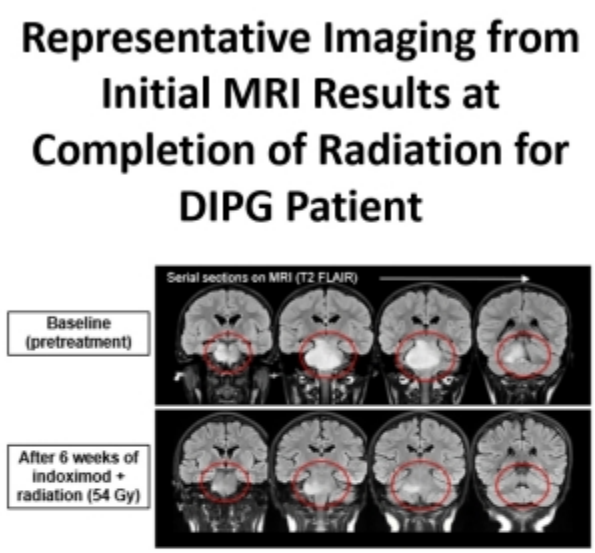
NewLink Genetics Announces Positive Updated Phase 1 Data with Indoximod Plus Radio-Immunotherapy for Pediatric Patients with DIPG Presented at ISPNO 2018

July 2, 2018

AMES, Iowa--(BUSINESS WIRE)--Jul. 2, 2018-- NewLink Genetics Corporation (NASDAQ:NLNK), reported that updated Phase 1 data evaluating indoximod plus front-line radiation and maintenance chemotherapy for the treatment of pediatric patients with newly diagnosed diffuse intrinsic pontine glioma (DIPG) were presented Sunday, July 1, at the International Symposium of Pediatric Neuro-Oncology (ISPNO) 2018 Annual Meeting in Denver.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20180702005283/en/



(Graphic: Business Wire)

Data were presented on ten newly diagnosed DIPG patients, all of whom had initiated therapy at the time of this assessment. All (10/10) demonstrated initial symptomatic improvement. Eight of ten had completed radiation, with the remaining 2 of 10 patients continuing radiotherapy. While a subset of the patient cohort developed inflammatory and other adverse symptomology, a common occurrence in this patient population, these symptoms were actively managed. Currently, 9/10 patients remain on study, with the longest time on study of 8.5 months. These data include more mature follow-up on the 6 patients previously presented at AACR 2018.

“These data continue to demonstrate the potential for indoximod plus radiochemotherapy as a combination treatment regimen which may improve disease related symptoms for these pediatric patients with an otherwise dire prognosis,” said Dr. Theodore S. Johnson, M.D., Ph.D., Associate Professor of Pediatrics at Augusta University, lead investigator for the trial. “We remain encouraged and look forward to additional data as the study proceeds.”

This DIPG cohort is a subset of NLG2105, a Phase 1 study evaluating indoximod, NewLink’s IDO pathway inhibitor, in combination with radiation and chemotherapy for pediatric patients with malignant brain tumors. The DIPG cohort has been expanded from an initial pilot study based on early safety and efficacy data and is currently enrolling with a target of 30 DIPG patients.

About Diffuse Intrinsic Pontine Glioma (DIPG)

Diffuse intrinsic pontine glioma, or DIPG, is a rare, aggressive brain tumor found in the brain stem that almost exclusively affects children. Every year in the United States, approximately 200-400 children, ages ranging from 4 to 11, are diagnosed with DIPG. As the tumor grows, it puts pressure on the nerves that control essential bodily functions. Children experience symptoms including, but not limited to: vision issues, arm and leg weakness and difficulty speaking, breathing and heartbeat resulting in death. The median survival time is 9 months, with only 1% of all children diagnosed with DIPG surviving more than 5 years.[1]

[1]Defeat DIPG Foundation

About Indoximod

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is a key immuno-oncology target involved in regulating the tumor microenvironment and immune escape. Indoximod is being evaluated in combination with treatment regimens including chemotherapy, radiation, checkpoint blockade and cancer vaccines across multiple indications such as AML, DIPG and melanoma.

About NewLink Genetics Corporation

NewLink Genetics is a clinical stage biopharmaceutical company focusing on discovering, developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' IDO pathway inhibitors are designed to harness multiple components of the immune system to combat cancer. For more information, please visit www.newlinkgenetics.com and follow us on Twitter @NLNKGenetics.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink Genetics that involve substantial risks and uncertainties. All statements contained in this press release are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "may," “appear to,” “has potential to,” “look forward to,” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about results of NewLink’s clinical trials for product candidates and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that NewLink Genetics makes due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in NewLink Genetics' Annual Report on Form 10-K for the year ended December 31, 2017 and other reports filed with the U.S. Securities and Exchange Commission (SEC). The forward-looking statements in this press release represent NewLink Genetics’ views as of the date of this press release. NewLink Genetics anticipates that

subsequent events and developments will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing NewLink Genetics' views as of any date subsequent to the date of this press release.

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