UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 8, 2018

NewLink Genetics Corporation
(Exact name of registrant as specified in its charter)

Delaware	**001-35342**	**42-1491350**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2503 South Loop Drive **Ames, IA**	**50010**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(515) 296-5555**

Not applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act o

Section 8 - Other Events

Item 8.01. Other Events.

On January 8, 2018, NewLink Genetics Corporation, a Delaware corporation, or the Company, issued a press release titled "NewLink Genetics Outlines 2018 Business Priorities to Support Phase 3 Pivotal Trial of Indoximod Plus PD-1 Inhibitors."

A copy of the press release and the related presentation are attached hereto as Exhibit 99.1 and 99.2, respectively, and are incorporated herein by reference.

Section 9 - Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated January 8, 2018, entitled “NewLink Genetics Outlines 2018 Business Priorities to Support Phase 3 Pivotal Trial of Indoximod Plus PD-1 Inhibitors”
99.2	J.P. Morgan Healthcare Conference Presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: January 8, 2018

NewLink Genetics Corporation

By: /s/ John B. Henneman III
John B. Henneman III
Its: Chief Financial Officer

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release, dated January 8, 2018, entitled "NewLink Genetics Outlines 2018 Business Priorities to Support Phase 3 Pivotal Trial of Indoximod Plus PD-1 Inhibitors"
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NewLink Genetics Outlines 2018 Business Priorities to Support Phase 3 Pivotal Trial of Indoximod Plus PD-1 Inhibitors

NewLink Genetics updates financial and clinical guidance

AMES, Iowa, January 8, 2018 -- NewLink Genetics Corporation (NASDAQ: NLNK) today announced Indigo301, the name of its upcoming Phase 3 trial of indoximod plus PD-1 inhibitors for patients with advanced melanoma, and outlined 2018 business priorities to support this trial. In addition, the company updated clinical and financial guidance and provided preliminary unaudited financial information for year-end 2017.

These updates were made in conjunction with the 36th Annual JP Morgan Healthcare Conference that begins today in San Francisco. NewLink Genetics' Chairman and Chief Executive Officer, Charles J. Link, Jr., M.D., will discuss the Company's continued execution of its corporate strategy and 2018 priorities as part of a live presentation on Thursday, January 11, 2018, at 11:00 AM PT/2:00 PM ET. The slide presentation with updated guidance has been posted on the Company's website and may be found here. The oral presentation will be webcast and available on the NewLink Genetics website under the Investors & Media tab under Events & Presentations.

Indigo301 is a randomized Phase 3 study of indoximod or placebo plus KEYTRUDA® (pembrolizumab) or OPDIVO® (nivolumab) for patients with unresectable or metastatic melanoma. The choice of PD-1 inhibitors will be at the physician's discretion, mirroring the general clinical setting. The study will consist of a planned 624 patients enrolled at approximately 100 sites in multiple countries and will include co-primary endpoints of Progression-Free Survival (PFS) and Overall Survival (OS), with a secondary endpoint of Objective Response Rate (ORR).

"NewLink has focused its business priorities on the execution of Indigo301 for patients with advanced melanoma," said Dr. Link. "We will also initiate a randomized Phase 2 trial in collaboration with AstraZeneca for patients with metastatic pancreatic cancer, and we anticipate clinical data from additional development programs."

To expedite the enrollment of Indigo301, NewLink Genetics has expanded the planned number of trial sites both within and outside of the US and plans several clinical recruitment initiatives to engage with the oncology community with the goal to enroll the majority of patients in 2018. As a result of these clinical planning efforts, NewLink Genetics is accordingly updating its guidance for clinical trials as follows:

Clinical Guidance and Milestones

- Enroll the majority of Indigo301 trial by the end of 2018
- Phase 2 results for indoximod + PD-1 blockade in advanced melanoma expected in 2018
- Phase 2 results for indoximod + gem/nab-paclitaxel in pancreatic cancer expected 1H 2018
- Phase 2 randomized AstraZeneca collaboration in pancreatic cancer to initiate 1H 2018

Financial Guidance and Outlook

“Entering 2018, we have aligned our business and investments to drive Indigo301 and other high-potential development programs,” said Jack Henneman, Executive Vice President and Chief Financial Officer for NewLink Genetics. “As we continue to progress, we remain committed to maintaining the strength of our balance sheet in support of our most promising clinical programs.”

NewLink Genetics ended 2017 with approximately $158 million in cash and cash equivalents. Updated guidance for use of cash is provided in the slide presentation available on the company’s website.

About Indoximod

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is one of the key immuno-oncology targets involved in regulating the tumor microenvironment and immune escape. NewLink Genetics is currently evaluating indoximod in multiple combination studies for patients with various types of cancer including melanoma, pancreatic cancer and other malignancies.

About NewLink Genetics Corporation

NewLink Genetics is a late-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. Indoximod is being evaluated in combination with treatment regimens including anti-PD-1/PD-L1 agents, cancer vaccines, and chemotherapy across multiple indications such as melanoma, pancreatic cancer and other malignancies. For more information, please visit www.newlinkgenetics.com and follow us on Twitter @NLNKGenetics.

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

OPDIVO® is a registered trademark of Bristol-Myers Squibb Company.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink 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 “guidance,” “upcoming,” “will,” “plan,” "anticipate," "approximate," "expect," 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 NewLink Genetics' financial guidance for 2018; results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to moving additional indications into clinical development; NewLink Genetics' future financial performance, results of operations, cash position and sufficiency of capital resources to fund its operating requirements; 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 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, 2016 and other reports filed with the U.S. Securities and Exchange Commission (SEC). The forward-looking statements in this press release represent NewLink's views as of the date of this press release. NewLink 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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36th Annual J.P. Morgan Healthcare Conference

NewLink Genetics Corporation

NASDAQ: NLNK
January 8-11, 2018

Forward-Looking Disclaimer

This presentation contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "potential," "will," "could," "should," "seek" 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 NewLink Genetics' financial guidance for 2017 and 2018; results of its clinical trials for product candidates; its timing of enrollment of patients and release of data from ongoing clinical studies; its plans related to moving additional indications into clinical development; NewLink Genetics' future financial performance, results of operations, cash position and sufficiency of capital resources to fund its operating requirements; 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 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, 2016 and other reports filed with the U.S. Securities and Exchange Commission (SEC). The forward-looking statements represent NewLink's views as of the date of this presentation. NewLink 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 presentation.

NewLink Genetics

Focused on Indoximod, an IDO Pathway Inhibitor

- Indoleamine 2,3-dioxygenase (IDO) pathway is a key immuno-oncology target
- Our leading IDO pathway inhibitor, indoximod, has a differentiated mechanism of action (MOA)
- Indoximod's unique MOA may allow effectiveness in different combinations and therapeutic settings than direct enzymatic inhibitors
- Clinical data suggest indoximod combinations may enhance multiple therapeutic modalities
  - PD-1 checkpoint inhibitors (advanced melanoma)
  - Cancer vaccine (metastatic prostate cancer)
  - Chemotherapy (pancreatic cancer and acute myeloid leukemia)
- Indoximod has the potential to improve patient outcomes across a broad range of cancers including both hematologic and solid tumor indications

Indoximod has been studied in more than 700 patients

NewLink Genetics
Highlights

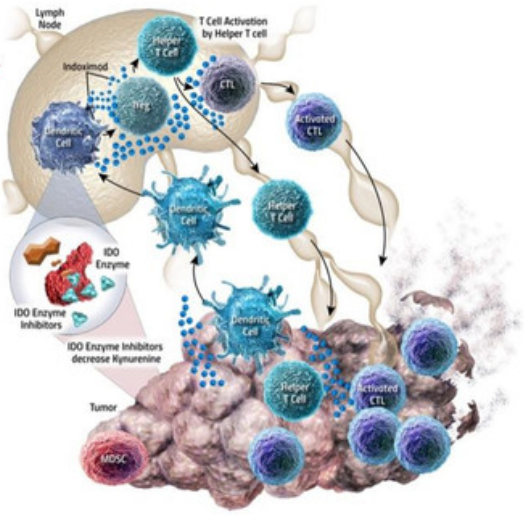
- Launching pivotal trial (Indigo301) of indoximod plus PD-1 inhibitors for patients with advanced melanoma
- Phase 2 data for indoximod (IDO) plus pembrolizumab (PD-1) suggest potential for improvement of both response rate and PFS for patients with advanced melanoma
- Indoximod granted Orphan Drug Designation by the FDA for Stage IIb-IV melanoma
- Phase 2 clinical collaboration with AstraZeneca to evaluate indoximod plus durvalumab plus standard-of-care chemotherapy for patients with metastatic pancreatic cancer
- First patients dosed with novel salt formulation of indoximod
- First patients dosed with NLG802, prodrug of indoximod
- Cash and equivalents of approximately $158 million at YE 2017

Indoximod program made substantial progress in 2017

Targeting the IDO Pathway

Indoximod - A Unique Approach To Inhibiting the IDO Pathway

- **Indoximod**
  - Acts directly on immune cells to reverse IDO pathway-mediated suppression
- **Other IDO inhibitors**
  - Direct IDO enzymatic inhibitors such as NLG919, epacadostat and BMS-986205 block tryptophan metabolism[1,2]

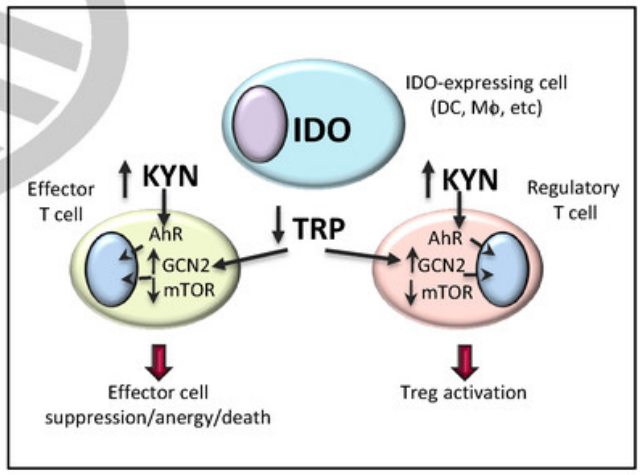


Indoximod has a differentiated mechanism of action

IDO, indoleamine 2,3-dioxygenase; Treg, regulatory T cell; MDSC, myeloid-derived suppressor cell; CTL, cytotoxic T lymphocyte.
[1]Mautino M. AACR 2013. Abstract 491. [2]Jochems C. *Oncotarget.* 2016;7(25):37762-37772.

IDO Pathway Mediated Immuno-Suppression

Treg Activation and Effector Cell Reduction



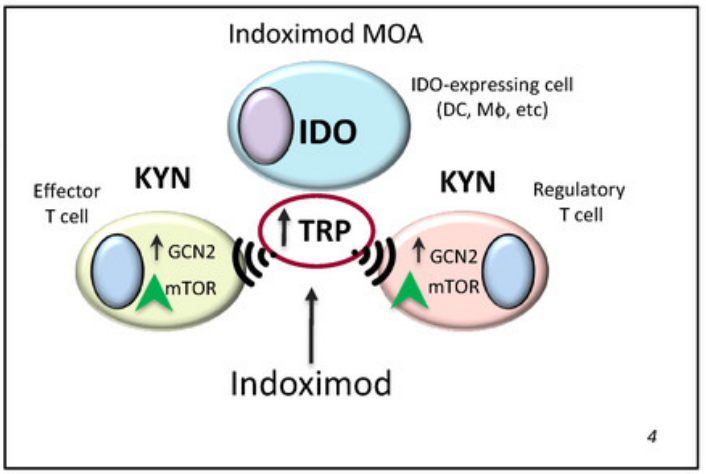
Immuno-suppressive feedback loop dependent on multiple components

Munn, D et al. *Trends in Immunology*. Page 12, Figure 1, March 2012.

Indoximod is an IDO Pathway Inhibitor with a Differentiated MOA

A Proposed Mechanism with a Broad Spectrum of Potential Clinical Utility

- Orally available tryptophan mimetic[1]
- Counteracts immunosuppressive effects of kynurenine[1]
- Activates multiple immune cells (effector cells)[2]
- Prevents activation of regulatory T cells (Tregs)[3]
- Reprograms Tregs into helper T cells[3]



Indoximod interrupts the IDO mediated immuno-suppressive feedback loop

[1]Metz R. *Oncoimmunology*. 2012;1(9):1460-1468; [2]Holmgaard RB, et al. Cell Reports. 2015;13(2):412-424;
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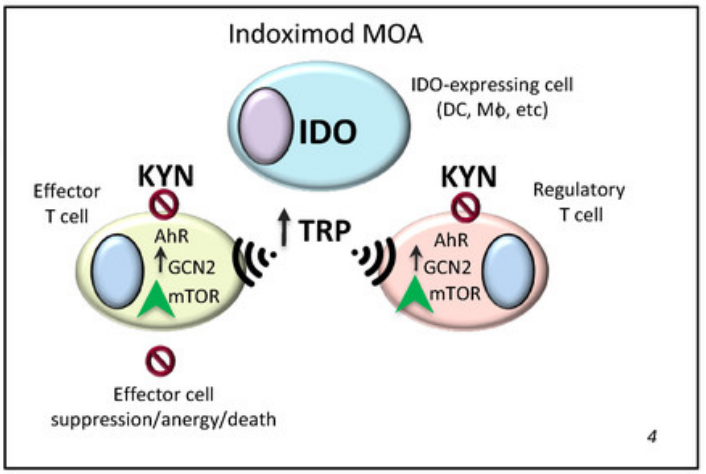

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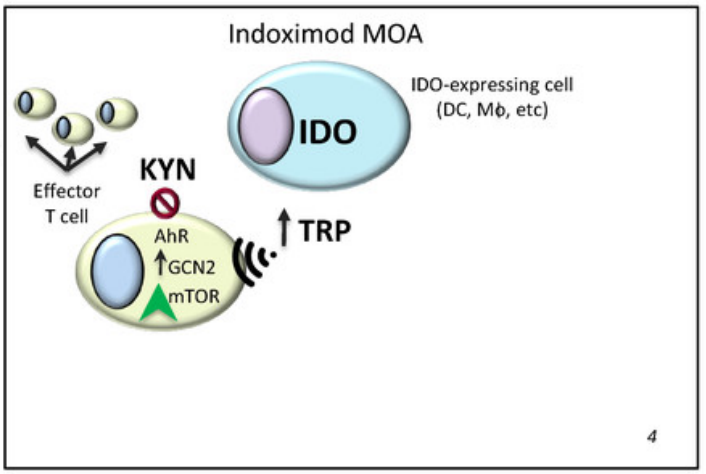

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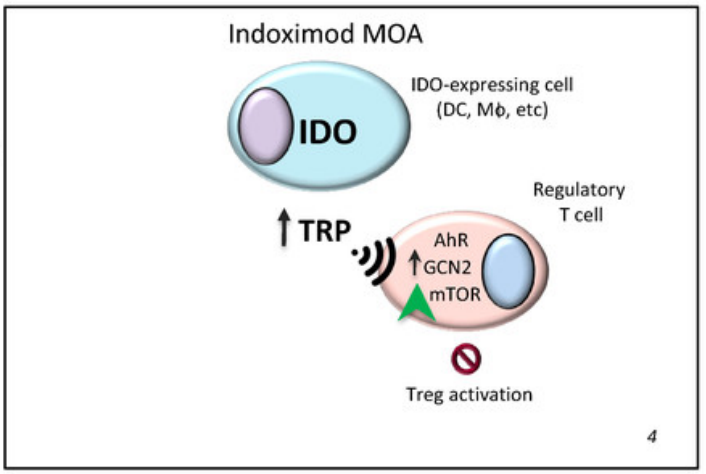

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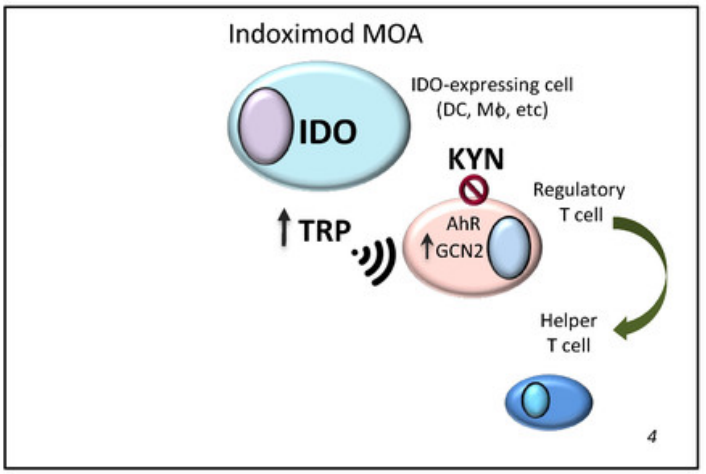

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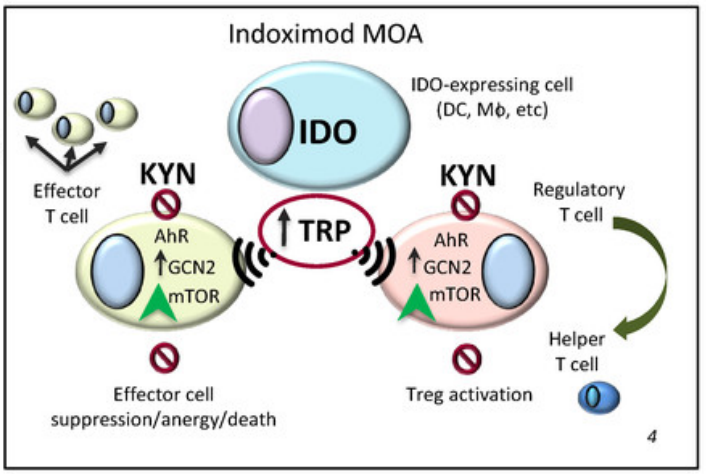

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Indoximod (IDO) plus Pembrolizumab (PD-1) in Advanced Melanoma

Phase 2: Baseline Demographics and Clinical Characteristics

Characteristic	n = 51*
Median age (range), yr	62.9 (27–88)
Male, n (%)	34 (67)
Race/Ethnicity, n (%)	
White, non-Hispanic†	50 (98)
LDH above ULN, n (%)	12 (24)
Disease stage, n (%)	
III	8 (16)
IV	43 (84)
M1a	9 (18)
M1b	13 (25)
M1c	21 (41)

Characteristic	n = 51*
ECOG PS, n (%)	
0	38 (75)
1	13 (25)
Primary site, n (%)	
Cutaneous	40 (78)
Mucosal or primary unknown	11 (22)
Prior therapy, n (%)	
Radiation	9 (18)
Systemic therapy	14 (27)
None	28 (55)

ECOG PS, Eastern Cooperative Oncology Group performance status; LDH, lactate dehydrogenase; ULN, upper limit of normal.
*Excludes uveal melanoma patients.
†One patient declined to answer.

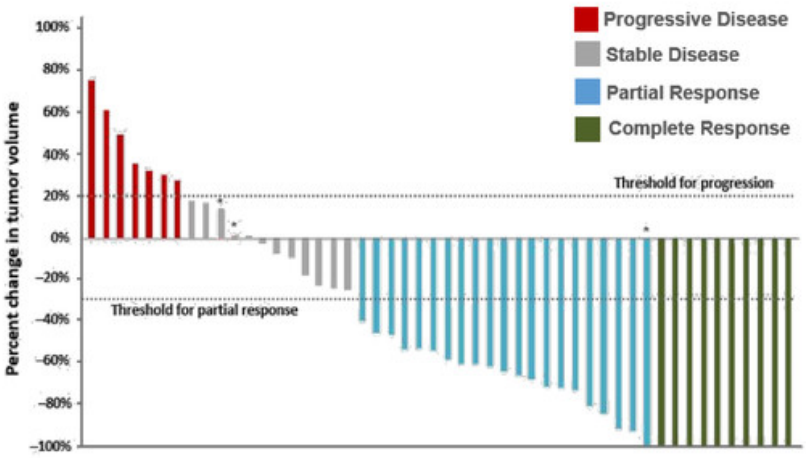
Zakharia Y, et al. Oral presentation at: Third International Cancer Immunology Conference; September 6-9, 2017; Frankfurt, Germany.

Indoximod (IDO) plus Pembrolizumab (PD-1) in Advanced Melanoma

Phase 2: Impressive Response Rate and Progression Free Survival (N=51)

Response	N (%)
ORR	**31 (61)**
CR	10 (20)
PR	21 (41)
SD	10 (20)
DCR	**41 (80)**
PD	10 (20)

Survival	
Median PFS	**12.9 months**
PFS at 12 months	**56%**

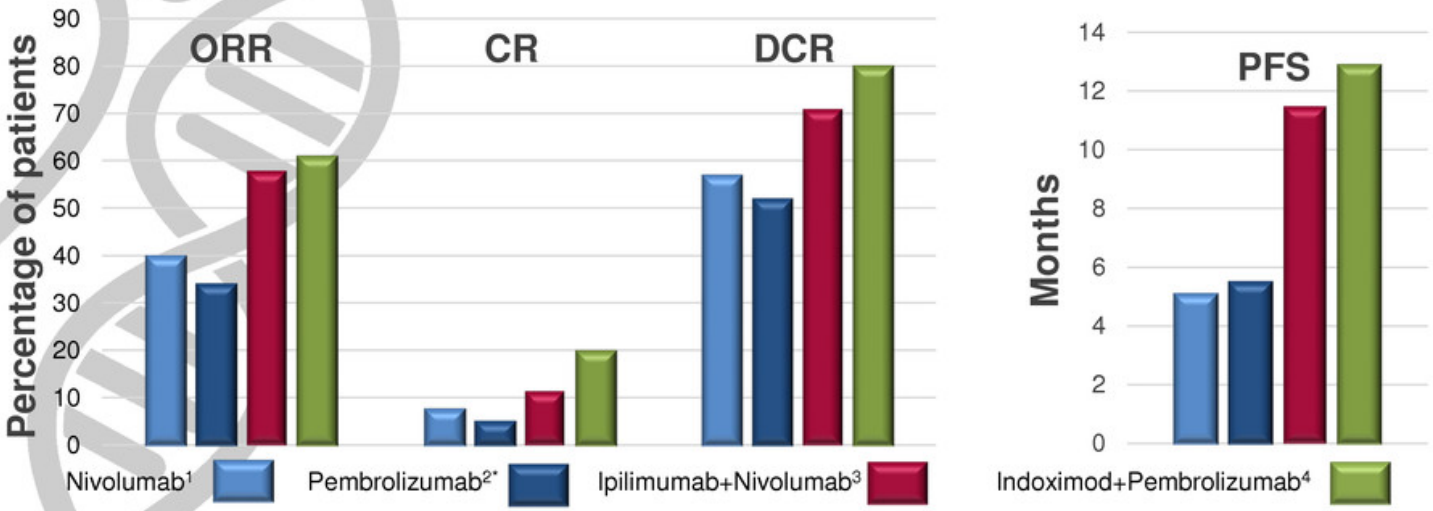


Significant depth of response observed in a large number of patients

*Patients that progressed due to new non-target lesions.
Note: 1 patient was unevaluable for response due to pleural effusion/collapsed left lung; the patient progressed based on several new non-target lesions.
Zakharia Y, et al. Oral presentation at: Third International Cancer Immunology Conference; September 6-9, 2017; Frankfurt, Germany.

Indoximod Plus PD-1 Response and Survival in Advanced Melanoma

Potential to Improve Outcomes Without Added Toxicity of Ipilimumab + Nivolumab



Comparative anti-PD-1 monotherapy & anti-PD-1 + anti-PD-1 combination data provided for illustrative purposes only; no head-to-head trials conducted.

*Data are for Q2W regimen. ORR, overall response rate; CR, complete response; DCR, disease control rate; PFS, progression-free survival.

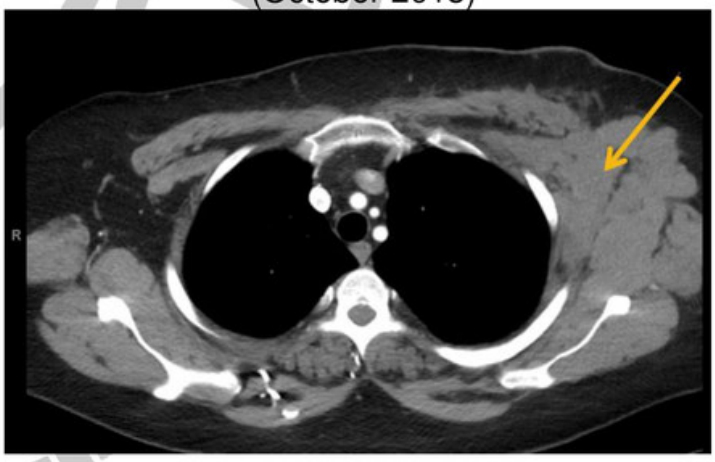
[1]Robert C, et al. *N Engl J Med.* 2015;372(4): 320-330. [2]Robert C, et al. *N Engl J Med.* 2015;372(26): 2521-2532. [3]Larkin J, et al. *N Engl J Med.* 2015;373(1):23-34.

[4]Zakharia Y. Oral presentation at: Third International Cancer Immunotherapy Conference, September 6-9, 2017; Frankfurt, Germany.

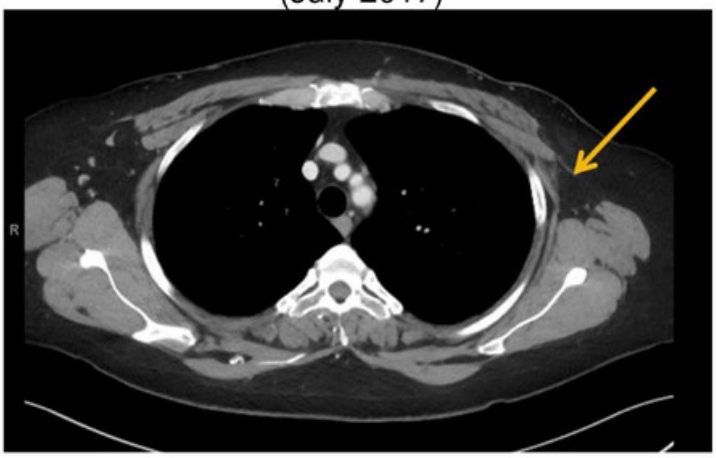
Complete Response in Advanced Melanoma

Indoximod plus Pembrolizumab Phase 2 Patient

Before Treatment
(October 2015)



After Treatment
(July 2017)



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Indoximod (IDO) plus Pembrolizumab (PD-1) in Advanced Melanoma

Adverse Event Profile Appears Comparable to Pembrolizumab Alone

- Combination was generally well tolerated
- No treatment-related Grade 4/5 adverse events reported to date
- Serious Adverse Events (SAEs) led to discontinuation in only 3 patients
- SAEs labelled as possibly related to indoximod reported in 4 patients
- Limited immune-mediated adverse events reported regardless of attribution to treatment
- No treatment-related deaths were reported

Full dose combination generally well tolerated

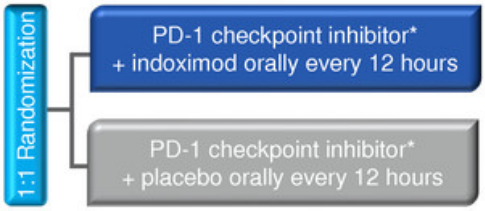
Zakharia Y, et al. Oral presentation at: Third International Cancer Immunology Conference; September 6-9, 2017; Frankfurt, Germany.

Indigo301

A Phase 3 Study of Indoximod or Placebo Plus Pembrolizumab or Nivolumab For Patients With Unresectable or Metastatic Melanoma

PATIENT POPULATION

- Adults ≥18 years of age with unresectable stage III or IV advanced melanoma
- No prior melanoma therapy, except
  - BRAF/MEK inhibitor
  - Prior adjuvant or neoadjuvant therapy ≥4 weeks before randomization
  - Prior adjuvant immunotherapy (no relapse during treatment or ≤6 months of treatment discontinuation)
- Stable brain metastases allowed



*Standard-of-care dosing per country.

- Randomization (via an interactive web randomization system) stratified by:
  - Choice of checkpoint inhibitor (pembrolizumab or nivolumab)
  - Prior BRAF/MEK therapy
  - M stage at randomization
- Treatment until disease progression or unacceptable toxicity

EFFICACY ENDPOINTS

Co-primary endpoints

- Progression-free survival
- Overall survival

Secondary endpoint

- Objective response rate

ENROLLMENT

- Total planned enrollment: 624 patients
- ~100 sites in multiple countries

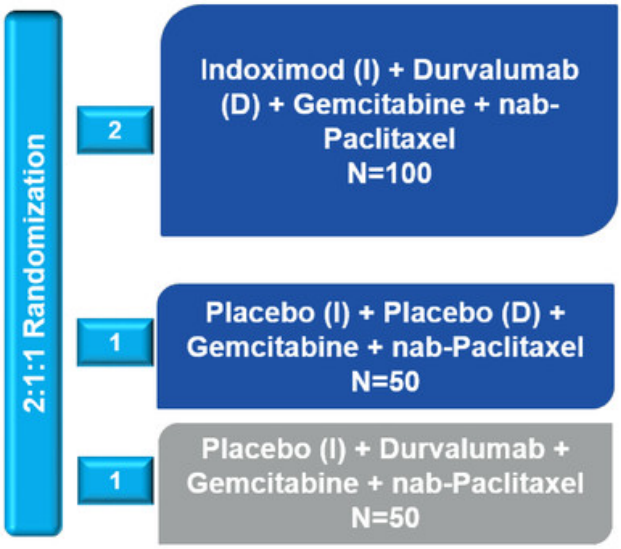
Indigo301 Trial Support

Broad Set of Initiatives to Drive Enrollment and Expand Awareness

- Launching Indigo clinical trials initiative
  - Physician and patient information website
  - Targeted online and print advertising
  - Patient advocacy partnerships
- Deploying field based medical affairs team in Q1:18
  - Work directly with trial sites to accelerate enrollment
  - Facilitate patient recruitment activities at local and regional levels
  - Engage Key Opinion Leaders
- Enlisting support from multiple industry leading experts
  - Additional clinical trial specialists targeting Ex US sites
  - Specialty accrual programs tailored to individual site needs and requirements

Indigo201 | Phase 2 Randomized, Placebo Controlled Trial* of IDO plus anti-PD-L1 and Chemotherapy for Patients with Metastatic Pancreatic Cancer

- Objective: Evaluate 4 drug regimen vs SOC
- Planned enrollment of 200 patients
- Primary Endpoint: Overall Response
- Secondary Endpoints:
  - Overall Survival
  - Progression-Free Survival
  - Safety
- Status and Milestones
  - First Patient 1H:18
  - 50/50 Cost Sharing
  - NewLink to be study sponsor



* Clinical collaboration with AstraZeneca

Indoximod plus Standard of Care Chemotherapy

Phase 1/2 for Indoximod plus Standard of Care Chemotherapy for Patients with Acute Myeloid Leukemia

- Patients with newly diagnosed Acute Myeloid Leukemia (AML)
- Surrogate efficacy endpoint being explored as potential fast to market strategy
- Currently completing initial Phase 1b dose escalation

EHA '17 Abstract E-912, Emadi, et al June 23rd 2017

- 15 patients enrolled as of June 1, 2017
- Indoximod does not appear to add significant toxicity
- 7/9 patients who completed treatment per protocol (>80% compliance) achieved morphologic CR
- 7/7 patients with CR had no evidence of minimal residual disease

Strong preclinical data and significant unmet need

NLG919

Direct IDO1 Enzymatic Inhibitor

- Phase 2 ready asset
- Favorable safety profile with no appreciable increase in AEs in combination with PD-L1 blockade*
- Peripheral PD showed dose-dependent decreases in plasma kynurenine, consistent with systemic modulation of IDO1*
- NLG919 + indoximod preclinical data showed synergistic anti-tumor activity**
- NewLink Genetics has worldwide rights to NLG919
- Potential for development or licensing opportunities

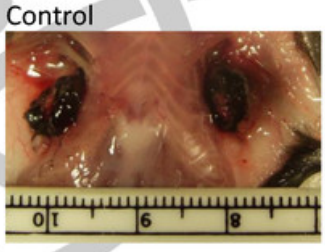
Significant retained value and clinical development opportunity

* Burris, H et al. ASCO, June 2017. Abstract 105.
** Mautino, M et al. AACR, October 2013. Abstract 491.

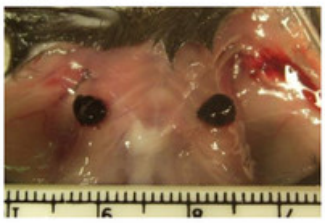
NLG919 & Indoximod

NLG919 & Indoximod - Antitumor Activity Alone & Synergy in Combination

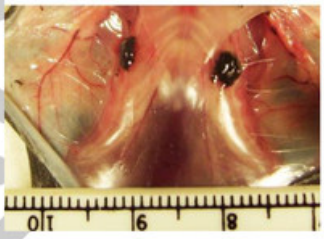
Control



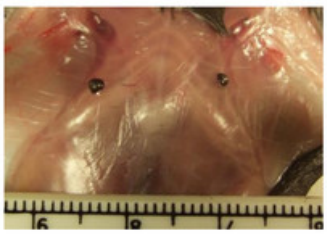
Indoximod



NLG919



Indoximod + NLG919



Control: pmel1 cells + gp100 vaccine + CpG + IFA

Indoximod differentiated MOA may demonstrate synergistic activity with direct IDO1 inhibitors

Mautino, M et al; AACR Annual Meeting Poster Presentation, Abstract 491, April 7th, 2013

NewLink Genetics

Near and Medium Term Catalysts

- Enroll the majority of Indigo301 trial by the end of 2018
- Phase 2 results for indoximod + checkpoint blockade in melanoma expected in 2018
- Phase 2 results indoximod + gem/nab-paclitaxel in pancreatic cancer expected 1H 2018
- AstraZeneca randomized Phase 2 collaboration in pancreatic cancer to initiate 1H 2018

Indoximod offers opportunity to address unmet need in multiple indications

Financial Position

YE 2017 Cash and Equivalents[1]	$158 million
Debt	~$0.3 million
YE 2018 Cash (Projected)[2]	~$75 million
Forecast Quarterly Cash Use	~$20-22 million
Shares Outstanding as of October 31,2017	37.1 million

[1] Preliminary unaudited cash position at year-end 2017
[2] Excludes projections of proceeds, if any, from financings not yet completed

Financially well-positioned to execute our business strategy