

## **NewLink Genetics Corp**

### **CORTELLIS COMPANY DETAILED PIPELINE REPORT**

A comprehensive coverage of the the company's drug pipeline portfolio including detailed product records.

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# ABOUT CORTELLIS COMPANY DETAILED PIPELINE REPORT

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## GLOSSARY

### Number of Drugs in Active Development

Number of drugs associated with the company or subsidiary that are currently in active development, i.e. the development status for the drug(s) is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

### Number of Inactive Drugs

Number of drugs associated with the company or subsidiary that are currently classified as inactive, i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.

### Number of Patents as Owner

Number of patents associated with the company where the company is listed as owner; i.e. the relationship type (or way the patent refers to the company) is: Patent Assignee/Owner, Patent owner (not assignee), Licensee for development and marketing, Licensee – marketing only (Distributor), Patent assignee of family member, Inferred assignee.

### Number of Patents as Third Party

Number of patents associated with the company where the company is listed as third party; i.e. the relationship type (or way the patent refers to the company) is: Patent assignee (not owner), Ex-Licensee for development and marketing, Ex-Licensee marketing only (Distributor), Customer of technology, Ex-Customer of technology, Patent opponent or infringer, Affiliate organization of inventor, Owner of underlying technology.

### Patents summary table

This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.

### Number of Deals

A count of deals where the company or one of its subsidiaries is the primary company.

### Key Indications

Displays top ten key indications for the company and its subsidiaries based on frequency (indications occurring with high and identical frequency are always included, and this may result in more than ten Key Indications being listed). Includes both indications associated with patents where the company is patent owner and indications associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

### Key Target-based Actions

Displays top ten key target-based actions for the company and its subsidiaries based on frequency (actions occurring with high and identical frequency are always included, and this may result in more than ten Key Target-based Actions being listed). Includes both target-based actions associated with patents where the company patent owner and target-based actions associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended. A target-based action is one that is associated with a target.

### Key Technologies

Displays top ten key technologies for the company and its subsidiaries based on frequency (technologies occurring with high and identical frequency are always included, and this may result in more than ten Key Technologies being listed). Includes both key technologies associated with patents where the company relationship is patent owner and key technologies associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

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# NewLink Genetics Corp

## COMPANY OVERVIEW

Company Name	NewLink Genetics Corp
Parent Company Name	NewLink Genetics Corp
Website	http://www.linkp.com/
Country	US
Number of Drugs in Active Development	8
Number of Inactive Drugs	1
Number of Patents as Owner	8
Number of Patents as Third Party	0
Number of Deals	3
Key Indications	Cancer,Melanoma,Pancreas tumor,Breast tumor,Hormone refractory prostate cancer,Non-small-cell lung cancer,Solid tumor,Colon tumor,HIV infection,Hepatitis C virus infection
Key Target-based Actions	Galactosyltransferase modulator,Indoleamine-pyrrole-2,3-dioxygenase inhibitor
Key Technologies	Biological therapeutic,Cell therapy,Tumor antigen,Intradermal formulation,Parenteral formulation unspecified,Small molecule therapeutic,Oral formulation,Tablet formulation,Peptide,Tumor antigen therapeutic

## COMPANY PROFILE

### SUMMARY

NewLink Genetics Corp is a biopharmaceutical company focused on discovering, developing and commercializing immunotherapeutic products for the cancer treatment.

### COMPANY LOCATION

In April 2010, NewLink moved to a new administrative and manufacturing facility at Iowa State University in Ames, IA.

### FINANCIAL

In March 2012, the company secured a \$6 million loan from the Iowa Economic Development Authority.

By December 2011, the company had completed a Series E preferred private stock round and an initial public offering of \$43.4 million.

In November 2011, NewLink offered 6.2 million shares at \$7 each in an initial public offering.The underwriters were granted a 30-day over-allotment option to buy 930,000 shares. At that time, the company started trading on the NASDAQ Global Market under the symbol 'NLNK'.

In December 2010, NewLink filed a registration statement with the SEC for a proposed IPO.

In November 2009, the company closed a \$30 million Series C preferred financing round.

In July 2009, NewLink Genetics raised \$7.5 million from a series D financing round.

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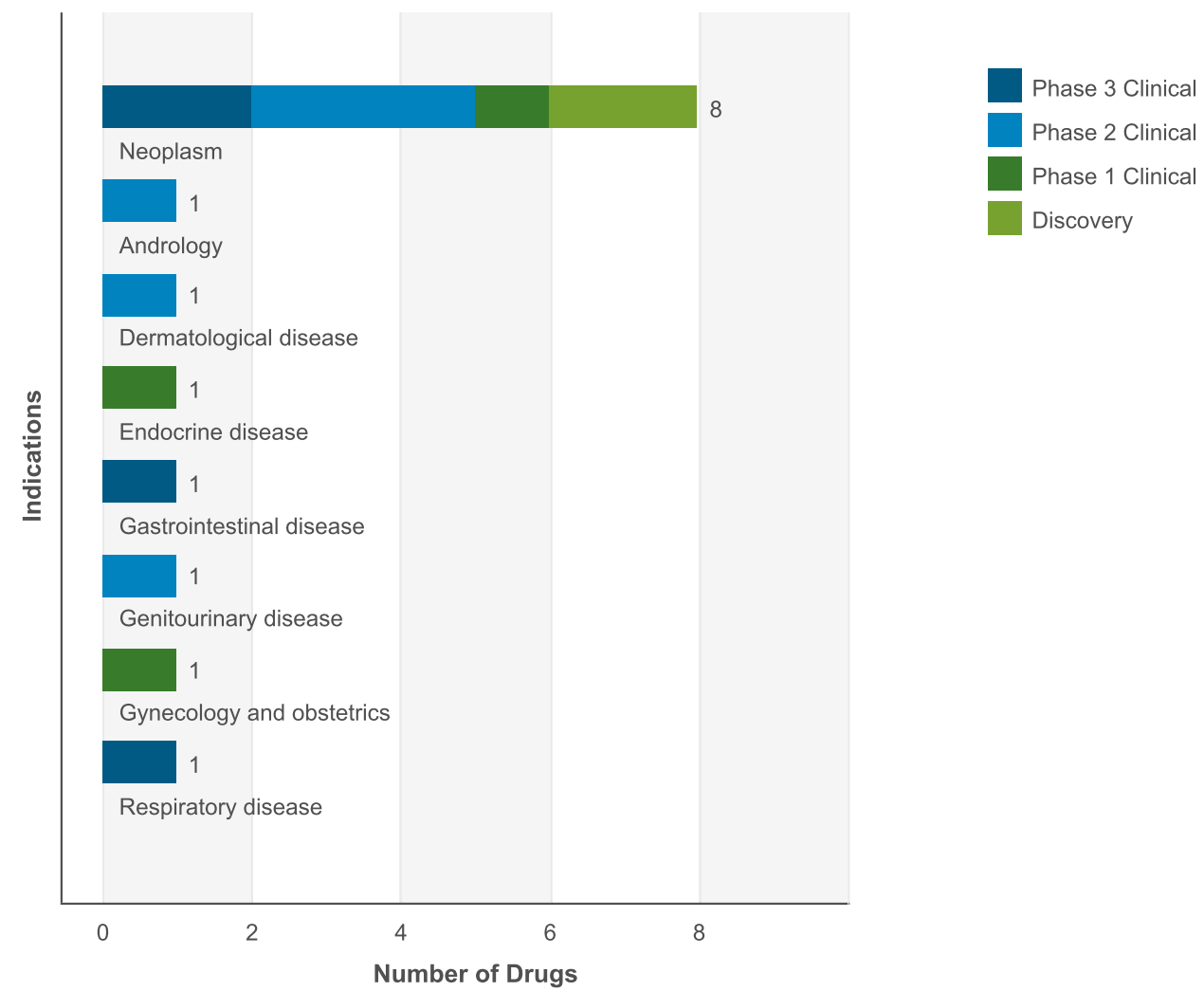


PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



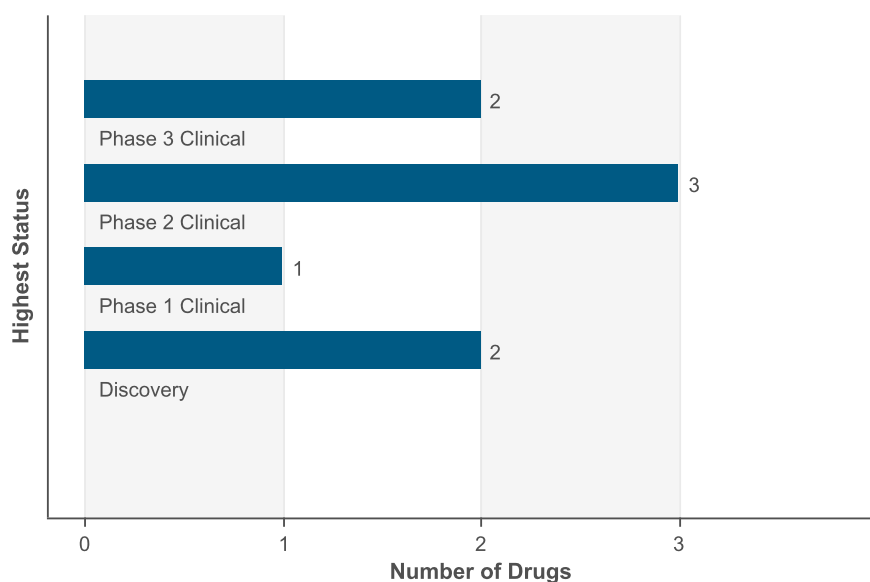
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## Drugs by Indication Table

Indication	Active	Inactive	Total
Neoplasm	8	0	8
Respiratory disease	1	1	2
Gastrointestinal disease	1	0	1
Gynecology and obstetrics	1	0	1
Andrology	1	0	1
Infectious disease	0	1	1
Genitourinary disease	1	0	1
Dermatological disease	1	0	1
Endocrine disease	1	0	1

## Drugs by Highest Status

### Active Drugs by Highest Status Chart



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## Drugs by Highest Status Table

Development Status	Number of Drugs
Phase 3 Clinical	2
Phase 2 Clinical	3
Phase 1 Clinical	1
Discovery	2
No Development Reported	1

## DEALS

Deal Type	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Patent - Exclusive Rights	0	0	1	0	1
Drug - CRADA	0	0	1	0	1
Drug - Development Services	0	0	1	0	1

## CLINICAL TRIALS

### Trials by Condition Studied

Condition Studied	Ongoing	All
Neoplasm	1	10
Gastrointestinal disease	1	5
Dermatological disease	0	3
Endocrine disease	0	2
Respiratory disease	0	2
Gynecology and obstetrics	0	2
Andrology	0	1
Genitourinary disease	0	1

### Trials by Phase

Phase	Ongoing	All
Phase 3	1	1
Phase 2	0	4
Phase 1	0	5

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## Phase Definitions

### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

### Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

## PATENTS \*

Indication	As Owner	As Third Party	Total
Immune disorder	4	0	4
Neoplasm	7	0	7
Ocular disease	1	0	1
Metabolic disorder	1	0	1
Neurological disease	2	0	2
Prophylaxis	1	0	1
Andrology	1	0	1
Endocrine disease	4	0	4
Genitourinary disease	2	0	2
Dermatological disease	5	0	5
Surgical procedure	1	0	1
Gastrointestinal disease	5	0	5
Hematological disease	1	0	1
Respiratory disease	4	0	4
Infectious disease	4	0	4
Inflammatory disease	2	0	2
Gynecology and obstetrics	4	0	4

\* This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.

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## PRODUCT PORTFOLIO DRUG PIPELINE DETAIL

**PLEASE NOTE:** Highest status refers to highest development of that drug for one of the active companies

### tergenpumatucl-L

#### tergenpumatucl-L SNAPSHOT

<b>Drug Name</b>	tergenpumatucl-L
<b>Key Synonyms</b>	HyperAcute-Lung;tergenpumatucl-L
<b>Originator Company</b>	NewLink Genetics Corp
<b>Active Companies</b>	NewLink Genetics Corp
<b>Inactive Companies</b>	
<b>Highest Status</b>	Phase 3 Clinical
<b>Active Indications</b>	Non-small-cell lung cancer
<b>Target-based Actions</b>	Galactosyltransferase modulator
<b>Other Actions</b>	Anticancer;Vaccine
<b>Technologies</b>	Tumor antigen;Biological therapeutic;Cell therapy;Intradermal formulation
<b>Last Change Date</b>	04-Oct-2012

#### tergenpumatucl-L DEVELOPMENT PROFILE

##### SUMMARY

NewLink Genetics is developing tergenpumatucl-L (HyperAcute-Lung, HAL), an intradermally injected HyperAcute vaccine, for the potential treatment of non-small-cell lung cancer (NSCLC),. In October 2012, a phase IIb/III trial was launched.

#### tergenpumatucl-L DEVELOPMENT STATUS

##### CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
NewLink Genetics Corp	Non-small-cell lung cancer	US	Phase 3 Clinical	03-Oct-2012

#### tergenpumatucl-L DEVELOPMENT STATUS

##### HISTORICAL DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
NewLink Genetics Corp	Non-small-cell lung cancer	US	Phase 2 Clinical	18-Nov-2003
NewLink Genetics Corp	Non-small-cell lung cancer	US	Discovery	02-May-2003

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## tergenpumatu cel-L DRUG NAMES

Names	Type
HyperAcute vaccine (lung cancer), NewLink	
HyperAcute vaccine (intradermal, lung cancer), Newlink Genetics	
tergenpumatu cel-L	USAN
HAL	Research Code
HyperAcute-Lung	Trade Name

## tergenpumatu cel-L CLINICAL TRIALS

### Trials by Phase and Condition Studied

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Non-small-cell lung cancer											
0	0	0	0	0	1	0	0	0	0	0	1
Metastatic non small cell lung cancer											
0	0	0	0	0	0	0	1	0	0	0	1

### Total Trials by Phase and Status

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Total by Phase and Status											
0	0	0	0	0	1	0	1	0	0	0	2

### Phase Definitions

#### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

#### Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

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tergenpumatu cel-L DEALS AND PATENTS

DEALS

Deals by Parent Company Chart



Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
NewLink Genetics Corp	0	0	1	0	1
US Government	1	0	0	0	1

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Deals by Type Chart



Deals by Type Table

Deal Type	Active	Inactive	Total
Drug - Development Services	1	0	1

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## algenpantucel-L

### algenpantucel-L SNAPSHOT

Drug Name	algenpantucel-L
Key Synonyms	algenpantucel-L;HyperAcute Pancreas
Originator Company	NewLink Genetics Corp
Active Companies	NewLink Genetics Corp
Inactive Companies	
Highest Status	Phase 3 Clinical
Active Indications	Pancreas tumor
Target-based Actions	Galactosyltransferase modulator
Other Actions	Therapeutic vaccine;Anticancer;Adjuvant
Technologies	Tumor antigen;Biological therapeutic;Cell therapy;Intradermal formulation
Last Change Date	18-Sep-2012

### algenpantucel-L DEVELOPMENT PROFILE

#### SUMMARY

NewLink Genetics is developing algenpantucel-L (HyperAcute Pancreas; HAPa), an intradermally injected HyperAcute vaccine, which comprises a mixture of equal doses of two murine alpha(1,3)galactosyltransferase-expressing allogeneic pancreatic cancer cell lines (HAPa-1 and HAPa-2), for the potential adjuvant treatment of pancreatic cancer, . In April 2010, a phase III trial was initiated in the US ; in June 2012, the first interim analysis was expected in early 2013. In November 2011, the company was seeking to outlicense the vaccine.

### algenpantucel-L DEVELOPMENT STATUS

#### CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
NewLink Genetics Corp	Pancreas tumor	US	Phase 3 Clinical	21-Apr-2010

### algenpantucel-L DEVELOPMENT STATUS

#### HISTORICAL DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
NewLink Genetics Corp	Pancreas tumor	US	Phase 2 Clinical	16-Nov-2005
NewLink Genetics Corp	Pancreas tumor	US	Discovery	31-Jul-2005

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## algenpantucel-L DRUG NAMES

Names	Type
HyperAcute vaccine (pancreatic cancer), NewLink	
alpha(1,3)galactosyltransferase vaccine (pancreatic cancer), NewLink	
HyperAcute vaccine (intradermal, pancreatic cancer), Newlink Genetics	
algenpantucel-L	USAN
HAPa	Research Code
HyperAcute Pancreas	Trade Name
HAPa-1 + HAPa-2	

## algenpantucel-L CLINICAL TRIALS

### Trials by Phase and Condition Studied

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Pancreas tumor											
0	0	1	1	0	2	0	1	0	0	1	4

### Total Trials by Phase and Status

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Total by Phase and Status											
0	0	1	1	0	2	0	1	0	0	1	4

### Phase Definitions

#### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

#### Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

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## HyperAcute vaccine (intradermal, prostate cancer), Newlink Genetics

### HyperAcute vaccine (intradermal, prostate cancer), Newlink Genetics SNAPSHOT

Drug Name	HyperAcute vaccine (intradermal, prostate cancer), Newlink Genetics
Key Synonyms	
Originator Company	NewLink Genetics Corp
Active Companies	NewLink Genetics Corp
Inactive Companies	
Highest Status	Phase 2 Clinical
Active Indications	Hormone refractory prostate cancer
Target-based Actions	Galactosyltransferase modulator
Other Actions	Therapeutic vaccine;Anticancer
Technologies	Biological therapeutic;Cell therapy;Intradermal formulation
Last Change Date	02-Feb-2012

### HyperAcute vaccine (intradermal, prostate cancer), Newlink Genetics DEVELOPMENT PROFILE

#### SUMMARY

NewLink is developing an intradermally injected HyperAcute vaccine, which comprises killed allogenic tumor cells expressing murine alpha(1,3)galactosyltransferase, for the potential treatment of hormone resistant prostate cancer,. In March 2005, a phase I/II study began. The trial was completed in September 2007 ; however, in November 2009, the drug was listed as being in phase I development. In January 2012, development was ongoing.

### HyperAcute vaccine (intradermal, prostate cancer), Newlink Genetics DEVELOPMENT STATUS

#### CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
NewLink Genetics Corp	Hormone refractory prostate cancer	US	Phase 2 Clinical	03-Mar-2005

### HyperAcute vaccine (intradermal, prostate cancer), Newlink Genetics DEVELOPMENT STATUS

#### HISTORICAL DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
NewLink Genetics Corp	Hormone refractory prostate cancer	US	Discovery	31-Oct-2004

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## HyperAcute vaccine (intradermal, prostate cancer), Newlink Genetics DRUG NAMES

Names	Type
HyperAcute vaccine (prostate cancer), NewLink	
alpha(1,3)galactosyltransferase vaccine (prostate cancer), NewLink	
HyperAcute vaccine (intradermal, prostate cancer), Newlink Genetics	

## HyperAcute vaccine (intradermal, prostate cancer), Newlink Genetics CLINICAL TRIALS

### Trials by Phase and Condition Studied

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Hormone refractory prostate cancer											
0	0	0	0	0	0	0	1	0	0	0	1

### Total Trials by Phase and Status

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Total by Phase and Status											
0	0	0	0	0	0	0	1	0	0	0	1

### Phase Definitions

#### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

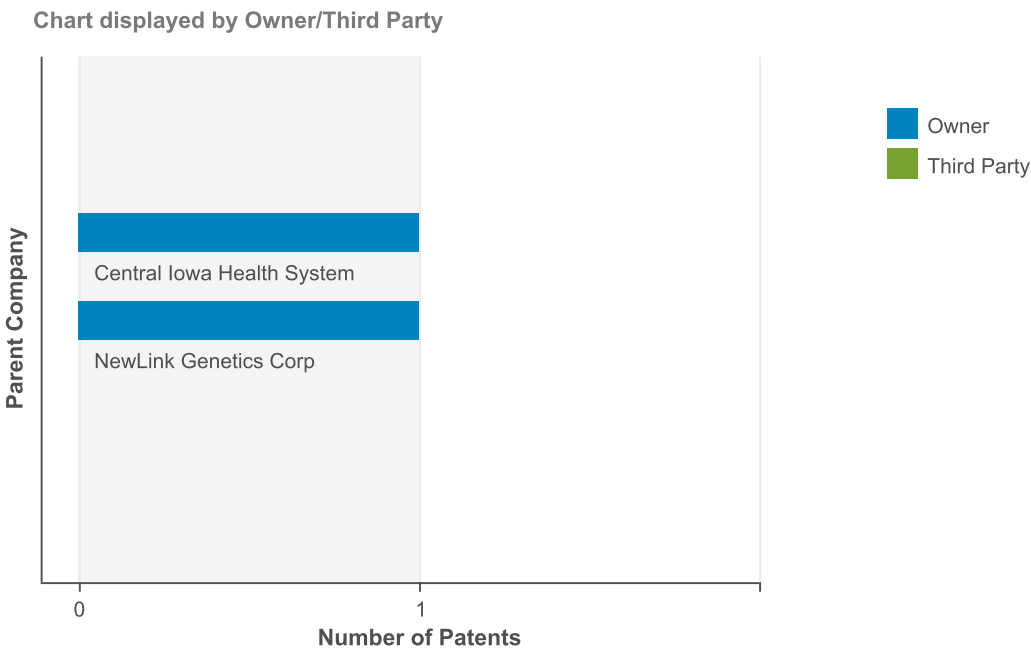
#### Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

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PATENTS

Patents by Parent Company Chart

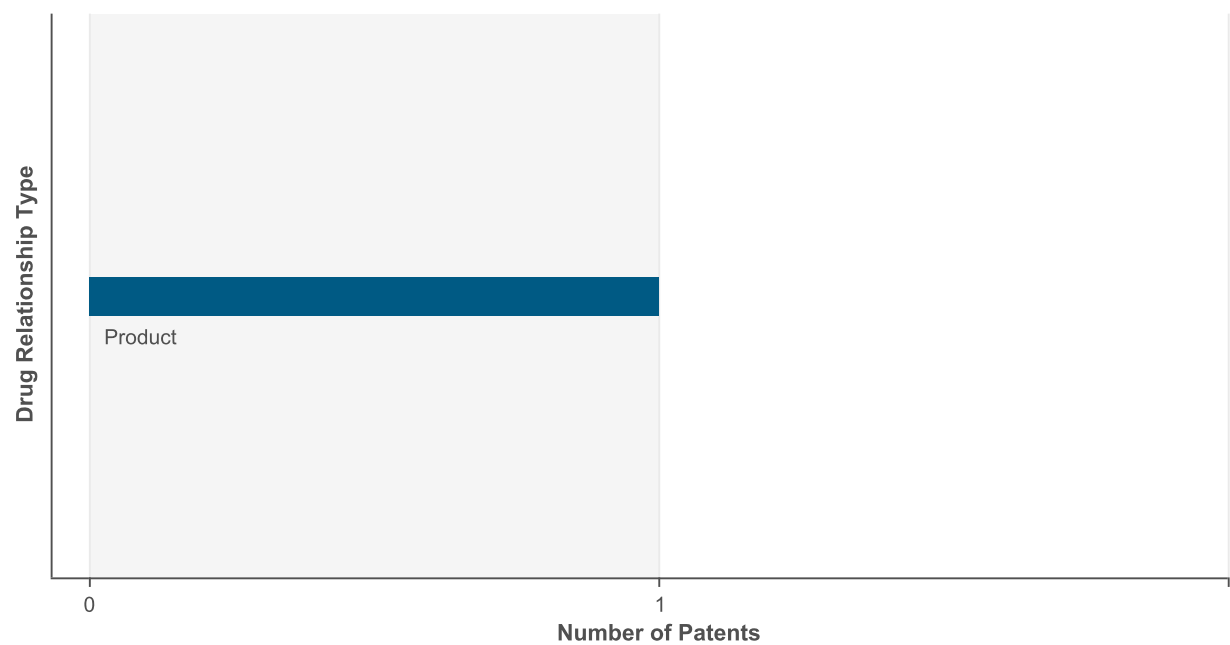


Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
NewLink Genetics Corp	1	0	1
Central Iowa Health System	1	0	1

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Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
Product	1

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## HyperAcute vaccine (melanoma), Newlink Genetics

### HyperAcute vaccine (melanoma), Newlink Genetics SNAPSHOT

Drug Name	HyperAcute vaccine (melanoma), Newlink Genetics
Key Synonyms	
Originator Company	NewLink Genetics Corp
Active Companies	NewLink Genetics Corp
Inactive Companies	
Highest Status	Phase 2 Clinical
Active Indications	Melanoma
Target-based Actions	Galactosyltransferase modulator
Other Actions	Therapeutic vaccine;Anticancer
Technologies	Biological therapeutic;Parenteral formulation unspecified;Cell therapy
Last Change Date	21-Jun-2012

### HyperAcute vaccine (melanoma), Newlink Genetics DEVELOPMENT PROFILE

#### SUMMARY

NewLink Genetics is developing an alpha(1,3)galactosyltransferase xenoepitope vaccine, using its HyperAcute technology, for the potential treatment of melanoma. In March 2006, a phase I/II trial began ; in August 2009, an additional phase II trial was ongoing ; in June 2010, positive preliminary results from the phase II study were presented. In November 2011, the vaccine was listed as being in phase II development and at that time, the company was seeking to outlicense the vaccine .

### HyperAcute vaccine (melanoma), Newlink Genetics DEVELOPMENT STATUS

#### CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
NewLink Genetics Corp	Melanoma	US	Phase 2 Clinical	31-Mar-2006

### HyperAcute vaccine (melanoma), Newlink Genetics DEVELOPMENT STATUS

#### HISTORICAL DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
NewLink Genetics Corp	Melanoma	US	Clinical	08-Jun-2004

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## HyperAcute vaccine (melanoma), Newlink Genetics DRUG NAMES

Names	Type
alpha(1,3)galactosyl xenoepitope vaccine (HyperAcute, melanoma), NewLink Genetics	
HyperAcute vaccine (melanoma), Newlink Genetics	
HyperAcute melanoma	

## HyperAcute vaccine (melanoma), Newlink Genetics CLINICAL TRIALS

### Trials by Phase and Condition Studied

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Melanoma											
0	0	0	0	0	0	0	1	0	0	0	1
Stage III melanoma											
0	0	0	0	0	1	0	0	0	0	0	1
Stage IV melanoma											
0	0	0	0	0	1	0	0	0	0	0	1

### Total Trials by Phase and Status

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Total by Phase and Status											
0	0	0	0	0	1	0	1	0	0	0	2

### Phase Definitions

#### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

#### Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

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## 1-methyltryptophan

### 1-methyltryptophan SNAPSHOT

Drug Name	1-methyltryptophan
Key Synonyms	
Originator Company	NewLink Genetics Corp
Active Companies	NewLink Genetics Corp
Inactive Companies	
Highest Status	Phase 2 Clinical
Active Indications	Solid tumor
Target-based Actions	Indoleamine-pyrrole-2,3-dioxygenase inhibitor
Other Actions	Anticancer;Immunostimulant
Technologies	Tablet formulation;Small molecule therapeutic;Oral formulation
Last Change Date	24-Sep-2012

### 1-methyltryptophan DEVELOPMENT PROFILE

#### SUMMARY

NewLink Genetics is developing an oral small molecule, 1-methyltryptophan (1-MT, D-1MT, D-1-methyltryptophan, indoximod, NLG-8189, structure shown) (presumed to be NLG-001), the lead from brassinin-derived indoleamine 2,3-dioxygenase (IDO) inhibitors, for the potential treatment of solid tumor,.. A phase I/II trial began in December 2009 ; in January 2012, two phase I/II trials were ongoing. In November 2011, the company was seeking to outlicense the drug.

### 1-methyltryptophan DEVELOPMENT STATUS

#### CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
NewLink Genetics Corp	Solid tumor	US	Phase 2 Clinical	31-Dec-2009

### 1-methyltryptophan DEVELOPMENT STATUS

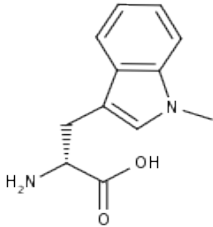
#### HISTORICAL DEVELOPMENT STATUS

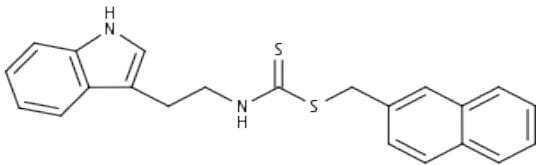
Company	Indication	Country	Development Status	Date
NewLink Genetics Corp	Solid tumor	US	Phase 1 Clinical	31-Oct-2007
NewLink Genetics Corp	Solid tumor	US	Discovery	14-Nov-2005

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## 1-methyltryptophan CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
	4
	
Name	Type
D-1MT	Research Code
D-1-methyltryptophan	
1-methyl-D-tryptophan	

CAS Registry Number:	Confidence Level:
	3
	

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## 1-methyltryptophan DRUG NAMES

Names	Type
indoleamine 2,3-dioxygenase inhibitors (solid tumor), Newlink Genetics NLG-001	Research Code
1-methyltryptophan	
1-methyl-D-tryptophan	
D-1MT	Research Code
D-1-methyltryptophan	
NLG-8189	Research Code
indoximod	

## 1-methyltryptophan CLINICAL TRIALS

### Trials by Phase and Condition Studied

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On- going	All	On- going	All	On- going	All	On- going	All	On- going	All	On- going	All
Solid tumor											
0	0	0	0	0	0	0	3	0	0	0	3
Advanced solid tumor											
0	0	0	0	0	0	2	2	0	0	2	2
Breast tumor											
0	0	0	0	0	0	1	2	0	0	1	2
Hormone refractory prostate cancer											
0	0	0	0	1	1	0	0	0	0	1	1
Melanoma											
0	0	0	0	0	0	0	1	0	0	0	1
Pancreas tumor											
0	0	0	0	0	0	0	1	0	0	0	1
Lung tumor											
0	0	0	0	0	0	0	1	0	0	0	1

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Total Trials by Phase and Status

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Total by Phase and Status											
0	0	0	0	1	1	3	6	0	0	4	7

Phase Definitions

Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

1-methyltryptophan DEALS AND PATENTS

DEALS

Deals by Parent Company Chart



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Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
NewLink Genetics Corp	0	0	2	0	2
Georgia Health Sciences University	1	0	0	0	1
US Government	1	0	0	0	1

Deals by Type Chart



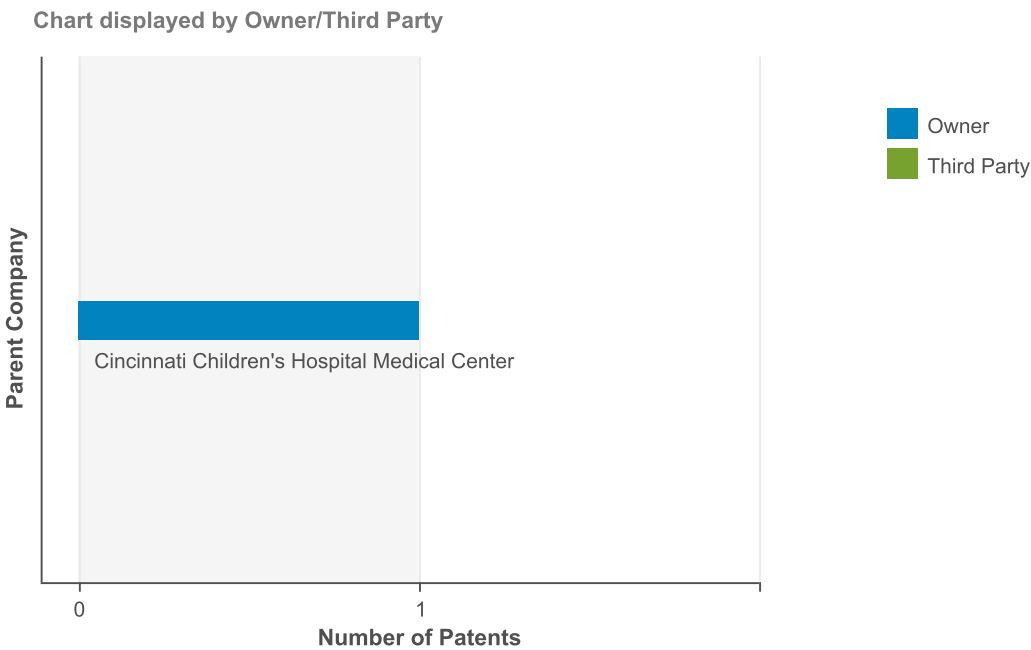
Deals by Type Table

Deal Type	Active	Inactive	Total
Drug - CRADA	1	0	1
Patent - Exclusive Rights	1	0	1

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PATENTS

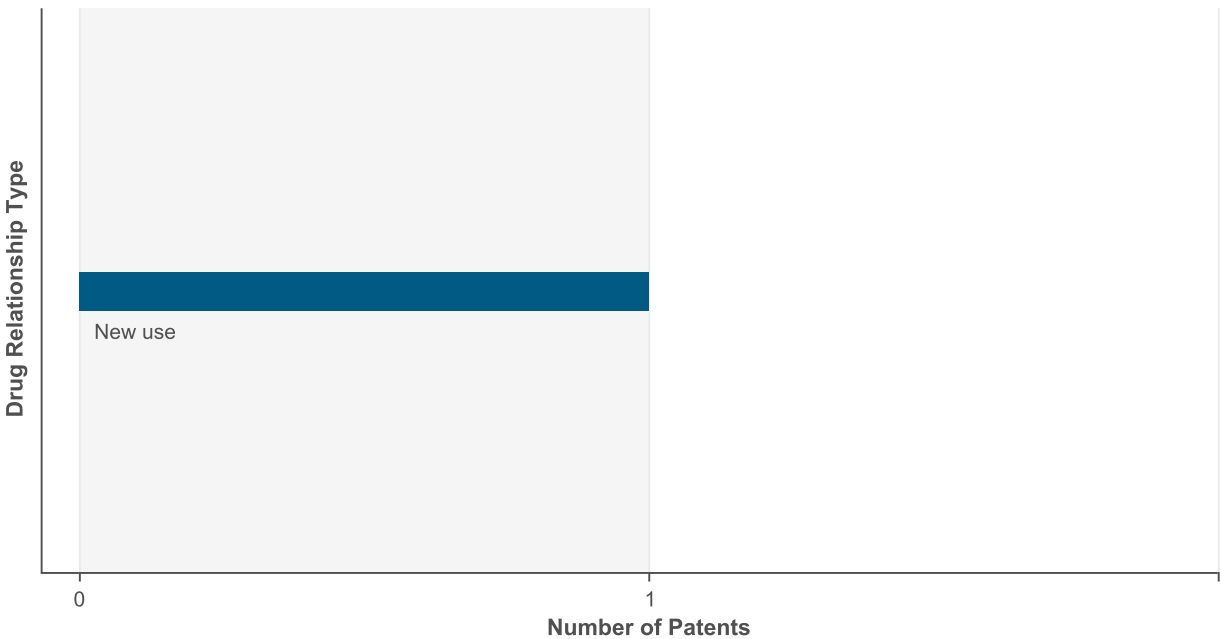
Patents by Parent Company Chart



Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Cincinnati Children's Hospital Medical Center	1	0	1

Patents by Drug Relationship Type Chart



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Patents by Drug Relationship Type Table

Drug Relationship	Total
New use	1

## HyperAcute vaccine (breast cancer), NewLink

### HyperAcute vaccine (breast cancer), NewLink SNAPSHOT

Drug Name	HyperAcute vaccine (breast cancer), NewLink
Key Synonyms	
Originator Company	NewLink Genetics Corp
Active Companies	NewLink Genetics Corp
Inactive Companies	
Highest Status	Phase 1 Clinical
Active Indications	Breast tumor
Target-based Actions	Galactosyltransferase modulator
Other Actions	Therapeutic vaccine;Anticancer
Technologies	Tumor antigen;Cell therapy;Biological therapeutic;Parenteral formulation unspecified
Last Change Date	19-Apr-2012

### HyperAcute vaccine (breast cancer), NewLink DEVELOPMENT PROFILE

#### SUMMARY

NewLink Genetics is developing a HyperAcute vaccine which comprises alpha(1,3)galactosyltransferase-expressing allogeneic tumor cells, for the potential treatment of breast cancer. In August 2004, a phase I/II trial began; however, by July 2006, the trial had been terminated. In November 2009, the drug was listed as being in phase I development. In January 2012, development was ongoing.

### HyperAcute vaccine (breast cancer), NewLink DEVELOPMENT STATUS

#### CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
NewLink Genetics Corp	Breast tumor	US	Phase 1 Clinical	31-Aug-2004

### HyperAcute vaccine (breast cancer), NewLink DEVELOPMENT STATUS

#### HISTORICAL DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
NewLink Genetics Corp	Breast tumor	US	Discovery	02-May-2003

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## HyperAcute vaccine (breast cancer), NewLink DRUG NAMES

Names	Type
HyperAcute vaccine (breast cancer), NewLink	
alpha(1,3)galactosyltransferase vaccine (breast cancer), Newlink Genetics	

## HyperAcute vaccine (breast cancer), NewLink CLINICAL TRIALS

### Trials by Phase and Condition Studied

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Breast tumor											
0	0	0	0	0	0	0	1	0	0	0	1

### Total Trials by Phase and Status

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Total by Phase and Status											
0	0	0	0	0	0	0	1	0	0	0	1

### Phase Definitions

#### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

#### Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

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## HyperAcute immunotherapeutics (cancer), NewLink Genetics

### HyperAcute immunotherapeutics (cancer), NewLink Genetics SNAPSHOT

Drug Name	HyperAcute immunotherapeutics (cancer), NewLink Genetics
Key Synonyms	
Originator Company	NewLink Genetics Corp
Active Companies	NewLink Genetics Corp
Inactive Companies	
Highest Status	Discovery
Active Indications	Cancer
Target-based Actions	Galactosyltransferase modulator
Other Actions	Anticancer
Technologies	Tumor antigen;Cell therapy;Biological therapeutic;Parenteral formulation unspecified
Last Change Date	02-Feb-2012

### HyperAcute immunotherapeutics (cancer), NewLink Genetics DEVELOPMENT PROFILE

#### SUMMARY

NewLink Genetics is investigating HyperAcute immunotherapeutics, comprised of alpha (1,3)galactosyltransferase-expressing allogeneic tumor cells, for the potential treatment of cancer. In January 2012, the program was in lead optimization.

### HyperAcute immunotherapeutics (cancer), NewLink Genetics DEVELOPMENT STATUS

#### CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
NewLink Genetics Corp	Cancer	US	Discovery	25-Jan-2012

### HyperAcute immunotherapeutics (cancer), NewLink Genetics DRUG NAMES

Names	Type
HyperAcute immunotherapeutics (cancer), NewLink Genetics	

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## IDO pathway inhibitors (cancer), NewLink Genetics

### IDO pathway inhibitors (cancer), NewLink Genetics SNAPSHOT

Drug Name	IDO pathway inhibitors (cancer), NewLink Genetics
Key Synonyms	
Originator Company	NewLink Genetics Corp
Active Companies	NewLink Genetics Corp
Inactive Companies	
Highest Status	Discovery
Active Indications	Cancer
Target-based Actions	Indoleamine-pyrrole-2,3-dioxygenase inhibitor
Other Actions	Anticancer;Immunostimulant
Technologies	Small molecule therapeutic
Last Change Date	02-Feb-2012

### IDO pathway inhibitors (cancer), NewLink Genetics DEVELOPMENT PROFILE

#### SUMMARY

NewLink Genetics is investigating indoleamine 2,3-dioxygenase (IDO) pathway inhibitors for the potential treatment of cancer. In January 2012, the program was listed as being in lead optimization.

### IDO pathway inhibitors (cancer), NewLink Genetics DEVELOPMENT STATUS

#### CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
NewLink Genetics Corp	Cancer	US	Discovery	25-Jan-2012

### IDO pathway inhibitors (cancer), NewLink Genetics DRUG NAMES

Names	Type
IDO pathway inhibitors (cancer), NewLink Genetics	
indoleamine 2,3-dioxygenase pathway inhibitors (cancer), NewLink Genetics	

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