



Annual Meeting of Stockholders

NewLink Genetics Corporation

Nasdaq: NLNK
May 12, 2017

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NewLink Genetics

Building a Leading Immuno-Oncology Company

- Emerging clinical data are validating the IDO pathway as central to immunosuppression
- IDO pathway inhibition has the potential to enhance patient outcomes when used in combination with other cancer therapies
- NewLink Genetics has two distinct types of IDO pathway inhibitors in the clinic:
 - Indoximod: wholly owned by NewLink
 - Navoximod (GDC-0919): partnered with Genentech/Roche
- NewLink's next-generation prodrug of indoximod (NLG802) to enter the clinic later this year
- The Company is scientifically visionary, with novel programs, such as PTEN
- NewLink Genetics has a proven track record in both in-licensing and out-licensing
- The Company has a strong balance sheet to advance current preclinical and clinical programs

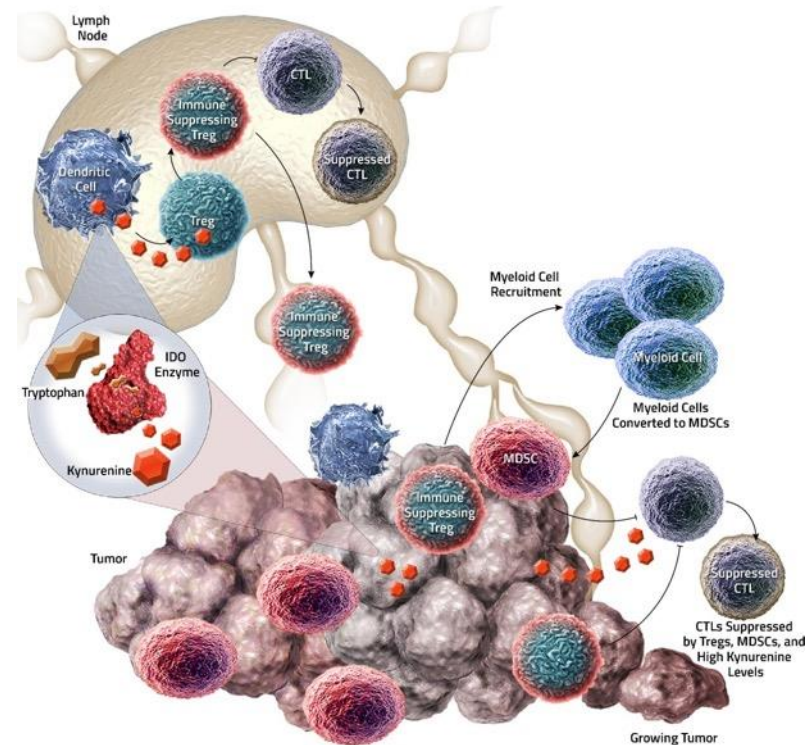


IDO (Indoleamine 2,3-Dioxygenase) Pathway A Key Immune Checkpoint

IDO Pathway and Cancer

Key Immuno-Oncology Target

- IDO (indoleamine 2,3-dioxygenase) is an enzyme within cells that regulates immune response by degrading the amino acid, tryptophan
- The immune response cells require a sufficient amount of tryptophan present to turn themselves on and attack and kill cancer cells
- Thus, when IDO is present, tryptophan declines to a level too low to activate an immune response
- In that scenario, tumor cells go unrecognized by suppressed immune cells and, therefore, are allowed to escape, spread and grow



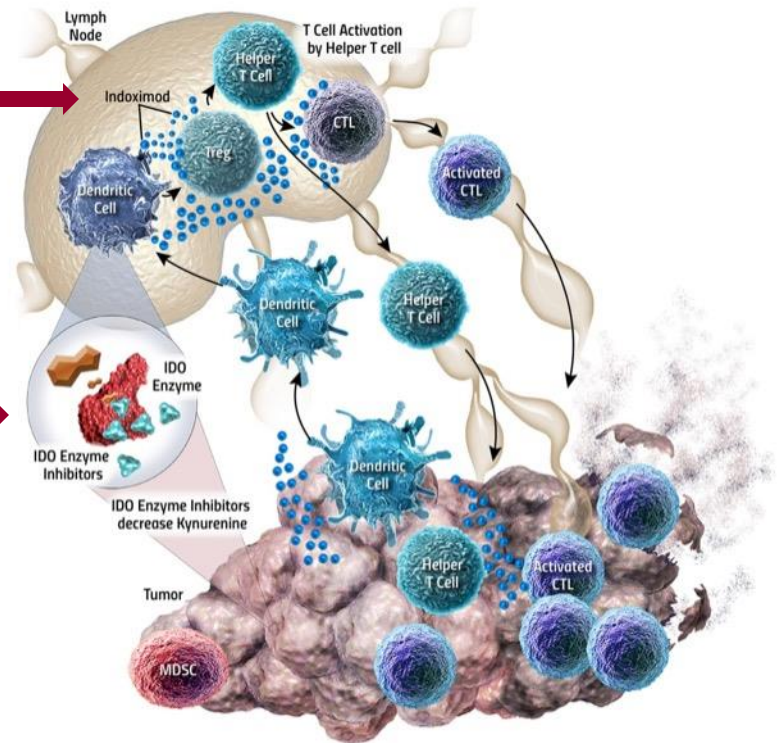
Treg, regulatory T cell; IDO, indoleamine 2,3-dioxygenase; MDSC, myeloid-derived suppressor cell; CTL, cytotoxic T lymphocyte.

¹Metz R. *Oncoimmunology*. 2012;1(9):1460-1468. ²Johnson TS. *Immunol Invest*. 2012;41(6-7):765-797.

Targeting the IDO Pathway

Two Distinct Strategies for Inhibiting the IDO Pathway

- **Indoximod**
 - Acts directly on immune cells to reverse IDO pathway-mediated suppression
- **Navoximod (GDC-0919)**
 - Direct IDO enzymatic inhibitors, block tryptophan metabolism^{1,2}
- Available data indicate similar activity with both approaches³



IDO, indoleamine 2,3-dioxygenase; Treg, regulatory T cell;
MDSC, myeloid-derived suppressor cell; CTL, cytotoxic T lymphocyte.

¹Mautino M. AACR 2013. Abstract 491. ²Jochems C. *Oncotarget*. 2016;7(25):37762-37772.










³Mautino M. AACR 2013. Abstract 5023.

NewLink and Genentech/Roche Partnership

IDO and TDO Pathway Inhibitors

- Navoximod (GDC-0919): joint clinical development ongoing
- Exclusive worldwide license agreement
- \$150M upfront payment with >\$1B in potential milestones
- Joint research collaboration: IDO and TDO pathway inhibitors
- NewLink retains exclusive rights to indoximod and any indoximod prodrugs

IDO Pathway Inhibitor Clinical Development

AGENT	INDICATION	REGIMEN	PHASE 1	PHASE 2	PHASE 3
Indoximod	Advanced Melanoma	Indoximod + PD-1 inhibitors or ipilimumab	ENROLLING 		
	Metastatic Pancreatic Cancer	Indoximod + gemcitabine and nab-paclitaxel	ENROLLED 		
	Metastatic Breast Cancer	Indoximod + taxane	ENROLLED 		
	Malignant Brain Tumors	Indoximod + temozolomide	ENROLLING 		
	Castrate Resistant Prostate Cancer (CRPC)	Indoximod + sipuleucel-T	ENROLLED 		
	Newly Diagnosed Acute Myeloid Leukemia (AML)	Indoximod + standard of care	 ENROLLING		
	Advanced Non-Small Cell Lung Cancer (NSCLC)	Indoximod + tergenpumatucel-L + chemotherapy	 ENROLLING		
GDC-0919*	Solid Tumors	Navoximod(GDC-0919) + atezolizumab (PDL-1)	 ENROLLING		
	Solid Tumors	Navoximod	 ENROLLED		

*Partnered with Genentech/Roche

NLG2103 Study: Indoximod + Checkpoint Inhibitors in Melanoma

Key Highlights

- NLG2103 is a single-arm study designed to assess tolerability and efficacy of indoximod plus standard of care checkpoint inhibitors in advanced melanoma patients
- Over 100 patients were enrolled in this Phase 2 study as of March 2017
- Patient cohort characteristics were similar to a typical metastatic melanoma patient population
- Interim Phase 2 data were presented by a key independent investigator at the 107th Annual Meeting of the American Association of Cancer Research (AACR) on April 4, 2017
- Data showed significant improvement in response rates versus monotherapy
- Durability of response was also evident with continued trend toward complete response
- Indoximod combination was well tolerated with minimal mild to moderate adverse events noted

Phase 2 Interim Results for NLG2103 Presented at AACR

Indoximod Plus Pembrolizumab Response Rates*

n (%)	All patients (n = 60)	Cutaneous/non-ocular† (n = 51)
ORR	31 (52)	30 (59)
CR	6 (10)	6 (12)
PR	25 (42)	24 (47)
SD	13 (22)	11 (22)
DCR	44 (73)	41 (80)
PD	16 (27)	10 (20)

*Based on Response Evaluation Criteria in Solid Tumors (RECIST) guidelines version 1.1.

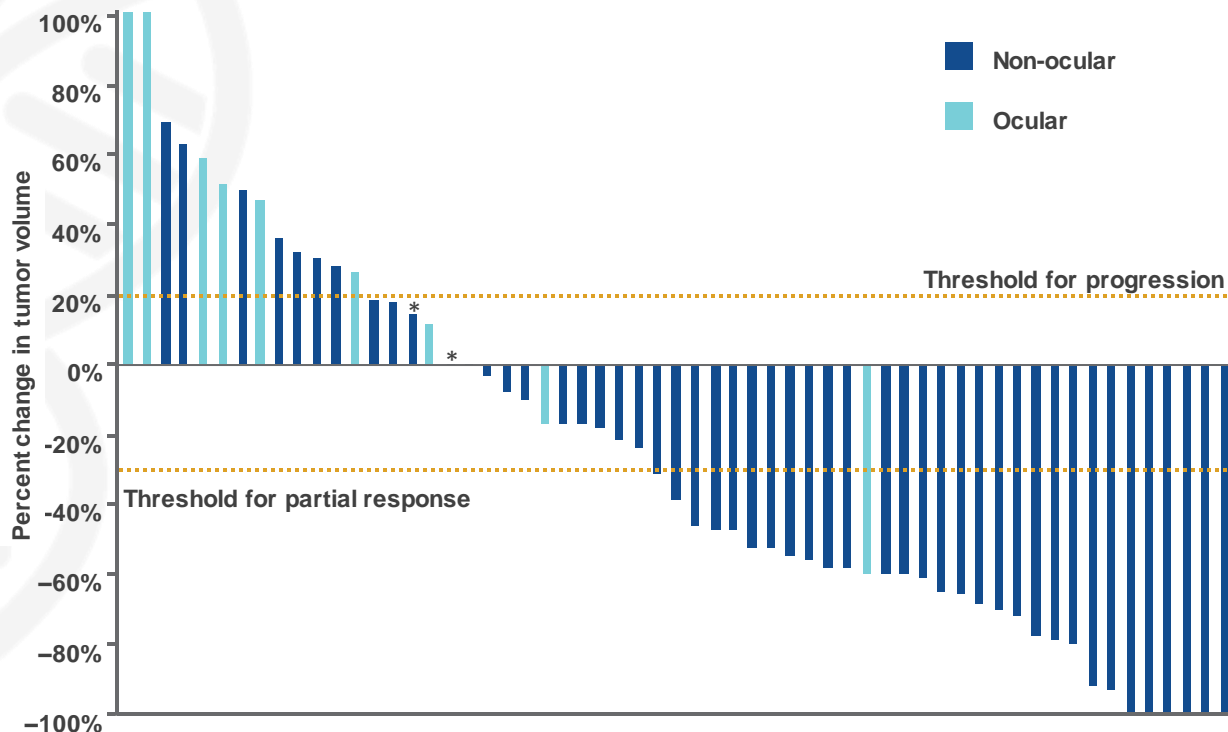
†Includes mucosal, primary of unknown origin, and primary location not reported.

ORR, objective response rate; CR, complete response; PR, partial response; SD, stable disease; DCR, disease control rate; PD, progressive disease.

Zakharia Y, et al. Oral presentation at: 107th Annual Meeting of the American Association for Cancer Research (AACR); April 1-5, 2017; Washington, DC. Abstract CT117.

Best Response by Patient

Distinct Difference in Non-ocular Versus Ocular Patients



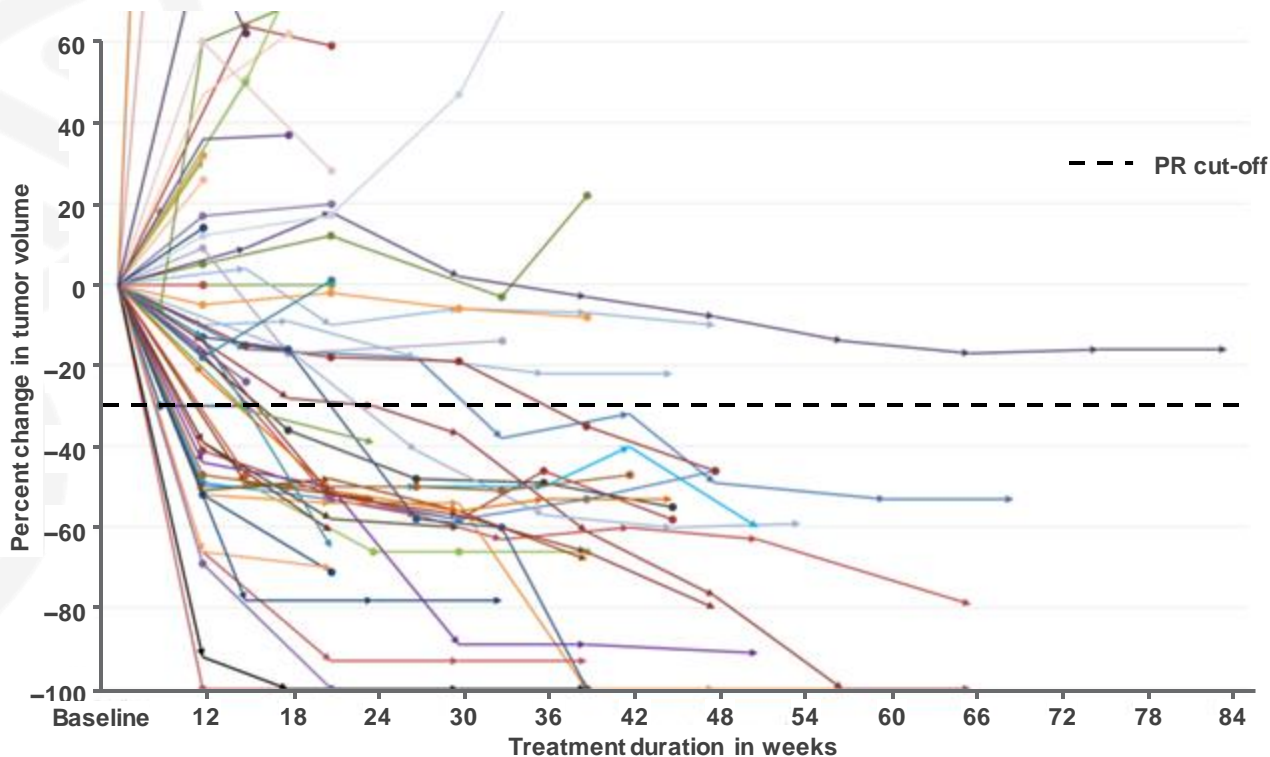
*Stable disease of primary lesion; new non-target lesions classified patients as progressive disease.

Note: 1 patient was unevaluable for response due to pleural effusion/collapsed left lung; the patient progressed based on several new non-target lesions at Week 13.

Zakharia Y, et al. Oral presentation at: 107th Annual Meeting of the American Association for Cancer Research (AACR); April 1-5, 2017; Washington, DC. Abstract CT117.

Change in Tumor Volume Over Time

Durable and Ongoing Responses



PR, partial response.

Note: 1 patient was unevaluable for response due to pleural effusion/collapsed left lung; the patient progressed based on several new non-target lesions at Week 13.
Zakharia Y, et al. Oral presentation at: 107th Annual Meeting of the American Association for Cancer Research (AACR); April 1-5, 2017; Washington, DC. Abstract CT117.

Indoximod for Patients with Advanced/Metastatic Melanoma

Summary of Interim Phase 2 Data and Next Steps

- Indoximod has shown apparent activity as an IDO pathway inhibitor
- Interim data for indoximod plus pembrolizumab (anti-PD1)
 - 59% (30/51) ORR and an 80% (41/51) DCR in patients with cutaneous and non-ocular metastatic melanoma
 - Combination was generally well tolerated and comparable to reported data for pembrolizumab alone
- Interim data support expansion of the indoximod clinical development program
- NewLink's goal is to initiate adaptive design pivotal trial with dose confirmation stage in 2017

Indoximod Clinical Development in Pancreatic Cancer

Combination with Chemotherapy; Gemcitabine/nab-paclitaxel

NLG2104 – 1st line Metastatic Pancreatic Cancer

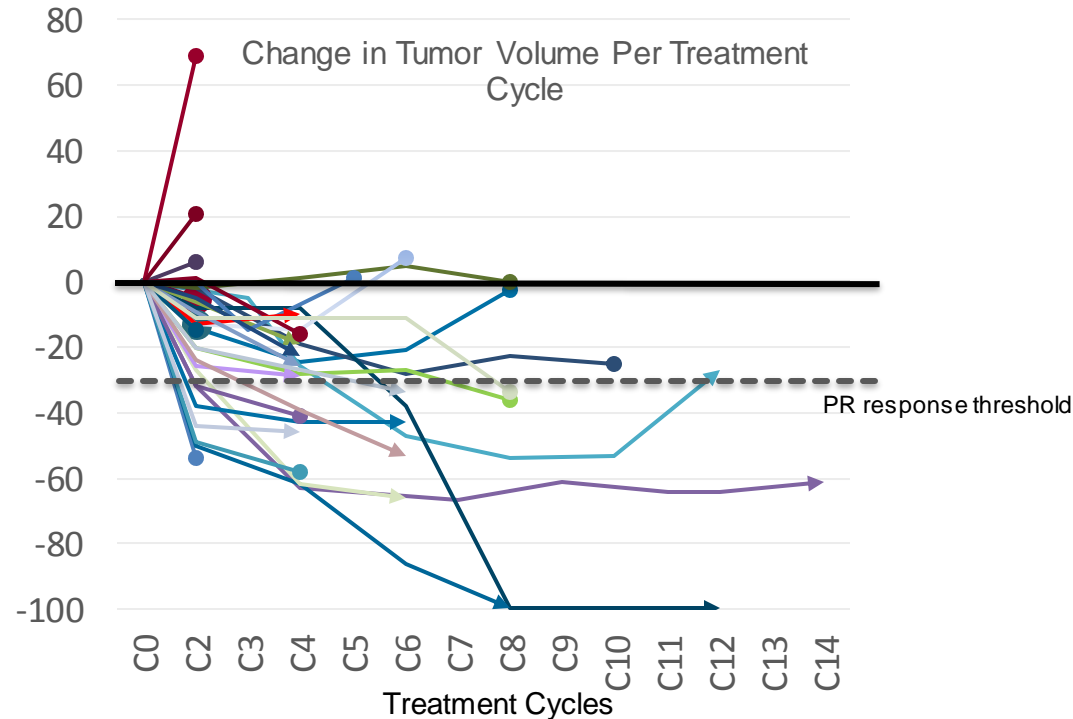
Primary Endpoint	<ul style="list-style-type: none"> Overall survival
Key Secondary Clinical End-Points	<ul style="list-style-type: none"> Objective response rate Progression free survival
Trial Design	<ul style="list-style-type: none"> Phase 2 single arm study Indoximod in combination with gemcitabine / nab-paclitaxel
Trial Size	<ul style="list-style-type: none"> 80+ patients in Phase 2 40 patients in biopsy expansion cohort
Status	<ul style="list-style-type: none"> Initial cohort fully enrolled Anticipate data 2H:17 Biopsies cohort enrolling NCT02077881

Early data* suggest potential to enhance overall response and extend duration of benefit

Indoximod Plus Nab-Paclitaxel

Phase 2 in Patients with Metastatic Pancreatic Cancer (early data)

- Overall, combination was well tolerated
- 45 patients enrolled 4 months or longer
- 31 patients evaluable for response
 - 45% (14/31) overall response rate
 - Two complete responses
- Investigator reported response
- Kinetics and durability of responses suggest immune mediated mechanism



Bahary et al, ASCO 2016 Abstract #3020

Depth and duration of response suggest immune mediated mechanism

Indoximod Clinical Development in AML

Combination with SOC Chemotherapy

NLG2106 – 1st line Acute Myeloid Leukemia

Primary Endpoint	▪ Safety of combination
Key Secondary Clinical End-Points	▪ Evidence of minimal residual disease
Trial Design	<ul style="list-style-type: none"> ▪ Phase 1b dose escalation ▪ In combination with standard chemotherapy
Trial Size	▪ Up to 18 patients
Status	<ul style="list-style-type: none"> ▪ Anticipate full Phase 1 enrollment 1H:17 ▪ Phase 2 expansion opportunity 2H:17 ▪ NCT02835729

Strong preclinical data and significant unmet need

Indoximod Clinical Development in Prostate Cancer

Combination with Sipuleucel-T in Castrate Resistant Prostate Cancer (CRPC)

Masonic Cancer Center, University of Minnesota

Primary Endpoint	<ul style="list-style-type: none"> ▪ Augmentation of immune response to sipuleucel-T
Key Secondary Clinical End-Points	<ul style="list-style-type: none"> ▪ Radiographic Progression Free Survival (rPFS) ▪ Objective Response ▪ Overall Survival
Trial Design	<ul style="list-style-type: none"> ▪ Randomized, double blind, placebo controlled Phase 2 ▪ In combination with sipuleucel-T
Trial Size	<ul style="list-style-type: none"> ▪ Enrolled 46 patients
Status	<ul style="list-style-type: none"> ▪ Enrollment complete ▪ Data to be presented in June 2017 ▪ NCT01560923

Combination of IDO Pathway Inhibitor, indoximod with cancer vaccine

Summary of Recent Highlights

- Presented promising interim Phase 2 data of the IDO pathway inhibitor, indoximod, in combination with KEYTRUDA® (pembrolizumab) for patients with advanced melanoma at the American Association of Cancer Research (AACR) plenary session on April 4, 2017
- Presented a poster on NLG802, “*A novel prodrug of indoximod with enhanced pharmacokinetic properties,*” at AACR on April 4, 2017
- Abstract accepted for presentation at the 2017 Annual Meeting of the American Society of Clinical Oncology (ASCO) for a randomized double-blind, placebo-controlled Phase 2 study of indoximod in combination with the vaccine, PROVENGE® (sipuleucel-T), for patients with metastatic castration resistant prostate cancer
- Abstract accepted for presentation at the 2017 ASCO Annual Meeting submitted by our partner on a Phase 1b dose-escalation study of navoximod (GDC-0919) in combination with TECENTRIQ® (atezolizumab) in multiple solid tumors

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

TECENTRIQ® is a registered trademark of Genentech, a member of the Roche Group.

PROVENGE® is a registered trademark of Dendreon/Valeant Pharmaceuticals International, Inc.

Anticipated Highlights for 2017 Clinical Programs

- Metastatic castration resistant prostate cancer:
 - Abstract 3066: Randomized placebo-controlled Phase 2 clinical trial data to be presented at ASCO on *Monday, June 5, 2017, 9:00 AM ET-12:30 PT ET*
- Metastatic pancreatic cancer:
 - Indoximod in combination with gemcitabine + ABRAXANE® (nab-paclitaxel) Phase 2 trial data available at an upcoming medical meeting in the second half of 2017
- Acute Myeloid Leukemia (AML):
 - Interim data from a Phase 1b dose-escalation study of indoximod in combination with standard of care chemotherapy for patients with newly diagnosed AML available second half of 2017
- Multiple solid tumors:
 - Phase 1b dose-escalation trial data for navoximod (GDC-0919) plus TECENTRIQ® (atezolizumab) to be presented at ASCO on *Sunday, June 4, 2017 from 10:45 AM ET-12:15 PM ET* by our partner (Abstract 105)
- NLG802: next-generation, novel prodrug to enter clinic by end of Q3 2017
- Advanced Melanoma:
 - Initiate a pivotal trial of indoximod + anti-PD-1 inhibitors with dose confirmation stage in 2017 followed by a randomized stage



Other Programs/R&D

Infectious Disease Programs

Ebola and Zika Virus Vaccines

- Ebola vaccine candidate receives breakthrough therapy designation from FDA and PRIME status from EMA; December 2016 final results confirm efficacy
- Developing new treatment options for the Zika virus with goal of a strategic collaboration



Jul 25, 2016

NewLink Genetics Announces Merck Receives Breakthrough Therapy Designation from FDA and PRIME Status from EMA for Investigational Ebola Zaire Vaccine (V920)

AMES, Iowa, July 25, 2016 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK), announced today that Merck (NYSE:MRK), known as MSD outside the United States and Canada, has reached two key regulatory milestones for the Ebola Zaire vaccine candidate known as V920 (rVSVΔG-ZEBOV-GP). The U.S. Food and Drug Administration (FDA) has granted the vaccine candidate Breakthrough Therapy Designation, and the European Medicines Agency (EMA) has provided the vaccine candidate PRIME (PRiority Medicines) status.

V920 was initially one of the Ebola outbreak response efforts, and was approved, and available, in 2014. Since that time, "These regulatory designations are a testament to the vaccine's potential to stop the next outbreak in its tracks," said Dr. Robert T. Jackson, President of Infectious Disease Development at NewLink. "We are encouraged by these designations and the progress we have made in the development of this vaccine."

About NewLink Genetics
NewLink Genetics is a biotechnology company focused on developing and commercializing innovative biologics and small molecule drugs designed to harness the power of the immune system.

DRUG DEVELOPMENT

Merck's Ebola vaccine promises to stop the next outbreak in its tracks

by JOHN CARROLL

December 23, 2016 09:54 AM EST

The last Ebola outbreak ended months ago. But it will be back, and next time there will be an effective vaccine to halt the virus before it can spread. The vaccine is Merck's rVSV-ZEBOV, which proved to be 100% effective in blocking outbreaks.

THE WALL STREET JOURNAL.

Drug Industry Starts Race to Develop Zika Vaccine

U.S. biotech company NewLink Genetics Corp. said it too was working on developing treatment options for the disease.

At least a dozen Ebola vaccine and drug candidates were under development when the virus began to spread in West Africa.

Even so, there is still no licensed treatment or vaccine. One vaccine candidate, developed by NewLink and licensed out to Merck & Co. proved effective in a clinical trial, and the company is gathering data to apply for licensure.

PTEN as a Pharmacological Target

PTEN Inhibitors Could Reverse IDO-Mediated Systemic Immunosuppression

- PTEN is a promising target for pharmacological inhibition in immuno-oncology
- Licensing and research collaboration between AURI and NewLink
- We are working to identify lead PTEN inhibitor compounds
- Multiple assays to test PTEN inhibitors potency, activity and specificity
- PTEN inhibition could also find applications in other fields such as diabetes, nerve regeneration, prevention of ischemia damages

PTEN inhibitors are a promising opportunity in immuno-oncology



Financial Update

First Quarter 2017 Financial Results

Cash and Equivalents	\$118.2 million
Debt	~\$0.5 million
YE 2017 Cash (Projected)	~\$75 million
Quarterly Negative Cash-Flow	~\$13 million
Shares Outstanding	29.2 million
Market Capitalization	~\$500 million
Headcount	127

Major 2017 YE Cash Projection Assumptions: This excludes potential payments from partners, the proceeds from any offerings, and any costs associated with any strategic transactions.



Summary

SUMMARY

- IDO inhibition is increasingly validated as a key immuno-oncology target
- NewLink Genetics is building a leading IDO company with two IDO pathway inhibitors in the clinic and a next-generation molecule to enter the clinic soon
- 2017 will prove to be a busy year for trial data releases by NewLink Genetics and its partners
- The Company is progressing toward initiation of a pivotal trial in melanoma
- NewLink Genetics is increasingly recognized as a pure-play in IDO pathway inhibition with the ability to partner with other immuno-oncology companies to enhance monotherapy performance
- The company has a solid balance sheet enabling it to proceed with its clinical strategy