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Oncothyreon and Celldex Therapeutics Announce Collaboration for Combination Immunotherapy Clinical Trial of ONT-10 and Varlilumab

SEATTLE, WA and HAMPTON, NJ, May 29, 2014 /PRNewswire/ - Oncothyreon Inc. (ONTY) and Celldex Therapeutics, Inc., (CLDX) today announced that they have agreed to collaborate on a combined clinical trial of ONT-10 and varlilumab. ONT-10 is a therapeutic vaccine targeting the tumor-associated antigen MUC1. Varlilumab is a fully human monoclonal antibody that targets CD27, a critical molecule in the activation pathway of lymphocytes.

The planned trial is an open-label Phase 1b study of ONT-10 administered at the recommended single agent dose in combination with varlilumab at two dose levels in up to 42 patients with advanced breast or ovarian cancer. The primary objective of the trial is to determine the safety and tolerability of the combined therapy. Additional objectives include evaluations of the impact of combination treatment on MUC1-specific humoral and cellular immune responses and anti-tumor effects.

"Recent advances in the immunotherapy of cancer have created new opportunities for evaluating the effectiveness of combination approaches," said Diana Hausman, M.D., Chief Medical Officer at Oncothyreon. "We believe the combination of a therapeutic vaccine with an agent which activates T-cells has the potential to be particularly exciting."

"The combination of an immunogenic tumor-targeted vaccine such as ONT-10 and a broad immune co-stimulator like varlilumab could create potent immunity that may result in anticancer activity, either together or in combination with a checkpoint inhibitor," said Tom Davis, M.D., Senior Vice President and Chief Medical Officer of Celldex. "We believe combination approaches represent the future of immuno-oncology and look forward to starting this study and gathering more information on the potential of varlilumab in combination with this promising MUC1 vaccine and other potentially complementary agents."

The collaboration agreement provides that Oncothyreon will supply ONT-10 and Celldex will supply CDX-1127. The Phase 1b trial will be conducted and funded by Oncothyreon, which plans to submit a new Investigational New Drug (IND) application for the combination trial. Oncothyreon and Celldex will jointly own the data from the trial and will make any plans for potential future development of the combination therapy together. Under the agreement, neither company has granted the other a license, or any other rights, to its product candidate.

About ONT-10

ONT-10 is a therapeutic vaccine targeting MUC1, a tumor-associated antigen present on many types of human malignant tumors, including lung, breast, colorectal, prostate and ovarian cancer. ONT-10 contains a glycosylated antigen designed to mimic the hypoglycosylated state of tumor-associated MUC1 and intended to stimulate both the humoral and cellular arms of the immune response. Additionally, ONT-10 contains the adjuvant PET-Lipid A, a fully synthetic toll like receptor 4 (TLR4) agonist proprietary to Oncothyreon. In an ongoing Phase 1 trial ONT-10 has been well-tolerated, has led to a robust anti-MUC1 antibody response, and has been associated with prolonged stable disease of greater than six months in advanced stage patients. Oncothyreon currently plans to expand the Phase 1 trial in two disease-specific cohorts in patients with advanced breast or ovarian carcinoma.

About Varlilumab

Varlilumab is a fully human monoclonal antibody that targets CD27, a critical molecule in the activation pathway of lymphocytes. CD27 can be effectively manipulated with activating antibodies to induce potent anti-tumor responses, and may result in less toxicities due to its restricted expression and regulation. Varlilumab is a potent anti-CD27 agonist that induces activation and proliferation of human T cells when combined with T-cell receptor stimulation. In lymphoid malignancies that express CD27 at high levels, varlilumab has an additional mechanism through a direct anti-tumor effect. In ongoing Phase 1 trials varlilumab has shown an excellent safety profile and demonstrated clear biologic activity and promising signs of clinical activity in an advanced, refractory patient population.

About Oncothyreon

Oncothyreon is a biotechnology company specializing in the development of innovative therapeutic products for the treatment of cancer. Oncothyreon's goal is to develop and commercialize novel synthetic vaccines and targeted small molecules that have the potential to improve the lives and outcomes of cancer patients. For more information, visit www.oncothyreon.com.

About Celldex

Celldex is developing targeted therapeutics to address devastating diseases for which available treatments are inadequate. Our pipeline is built from a proprietary portfolio of antibodies and immunomodulators used alone and in strategic combinations to create novel, disease-specific therapies that induce, enhance or suppress the body's immune response. Visit www.celldex.com.

Oncothyreon Forward-Looking Statements

In order to provide Oncothyreon's investors with an understanding of its current results and future prospects, this release contains statements that are forward-looking. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include Oncothyreon's expectations regarding clinical development activities and potential benefits of its product candidates.

Forward-looking statements involve risks and uncertainties related to Oncothyreon's business and the general economic environment, many of which are beyond its control. These risks, uncertainties and other factors could cause Oncothyreon's actual results to differ materially from those projected in forward-looking statements, including those predicting the timing, duration and results of clinical trials, the timing and results of regulatory reviews, the safety and efficacy of our product candidates, and the indications for which our product candidates might be developed. There can be no guarantee that the results of preclinical studies or clinical trials will be predictive of either safety or efficacy in future clinical trials. Although Oncothyreon believes that the forward-looking statements contained herein are reasonable, it can give no assurance that its expectations are correct. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. For a detailed description of Oncothyreon's risks and uncertainties, you are encouraged to review the documents filed with the securities regulators in the United States on EDGAR and in Canada on SEDAR. Oncothyreon does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

Celldex Therapeutics Forward-Looking Statements

This release contains "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including those related to the Company's strategic focus and the future development and commercialization (by Celldex and others) of rindopepimut (CDX-110), glembatumumab vedotin ("glemba"; CDX-011), varlilumab (CDX-1127), CDX-1401, CDX-301 and other products and our goals for 2014. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct and you should be aware that actual results could differ materially from those contained in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, our ability to successfully complete research and further development and commercialization of rindopepimut, glembatumumab vedotin and other drug candidates; our ability to obtain additional capital to meet our long-term liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials that we have initiated or plan to initiate; the uncertainties inherent in clinical testing and accruing patients for clinical trials; our limited experience in bringing programs through Phase 3 clinical trials; our ability to manage and successfully complete multiple clinical trials and the research and development efforts for our multiple products at varying stages of development; the availability, cost, delivery and quality of clinical and commercial grade materials produced by our own manufacturing facility or supplied by contract manufacturers, who may be our sole source of supply; the timing, cost and uncertainty of obtaining regulatory approvals; the failure of the market for the Company's programs to continue to develop; our ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; and other factors listed under "Risk Factors" in our annual report on Form 10-K.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise.

Additional Information

Additional information relating to Oncothyreon can be found on EDGAR at www.sec.gov and on SEDAR at www.sedar.com.

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