



Jefferies 2016 Healthcare Conference

NewLink Genetics Corporation

Nasdaq: NLNK
June 8, 2016

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NASDAQ: NLNK

NewLink Genetics

Building a Leading Immuno-Oncology Company

Oncology Focused Pipeline

- Two IDO pathway inhibitors in clinical development (indoximod and GDC-0919)
- Research collaboration with Genentech for TDO and IDO inhibitors
- Small molecule programs focused on additional immuno-oncology targets

Strong Scientific and Business Leadership

- Executing on vision to bring immunotherapies to patients
- Strategic collaborations with Genentech/Roche and Merck
- Strong cash position

Substantial Near-term News Flow

- Multiple opportunities to validate IDO pathway inhibitor programs
- Clinical updates on the indoximod program
- Clinical advances from partnership with Genentech/Roche for GDC-0919



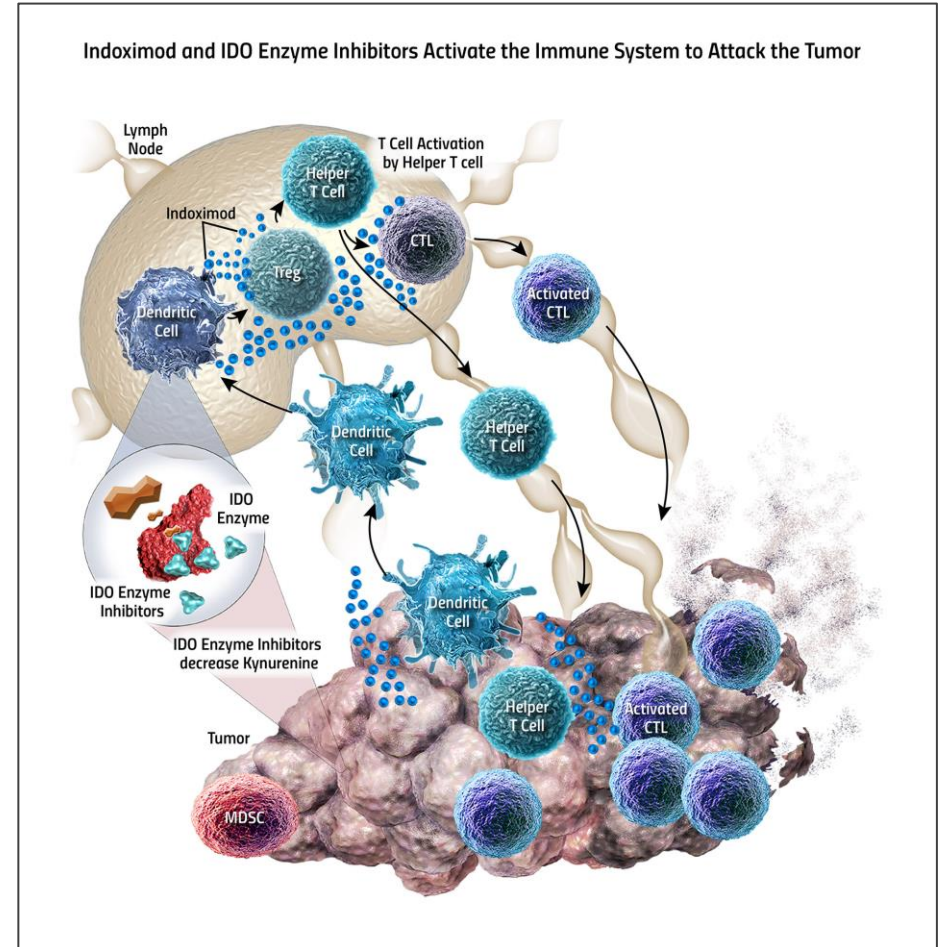
IDO (Indoleamine 2,3-Dioxygenase) Pathway

A Key Immune Checkpoint

Indoleamine 2,3-Dioxygenase (IDO) Pathway

A Key Immune Checkpoint

- Regulates innate and adaptive immune response
- Dominant regulatory role
- Overexpressed in many different cancers
- Interrelated to numerous other checkpoints

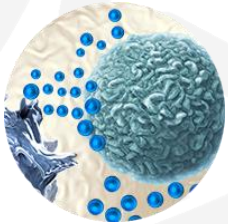


IDO overexpression is central to immune escape

NewLink Genetics' IDO Pathway Inhibitors

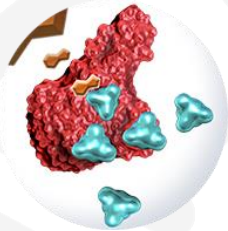
Two Distinct Small Molecules in Clinical Development

IDO pathway inhibitors reprogram immune cells, allowing effector T cells to activate and proliferate.



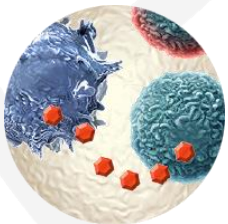
Indoximod

- Interferes with the effects of IDO-mediated tryptophan degradation in effector T cells and Tregs



GDC-0919

- Directly inhibits IDO enzymatic activity



IDO Pathway Inhibitors

- Tregs are transformed into helper-like T cells
- Suppressive dendritic cells are transformed into immuno-stimulatory dendritic cells

NewLink Genetics' IDO Pathway Inhibitors

Clinical Development Programs

AGENT	INDICATION	DESIGN	STATUS
Indoximod	Breast cancer (metastatic)	Indoximod + taxane; randomized	Phase 2 Fully Enrolled
	Pancreatic cancer (metastatic)	Indoximod + gemcitabine and nab-paclitaxel	Phase 2 Currently Enrolling
	Glioblastoma multiforme	Indoximod + temozolomide	Phase 2 Currently Enrolling
	Melanoma (advanced)	Indoximod + ipilimumab and PD-1 inhibitors	Phase 2 Currently Enrolling
	Advanced NSCLC	Tergenpumatucel-L + indoximod and docetaxel	Phase 1 Currently Enrolling
GDC-0919	Solid tumors	GDC-0919	Phase 1 Currently Enrolling
	Solid tumors	GDC-0919 + atezolizumab	Phase 1 Currently Enrolling



Indoximod Clinical Development Program Highlights

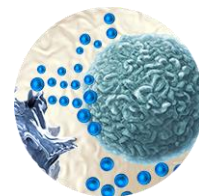
Indoximod

Clinical Development in Breast Cancer

NLG2101 – 1st line Metastatic Breast Cancer

Primary Endpoint	<ul style="list-style-type: none"> Progression free survival
Key Secondary Clinical End-Points	<ul style="list-style-type: none"> Overall survival Objective response rates
Trial Design	<ul style="list-style-type: none"> Phase 2 randomized, double blind In combination with taxane chemotherapy
Trial Size	<ul style="list-style-type: none"> 154 patients
Status	<ul style="list-style-type: none"> Fully enrolled, awaiting data readout Preliminary safety data presented at SABC 2015

Largest randomized indoximod trial to date



Indoximod Clinical Development

Phase 2 Trial for Metastatic Pancreatic Cancer

NLG2104 – 1st line Metastatic Pancreatic Cancer

Primary Endpoint

- Overall survival

Key Secondary Clinical End-Points

- Objective response rate
- Progression free survival

Trial Design

- Phase 2 single arm study
- Indoximod in combination with gemcitabine and nab-paclitaxel

Target Enrollment

- 80 patients in Phase 2
- Up to 40 patients in serial biopsy extension

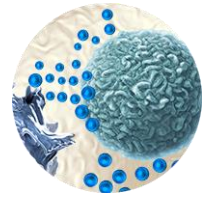
Status

- Enrolling Phase 2
- Phase 2 interim data presented at ASCO 2016

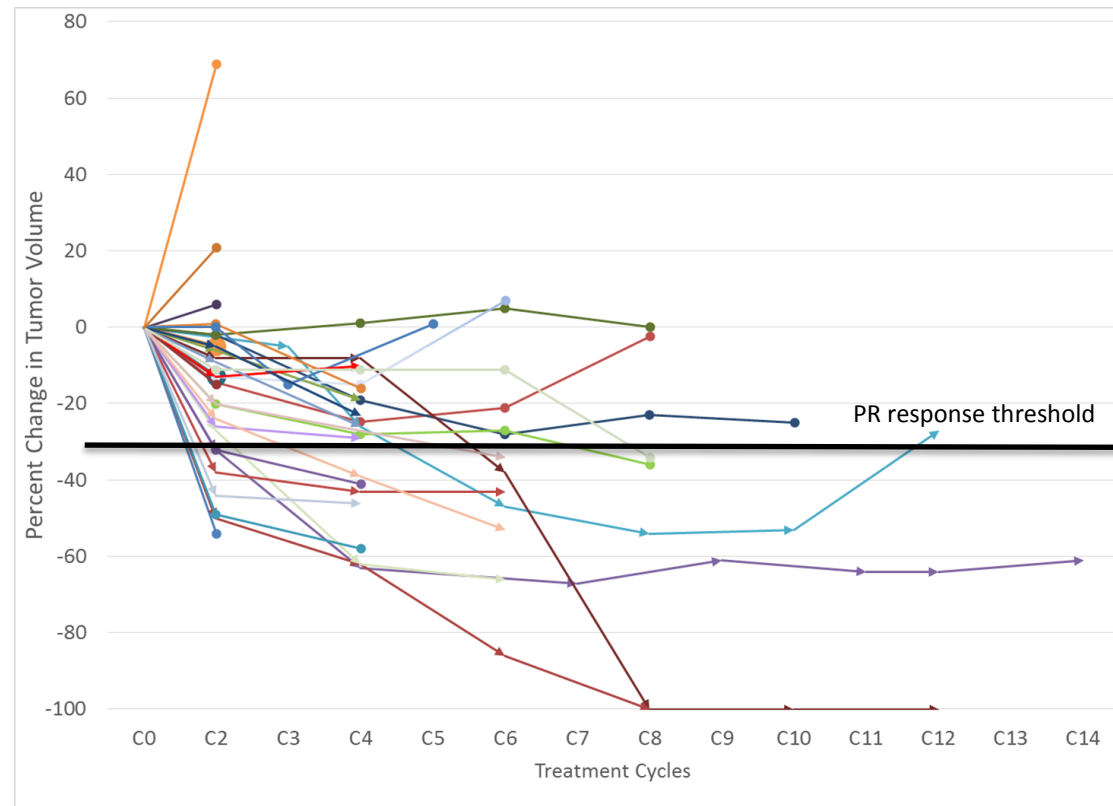
Initial study of combination of indoximod with standard of care in metastatic pancreatic cancer

Indoximod - Metastatic Pancreatic Cancer

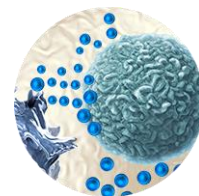
Phase 2 Interim Data Presented at ASCO 2016



- A total of 45 patients (Phase 1 and 2) enrolled in the trial long enough to potentially have cycle 4 imaging available by ASCO 16
- Response data available on 31 patients at time of data cut off via site reports
- At the time of this analysis, objective response rate (CR + PR) was 45% (14/31) and multiple durable responses ≥ 6 months were observed
- A delayed response pattern was observed in multiple patients
- Two patients achieved a complete response (CR; 6%), both at Cycle 8



Pattern of delayed and durable responses



Indoximod Clinical Development

Phase 2 Trial for Advanced Melanoma

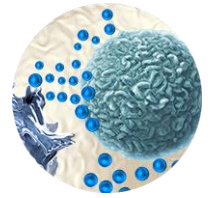
NLG2103 – Advanced Melanoma

Primary Endpoint	<ul style="list-style-type: none"> ▪ Best Overall Response Rate
Key Secondary Clinical End-Points	<ul style="list-style-type: none"> ▪ Progression Free Survival ▪ Overall Survival ▪ Correlative scientific studies ▪ Safety
Trial Design	<ul style="list-style-type: none"> ▪ Phase 2 single arm study ▪ Indoximod combination with checkpoint inhibitors
Target Enrollment	<ul style="list-style-type: none"> ▪ 96 patients in Phase 2
Status	<ul style="list-style-type: none"> ▪ Enrolling Phase 2 ▪ Phase 2 interim data presented at ASCO 2016

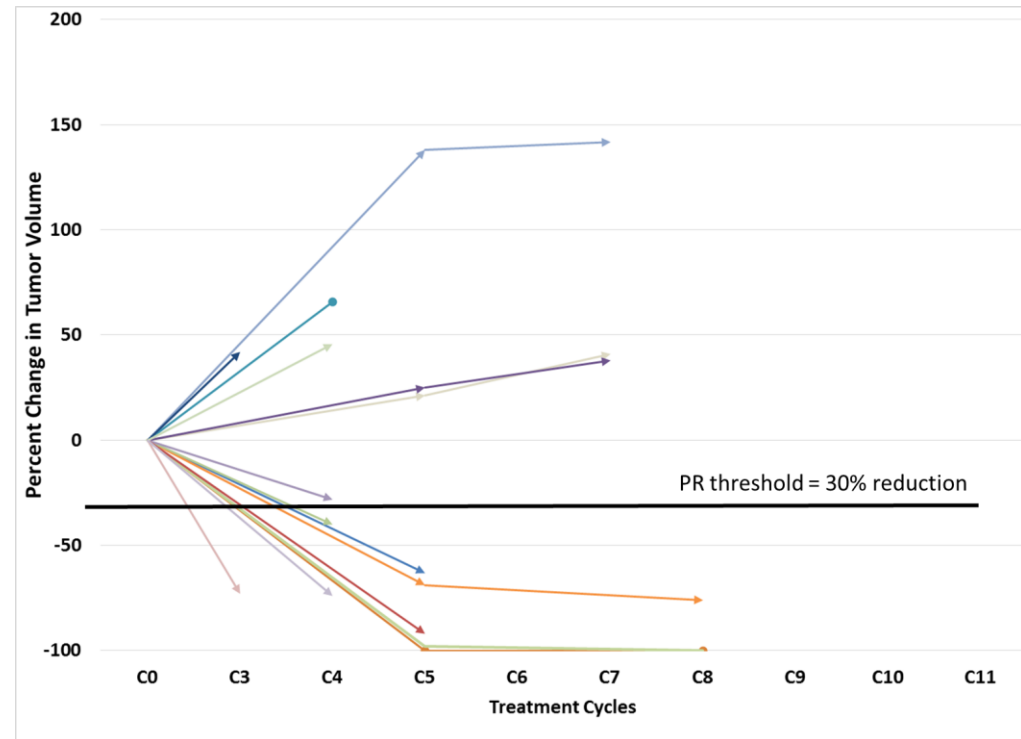
Study underway with combination of indoximod plus PD-1 and CTLA-4 inhibitors in melanoma

Indoximod – Advanced Melanoma

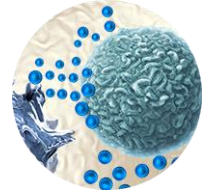
Phase 2 Interim Data Presented at ASCO 2016



- 40 patients enrolled between Phase 1 and 2 at data cut off for ASCO 2016
- 22 patients received pembrolizumab as initial checkpoint in combination with indoximod
- Response data by site PI report available on 15 subjects
- Objective response rate 53% (8/15) with 2 CR's



Initial data shows increase in response rate over PD-1 alone



Indoximod

Intellectual Property

- Indoximod compositions and methods of use filed June 2, 2016
- Novel indoximod analogs and compositions that enhance the pharmacokinetic profile of indoximod
- Potential for increased patent life and territorial coverage

Improved IP position will extend economic value

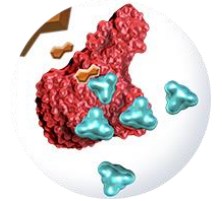


GDC-0919

Collaboration with Genentech/Roche

NewLink Genetics and Genentech Partnership

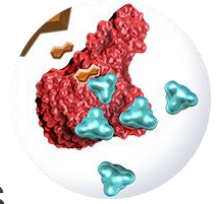
IDO and TDO Pathway Inhibitors



- Exclusive worldwide license agreement
- \$150M upfront payment; >\$1B in potential milestones
- Clinical collaboration for GDC-0919
- Joint research collaboration for IDO and TDO pathway inhibitors
- Escalating double-digit royalties on net sales
- NewLink retains U.S. co-promote option, with royalty escalation
- NewLink Genetics retains exclusive rights to indoximod

NewLink Genetics and Genentech Partnership

GDC-0919 Clinical Development Overview

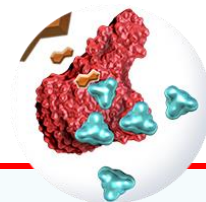


- Joint Development Committee for clinical development activities
- Phase I single agent of GDC-0919
 - Dose escalation in solid tumors
 - Target enrollment of 36 patients (enrolling)
- Phase 1b combination of GDC-0919 (IDO) and atezolizumab (PDL-1)
 - Initiated Q3 2015
 - Dose escalation and expansion study in solid tumors
 - Target enrollment of 224 patients (enrolling)
- Plans to combine with additional checkpoint inhibitors

Combination with Recently Approved Immunotherapy

GDC-0919 Clinical Development

Phase 1b Trial Design



Dose Escalation

GDC-0919 50 mg
Atezo 1200 mg

GDC-0919 100 mg
Atezo 1200 mg

GDC-0919 200 mg
Atezo 1200 mg

GDC-0919 400 mg
Atezo 1200 mg

Expansion
cohorts at or
below MTD/MAD

- Advanced solid tumors
- Combination treatment
- 3+3 escalation design
- DLT window: 21 days
- Mandatory archival tissue

Disease Specific Expansion Cohorts

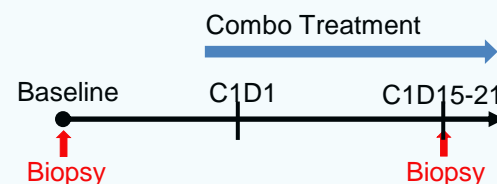
NSCLC

Renal

Bladder

Triple Neg Breast

- Selection by PD-L1 IHC:
- Optional tumor biopsies



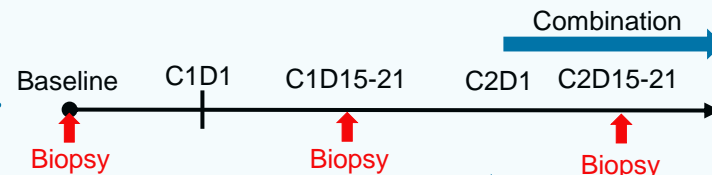
Biopsy Expansion Cohorts

SCCHN

Melanoma

Gastric

- Mandatory serial biopsies
- Selection by PD-L1 IHC and/or IDO1 (cohort A)



Cohort A: GDC-0919 run-in
Cohort B: MPDL3280A run-in

Estimated enrollment up to 224 patients in multiple indications

Infectious Disease Programs

Ebola and Zika Virus Vaccines

- Ebola vaccine candidate found to have 100% efficacy in an analysis of interim data from a Phase 3 ring vaccination trial in Guinea*
 - Program being supported by Merck in an agreement signed in November 2014 - \$50M of milestones through July 2015
- Project underway to develop new treatment options for the Zika virus

THE LANCET

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.

*Published in The Lancet (July 31, 2015)

2016-2018 Initiatives

Investing and compliance initiatives

- Continue and expand/accelerate indoximod trials and indoximod prodrug development efforts
- Continue Genentech and Merck Alliances
- Continue PTEN research
- Continue Zika virus research
- Pursue attractive in-licensing opportunities
- Maintain momentum building quality systems and developing regulatory capabilities

2016-2018 Initiatives

Cash conservation initiatives

- Wind-down HA trials and manufacturing activities
- Carefully planned company-wide headcount reductions to ~125
- Consolidate/scale-back facilities footprint
- Eliminate market access and marketing program spending
- Capital spending reduced to primarily supporting R&D needs

Conserve cash to continue cancer and
infectious disease transition

Key 2016-2018 Base Case Assumptions

Major assumptions in base case

- No new Phase III trials or acquisitions
- No new Genentech or Merck revenue
- No priority review voucher
- No new financing
- Grants to finance a significant portion of infectious disease program
- \$178 million in cash/equivalents at March 31, 2016

Plan executing in Q2-3 2016

“Before and After” Summary

	Before	After
Headcount	~230	~125
Facilities	133K sq ft	66K sq ft
Annual Lease Cost	\$1.4mm	\$0.8mm
Clinical Trials	19 (finish 15 existing, 4 new)	4-8
Quarterly Negative Cash-flow	~\$20mm	~\$10mm
Quarters of Cash	~8	10+

Substantial cash runway

Financial Guidance

Strong Balance Sheet

Strong Capital Position

- Stable and reliable cash position - \$178M at Q1 2016
- Goal and expectation to finish 2016 with two years of cash-on-hand

Increased Investment

- Significantly increasing our clinical programs, especially indoximod, and building the pipeline of new opportunities

Multiple Value Drivers

- Potential for combinations of IDO pathway inhibitors
- Infectious disease initiatives

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Questions?