

Cantor Fitzgerald 2018 Global Healthcare Conference

NewLink Genetics Corporation

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NewLink Genetics

A Clinical Development Stage Immuno-Oncology Company

- Strategic focus on indoximod, an IDO pathway inhibitor with a differentiated MOA
 - Clinical data suggest indoximod combinations may enhance multiple therapeutic modalities
 - Potential to improve patient outcomes across both hematologic cancer and solid tumor indications
- Supportive indoximod MOA and clinical data presented at recent medical meetings
 - AACR Abstract 3753 – *Indoximod modulates AhR-driven transcription of genes that control immune function*
 - AACR Abstract 10973 – *Front-line therapy of DIPG using the IDO pathway inhibitor indoximod in combination with radiation and chemotherapy*
 - ASCO Abstract 9512 – *Phase 2 trial of the IDO pathway inhibitor indoximod plus checkpoint inhibition for the treatment of patients with advanced melanoma*
 - ISPNO poster – *Radio-immunotherapy using the IDO pathway inhibitor indoximod for children with newly-diagnosed DIPG*

MOA and clinical data support potential of indoximod as unique I-O therapeutic

Clinical Strategy

Targeted Clinical Development

Targeted Clinical Plan

To evaluate indoximod in recurrent pediatric brain tumors, newly diagnosed DIPG, & newly diagnosed AML

To evaluate NLG802, prodrug of indoximod

Purpose

To focus on indications with greatest potential to validate indoximod

Targeted clinical plan to validate indoximod within financial horizon

Clinical Priorities

Clinical Plan Oriented Toward Indications with Greatest Unmet Need

- Recurrent malignant pediatric brain tumors
 - Indoximod plus radio-chemotherapy for pediatric patients with malignant brain tumors
 - Phase 1b trial ongoing with updated data anticipated 1H 2019

- Front-line diffuse intrinsic pontine glioma (DIPG)
 - Indoximod plus radio-chemotherapy for pediatric patients with DIPG
 - Early data show all patients demonstrated initial symptomatic improvement on therapy
 - Phase 1b trial ongoing with encouraging updated data presented July 2018

Encouraging early clinical data for indoximod in pediatric brain tumors

Clinical Priorities

Clinical Plan Oriented Toward Indications with Greatest Unmet Need

- Front-line acute myeloid leukemia (AML)
 - Indoximod plus standard-of-care chemotherapy for patients with front-line AML
 - Early data show no minimal residual disease in 7/7 patients who initially responded to therapy
 - Phase 1b trial ongoing with update data anticipated 2H 2018

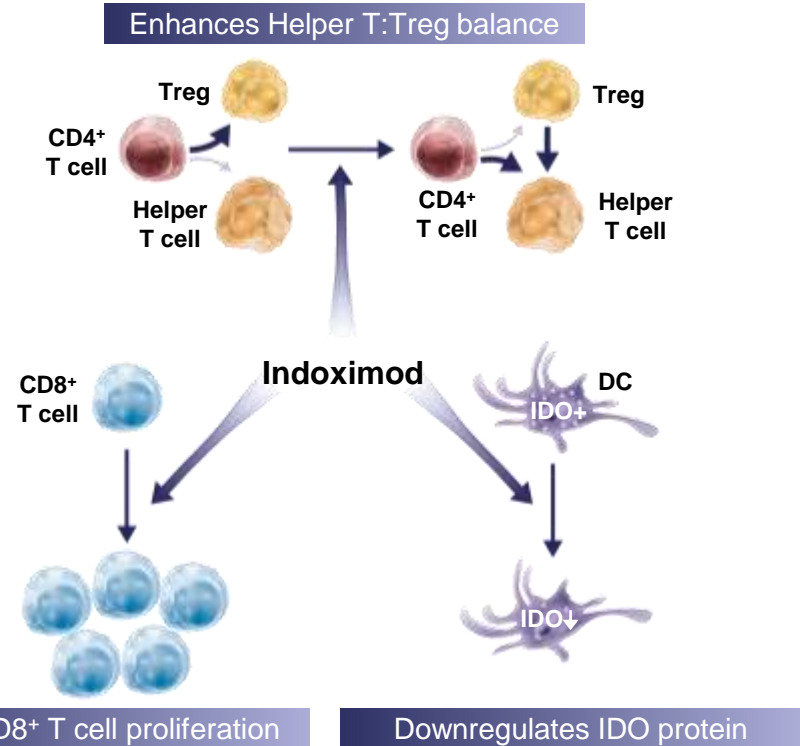
- NLG802, prodrug of indoximod
 - Preclinical data show significantly higher PK levels with NLG802
 - Phase 1 trial ongoing
 - Initial Phase 1 data to be presented at SITC, Nov 2018

Promising clinical data for indoximod in AML and preclinical data for prodrug

Indoximod Mechanism of Action

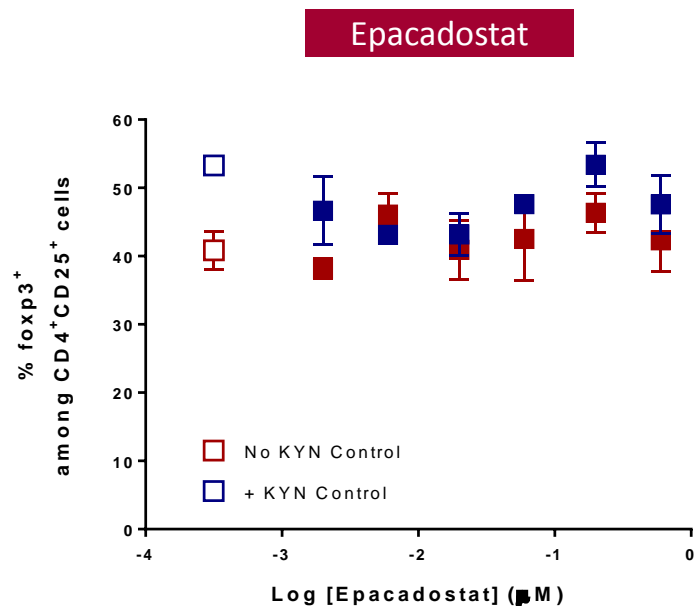
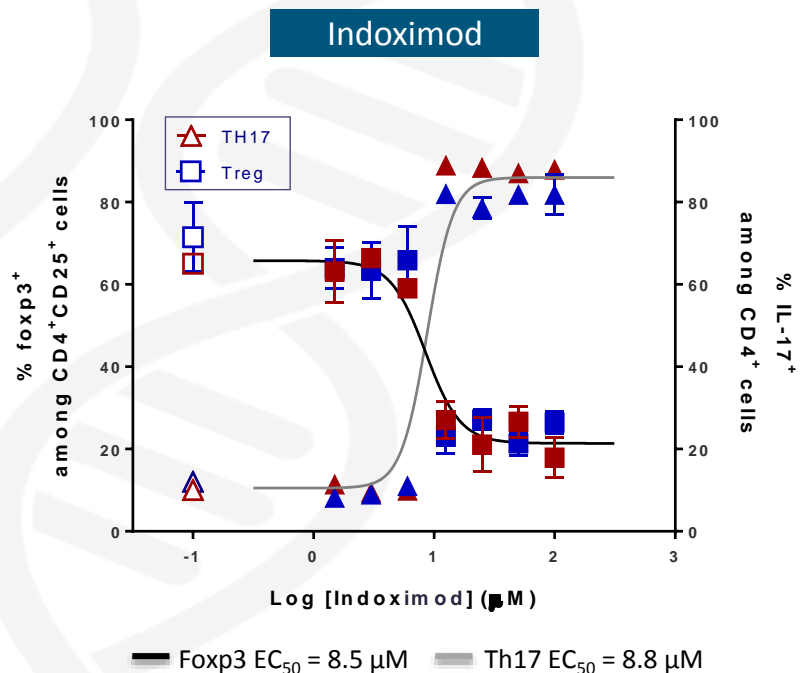
A Unique Approach to Reversing Immunosuppression

- Orally administered, small-molecule that reverses the immunosuppressive effects of low tryptophan and high kynurenine that result from IDO activity
- Immuno-stimulatory effects of indoximod impact 4 main cell types: CD8⁺ T cells, CD4⁺ T helper cells, T regulatory cells, and dendritic cells
 - Reverses the effects of low tryptophan by increasing proliferation of effector T cells
 - Drives differentiation into T helper cells vs regulatory T cells
 - Downregulates IDO expression in dendritic cells
- Potential synergy has been shown with checkpoint blockade, chemotherapy, radiation and vaccines



Indoximod vs Epacadostat: A Different Mechanism of Action

Indoximod Drives Differentiation of Helper vs Regulatory T Cells



Indoximod reduces T-regs and increases effector T-cells

Pediatric Brain Tumors

Market Statistics and Indoximod Data

- ~4600 new cases of pediatric brain tumors are diagnosed in the US each year¹
 - In the relapsed setting, despite further conventional therapy, the prognosis is poor
 - Recurrent brain tumors represent #1 cause of mortality in pediatric cancer
- Phase 1b data encouraging for indoximod + radio-chemotherapy in relapsed setting
 - Targeting relapsed pediatric brain tumors (glioblastoma, medulloblastoma, and ependymoma)
 - Early data in 29 patients showed improved time on therapy and reduced toxicity with indoximod²
 - Trial ongoing with updated data presentation anticipated 1H 2019

Early data encouraging for indoximod in recurrent pediatric brain tumors

1. American Cancer Society.

2 Johnson T, *et al.* SNO 2017.

3 Johnson T, *et al.* AACR 2018. Plenary #10973.

Early Results for Children with Diffuse Intrinsic Pontine Glioma (DIPG)

Encouraging Early Data from Pilot Cohort of 10 Patients

- DIPG is rapidly fatal with significant unmet need
 - Standard of care treatment is palliative radiation (usually 54 Gy)
 - Median time to progression after radiation is ~6 months¹
 - No surgical options for patients with DIPG
- Encouraging updated results from Phase 1b trial presented at ISPNO – July 2018²
 - Phase 1 data suggest indoximod-based immunotherapy enhances conventional therapy
 - Updated data in July showed 10/10 patients experienced symptomatic improvement
 - Longest time on study was 8.5 months

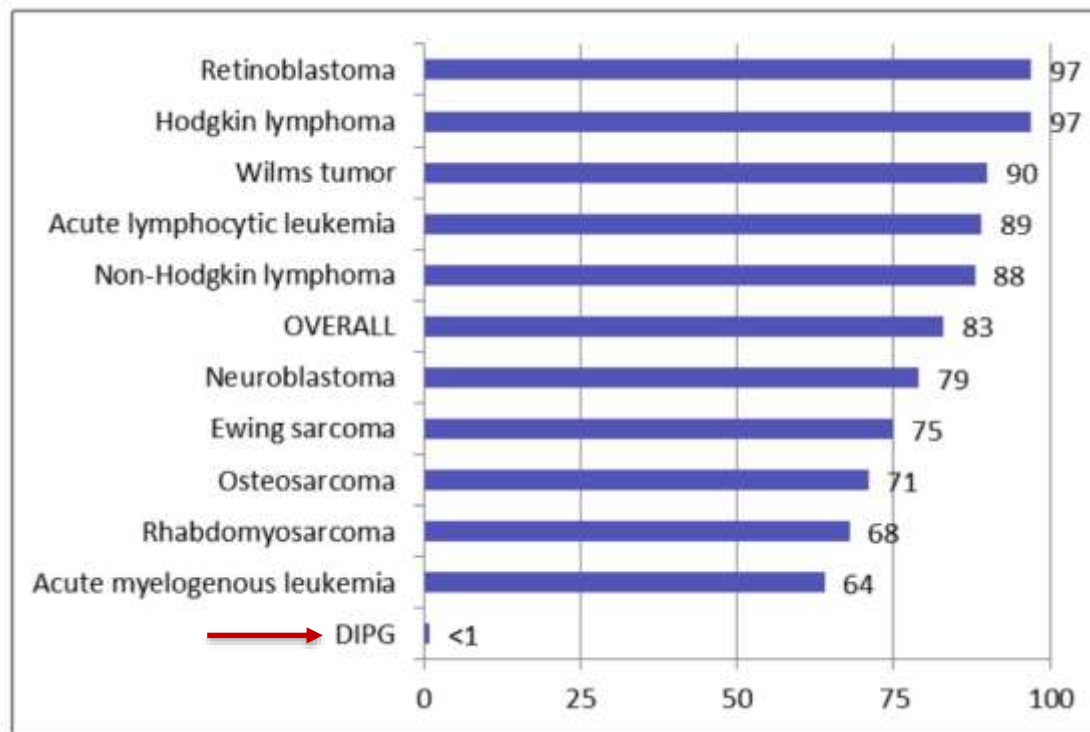
Indoximod plus radio-chemotherapy data encouraging in DIPG, most lethal pediatric cancer

1. Wolff JE, et al. *J Neurooncol.* 2012;106(2):391-397. 2. Cohen KJ, et al. *Neuro Oncol.* 2011;13(4):410-416.

2 Johnson T, et al. ISPNO 2018.

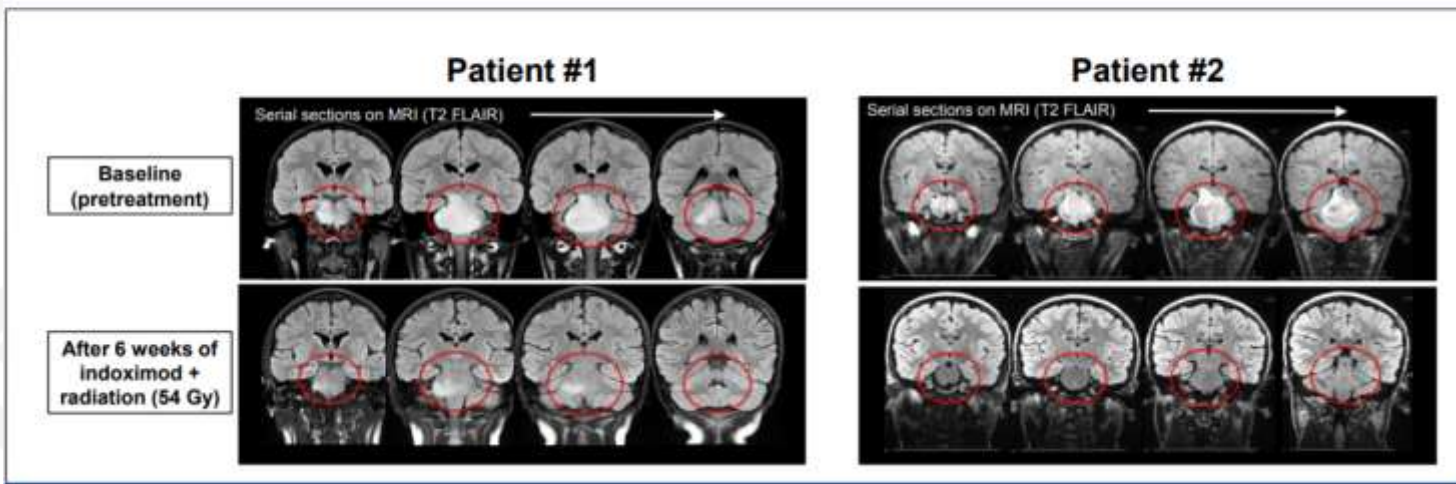
DIPG Prognosis Worst of All Pediatric Cancers

Pediatric Cancer 5-Year Survival Rates



Encouraging Updated DIPG Data Presented at ISPNO

Representative Imaging from the Initial MRI Results at Completion of Radiation for the First Two DIPG Patients

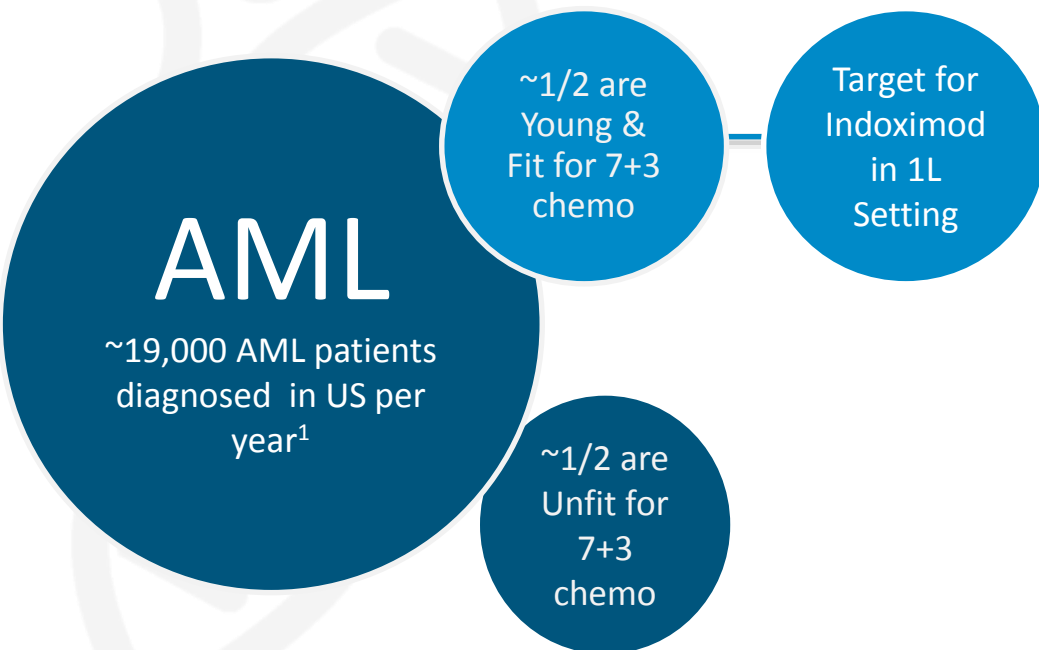


Reported Results for 10 DIPG Patients (ISPNO July 2, 2018)

- 9/10 remained on study
- Longest treated 8.5 months at the time of the report
- 10/10 experienced initial improvement in symptoms

Acute Myeloid Leukemia (AML)

Market Characteristics



- Only ~25% of newly diagnosed AML patients expected to survive > 3 years¹
- Recent clinical development has focused on second-line patient population
- Front-line treatment for young & fit patient population has been met with minimal success

Newly-diagnosed AML continues to be an area of unmet need

Indoximod plus Chemotherapy in Acute Myeloid Leukemia (AML)

Phase 1/2 Exploring Minimal Residual Disease as a Surrogate Endpoint

- Phase 1/2 trial for patients with newly diagnosed AML
 - Combination with current standard of care (7+3 chemotherapy)
 - Currently enrolling Phase 1b expansion cohort
 - Minimal residual disease evaluated by sensitive flow cytometry assay
- Data presented by Emadi, et al at EHA, June 2017 (abstract E-012)
 - Indoximod does not appear to add significant toxicity
 - 7/9 patients who completed treatment per protocol achieved morphologic complete response (CR)
 - 7/7 patients who achieved a CR had no evidence of minimal residual disease

Updated data anticipated in 2H 2018

Phase 2 Results of Indoximod + Pembrolizumab in Advanced Melanoma

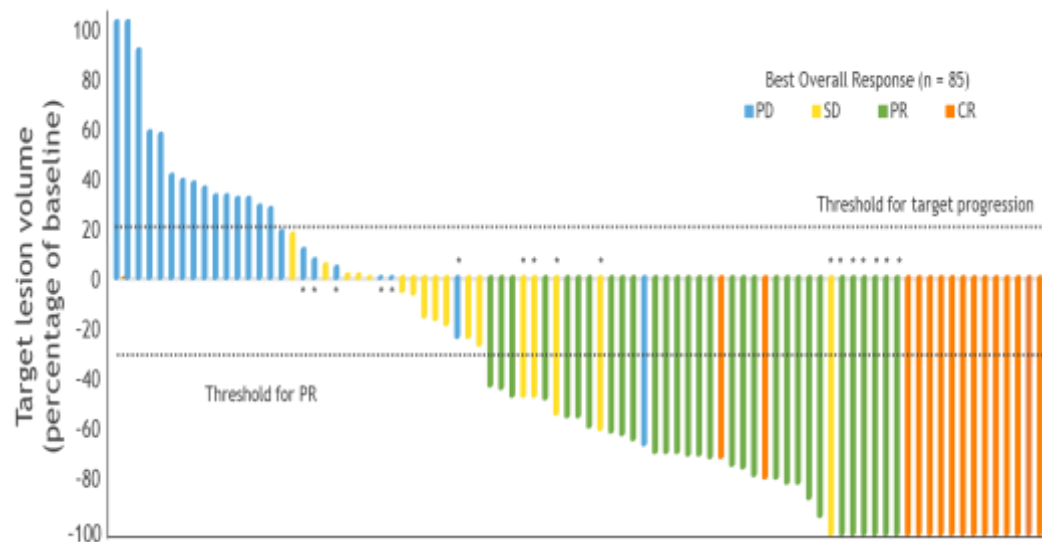
Encouraging Overall and Complete Response Rates

Response status	Efficacy evaluable population + biopsy cohort (N = 85)*		
	Overall (N = 85)	Prior systemic therapy (N = 16)†	Prior radiation therapy (N = 14)
PFS, median months (95% CI)	12.4 (7.1, 24.9)	–	–
ORR, n (%)	45 (53)	10 (63)	9 (64)
CR	15 (18)	5 (31)	5 (36)
PR	30 (35)	5 (31)	4 (29)
SD	17 (20)	2 (13)	3 (21)
DCR	62 (73)	12 (75)	12 (86)
PD	23 (27)	4 (25)	2 (14)

PFS, progression-free survival; CI, confidence interval; CR, complete response; PR, partial response; SD, stable disease; DCR, disease control rate; PD, progressive disease; BRAF, B-Raf proto-oncogene, serine/threonine kinase; IL-2, interleukin 2.

* Excludes uveal melanoma patients.

† Prior systemic therapy includes BRAF inhibitors and IL-2.



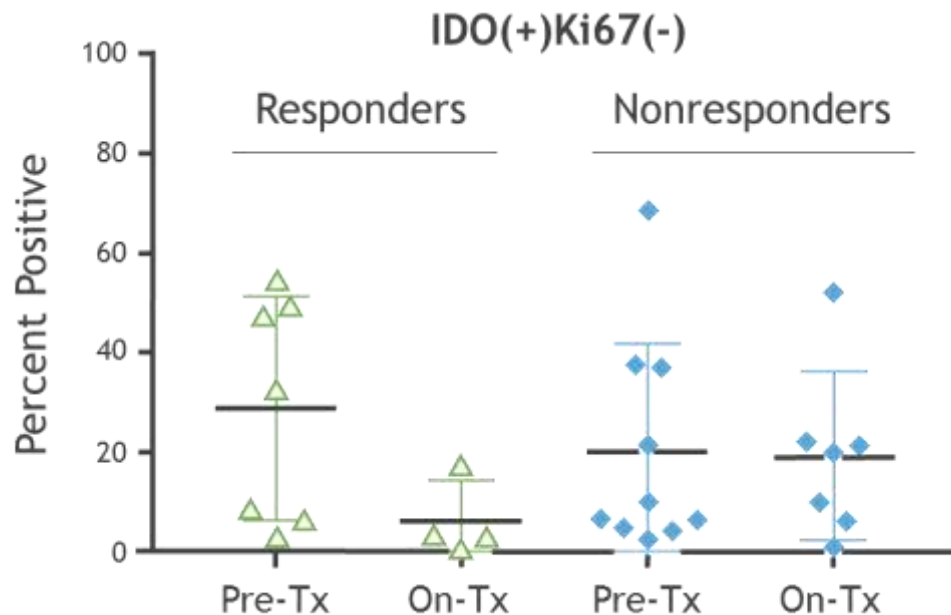
Note. All responses assessed per RECIST V 1.1. CR patients where best response in change in tumor volume is not –100% have target lesions that are pathological lymph nodes that are less than 10 mm. SD or PD patients with a reduction in tumor volume of 30% or more due to either unequivocal non-target lesion progression or an unconfirmed response. PD, progressive disease; SD, stable disease; PR, partial response; CR, complete response.
* Patients who progressed due to new non-target lesions.

Phase 2 Results of Indoximod + Pembrolizumab in Advanced Melanoma

Impact of PD-L1 Status and IDO Expression

PD-L1 Status	Indoximod + Pembrolizumab
Tissue available, n/N (%)	41/70 (59)
PD-L1(+) staining	22/41 (54)
PD-L1(-) staining	19/41 (46)
Response by PD-L1, %	
PD-L1(+) ORR	77%
PD-L1(-) ORR	42%

IDO(+)Ki67(-) cells, most likely representing dendritic cells expressing IDO, tend to decrease IDO expression upon treatment in responders



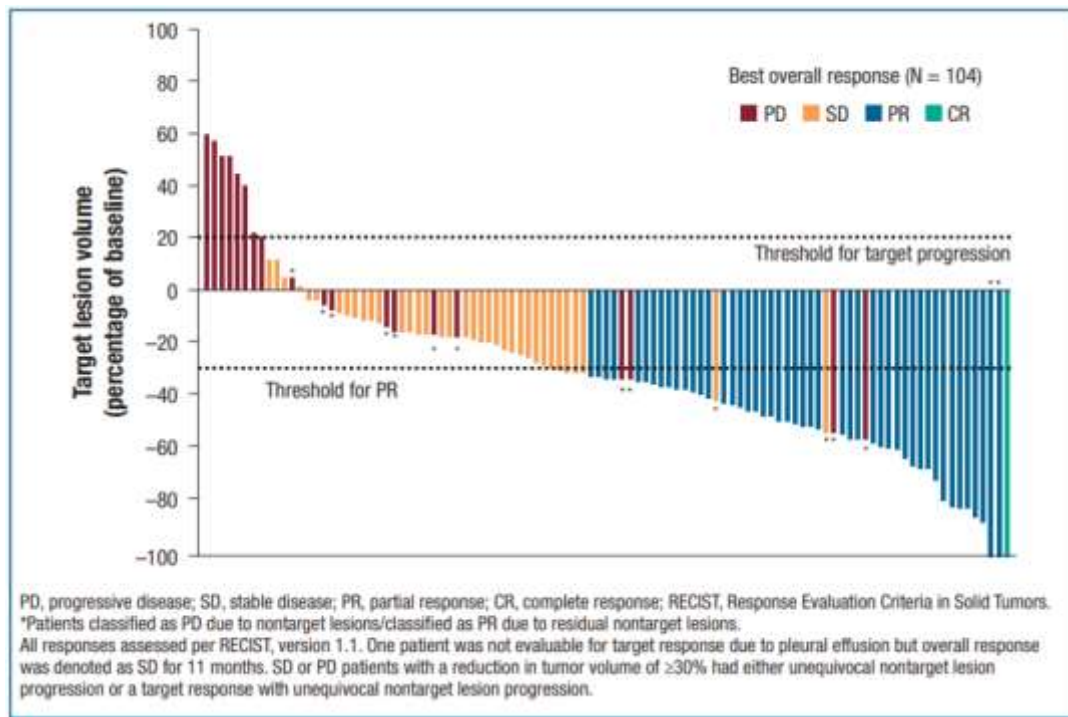
Phase 2 Results of Indoximod + Chemotherapy in Pancreatic Cancer

Encouraging Activity Seen in Patients with Metastatic Pancreatic Cancer

	Efficacy evaluable population + biopsy cohort (N = 104)*
OS, median (95% CI), months	10.9 (8.9, 13.7)
PFS, median (95% CI), months	5.8 (4.1, 7.3)
ORR, n (%)	48 (46)
CR, n (%)	1 (1)
PR, n (%)	47 (45)
SD, n (%)	36 (35)
DCR, n (%)	84 (81)
PD, n (%)	19 (18)

OS, overall survival; CI, confidence interval; PFS, progression-free survival; ORR, overall response rate; CR, complete response; PR, partial response; SD, stable disease; DCR, disease control rate; PD, progressive disease.

* One patient was not evaluable for target response, but deemed stable for 11 mos.



Anticipated Milestones

Near-term Data

- 2H 2018: Updated Phase 1b AML data anticipated
- 2H 2018: Presentations at the Society for Immunotherapy of Cancer (SITC) Annual Meeting, Nov 2018
 - Initial Phase 1 data from NLG802, prodrug of indoximod
 - Biomarker data from Phase 2 study of indoximod in melanoma patients
- 1H 2019: Updated Phase 1b Pediatric brain tumors data anticipated

Data from clinical programs anticipated near-term

Financial Position

Q2 2018 End Cash and Equivalents	\$137.1 Million
Quarterly Cash Use Projected	~\$10 Million
Cash Runway Projected	~3 Years
Shares Outstanding as of June 30, 2018	37.2 Million

† Financial interest in potential priority review voucher (PRV) in connection with Ebola vaccine candidate

Resources sufficient to support focused clinical development programs

NewLink Genetics: Key Takeaways

Indoximod, an Immuno-Oncology Candidate with Differentiated MOA

- Clinical development plan targeting the most promising programs
 - Recurrent Pediatric Brain Tumors (rPBT), Front-Line DIPG, Front-Line AML, NLG802
- Cash on hand at Q2 end \$137.2 million
 - Estimated cash runway into the second half of 2021
- Additional indoximod data to be presented at upcoming medical conferences
 - 2H 2018: Updated Phase 1b AML data anticipated
 - 2H 2018: Initial Phase 1 NLG802 data; Phase 2 indoximod biomarker data from melanoma patients to be presented at SITC (Nov '18)
 - 1H 2019: Updated Phase 1b Pediatric brain tumors data anticipated

Focusing on most promising clinical programs within financial horizon