Stifel Healthcare Conference Presentation

NewLink Genetics Corporation

NASDAQ: NLNK
November 13, 2018

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NewLink Genetics

A Clinical Development Stage Immuno-Oncology Company

- Clinical focus on cancer indications of great unmet need
  - AML
  - Recurrent pediatric brain tumors & DIPG
  - Relapsed ovarian cancer
- Three drug candidates in development
  - Indoximod
  - NLG802, prodrug of indoximod
  - NLG207 (formerly CRLX-101)
- Solid balance sheet to support clinical development programs
  - Strong cash position

Clinical focus and strong financial position support drug development strategy

Indoximod Clinical Programs

Front-line diffuse intrinsic pontine glioma (DIPG)

- Indoximod plus radiotherapy for pediatric patients with DIPG
- Early data show all patients demonstrated initial symptomatic improvement on therapy
- Phase 1b trial ongoing with updated data anticipated 2019

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 acute myeloid leukemia (AML)

- Indoximod plus standard-of-care chemotherapy for patients with front-line AML
- Updated data July 2018 showed promising MRD-negativity with indoximod
- Phase 1b trial ongoing with updated data in oral presentation at ASH, December 2018

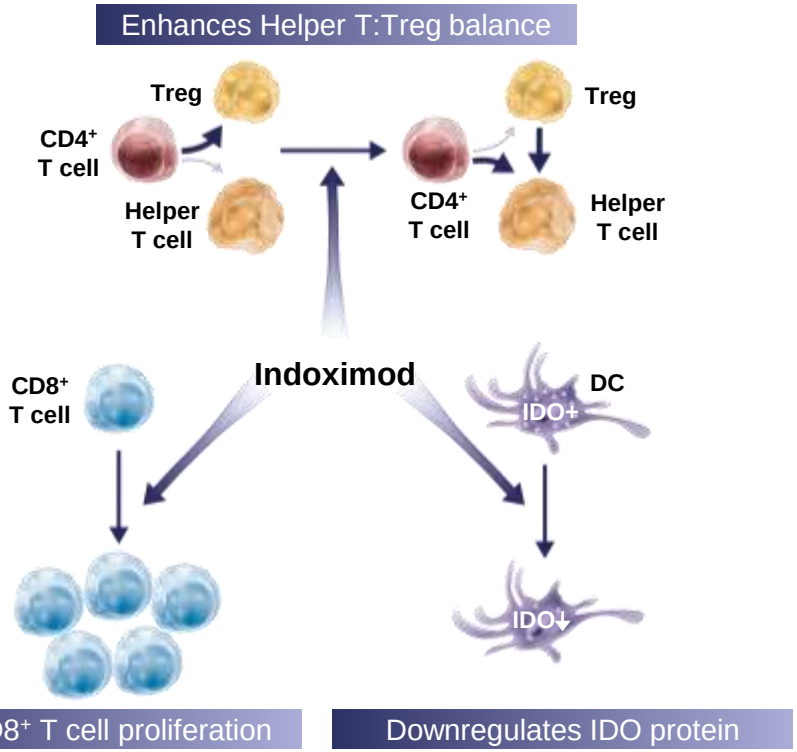
NLG802, prodrug of indoximod

- Preclinical data show significantly higher PK levels with NLG802
- Phase 1 trial ongoing with updated data at SITC, November 2018

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

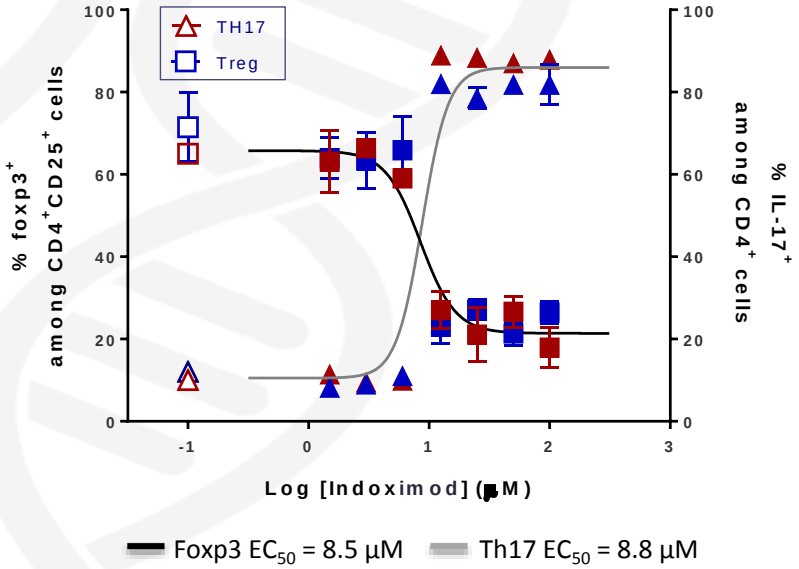


IDO, indoleamine 2,3-dioxygenase; Treg, T regulatory cell; DC, dendritic cell.
Brincks EL, *et al*. AACR 2018. Abstract 3753.

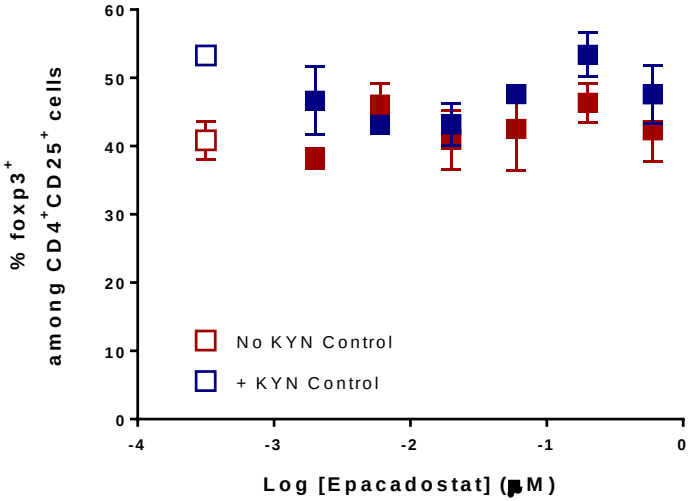
Indoximod vs Epacadostat: A Different Mechanism of Action

Indoximod Drives Differentiation of Helper vs Regulatory T Cells

Indoximod



Epacadostat



Indoximod reduces T-regs and increases effector T-cells

Brincks EL, *et al*. AACR 2018. Abstract 3753.

Pediatric Brain Tumors

Market Statistics and Indoximod Data

~4600 new cases of pediatric brain tumors diagnosed in US each year[1]

- ~70% of most common types have survival rates > 5 years
- Relapsed setting, conventional therapy is either unsuccessful or too toxic
- 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
- Early data in 29 patients showed improved time on therapy & reduced toxicity[2]
- Trial ongoing with updated data presentation anticipated 1H 2019

1. American Cancer Society.
2 Johnson T, *et al*. SNO 2017, 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 months[1]
- No surgical options for patients with DIPG

Encouraging updated results from Phase 1b trial presented at ISPNO – July 2018[2]

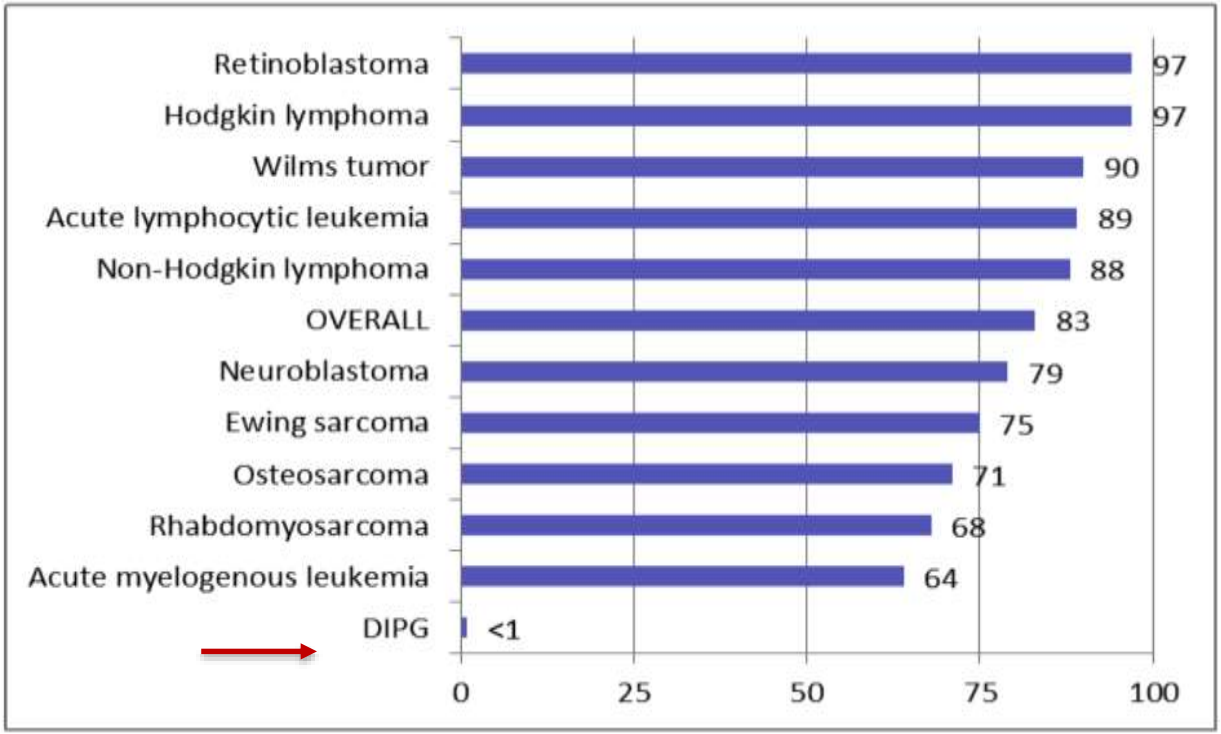
- Phase 1 data suggest indoximod-based immunotherapy enhances conventional therapy
- Updated data at ISPNO July '18 showed 10/10 patients experienced symptomatic improvement
- At last report, longest time on study of 8.5 months

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.* International Symposium on Pediatric Neuro-Oncology (ISPNO) 2018.

DIPG Prognosis Worst of All Pediatric Cancers

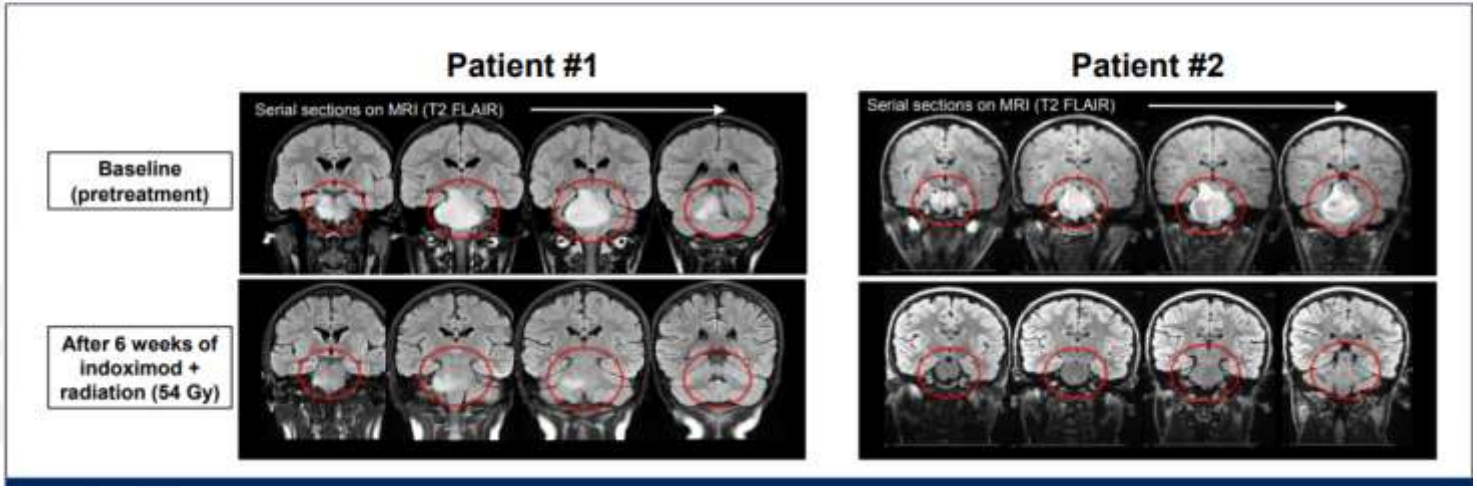
Pediatric Cancer 5-Year Survival Rates



Defeat DIPG Foundation

Encouraging DIPG Data Presented at ISPNO July 2018

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

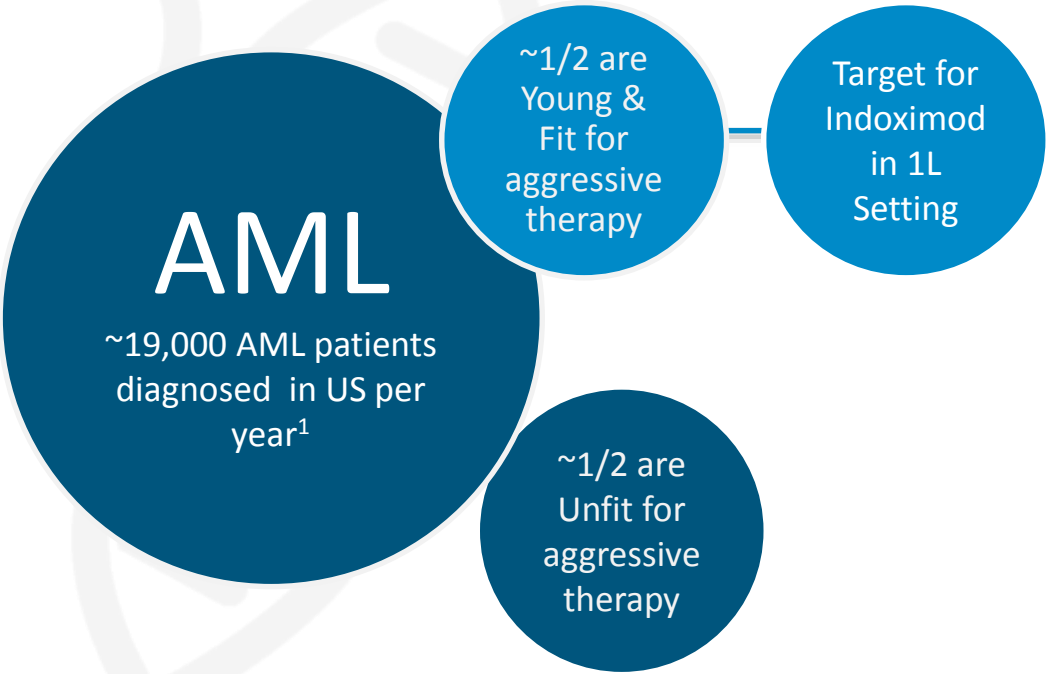


Reported Results for 10 DIPG Patients (ISPNO July 2, 2018)

- 9/10 remained on study as of July 2nd
- Longest treated 8.5 months at the time of last report
- 10/10 experienced initial improvement in symptoms

Acute Myeloid Leukemia (AML)

Market Characteristics



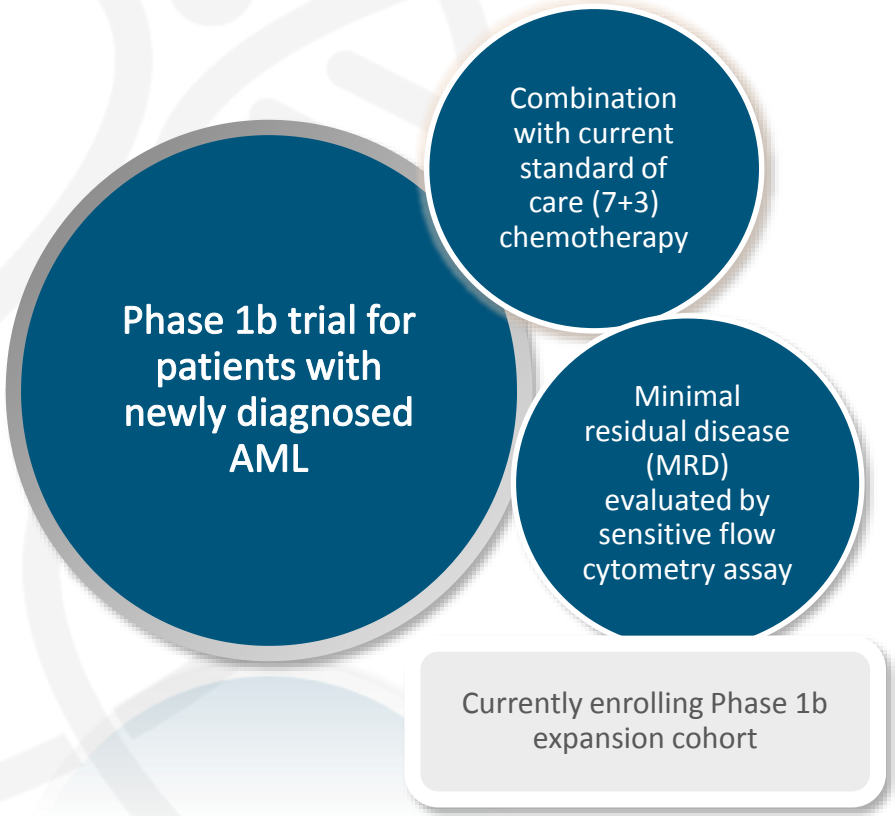
- Only ~25% of newly diagnosed AML patients expected to survive > 3 years[1]
- Recent clinical development has focused on second-line patient population
- Advancements in front-line therapy for young and fit patients have met with minimal success

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

[1] American Society of Clinical Oncology

Indoximod plus Chemotherapy in Acute Myeloid Leukemia (AML)

Phase 1b Exploring Minimal Residual Disease as a Surrogate Endpoint



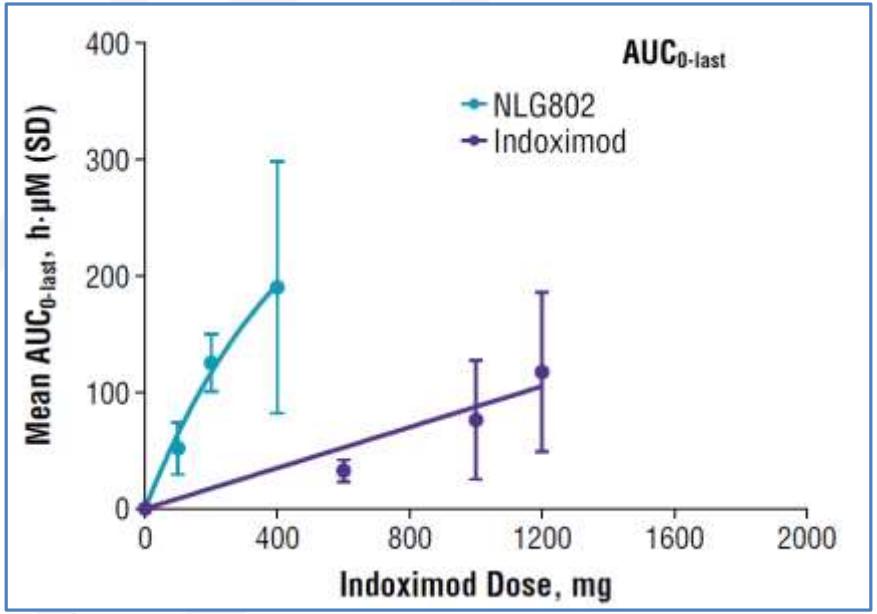
Data to be presented by Emadi, *et al* at ASH, December 2018[1]

- Indoximod was well tolerated and does not appear to add significant toxicity
- 21/25 (84%) ITT patients achieved morphologic complete response (CR)
- 15/19 (79%) per protocol patients achieved CR
- 10/12 (83%) patients MRD- at end of induction
- 11/11 (100%) patients MRD- at end of consolidation

[1] Emadi, A., et al. ASH 2018. Abstract 332.

NLG802, Indoximod Prodrug, Produces 4 to 5-Fold Increased Exposure in Humans

Preliminary Phase 1 Data Presented at SITC 2018 Indicate Improved PK from NLG802



1

Prodrug NLG802 developed to improve bioavailability of indoximod

Maximum tolerated dose (MTD) or maximum biologically achievable dose (MBAD) not yet reached with indoximod

Early Phase 1 data show NLG802 improves indoximod exposure in humans 4 to 5-fold[1]

NLG802 was well tolerated

[1] Rixe, O., et al. SITC 2018, poster 331.

Biomarker Data Show Impact of Indoximod on Tumor Microenvironment

Biopsy Data from Phase 2 Trials of Indoximod Presented at SITC 2018

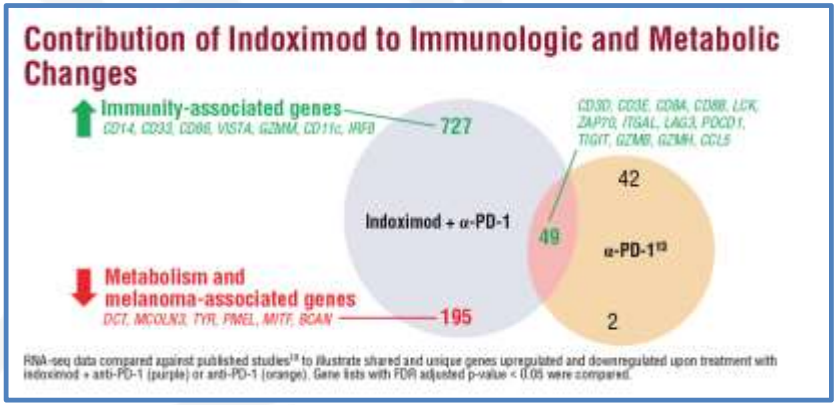
Phase 2 trial biopsy data for indoximod + pembrolizumab in advanced melanoma

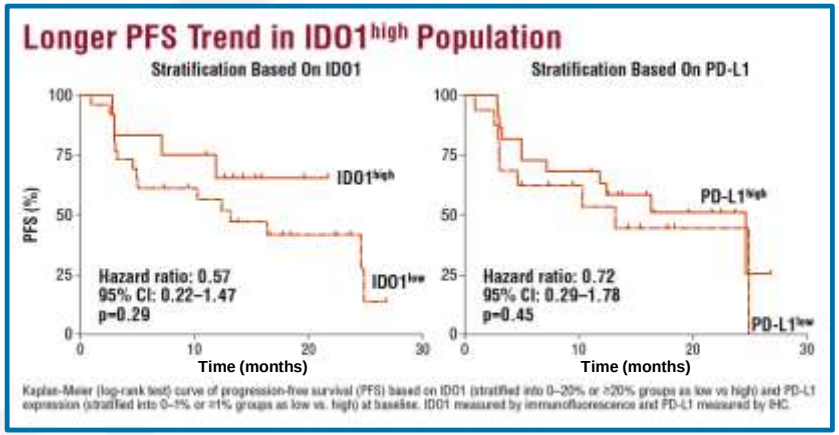
- Indoximod + pembro induced multiple immunologic & metabolic changes in tumor microenvironment (TME)
- Comparison to published studies suggests indoximod + PD-1 inhibitor contributed to immunologic and metabolic changes in markedly different manner than PD-1 blockade alone
- Indoximod-based combination therapy in patients with high baseline IDO1 expression may have better prognosis

Phase 2 trial biopsy data for indoximod + nab/paclitaxel in metastatic pancreatic cancer

- Responders to indoximod + chemotherapy were observed to have changes in TME consistent with proposed MOA for indoximod
- In responders, indoximod + chemotherapy increased density and activity of intra-tumoral T cells and increased density of innate immune cells (NK cells, neutrophils)
- Combination therapy downregulated Tregs and IDO expression in TME
- Indoximod + chemotherapy associated with increase in innate and adaptive responses in TME

Findings from Biopsy Data for Indoximod + Pembrolizumab in Melanoma[1]





Indoximod + anti-PD-1 leads to increase in immunity-related cells and decrease in melanoma-associated genes

Indoximod + anti-PD-1 trends toward longer PFS in IDO^{high} patients

1 Yu, J., et al. SITC 2018, poster 142.

Other Opportunities

Clinical Programs Under Evaluation

- NLG207 (formerly CRLX-101)
  - Nanoparticle formulation of the topoisomerase 1 inhibitor camptothecin
  - Acquired from Cerulean Pharma
  - Phase 2 trial to evaluate NLG207 plus weekly paclitaxel in recurrent ovarian cancer
  - Trial conducted in conjunction with GOG
  - Phase 2 data anticipated in 2019
- Pursuing additional opportunities to expand our pipeline

Multiple clinical opportunities addressing areas of unmet need

Anticipated Milestones

Near-term Data

- December 2018: Updated Phase 1b AML data accepted for oral presentation at ASH
- 1H 2019: Updated Phase 1b pediatric brain tumors data anticipated
- 2019: Results from Phase 2 study of NLG207 (CRLX-101) anticipated

Data from clinical programs anticipated near-term

Financial Position

Q3 2018 End Cash and Equivalents	$122.1 Million
Average Quarterly Cash Use Projected	~$10 Million
Cash Runway Projected	Into 2H 2021
Shares Outstanding as of September 30, 2018	37.2 Million

Resources sufficient to support focused clinical development programs

NewLink Genetics: Key Takeaways

Clinical development plan targeting the most promising programs

- Recurrent pediatric brain tumors, front-line DIPG, front-line AML, NLG802, NLG207

Strong cash position

- Cash on hand at Q3 end $122.1 million
- Estimated cash runway into 2H 2021 excluding Ebola PRV monetization
- Substantial financial interest in Priority Review Voucher (PRV) associated with approval of the Ebola vaccine licensed by NewLink Genetics

Indoximod data to be presented at upcoming medical conferences

- December 2018: Updated Phase 1b AML data presented in oral presentation at ASH
- 1H 2019: Updated data from Phase 1 trial of indoximod plus radiotherapy in DIPG anticipated
- 2019: Results from Phase 2 trial of NLG207 (formerly CRLX-101) plus paclitaxel in recurrent ovarian cancer anticipated

Supplemental Data

Phase 2 Results of Indoximod + Pembrolizumab in Advanced Melanoma

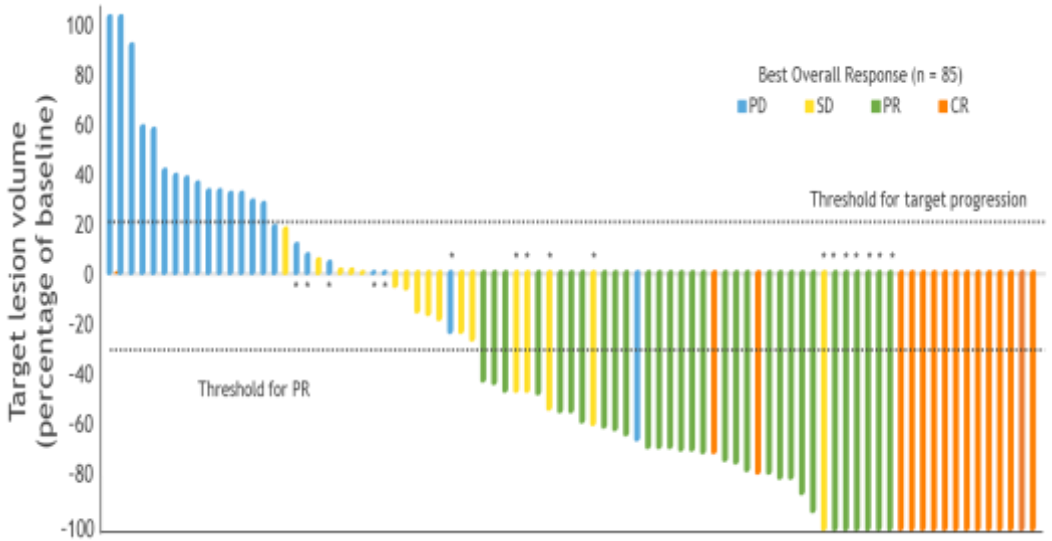
Encouraging Overall and Complete Response Rates

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.

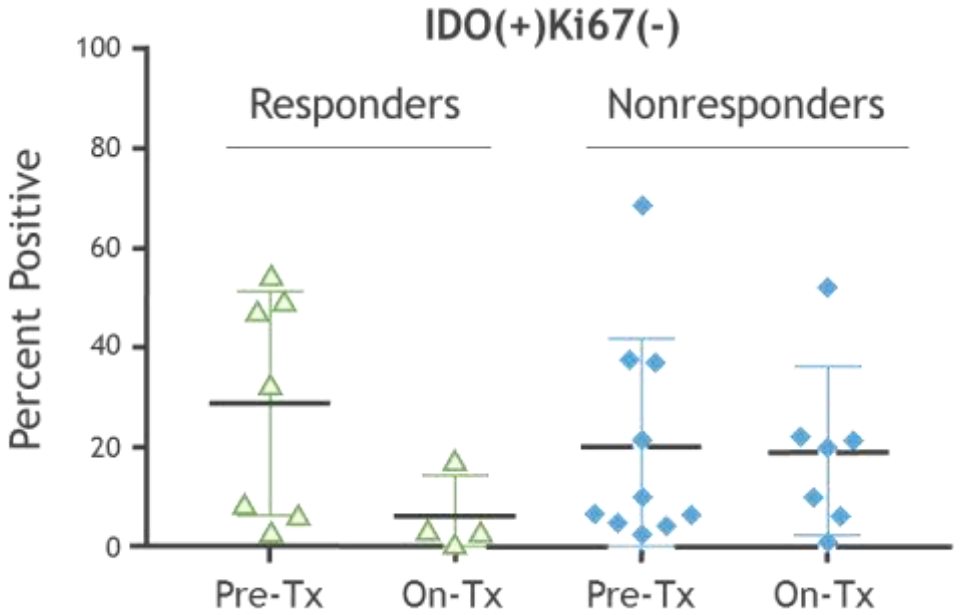
Zakharia, Y, et al. ASCO 2018; Chicago, USA

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



PD-L1, programmed death-ligand 1; ORR, overall response rate; IDO, indoleamine-pyrrole 2,3-dioxygenase; Pre-Tx, pretreatment; On-Tx, on-treatment.
Zakharia Y, et al. ASCO 2018; Chicago, USA.

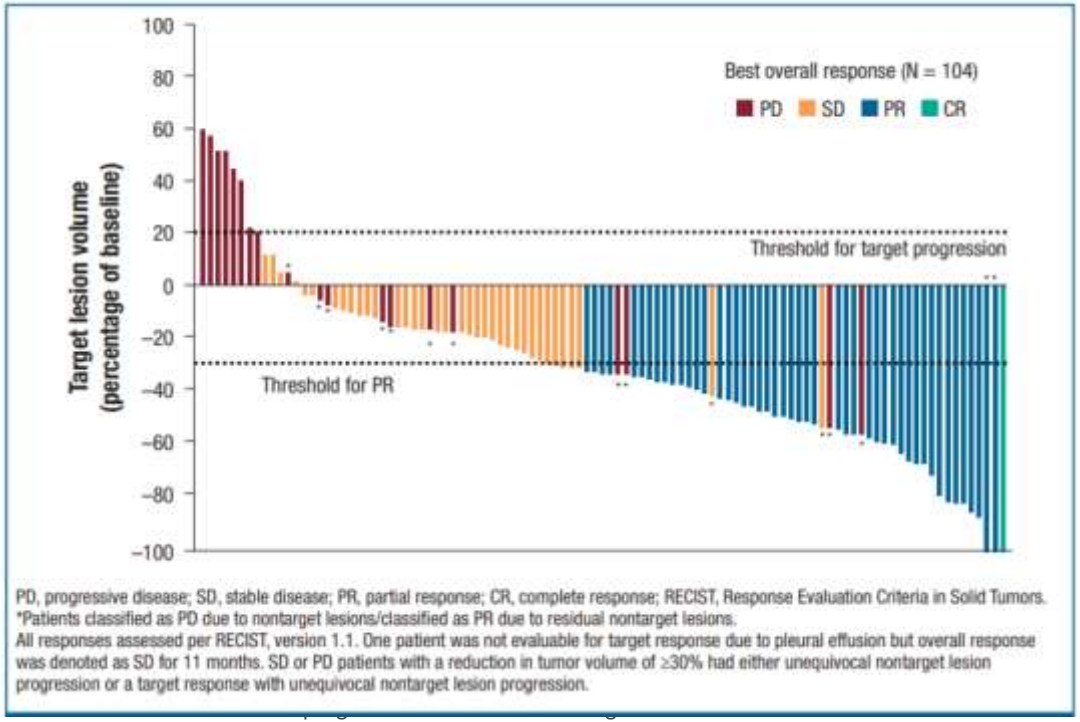
Phase 2 Results of Indoximod + Chemotherapy in Pancreatic Cancer

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.



PD, progressive disease; SD, stable disease; PR, partial response; CR, complete response; RECIST, Response Evaluation Criteria in Solid Tumors.
*Patients classified as PD due to nontarget lesions/classified as PR due to residual nontarget lesions.
All responses assessed per RECIST, version 1.1. One patient was not evaluable for target response due to pleural effusion but overall response was denoted as SD for 11 months. SD or PD patients with a reduction in tumor volume of ≥30% had either unequivocal nontarget lesion progression or a target response with unequivocal nontarget lesion progression.

Bahary, N, et al. ASCO 2018; Chicago, USA.