

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): September 26, 2013 (September 26, 2013)

**NewLink Genetics Corporation**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-35342**  
(Commission  
File Number)

**42-1491350**  
(IRS Employer  
Identification No.)

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

**50010**  
(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))

## Section 8 - Other Events

### Item 8.01. Other Events.

The executive officers of NewLink Genetics Corporation ("we", "our" or "us") intend to deliver presentations to investors and analysts beginning on September 26, 2013. We expect to use the presentation materials attached as Exhibit 99.1 hereto, in whole or in part and possibly with immaterial modifications, in connection with such meetings. The information contained in the presentation materials is summary information that is intended to be considered in the context of our filings with the Securities and Exchange Commission and other public announcements that we may make, by press release or otherwise, from time to time.

We expect to make copies of the presentation materials available for viewing at the "Investor Relations" section of our website located at [www.linkp.com](http://www.linkp.com), although we reserve the right to discontinue that availability at any time.

Some of the matters discussed in the attached presentation materials contain forward-looking statements that involve significant risks and uncertainties, including statements relating to our clinical trials and the potential advantages of our product candidates. Actual results could differ materially from those projected and we caution investors not to place undue reliance on the forward-looking statements contained in, or made in connection with, the presentation materials.

Among other things, the projected commencement, enrollment and completion of any of our clinical trials and the dissemination of the results of the clinical trials may be affected by difficulties or delays, including difficulties or delays caused by regulatory issues, patient enrollment, patient treatment, data collection or data analysis. In addition, our results may be affected by our effectiveness at managing our financial resources, our ability to successfully develop and market our product candidates, our ability to obtain or enforce patent protection for our product candidates, difficulties or delays in manufacturing our product candidates, and regulatory developments involving product candidates or any future products. Delays in clinical programs, whether caused by competition, adverse events, patient enrollment rates, regulatory issues or other factors, could adversely affect our financial position and prospects. Prior clinical trial program designs and results are not necessarily predictive of future clinical trial designs or results. Preliminary clinical trial results may not be confirmed upon full analysis of the detailed results of a trial. If our product candidates do not meet safety or efficacy endpoints in clinical evaluations, they will not receive regulatory approval and we will not be able to market them. Even if our product candidates meet safety and efficacy endpoints, regulatory authorities may not approve them, or we may face post-approval problems that require the withdrawal of any future product from the market. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue one or more of our drug development or discovery research programs. We are at an early stage of development and may not ever have any products that generate significant revenue.

It is our policy to update or reconfirm our public guidance only by issuing a press release or filing a publicly accessible document with the SEC. We generally plan to provide guidance as part of our annual and quarterly earnings releases but reserve the right to provide guidance at different intervals or to revise our practice in future periods. Clinical guidance contained in the presentation materials is as of September 26, 2013. We undertake no duty or obligation to update any forward-looking statements as a result of new information, future events or changes in our expectations.

The presentation materials are attached hereto as Exhibit 99.1 and incorporated herein by reference.

**Section 9 - Financial Statements and Exhibits**

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	NewLink Genetics Presentation Materials

**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: September 26, 2013

**NewLink Genetics Corporation**

By: /s/ Gordon H. Link, Jr.  
Gordon H. Link, Jr.  
Its: Chief Financial Officer

## INDEX TO EXHIBITS

Exhibit Number	Description
99.1	NewLink Genetics Presentation Materials



*NewLink*  
**GENETICS**

BioCentury  
NewsMakers in the Biotech Industry  
2013  
New York City

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## Forward-Looking Disclaimer

*These slides accompany an oral presentation by NewLink Genetics Corporation, which contains forward-looking statements. The Company's actual results may differ materially from those suggested here. Additional information concerning factors that could cause such a difference is contained in the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013 and other prior and subsequent regulatory filings.*

# **NewLink Genetics Corporation**

## ***Oncology-Focused Biopharmaceutical Company***

- Founded in 1999; IPO in 2011, Currently 100+ employees
- Pipeline includes biologic and small molecule candidates
- Completed enrollment for IMPRESS phase 3 trial
- Strong IP position for technology platforms
- Added to NASDAQ Biotech Index May 2013
- Advancing commercialization efforts for the U.S. market



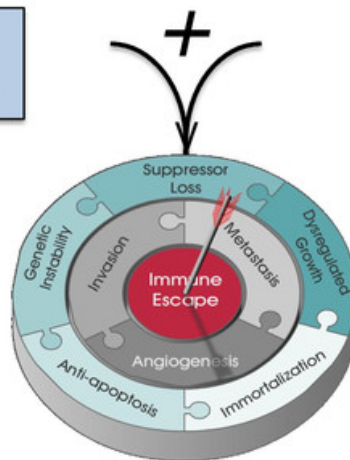
# NewLink Genetics

## Targeting Immune Escape

Developing two distinct, proprietary platforms that independently stimulate immune activation and disrupt tumor-mediated immunosuppression

“HyperAcute™” Vaccines\*

**Inducing  
Immune activation**



IDO Pathway Inhibitors

**Blocking  
Immunosuppression**

\*HyperAcute® is NewLink Genetics' propriety technology platform

# NewLink Clinical Development Pipeline

## Targeting Immune Activation & Immunosuppression

Product/ Tumor Type	Phase 1	Phase 2	Phase 3
<b>HyperAcute™ Platform</b>			
Algenpantucel-L (pancreas)	▶		
Tergenpumatucl-L (lung)	▶		
HyperAcute Melanoma	▶		
HyperAcute Prostate	▶		
HyperAcute Renal	Expected to enter clinical trials in 2013		
<b>IDO Pathway Inhibitor Platform</b>			
Indoximod – Solid Tumors			
Metastatic Prostate	▶		
Metastatic Breast	▶		
NLG 919 – Solid Tumors	Expected to enter clinical trials in 2013		

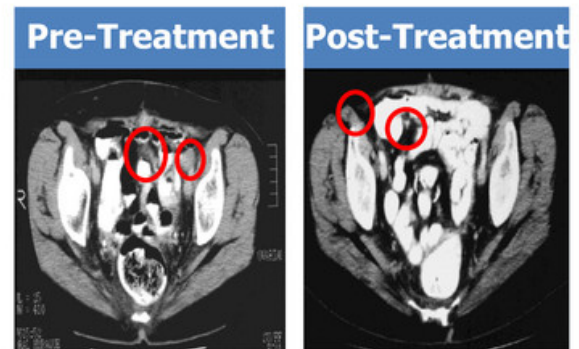
# HyperAcute™ Immunotherapy

“Stimulating the immune system to recognize and attack cancer cells.”

# HyperAcute™ Platform

## Activation of Immune Response via Innate Immunity

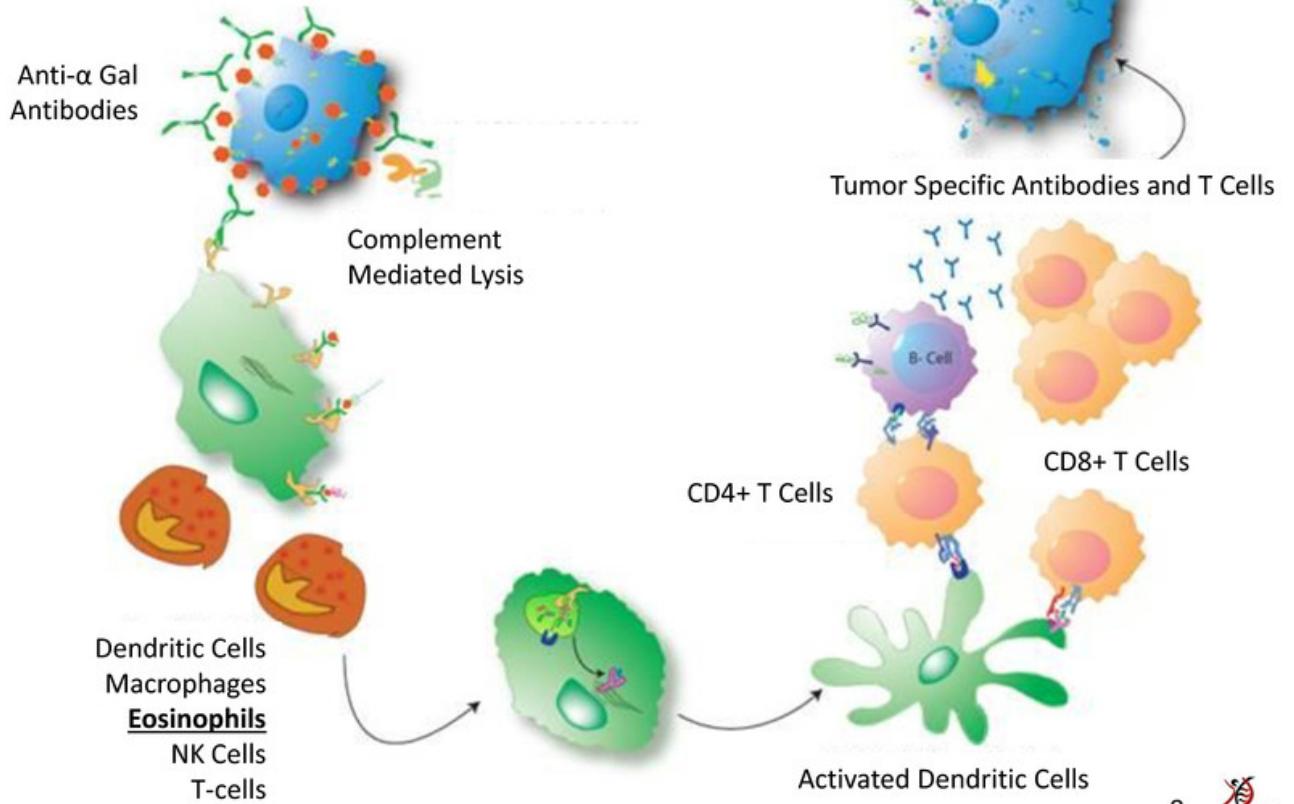
- Novel biologics designed to express alpha-gal carbohydrate which stimulates the immune system to recognize and attack cancer cells
- Cellular immunotherapy that is tumor specific, but does not require tissue from the patient
- Anti-alpha-gal Ab's in primates are responsible for "HyperAcute rejection" of xenotransplants
- Two Phase 3 studies underway for lead product candidate
- *Technology derived from unexpected anti-tumor responses observed in unrelated gene therapy experiment*



# Mechanism of Action

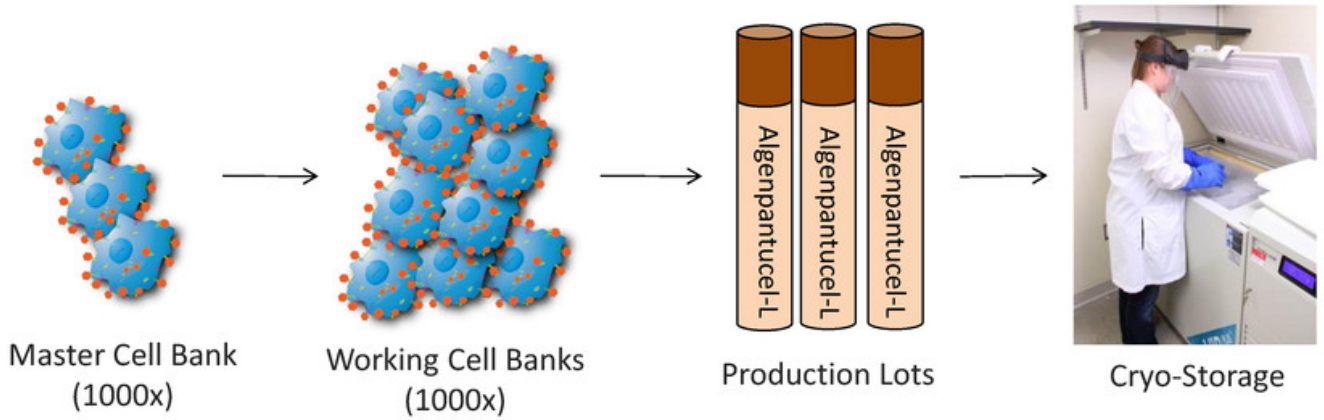
## *HyperAcute Response → Tumor Specific Activity*

### HyperAcute Immunotherapy



# HyperAcute Immunotherapy

## Scale-up & Production

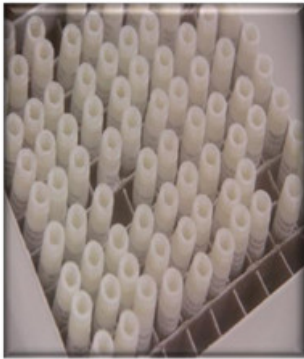


- Disease specific yet NOT patient specific (Allogeneic)
- Standardized, single site manufacturing
- Established, scalable production methodology
- Well characterized identity and potency

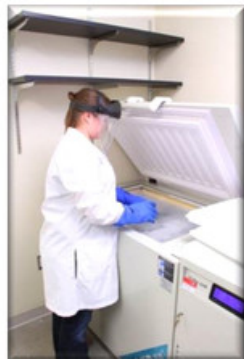


# HyperAcute Immunotherapy

## *Storage & Administration*



Shipping



Storage



Preparation



Administration

### HyperAcute Immunotherapy

- Vaccine is shipped on dry ice & stored at  $<-135^{\circ}\text{C}$ .
- Thawed to room temperature & drawn into a tuberculin syringe with 18g transfer needle.
- Administered via 6 intradermal injections (25g needle) of 50 million cells each

# Pancreatic Cancer

## *Epidemiology & Pathophysiology*



- 4<sup>th</sup> leading cause of cancer death in U.S.\*
- All stages, 5 year survival\*\* < 5%
- Stage IIB, resected, 5 year survival\*\* <8%

Annual Incidence in Major Markets			
Total	U.S.*	Europe	Japan
117,000	43,000	45,000	29,000

- Resection rate 20-25% U.S.\*
- Post resection standard of care
  - Chemotherapy +/- Radiotherapy
  - Gemcitabine +/- 5FU Concurrent Radiotherapy

\*2013 Cancer Facts & Figures

\*\*Bilimoria et al., Cancer; August 15, 2007: Volume 110, Number 4: 738-744



# Algenpantucel-L

## Phase 2 Results: Resected Pancreatic Cancer

### ➤ Eligibility & Treatment

- Post-resection patients with no evidence of residual disease
- SOC (gemcitabine+5FU+concurrent XRT) + algenpantucel-L
- Algenpantucel-L schedule: Q2weeks X 6 months
- High dose (300 million cells) & low dose (100 million cells)

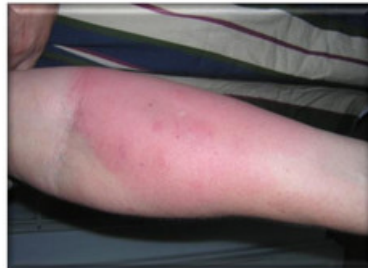
### ➤ Phase 2 Trial NLG-0205 (n = 69)

- Multicenter(16), open label, 2 arm study
- **Primary endpoint met: 1 year DFS 62%**
  - DFS: High dose (81%) superior to low dose (52%) p= 0.02
- Secondary endpoints: Overall Survival(OS)
  - OS: High dose (96 %) superior to low dose (79%) p= 0.049

# HyperAcute Immunotherapy Safety

## Minimal Grade 3 & No Grade 4 Events

- Most frequent AEs attributed to algenpantucel-L are grade 1/2 skin reactions at injection sites (51%)
- Grade 3 events possibly attributable to vaccine: lymphopenia (6%), skin reaction/pain (3%) & leukopenia/neutropenia (3%)
- No grade 4 drug related adverse events reported



Hardacre, J. et al, JCO, Vol 30, No 15\_suppl (May 20 supplement), ASCO 2012: Abstract 4049

# Prognostic Variables Impacting Survival

## *Nodal Status & Tumor Size have Greatest Impact*

RTOG 9704<sup>1</sup> Prognostic Variables N=388

Prognostic Variable	Hazard Ratio	P-Value
Nodal Status	1.53 (1.18-1.97)	0.001
Tumor Size	1.21 (0.95-1.53)	0.12
Surgical Margin Status	1.05 (0.80-1.37)	0.74

Brennan Nomogram<sup>2</sup> Validated Prognostic Variables N=555

Prognostic Variable	P-Value
Nodal Status	0.001
Tumor Size	0.002
Differentiation	0.002
Surgical Margin Status	0.74

<sup>1</sup> Regine et al, JAMA 2008; 299(9): 1019-1026

<sup>2</sup> Brennan, M et al, Annals of Surgery 2004 , Volume 240(2): 293-298

# Pancreatic Cancer: Survival by Disease Stage

## *NLG 0205: 96% High Risk Patients*

Stage	20,000 Patient Death Registry <sup>1</sup>				NLG 0205 <sup>2</sup>
	1 Year (%)	2 Year (%)	3 year (%)	Overall Survival	Patient Distribution
IA	71.3	50.2	40.7	24.1 mo	1%
IB	67.3	45.4	35.3	20.6 mo	3%
IIA	60.7	34.9	23.8	15.4 mo	15%
IIB	52.7	23.8	14.4	12.7 mo	81%

<sup>1</sup> Hidalgo, M, The New England Journal of Medicine 2010, 362:1605

<sup>2</sup> Hardacre, J. et al, JCO, Vol 30, No 15\_suppl (May 20 supplement), ASCO 2012: Abstract 4049

# NLG0205: High Risk Patients w/ Poorer Prognosis

Sponsor	RTOG	NewLink
Study	9704 <sup>1</sup>	NLG 0205 <sup>2</sup>
Median Age	61	62
Gender (male)	53 %	53 %
Whipple	85 %	86 %
Lymph Node Positive	68 %	81 %
Tumor ≥ 3 cm	61 %	66 %
Poorly Differentiated	30 %	35 %
CA 19-9 ≥180	9%**	18 %

#### NLG 0205 Additional High Risk Factors:

- 96% High Risk (Positive Nodes or Tumor ≥2cm)
- 90% Local Invasion
- Median Tumor Size = 3.2cm

<sup>2</sup>Hardacre, J. et al, JCO, Volume 30, No 15\_suppl (May 20 supplement), ASCO 2012: Abstract 4049

<sup>1</sup>Regine et al, JAMA 2008; 299(9): 1019-1026

\*\*Berger, A et al, Int J Radiation Oncol Biol Phys, Vol 84, No 3 pp e291-297, 2012 (N=385)

# Resected Pancreatic Cancer Survival Rates

## *NLG0205 vs. Predictive & Historical Controls*

Trial	1 Year	2 year	Overall Survival
NLG-0205 <sup>1</sup>	86%	51%	24.1 mo
RTOG 9704 <sup>2</sup>	69%	40%*	18.5 mo*
Nomogram <sup>3</sup>	63%	32%	16.6 mo
Hidalgo <sup>4</sup>	55%	26%	13.5 mo

- Phase 2 results show strong potential for benefit in Phase 3
- NLG-0205 patients had much worse prognosis than RTOG 9704
- Patients in Phase 3 receive only high dose & an additional 6 months

\*Estimate for all patients based on Kaplan-Meier

<sup>1</sup> Hardacre, J. et al, JCO, Volume 30, No 15\_suppl (May 20 supplement), ASCO 2012: Abstract 4049

<sup>2</sup> Regine et al, JAMA 2008; 299(9): 1019-1026

<sup>3</sup> Brennan, M et al, Annals of Surgery 2004 , Volume 240(2): 293-298

<sup>4</sup> Hidalgo, M et al, The New England Journal of Medicine 2010, 362:1605

# Algenpantucel-L

## Phase 2 Results: Long Term Follow Up at 3 Years

Time 3 Years	Overall Survival (OS)	Disease Free Survival (DFS)
NLG0205*	39%	26%
Brennan ** Nomogram	19%	NR

\*All patients  $\geq$  3 year follow up

\*\* Developed by Memorial Sloan Kettering Cancer Center and validated by Massachusetts General Hospital patient cohort

\*\*Brennan, M. et al, (2004) Annals of Surgery, Volume 240(2): p. 293-8

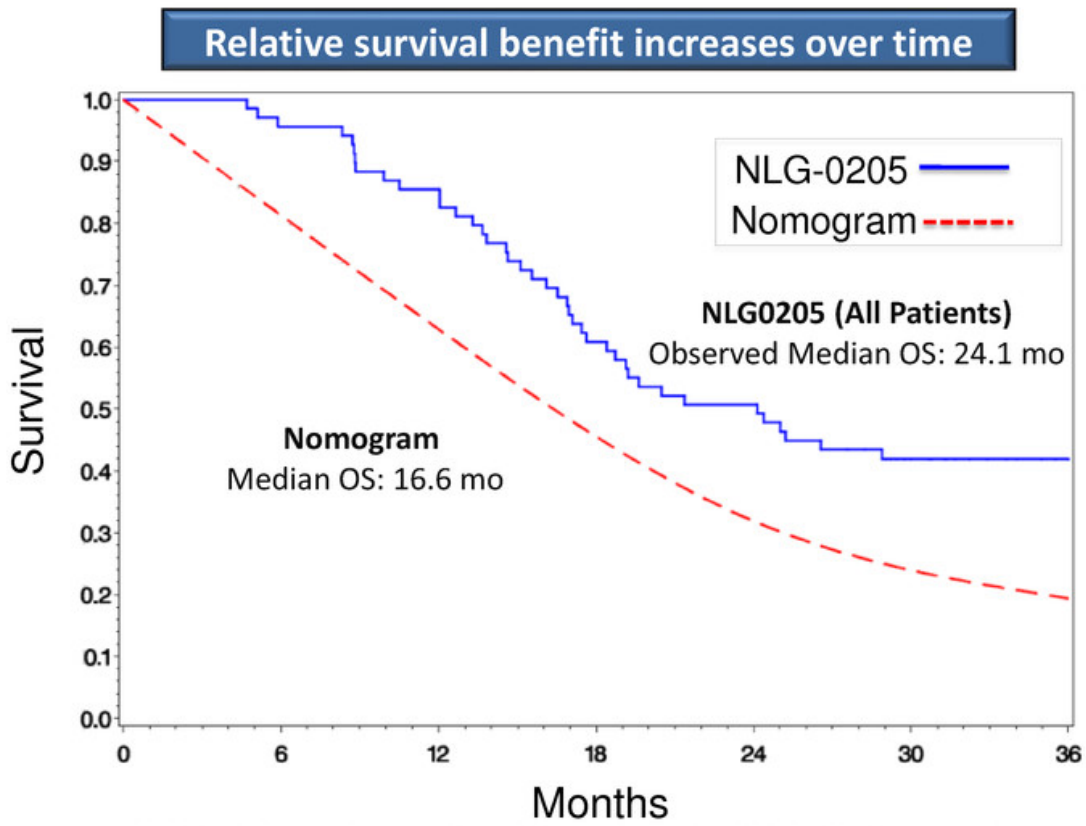
\*\*Ferrone, CR et al, (2005) Journal of Clinical Oncology, Volume 23(30): p. 7529-35

Rocha Lima, C. et al, JCO, Vol 31,\_suppl (May 15 supplement), ASCO 2013: Oral Abstract 3007

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# Algenpantucel-L

## Phase 2 Results: Overall Survival



Hardacre, J. et al, JCO, Vol 30, No 15\_suppl (May 20 supplement), ASCO 2012: Abstract 4049



# Algenpantucel-L

## NLG0205: Correlation of Survival & Ab Elevation

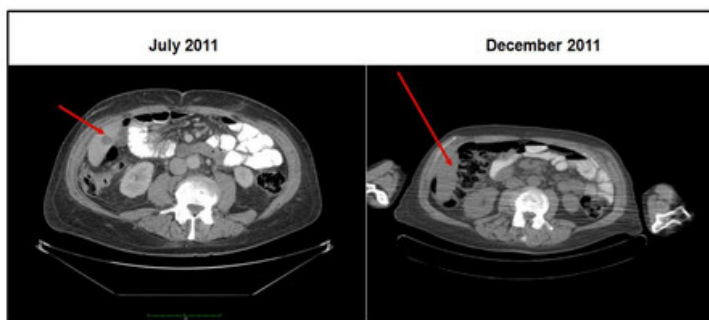
Assessed Parameters: anti-MSLN Ab, anti-CEA Ab and/or anti- $\alpha$ GAL Ab

Antibody Elevation	n	Survival Rate (3 year)	Median OS (months)	p-value
None	27	19%	17	
One Parameter	26	42%	26	0.0476
Multiple Parameters	13	69%	>36 (Not Reached)	0.0073

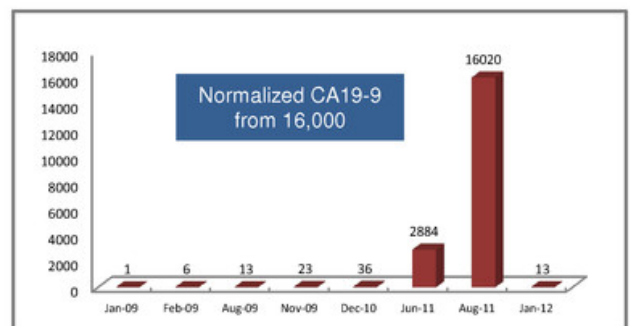
# Algenpantucel-L

## *Unexpected Clinical Observations*

- Recall skin reactions can occur 1-2 year after last vaccination
- 70% of patients showed eosinophilia; 30% lasted  $\geq 1$  year
- CR to salvage chemotherapy (post algenpantucel-L therapy) in 3 patients with recurrent disease



Regression of Liver Metastasis



CA-19.9

Hardacre, J. et al, JCO, Vol 30, No 15\_suppl (May 20 supplement), ASCO 2012: Abstract 4049

# Phase 3 Registration Trial - IMPRESS

## *Surgically Resected Pancreatic Cancer*

### ➤ IMPRESS Trial\* (n = 722)

- Initiated, May 2010 under SPA with the FDA
- FDA Fast Track and Orphan Drug
- Open label, 2 arm, randomized study
- Post surgical resection patients
- SOC +/- algenpantucel-L (SOC = gemcitabine +/- radiation)
- Algenpantucel-L: 300 million cells Q2wks X 6 mo → Q1m X 6 mo\*\*
- Overall Survival is the primary endpoint
- Stratified for Nodal Status, Radiotherapy & CA 19-9

### ➤ Accrual Status and Endpoints

- Completed enrollment September 2013 (722 patients)
- First interim look when 222 events occur, final analysis at 444 events
- Designed to detect ≈20% difference in overall survival at final analysis

\*Clinicaltrials.gov NCT01072981

\*\*Phase 2 trial administered 300 million Q2wks X 6 months

# IMPRESS Patient Characteristics\*

*Consistent with Previously Reported Large Studies*

Characteristics	RTOG 9704 <sup>1</sup> (n=221)	IMPRESS (n≈700)
Age (Median)	61	64
Gender (Male)	53	53
Disease Stage		
Ia	N/R	4%
Ib	N/R	5%
IIa	N/R	21%
IIb	N/R	70%
Nodal Status		
N0	32%	30%
N1	68%	70%
CA19-9 ≥180	9%**	9%

\*Initial analysis includes approximately 700 patients with available data

<sup>1</sup> Regine et al, JAMA 2008; 299(9): 1019-1026

\*\*Berger, A et al, Int J Radiation Oncol Biol Phys, Vol 84, No 3 pp e291-297, 2012 (N=385)

# Timing of IMPRESS Analysis

## *Potential Factors Impacting Trigger Events*

- Patient characteristics
  - Age, gender, tumor size , stage, grade, Nodal status, CA19-9 etc...
- New salvage treatment regimens
  - Gem+Abraxane, FOLFIRINOX, Tarceva
- Enrollment rate (IMPRESS is in line with study projections)
- Possible improvement in surgical or diagnostic techniques (PET?)
- Increased use of neoadjuvant therapy
- Delayed reporting of death events
- Treatment duration at 300M cell dose with Algenpantucel-L

# Second Phase 3 Trial - PILLAR

## *Locally Advanced Pancreatic Cancer*

- Locally Advanced Trial\* (n = 280)
  - Launched, October 2012 (FPI, Q113)
  - Open label, 2 arm, randomized study
  - FOLFIRINOX +/- algenpantucel-L
  - Algenpantucel-L: 300 million cells Q2 weeks up to 18 doses
  - Overall Survival is the primary endpoint
  - Includes borderline or locally advanced unresectable patients
  - Open to Enrollment

Positive results might more than double the treatable patient population of initial indication

# Commercialization Strategy

## *Algenpantucel-L for Patients with Pancreatic Cancer*

- NewLink plans to execute an independent US commercial launch
  - Leverage key pancreatic surgical centers as hubs
  - Provide strong product support across entire multidisciplinary team
- Key launch components currently being assembled
  - Utilizing state of the art cold chain distribution technology & services
  - Conducting reimbursement analysis & establishing support services
- Corporate & product branding initiatives underway
  - Partnered with ICC Lowe for corporate & product campaigns
  - Planned launch of new website in Q413
- Will Pursue Partnerships for Ex-U.S. commercialization
  - Ongoing discussions with various global & regional companies
  - Anticipate EMEA submission with IMPRESS results
  - Evaluating global manufacturing & distribution options

# Lung Cancer

## *Epidemiology & Pathophysiology*



- Leading cause of cancer death in U.S.\*
- All stages, 5 year survival 16%
- Advanced disease, 5 year survival <5%

U. S. Annual Incidence & Deaths (Lung Cancer)	
Incidence	Deaths
228,190	159,480

- 40% of patients present with metastatic disease
- A significant unmet need exists for new treatment options for these patients

\*2013 ACS Cancer Facts & Figures



# Tergenpumatulcel-L

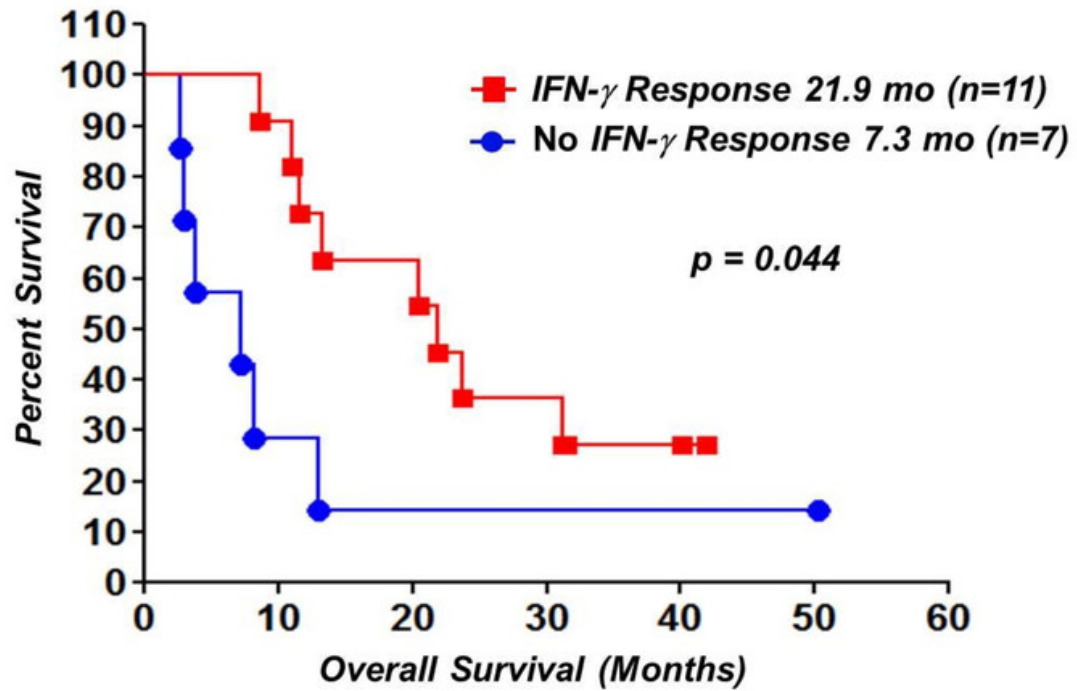
## *Phase 2 Study – Previously Treated NSCLC*

- Single agent survival and safety results for 28 NSCLC patients
  - Median OS was 11.3 months with 46% of patients surviving one year
  - Favorable safety profile, no grade 4 drug related adverse events
  
- Potential chemo-sensitization effect
  - 16 patients received follow on chemotherapy post tergenpumatulcel-L
  - Partial response rate of 31% (5/16) in patients
  - Stable disease achieved in an additional 25% (4/16)
  
- Correlative studies
  - Significantly improved OS in patients with elevated IFN- $\gamma$  secretion
  - Acquired reactivity to CL4-H522 cell line, not part of vaccine, suggests antigen cross-priming to shared tumor antigens

# Tergenpumatucel-L in NSCLC

## Phase 2: Survival Correlates with IFN- $\gamma$ Response<sup>8</sup>

### Single Agent in Previously Treated NSCLC



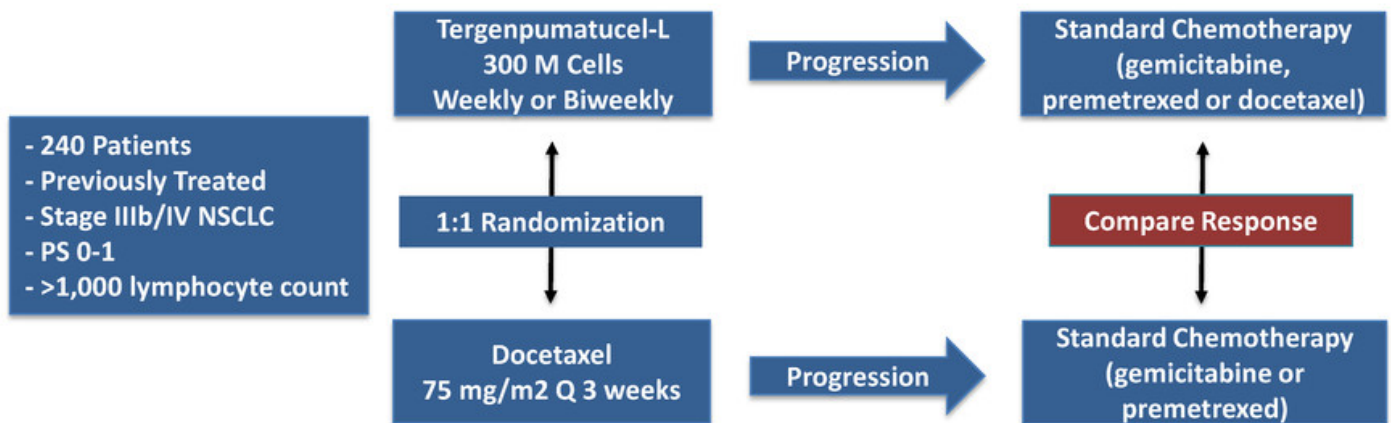
Morris, J. et al, JCO, Vol 31, \_suppl (May 15 supplement), ASCO 2013: Abstract 8094

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# Tergenpumatulcel-L

## NLG-0301 Randomized Phase 2b/3 NSCLC

- Primary Endpoint: Overall Survival
- Secondary Endpoints: Response to subsequent controlled chemotherapy, immunologic response and dosing schedule



# **IDO Pathway Inhibitors**

## **Indoleamine 2,3-dioxygenase (IDO)**

“Disrupting mechanisms by which tumors evade a patient’s immune system.”

### **NewLink Genetics IDO Pathway Inhibitors**

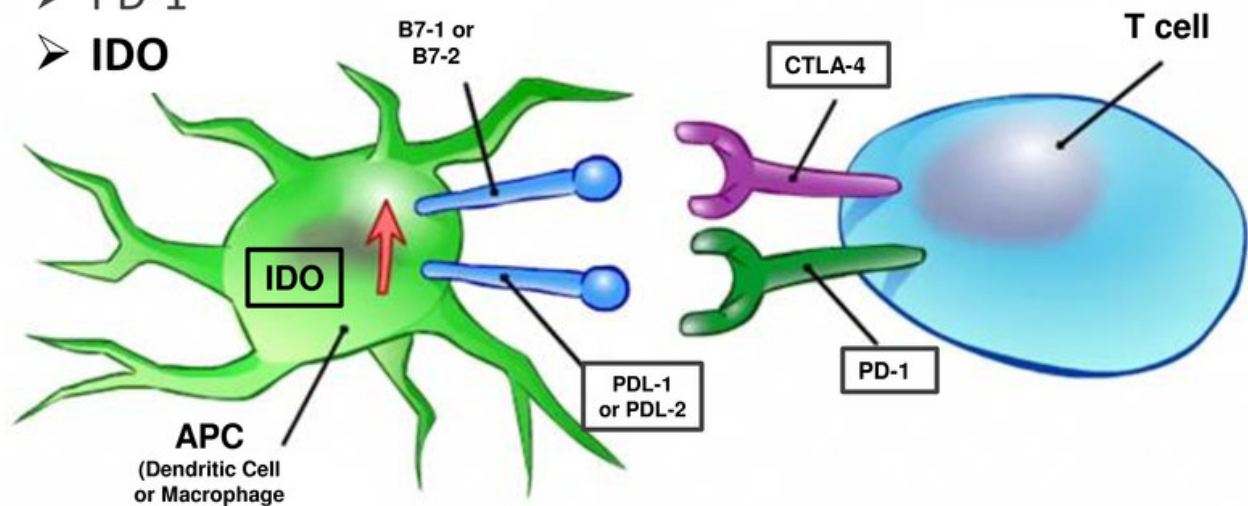
**Indoximod**

**NLG-919**

# Cancer Immunosuppression

## Three Key Checkpoint Targets

- CTLA-4
- PD-1
- **IDO**



Manipulation of IDO pathway related targets such as CTLA-4 and PD-1 offer potential breakthrough approaches to cancer therapy, targeting mechanisms by which tumors evade immune mediated destruction

# Indoleamine 2,3-dioxygenase (IDO)

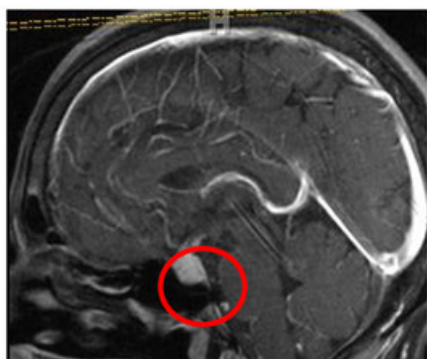
## *Supports Cancer Immunosuppression*

- Regulates immune response to cancer like CTLA-4 and PD-1
  - Inhibits effector T-cells, activates suppressive Tregs
  - Enables local tumor immune escape
  
- Overexpressed
  - Within tumor cells or antigen presenting cells to directly suppress T-cells, must be targeted with a small molecule
  
- NewLink actively developing two distinct IDO pathway inhibitors
  - Indoximod is being studied in various chemotherapy and immunotherapy combination clinical studies
  - NLG919 is expected to enter clinical trials by the end of 2013

# Indoximod

## *Phase 1: Key Results Summary*

- Well tolerated, 200 mg QD to 2000 mg BID
- Most common adverse events: fatigue, anorexia & nausea
- Biologic effects observed in 3 patients previously sensitized to immunotherapy (low dose) & 2 non-sensitized patients (high dose)
- Five patients with SD for  $\geq 6$  months (2 melanoma, 2 sarcoma, 1 colon)
- Multiple mixed responses including regression of visceral metastases



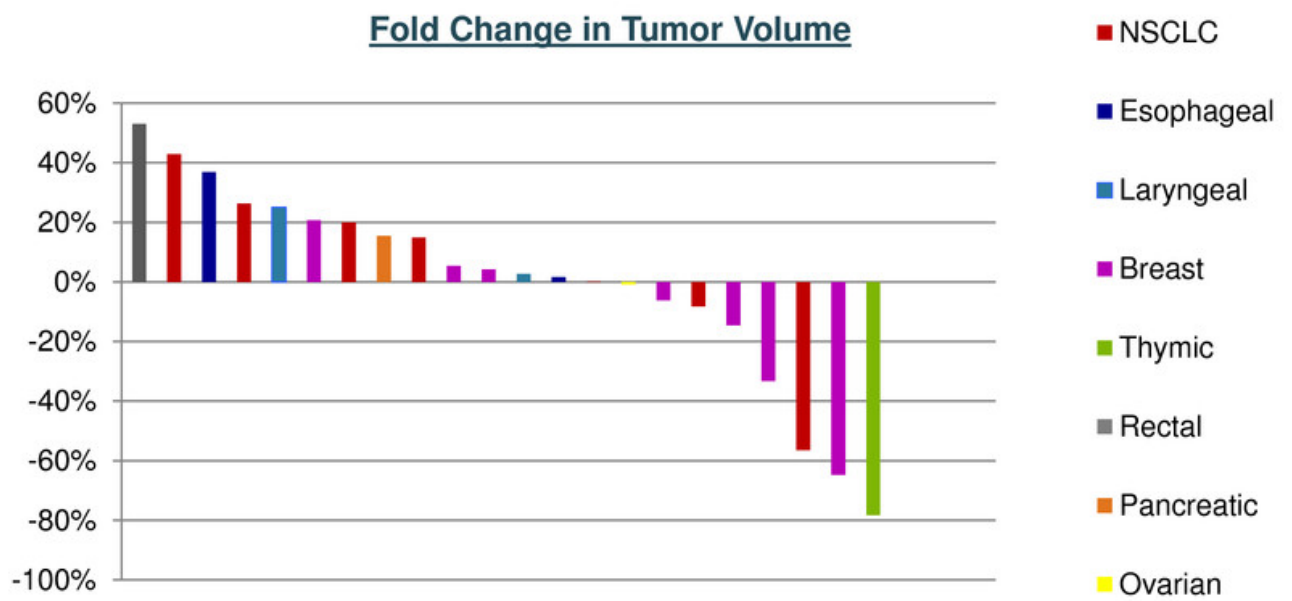
### **Hypophysitis**

- Auto-immune event correlated with beneficial anti-tumor responses in ipilimumab trials
- Condition resolved with short course of steroids

# Indoximod + Docetaxel Combination

## Phase 1: Efficacy Results

- 18% (4/22) partial response rate (2 breast, 1 lung, 1 thymic)
- 41% (9/22) rate of stable disease





# Indoximod

## *Clinical Development*

Phase	Design / Purpose/ Indication	Status
1	Indoximod as single agent Dose escalation to determine MTD & PK All Solid malignancies	Completed
1	Indoximod as single agent Dose escalation to determine MTD & PK All Solid malignancies	Completed
1b/2	Indoximod + Docetaxel Dose escalation of both agents Breast, lung, ovarian, prostate	Completed
1b/2	Indoximod + Dendritic cells loaded with Ad-p53 vaccine Dose escalation Breast, colon, lung	Completed
2	Sipuleucel-T +/- Indoximod Refractory Metastatic Prostate	Open
2	Docetaxel +/- Indoximod Metastatic Breast	Open

# NLG-919

## *Preclinical Results & Next Steps*

- Potent Inhibitor (nM) of IDO in vitro and in cell based assays
- Is orally bioavailable and has a favorable PK-Tox profile
- Blocked IDO-induced T cell suppression (EC50 ~ 100 nM)
- Enhanced antitumor activity in established tumors (B16F10)
- Shows synergistic T cell activation & antitumor activity w/ indoximod
- Expected to enter phase 1 by year end 2013

# NewLink Genetics Corporation

## *Highlights & Future Direction*

- Multiple near term value-generating milestones expected
  - Accrual now complete for IMPRESS trial
  - Conduct first interim analysis for IMPRESS trial
  - Continue expansion of current clinical programs (PILLAR, lung, IDO, etc.)
  - Initiate new clinical programs (HyperAcute Renal & NLG919)
  
- Strong financial position
  - Sufficient cash to fund development to next data inflection points
  
- Poised to build a commercial presence
  - Clear regulatory and commercial path for pancreatic market
  - Building internal infrastructure for North America
  - Seeking long term partnership(s) for ROW development
  - Exploring potential partnerships for follow on products

