Neoleukin Therapeutics Presents NL-201 Preclinical Data at Society for Immunotherapy of Cancer’s 36th Annual Meeting (SITC 2021)

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SEATTLE, Nov. 12, 2021 (GLOBE NEWSWIRE) -- Neoleukin Therapeutics, Inc., “Neoleukin” (NASDAQ:NLTX), a biopharmaceutical company utilizing sophisticated computational methods to design de novo protein therapeutics, today announced the presentation of new preclinical data on NL-201, an alpha-independent, de novo-designed IL-2 and IL-15 dual agonist, at the Society for Immunotherapy of Cancer’s 36th Annual Meeting (SITC 2021).

The presentation highlights preclinical data on NL-201 alone and in several combination regimens. NL-201 is a de novo agonist of the IL-2 and IL-15 receptors, designed to expand cancer-fighting CD8 T cells and natural killer (NK) cells without any bias toward cells expressing the IL-2 receptor alpha subunit (CD25).

“The SITC presentations highlight the broad potential of NL-201, which we believe to be the first fully de novo designed protein to enter clinical trials, to activate the immune system to fight cancer,” said Jonathan Drachman, M.D., Chief Executive Officer of Neoleukin. “New data demonstrate that NL-201 can activate the tumor microenvironment and increase T-cell receptor diversity. We also found that local, intratumoral administration can control both the injected and distant tumors with improved tolerability compared to systemic administration in pre-clinical models. We are pleased to share this research as we continue to advance the NL-201 phase 1 clinical trial.”

Further details from the presentations are as follows:

**Poster/Abstract Number: 716**

**NL-201 Induces Inflammation in a ‘Cold’ Tumor Microenvironment through Upregulation of MHC-I, Expansion of the TCR Repertoire, and Potent Antitumor Activity when Combined with PD-1 Inhibition**

- NL-201 turns “cold” tumors “hot” by increasing pro-inflammatory T cells and an immune signature in the tumor microenvironment and upregulating MHC-1 in tumors.
- NL-201 stimulates pro-inflammatory tumor reprogramming without the coincident Treg expansion observed with PD-1 antibodies and other immuno-oncology agents.
- NL-201 drives anti-tumor efficacy in a manner that is cooperative with PD-1 inhibition, including increasing TCR repertoire diversity.

**Poster/Abstract Number: 898**

**Intratumoral Administration of NL-201, an Alpha-Independent IL-2/15 Receptor Agonist, Inhibits the Growth of Both Injected and Uninjected Tumors in Preclinical Models**

- Intratumoral NL-201 administration demonstrated:
  - Dose-dependent antitumor activity in syngeneic murine tumor models;
  - Improved tolerability compared to systemic administration at equivalent dose levels and;
  - Durable tumor-specific immunity.
- Results support clinical investigation of intratumoral NL-201 administration to increase NL-201 concentration in accessible lesions and reduce systemic exposure.

**Poster/Abstract Number: 509**

**A First-in-Human Phase 1 Study of NL-201 in Patients with Relapsed or Refractory Cancer (Trials in Progress)**

- Assessing the safety profile and recommended Phase 2 dose and treatment schedule of NL-201.
- Dose escalation and dose expansion cohorts.
- Enrollment ongoing at multiple sites in North America and Australia.

**Poster/Abstract Number: 563**

**ICT01, an Anti-BTN3A Monoclonal Antibody, and NL-201, an Alpha-Independent IL-2/IL-15 Agonist, Combine to Elicit a Potent Anti-Tumor Response by Synergistically Stimulating g9d2 T Cell Activation and Proliferation**

- ICT01 plus NL-201 synergistically triggers gd T-cell activation, expansion and antitumor activity.
- Data support clinical evaluation of this novel therapeutic approach.

The poster presentations are available on the Neoleukin website publications page: [https://www.neoleukin.com/science/#pubs](https://www.neoleukin.com/science/#pubs)

**About NL-201**

NL-201 is a de novo agonist of the IL-2 and IL-15 receptors, designed to expand cancer-fighting CD8 T cells and natural killer (NK) cells without any bias toward cells expressing the alpha receptor subunit (CD25). Previously presented preclinical data has demonstrated the ability of NL-201 to stimulate and expand CD8+ and NK cells at low doses with minimal impact on immunosuppressive regulatory T cells. Furthermore, NL-201 has demonstrated both monotherapy and combination activity across a wide range of preclinical syngeneic tumor models.
About Neoleukin Therapeutics, Inc.

Neoleukin is a biopharmaceutical company creating next generation immunotherapies for cancer, inflammation and autoimmunity using de novo protein design technology. Neoleukin uses sophisticated computational methods to design proteins that demonstrate specific pharmaceutical properties that provide potentially superior therapeutic benefit over native proteins. Neoleukin’s lead product candidate, NL-201, is a combined IL-2 and IL-15 agonist designed to improve tolerability and activity by eliminating the alpha receptor binding interface. For more information, please visit the Neoleukin website: www.neoleukin.com.

Safe Harbor / Forward-Looking Statements

This press release contains “forward-looking” statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the therapeutic properties and potential of the company’s de novo protein design technology, the results of the clinical trial for NL-201, and planned clinical and development activities and timelines. Forward-looking statements can be identified by words such as: “anticipate,” “intend,” “plan,” “goal,” “seek,” “believe,” “project,” “estimate,” “expect,” “strategy,” “future,” “likely,” “may,” “should,” “will” and similar references to future periods. These statements are subject to numerous risks and uncertainties, including risks and uncertainties related to the company’s cash forecasts, the company’s ability to advance its product candidates, the receipt and timing of potential regulatory submissions, designations, approvals and commercialization of product candidates, the timing and results of preclinical and clinical trials, the timing of announcements and updates relating to the company’s clinical trials and related data market conditions and further impacts of COVID-19, that could cause actual results to differ materially from what Neoleukin expects. Further information on potential risk factors that could affect Neoleukin’s business and its financial results are detailed under the heading “Risk Factors” in documents the company files from time to time with the Securities and Exchange Commission (SEC), and other reports as filed with the SEC. Neoleukin undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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