunityBio, (v) possible disruptions from the proposed transaction that could harm NantKwest's or ImmunityBio's respective business, including current plans and operations, (vi) unexpected costs, charges or expenses resulting from the proposed transaction, (vii) uncertainty of the expected financial performance of the combined company following completion of the proposed transaction, including the possibility that the expected synergies and value creation from the proposed transaction will not be realized or will not be realized within the expected time period, (viii) the ability of each of NantKwest or ImmunityBio to continue its planned preclinical and clinical development of its respective development programs, and the timing and success of any such continued preclinical and clinical development and planned regulatory submissions, (ix) inability to retain and hire key personnel, and (x) the unknown future impact of the COVID-19 pandemic delay on certain clinical trial milestones and/or NantKwest's or ImmunityBio's operations or operating expenses. More details about these and other risks that may impact NantKwest's business are described under the heading "Risk Factors" in NantKwest's most recent Quarterly Report on Form 10-Q and Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") and in subsequent filings made by NantKwest with the SEC, which are available on the SEC's website at <a href="https://www.sec.gov">www.sec.gov</a>. NantKwest and ImmunityBio caution you not to place undue reliance on any forward-looking statements, which speak only as of the date hereof. NantKwest and ImmunityBio do not undertake any duty to update any forward-looking statement or other information in this communication, except to the extent required by law. No representation is made as to the safety or effectiveness of these product candidates for the therapeutic use for which such product candidates are being studied.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and NantKwest's and ImmunityBio's own internal estimates and research. While NantKwest and ImmunityBio believe these third-party sources to be reliable as of the date of this communication, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this communication involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while NantKwest and ImmunityBio each believes its own internal research is reliable, such research has not verified by any independent source.

### No Offer or Solicitation

This presentation is not intended to and does not constitute an offer to sell or the solicitation of an offer to buy, sell or solicit any securities or any proxy, vote or approval in any jurisdiction pursuant to or in connection with the proposed transaction or otherwise, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offer of securities shall be deemed to be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act.

## Additional Information and Where to Find It

In connection with the proposed transaction, NantKwest intends to file a registration statement on Form S-4 with the SEC, which will include a prospectus and joint proxy / solicitation statement of NantKwest and ImmunityBio (the "solicitation statement/prospectus"). NantKwest may also file other documents regarding the proposed transaction with the SEC. This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote or approval. This communication is not intended to be, and is not, a substitute for such filings or for any other document that NantKwest may file with the SEC in connection with the proposed transaction. BEFORE MAKING ANY VOTING OR INVESTMENT DECISION, INVESTORS AND SECURITY HOLDERS ARE URGED TO CAREFULLY READ THE ENTIRE REGISTRATION STATEMENT AND SOLICITATION STATEMENT / PROSPECTUS, WHEN THEY BECOME AVAILABLE, AND ANY OTHER RELEVANT DOCUMENTS FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION. Investors and security holders will be able to obtain free copies of the registration statement and solicitation statement/prospectus and other documents filed with the SEC by NantKwest through the website maintained by the SEC at <a href="https://www.sec.gov">www.sec.gov</a>. In addition, investors and security holders will be able to obtain free copies of the prospectus and other documents filed with the SEC on NantKwest's website at <a href="https://www.ir.nantkwest.com">www.ir.nantkwest.com</a>.

## Participants in the Solicitation

NantKwest and certain of its respective directors and executive officers may be deemed to be participants in the solicitation of proxies from stockholders of NantKwest in connection with the proposed transaction under the rules of the SEC. Investors may obtain information regarding the names, affiliations and interests of directors and executive officers of NantKwest in NantKwest's proxy statement for its 2020 annual meeting of stockholders, which was filed with the SEC on April 24, 2020, as well as its other filings with the SEC. Other information regarding the participants in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be included in the registration statement, solicitation statement / prospectus and other relevant materials to be filed with the SEC by NantKwest regarding the proposed transaction (if and when they become available). You may obtain free copies of these documents at the SEC's website at <a href="https://www.sec.gov">www.sec.gov</a>. Copies of documents filed with the SEC will also be available free of charge from NantKwest using the sources indicated above.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210113005928/en/

# Investors

Sarah Singleton 844-696-5235, Option 5

## Media

Andrew Siegel / Greg Klassen Joele Frank, Wilkinson Brimmer Katcher 212-355-4449

Amy Jobe LifeSci Advisors 315-879-8192

Source: NantKwest, Inc.