
**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 27, 2013

ZIOPHARM Oncology, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33038
(Commission
File Number)

84-1475672
(IRS Employer
Identification No.)

One First Avenue, Parris Building 34, Navy Yard Plaza
Boston, Massachusetts
(Address of Principal Executive Offices)

02129
(Zip Code)

(617) 259-1970
(Registrant's telephone number, including area code)

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- 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)).
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-

Item 8.01 Other Events

ZIOPHARM Oncology, Inc., or the Company, will present the attached discussion of the Company's DNA-based therapeutics at BioCentury's NewsMakers in the Biotech Industry Conference in New York, New York, being held on September 27, 2013.

A copy of the above referenced presentation is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Presentation of the Company dated September 27, 2013

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.

ZIOPHARM Oncology, Inc.

By: /s/ Caesar J. Belbel
Name: Caesar J. Belbel
Title: Executive Vice President and Chief Legal Officer

Date: September 27, 2013

INDEX OF EXHIBITS

**Exhibit
No.**

Description

99.1

Presentation of the Company dated September 27, 2013



ZIOPHARM Oncology

The Future of Cancer Therapy

BioCentury Newsmakers

Jonathan Lewis, MD, PhD
Chief Executive Officer

www.ziopharm.com

September 2013

Forward-Looking Statements

This presentation contains certain forward-looking information about ZIOPHARM Oncology that is intended to be covered by the safe harbor for “forward-looking statements” provided by the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. Words such as “expect(s),” “feel(s),” “believe(s),” “will,” “may,” “anticipate(s)” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding our ability to successfully develop and commercialize our therapeutic products; our ability to expand our long-term business opportunities; financial projections and estimates and their underlying assumptions; and future performance. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include, but are not limited to: whether any of our therapeutic candidates will advance further in the clinical trials process and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether any of our therapeutic candidates will be successfully marketed if approved; whether our DNA-based biotherapeutics discovery and development efforts will be successful; our ability to achieve the results contemplated by our collaboration agreements; the strength and enforceability of our intellectual property rights; competition from pharmaceutical and biotechnology companies; the development of and our ability to take advantage of the market for DNA-based biotherapeutics; our ability to raise additional capital to fund our operations on terms acceptable to us; general economic conditions; and the other risk factors contained in our periodic and interim reports filed with the SEC including, but not limited to, our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, and our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013. Our audience is cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence or non-occurrence of any events.

ZIOP

1. Clinical stage synthetic biology cancer company
2. We believe we are the farthest advanced at regulating gene function *in vivo* in humans, regulating gene expression, and titrating levels of expression
3. Lead clinical program is Ad-RTS-IL-12
4. We have multiple novel programs driving towards IND, and expect at least 8 INDs through 2015
5. These are built on a similar platform to Ad-RTS-IL-12, and in place of IL-12 will include different genes of interest for immunotherapy, cell signal targeting and novel multigenic approaches
6. Data will be presented near-term at AACR/NCI/EORTC, SABCS, and additional scientific meetings and publications



DNA-Based Medicine Enables

- Therapies with desired biofunction to be *purpose-built*
- The concentration/dose of biologic therapy to be *precisely controlled*
- *Improvement in therapeutic index*, because potent biologic modifiers can be turned on and off and targeted to specific tissues and cells
- Pursuit of combination biologic therapy in an *economically feasible* manner

Foundation in Place for Significant Growth

Strategic focus on synthetic biology

- Powerful, scalable technology platform
- Potential for innovation in cancer-drug development:

$$\textit{Precision engineering} + \textit{Statistical modeling} + \textit{Tumor targeting} = \textit{New cancer treatment paradigm}$$

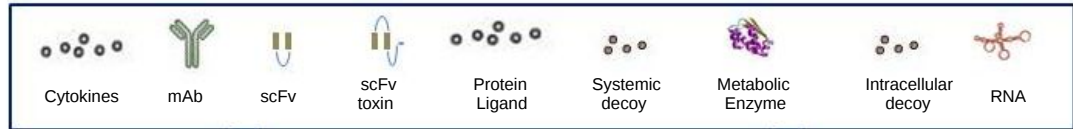
- ZIOP collaboration with Intrexon enables:
 - better control of therapeutic index/frequency
 - multigenic approaches
 - pipeline expansion with multiple INDs
 - attractive partnership opportunities

On Track to Execute

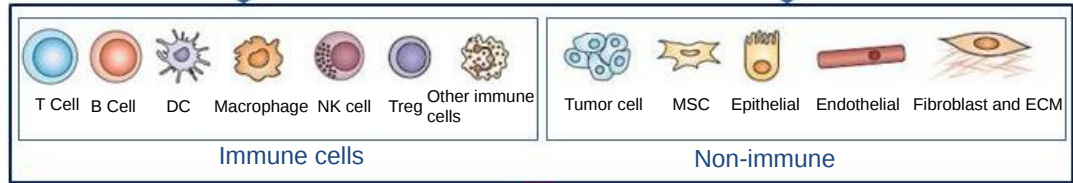
- Clinical stage synthetic biology platform (DNA and cell-based therapy) driving development
- Our advantage is that we are the farthest advanced at precisely regulating gene function *in vivo* in humans
- Multiple value-creating milestones in 2013/14
 - Pre-clinical/clinical data
 - Scientific publications and presentations
- Ad-IL-12 advancing through Phase 2 POC studies
- Poised to deliver multiple new INDs in 2014/15/16
 - New IND submissions will expand into new genes of interest, and cancer indications

Molecular and Cellular Oncology DNA-Coded Toolset

Effectors



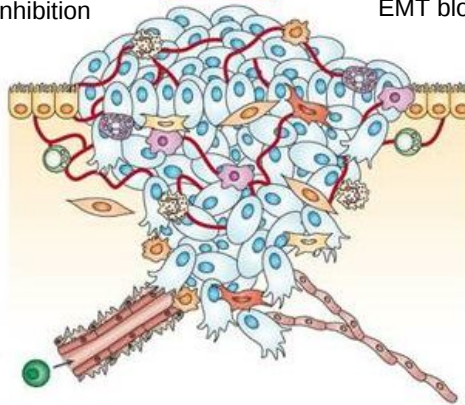
Cells



Anti-tumor function

- | | | |
|--|---|--|
| <ul style="list-style-type: none"> Direct tumor lysis ADCC Complement cytotoxicity Innate immunity stimulation Adaptive immunity stimulation Immune evasion inhibition | ↓ | <ul style="list-style-type: none"> Pro-apoptosis Necrosis Anti-angiogenesis Growth inhibition Anti-tumor metabolism EMT blockade |
|--|---|--|

Tumor and microenvironment



Intrexon Collaboration: Fueling the IND Engine

*Genetic control of cells
Controlled delivery of therapeutic proteins*



ZIOPHARM Oncology



INTREXON[®]

cancer drug
translational and
development expertise

gene engineering and
cell control technology

Promising portfolio of cancer therapeutics

Upcoming Milestones

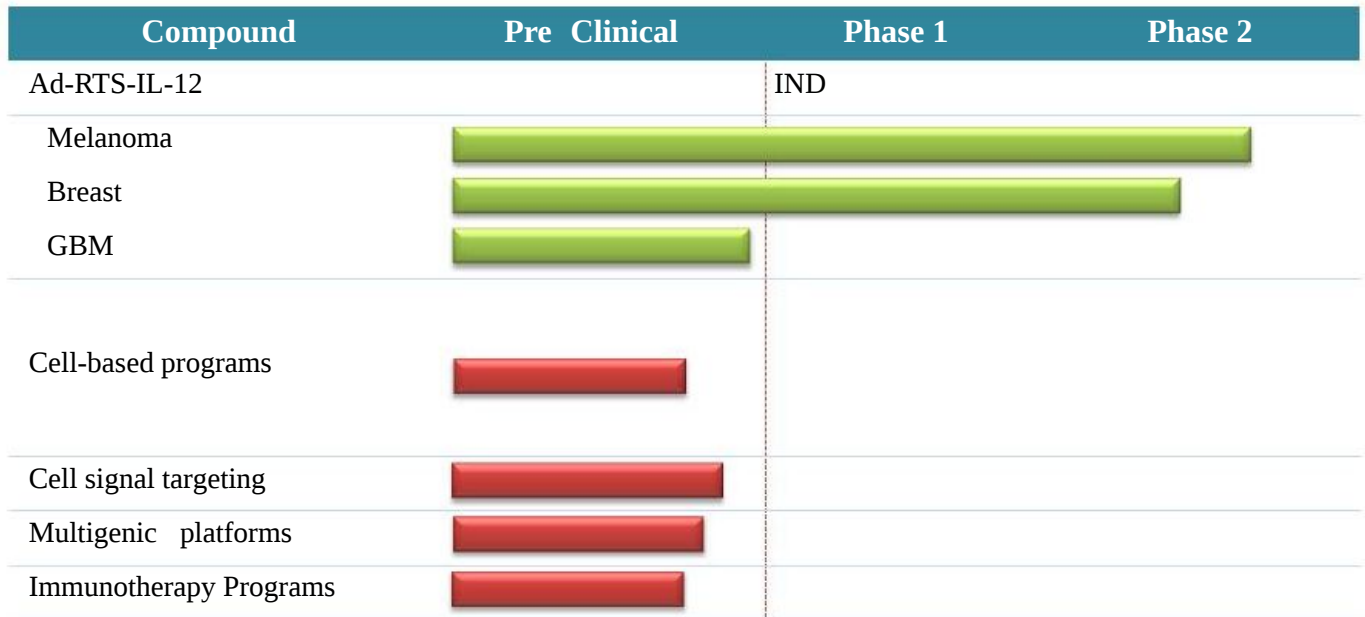
Program	Milestone	Timing
2013-2014		
IL-12	Phase 2 breast cancer study data	2H 2013/2014
	Phase 2 advanced melanoma study data	2H 2013/2014
	Initiate Phase 1/2 glioblastoma multiforme study	1H 2014
	Initiate Phase 2 melanoma combo study	1H 2014
	Initiate Phase 2 breast cancer combo study	1H 2014
Synthetic Biology	Report discovery and preclinical data	2H 2013/1H 2014
	Submit new INDs for monogenic/multigenic studies	2H 2014
Small Molecule Program	Report interim SCLC data (MATISSE)	1H 2014
Publications and Presentations	AACR-NCI-EORTC; SABCS; Scientific Publications	2H 2013
Corporate	Seek partnering opportunities	Ongoing
	Pursue new cancer targets	
	Divest non-strategic assets	

The Potential of DNA-Based Therapeutics

- *Improve* treatment of all cancers, starting with breast cancer, melanoma, and GBM
- *Treat* currently incurable cancers
- *Generate* a multi-billion-dollar opportunity

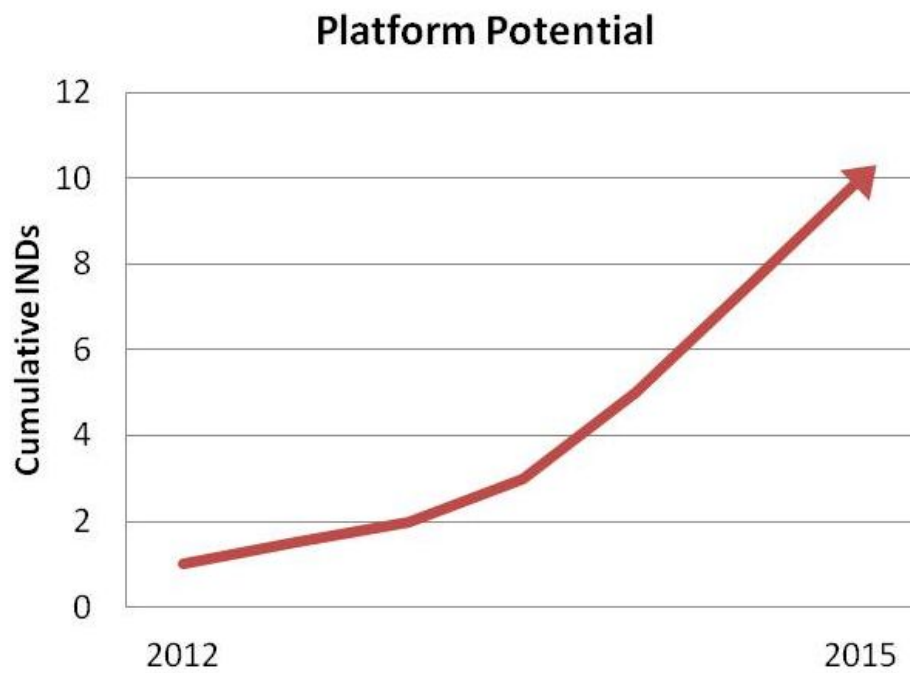


A Growing Oncology Portfolio



Aggressive IND Strategy Supporting Future Growth

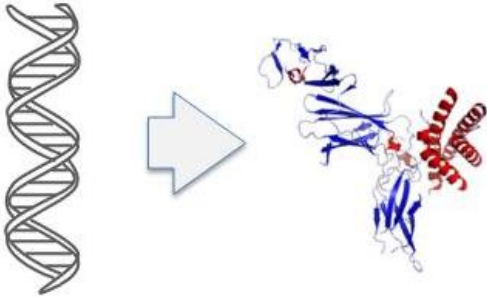
Multiple Opportunities for External Partnering



DNA-Based Therapeutics

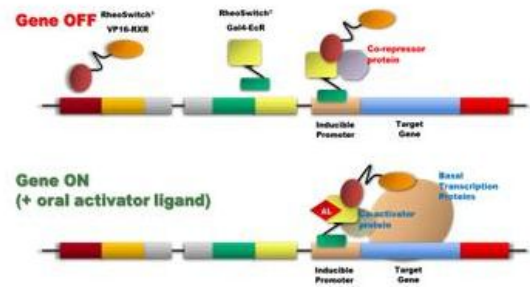
*Controlled Delivery of Therapeutic Proteins with RheoSwitch®:
This is the most advanced clinical method to turn genes on and off*

Gene Expression



Local
High Potency
Monogenic/Multigenic

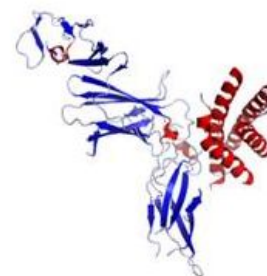
RheoSwitch®



Dose-control
Orally activated
biologic on/off switch

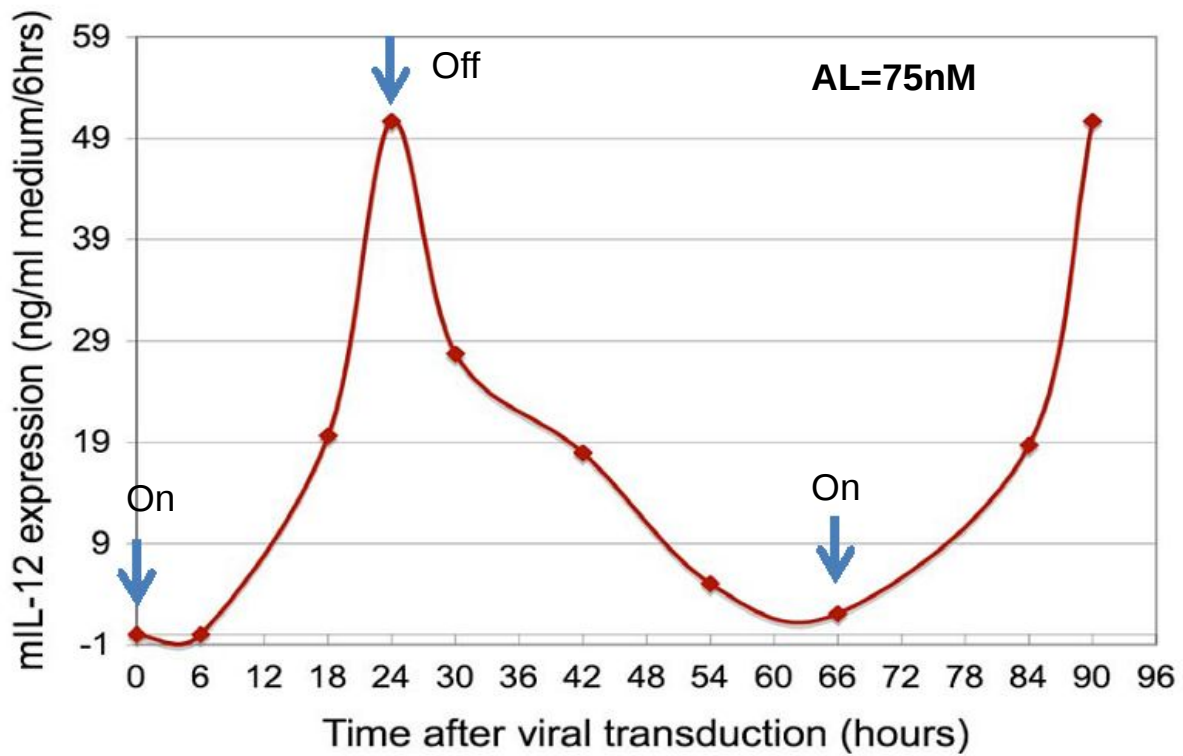
Initial Target: *Interleukin-12, A Potent Cancer Therapeutic*

- Cytokine with anti-tumor effects
- Potent Stimulation of T-cells and gamma interferon
- Narrow therapeutic index/ toxicity has limited IL-12 utility



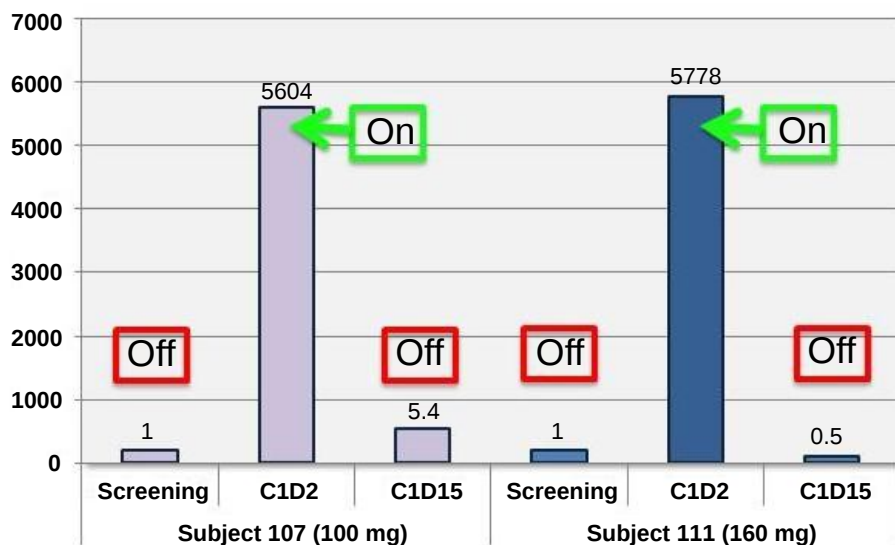
***Improved therapeutic index may be possible
using RheoSwitch[®] technology***

IL-12 Production is Modulated by Activator Ligand in HT 1080 Cells



Regulated expression of IL-12 in the tumor by switch control

IL-12 Fold Change Relative to Screening Visit


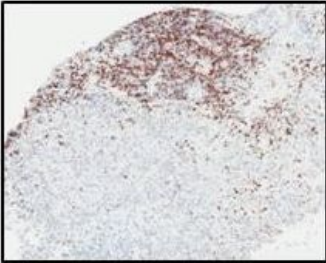
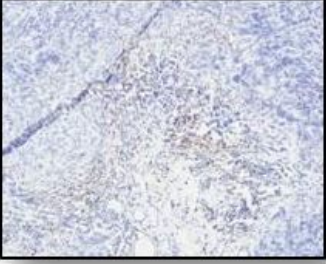



Subjects received intratumoral injection of 1×10^{12} viral particles (INXN-2001) on Day 1 of each cycle and INXN-1001 (subject 107, 100 mg; subject 111, 160 mg) on Days 1-7 of each cycle. Genomic DNA and total RNA were extracted and analyzed as described.¹

¹Livak KJ and TD Schmittgen. 2001. Methods 25(4):402-8.

ASCO 2013

Cytotoxic T Cells & Memory T Cells Increase in Tumor following Treatment with Ad-RTS-hIL-12

Subject 111 (160 mg)	Screening	C1D15
CD8 ⁺		
CD45RO ⁺		

Images were obtained using an Aperio ScanScope XT whole-slide imager and digitized at 20x.

ASCO 2013

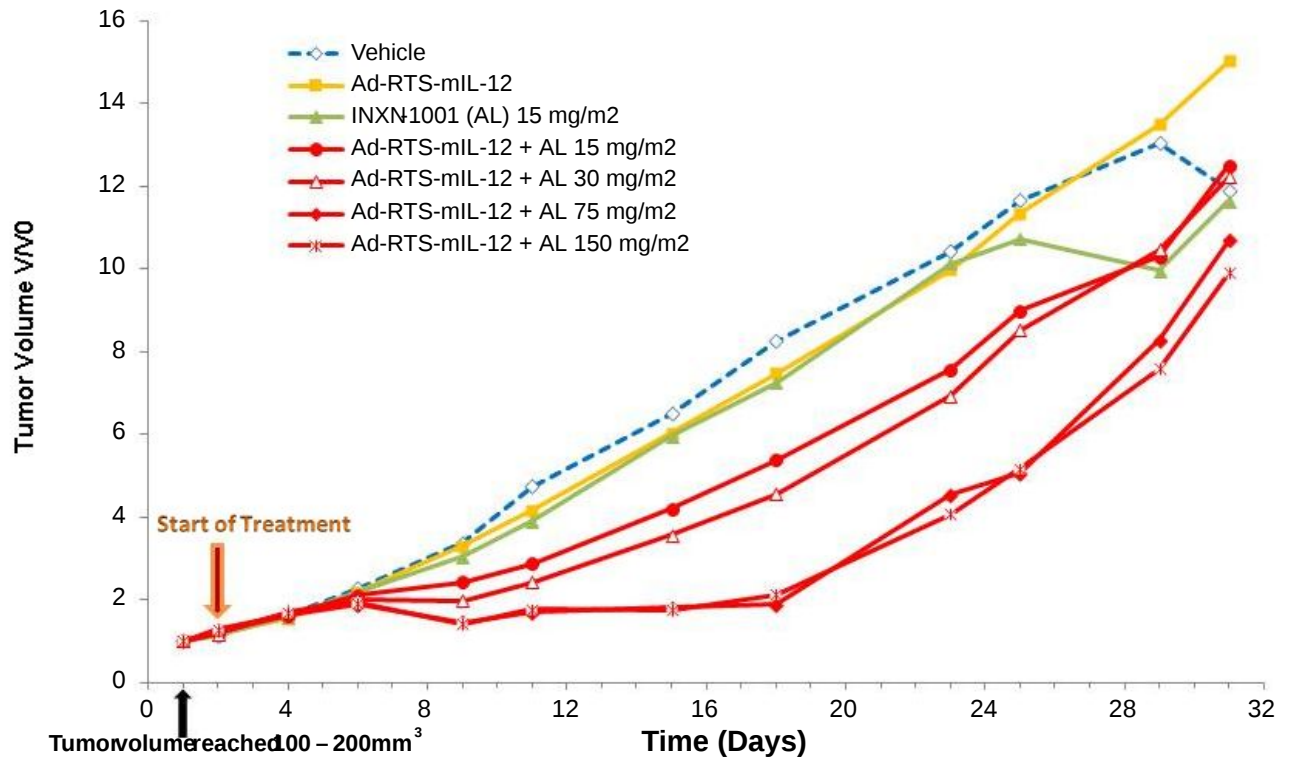
Prominent Inflammatory Response Correlates with High levels of IFN- γ



- Initial increase in lesion size due to inflammatory response seen at Cycle 1 Day 16
- Lesion was undetectable at Cycle 2 Day 1
- Subject ultimately progressed and was taken off study

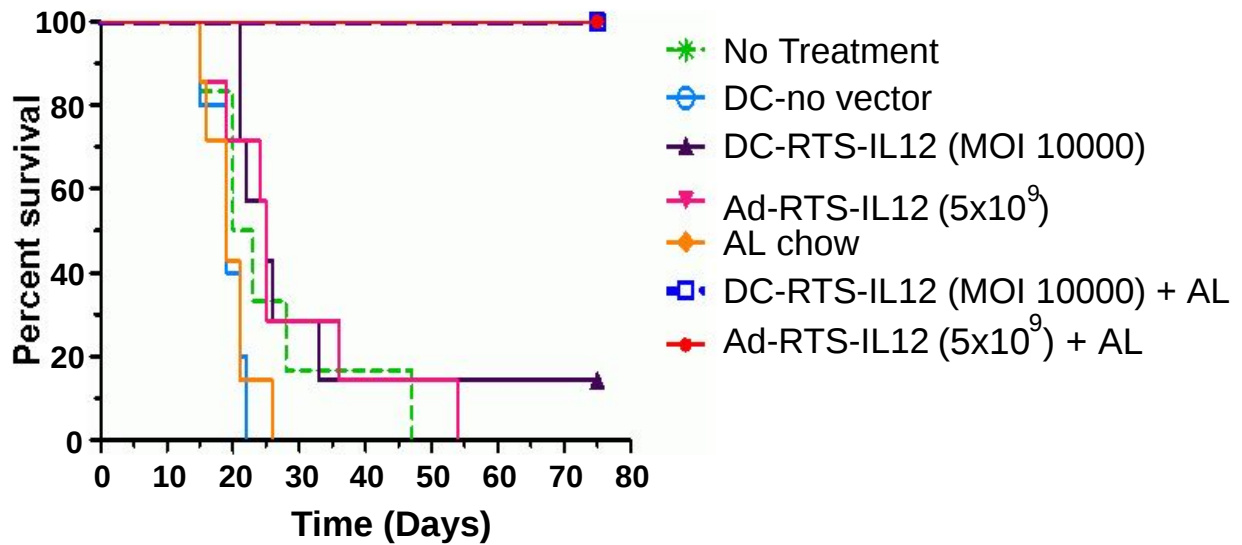


Dose-dependent Anti-Tumor Activity of Ad-RTS-mIL-12 + Activator Ligand (AL) in Murine 4T1 Breast Cancer Model



Glioblastoma Multiforme: *IL-12* Preclinical Activity

Kaplan Meier Survival in GL261 Orthotopic Syngeneic Mouse Glioma Model



INXN-1001 dosing Day 4 to EOS at ~ 675 mg/m²/day in chow; DC -RTS-IL12 or Ad-RTS-IL12 on Day 5

100% survival observed with Ad-RTS-IL-12 + AL or DC-RTS-IL-12 + AL

Highlights of IL-12 Program

- Currently demonstrating safety and efficacy in Phase 2 POC studies
- Preparing for combination studies in melanoma, breast cancer
- Expanding clinical program to GBM

IL-12 program reaching key milestones in 2013/2014

Significant Market Potential for IL-12

	Incidence
Melanoma	76,690
Breast Cancer	234,580
Glioblastoma	18,000

Source: American Cancer Society 2013/Schwartzbaum 2006

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