NantKwest and ImmunityBio Present Results of Landmark Trial of First-in-Human Natural Killer Cell Combination Immunotherapy With Durable, Complete Response Data and 78% Disease Control in Refractory Triple Negative Breast Cancer at SABCS

December 16, 2019

- World's first combination of off-the-shelf NK with checkpoint inhibitor plus antigen simulation via adenovirus to induce immune system activation
- Ongoing durable complete responses ranging from 8 to 11 months observed in TNBC patients who failed standard of care
- Disease control rate of 78% and overall response rate of 67% in heavily pretreated patients
- Median progression free survival exceeds 13 months compared to historical controls of 2-3 months in advanced third-line setting
- Ongoing survival to date of 78% of patients ranging from 2 to 12 months

CULVER CITY, Calif.--(BUSINESS WIRE)--Dec. 16, 2019-- NantKwest Inc. (Nasdaq: NK), a clinical-stage natural killer cell-based therapeutics company, and ImmunityBio, a privately held immunotherapy company, today announced results from their Phase 1b trial investigating a novel, first-in-human immunotherapy protocol consisting of NantKwest's off-the-shelf, antibody-targeted NK cells (haNK) combined with ImmunityBio's IL-15 superagonist (N-803), low-dose metronomic chemoradiation therapy, adenoviral and yeast tumor-associated antigen vaccines (MUC1, brachyury, CEA) and a PD-L1 checkpoint inhibitor in patients with metastatic triple negative breast cancer (TNBC) who had relapsed after prior therapy.

The results were presented at the 2019 San Antonio Breast Cancer Symposium (SABCS) on December 13, 2019, in San Antonio, Texas, in a poster titled "Safety and efficacy from first-in-human immunotherapy combining NK and T-cell activation with off-the-shelf, antibody-targeted CD16 NK cell line (haNK) in patients with 2nd-line or greater metastatic triple-negative breast cancer (TNBC)."

This landmark study is the world's first trial to combine cellular therapy with checkpoint inhibitors and IL-15 cytokine stimulation, as well as with adenoviral vectors, all acting in concert to induce immune simulation of both NK cells and T cells.

"We are extremely pleased that the FDA granted us IND authorization to initiate this novel immunotherapy trial enabling the safety and efficacy study of multiple novel biological agents administered as a single protocol in the outpatient setting," said Dr. Patrick Soon-Shiong, Chairman and CEO of NantKwest. "This important trial forms the basis of our approach to induce immunogenic cell death and long-term memory, and avoid the ravages of high dose chemotherapy."

"Achieving durable, complete responses in metastatic TNBC patients that have failed all current standards of care is a promising finding and further validates our approach to orchestrate both the innate and adaptive immune system," continued Soon-Shiong. "TNBC is a highly aggressive cancer, with limited treatment options and poor prognosis. These results are important proof-of-concept supporting our hypothesis that comprehensively activating the immune responses of the NK, T and Dendritic cells would induce immunogenic cell death leading to durable responses, even among this challenging patient population. We are thrilled with the safety and efficacy data from this first-in-human clinical trial of combination NK cell therapy, cytokine fusion protein, chemoradiation and checkpoint inhibitor, and look forward to advancing this exciting off-the-shelf cell therapy approach to randomized clinical trials in this setting."

Data Highlights Include:

- Of 9 patients treated, efficacy results include a disease control rate of 78% (7/9 patients) and an overall response rate of 67% (6/9 patients).
- 2 out of 9 patients to date have ongoing complete responses with durations ranging from 8 to 11 months, with a 3rd patient demonstrating a partial response (near complete response) in the target lesion after initiation of targeted and endocrine therapy off-study.
- To date, 7 patients are alive with durations of response ranging from 2 to 12 months with 4 patients remaining on study. Median progression-free survival rate is 13.7 months.
- All patients were treated in an outpatient setting with treatment generally safe and well tolerated and no observed cytokine release syndrome.
- No immune related SAEs were attributed to the immunotherapy investigational agents
- All patients had at least 1 grade ≥ 3 TRAE, primarily chemotherapy-related neutropenia or anemia. Grade ≥ 3 haNK-related AEs, namely fever and fatigue, were observed in 2 patients.
- Early data from peripheral blood analysis demonstrate clonal selection occurs with the immunotherapy regimen enabling targeted therapy tailored to patient specific mutations identified via next generation sequencing.

"The approximately 10-20% of breast cancer patients who are triple negative are faced with a grim prognosis with limited treatment options. These results are clinically significant, with overall response rates and complete response rates in this highly refractory, advanced metastatic patient population," said Dr. Chaitali Nangia, a Hematologist/Oncologist with the Chan Soon-Shiong Immuno-Oncology Network and study co-author. "Importantly, these responses to treatment are also durable, with median progression free survival exceeding 13 months compared to historical controls of approximately 3 months in this heavily pretreated population. We also observed a positive safety and tolerability profile, with no cytokine

release syndrome. Taken together, these efficacy and safety results point to the emergence of a new treatment paradigm for TNBC."

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 virally induced infectious diseases. We are the leading producer of clinical dose forms of off-the-shelf Natural Killer (NK) cell therapies. Our activated NK cell platform is designed to destroy cancer and virally infected cells from the body. The safety of our optimized, activated NK cells, as well as their activity against a broad range of cancers, have been tested in phase I clinical trials in Canada and Europe, as well as in multiple phase I and II 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 delivering living drugs in a bag and 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 https://nantkwest.com.

haNK is a registered trademark of NantKwest, Inc.

About ImmunityBio

ImmunityBio is a privately held immunotherapy company with a broad portfolio of biological molecules, including an albumin-linked chemotherapeutic, peptides, fusion proteins, cytokines, monoclonal antibodies, adenovirus, and yeast vaccine therapies.

ImmunityBio's oncological goals are two-fold: To employ the company's broad portfolio of biological molecules to activate endogenous NK and CD8+ T cells, and to develop a T cell memory cancer vaccine to combat multiple tumor types without the use of high-dose chemotherapy.

The company's platform of technologies has enabled it to achieve one of the most comprehensive, late-stage clinical pipelines, addressing both the innate (activated macrophage and natural killer cell) and the adaptive immune system (dendritic, CD4 and CD8 killer T cells). In 2020, ImmunityBio is planning to enroll patients in late-stage trials with molecules across multiple indications including triple negative breast cancer, lung cancer, head and neck cancer, Merkel cell carcinoma and glioblastoma.

In the field of infectious disease, ImmunityBio's goal is to develop vaccine therapies for the prevention and treatment of Influenza, Zika, Ebola, and HIV. For more information, please visit our website at https://www.immunitybio.com/.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements concerning or implying that NantKwest will be successful in improving the treatment of cancer. Risks and uncertainties related to this endeavor include, but are not limited to, obtaining FDA approval of NantKwest's NK cells as well as other therapeutics as part of the NANT Cancer Vaccine platform as a cancer treatment.

Forward-looking statements are based on management's current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements.

These and other risks regarding NantKwest's business are described in detail in its Securities and Exchange Commission filings, including in NantKwest's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019. These forward-looking statements speak only as of the date hereof, and we disclaim any obligation to update these statements except as may be required by law.

View source version on businesswire.com: https://www.businesswire.com/news/home/20191216005233/en/

Source: NantKwest Inc.

Media Contact:
Jen Hodson
562-397-3639
Jen@nant.com