

**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): **May 30, 2009**

**CELLEX THERAPEUTICS, INC.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**0-15006**  
(Commission File Number)

**13-3191702**  
(IRS Employer  
Identification No.)

**119 Fourth Avenue**  
**Needham, Massachusetts**  
(Address of principal executive offices)

**02494-2725**  
(Zip Code)

Registrant's telephone number, including area code: **(781) 433-0771**

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))

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**Item 8.01. Other Events**

*May 30, 2009 Joint Press Release*

On May 30, 2009, Pfizer, Inc. and the Registrant issued a press release concerning certain data with respect to Phase 2 ACTIVATE and ACT II studies with respect to its CDX-110 product, a copy of which is attached hereto as Exhibit 99.1.

*June 1, 2009 Press Release and Related Slides*

On June 1, 2009, the Registrant issued a press release concerning certain data with respect to two Phase 1 studies with respect to its CDX-1307 product, a copy of which is attached hereto as Exhibit 99.2. In connection with this press release, on June 1, 2009, the Registrant conducted an oral presentation, including presentation slides, at the 45th Annual Meeting of the American Society of Clinical Oncology in Orlando, Florida, concerning certain data regarding the two Phase I studies with respect to its CDX-1307 product. A copy of the presentation is attached hereto as Exhibit 99.3.

The press releases and the slides referred to above contain forward-looking information about product candidates, CDX-110 and/or CDX-1307, including their potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for such product candidate as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments. Other factors that might cause actual results to differ materially from those in the forward-looking statements including those set forth under the headings "Business," "Risk Factors" and Management's Discussion and Analysis of Financial Condition and Results of Operations" in each of the Registrant's Annual Report on Form 10-K, its current Reports on Form 8-K, as well as those described in its other press releases and filings with the Securities and Exchange Commission, from time to time. You should carefully review all of these factors, and you should be aware that there may be other factors that could cause these differences. The forward-looking statements were based on information, plans and estimates at the date of the press release, and the Registrant does not promise to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.

**Item 9.01. Financial Statements and Exhibits**

**(d) Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
Exhibit 99.1	Joint Press release issued by Celldex Therapeutics, Inc. and Pfizer, Inc., dated May 30, 2009.
Exhibit 99.2	Press release issued by Celldex Therapeutics, Inc., dated June 1, 2009.
Exhibit 99.3	Celldex Therapeutics, Inc. Slide Presentation, June 1, 2009.

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### SIGNATURE

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.

### CELLDEX THERAPEUTICS, INC.

By: /s/ Avery W. Catlin  
Name: Avery W. Catlin  
Title: Senior Vice President / Chief Financial Officer

Dated: June 1, 2009

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### EXHIBIT INDEX

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ASCO Abstract No. 2021

EMBARGOED UNTIL SATURDAY, MAY 30, 2009 at 8:00 a.m. EDT

**Pfizer and Celldex Therapeutics Present Update on CDX-110 (PF-04948568) Phase 2 Brain Cancer Studies at 45<sup>th</sup> Annual ASCO Meeting**

- Updated follow-up of time to progression and overall survival reported from Phase 2 clinical trials with CDX-110 (PF-04948568) and temozolomide -

ORLANDO—(Business Wire)—May 30, 2009— Pfizer (NYSE: PFE) and Celldex Therapeutics (NASDAQ: CLDX) today announced the presentation of updated data from two clinical trials of CDX-110 in newly-diagnosed glioblastoma multiforme (GBM) at the 45<sup>th</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO). CDX-110, an investigational immunotherapeutic vaccine that targets the tumor-specific molecule, epidermal growth factor receptor variant III (EGFRvIII), was developed by Celldex Therapeutics and is now partnered with Pfizer.

“Data from the 40 evaluable patients in ACTIVATE and ACT II continue to suggest that vaccination with CDX-110 may be able to improve time to tumor recurrence and overall survival when used in patients with newly-diagnosed GBM. These data also continue to suggest that tolerability and side effects associated with CDX-110 are minimal. These results are very encouraging and we look forward to the results from the ongoing multi-center ACT III Phase 2 study,” said John H. Sampson, MD, PhD, Associate Deputy Director of The Preston Robert Tisch Brain Tumor Center at Duke University Medical Center.

**ACTIVATE Results:**

In this single arm Phase 2 study, 18 patients with newly diagnosed and optimally resected EGFRvIII-positive GBM received CDX-110 as a monotherapy following completion of chemoradiation with concurrent temozolomide. Median overall survival (OS) was 26 months and median time to progression (TTP) was 14.2 months. Additionally, three patients remain without relapse more than 4 years from surgery and continue to receive the vaccine within the clinical trial.

**ACT II Results:**

In this single arm Phase 2 study, 22 patients with newly diagnosed and optimally resected EGFRvIII-positive GBM received CDX-110 in combination with maintenance temozolomide after having completed chemoradiation with concurrent temozolomide. Median time to progression (TTP) is 15.2 months and three patients continue without relapse after more than two years. Results to date from this ongoing study estimate median overall survival to be 23.6 months (data are not yet final). In addition, and in line with preclinical data that suggested the

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combination with temozolomide could augment immune responses, patients show robust serological evidence of an immune response against EGFRvIII.

Efficacy data from both ACTIVATE and ACT II compare favorably to data for a historical control group of 17 patients, matched for EGFRvIII expression, extent of resection and performance status (Median TTP: 6.3 months; Median OS: 15.0 months). In both studies, CDX-110 was generally well tolerated with local injection site reactions being the most commonly reported toxicity.

**Additional Results:**

In addition, preliminary data from a pilot study in a small number of patients with newly diagnosed GBM will be presented. In this study, CDX-110 was given in combination with daclizumab, an antibody that blocks suppressive T cells, to determine whether this combination could further augment immune responses. This data will be presented in a poster session on Sunday, May 31 from 8:00am — 12:00pm EDT.

ACT III, a multicenter, single-arm Phase 2 clinical trial in GBM in which all patients will receive CDX-110 in combination with maintenance temozolomide, is ongoing. Total enrollment is expected to be approximately 60 patients. In addition, Pfizer and Celldex are working on the design of a randomized Phase 2 study in GBM to compare CDX-110 plus standard of care to standard of care alone.

**About CDX-110 (PF-04948568)**

CDX-110 is an investigational immunotherapeutic vaccine that targets the tumor-specific molecule epidermal growth factor receptor variant III (EGFRvIII). EGFRvIII is a mutated form of the epidermal growth factor receptor (EGFR) that is only expressed in cancer cells and not in normal tissue and is a transforming oncogene that can directly contribute to cancer cell growth. It is reported to be present in 25-40 percent of GBM tumors.

**About Celldex Therapeutics, Inc.**

Celldex Therapeutics is an integrated biopharmaceutical company that applies its comprehensive Precision Targeted Immunotherapy Platform to generate a pipeline of candidates to treat cancer and other difficult-to-treat diseases. Celldex’s immunotherapy platform includes a complementary portfolio of monoclonal antibodies, antibody-targeted vaccines and immunomodulators to create novel disease-specific drug candidates. For more information, please visit <http://www.celldextherapeutics.com>.

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**About Pfizer Oncology**

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options for cancer patients worldwide. Our robust pipeline consists of 21 biologics and small molecules in clinical development across four scientific platforms — anti-angiogenesis, signal transduction, immune-oncology, and cytotoxic potentiators. Pfizer Oncology has over 200 clinical trials including robust Phase 3 programs in renal cell carcinoma, prostate cancer, non-small cell lung cancer, metastatic breast cancer, colorectal cancer, and hepatocellular carcinoma.

By working collaboratively with academic institutions, researchers, governments, and licensing partners, Pfizer Oncology strives to transform treatment by targeting the right drug for the right patient at the right time.

For more information, please visit [www.Pfizer.com](http://www.Pfizer.com).

**Pfizer Inc: Working together for a healthier world™**

Founded in 1849, Pfizer is the world's premier biopharmaceutical company taking new approaches to better health. We discover, develop, manufacture and deliver quality, safe and effective prescription medicines to treat and help prevent disease for both people and animals. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality health care and health system support. At Pfizer, more than 80,000 colleagues in more than 90 countries work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide.

**PFIZER DISCLOSURE NOTICE:**

The information contained in this release is as of May 30, 2009. Pfizer assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a product candidate, CDX-110, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for such product candidate as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

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A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and in its reports on Form 10-Q and Form 8-K.

**CELLDEX DISCLOSURE NOTICE:** The information contained in this release is as of May 30, 2009. Celldex assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains information about a product candidate, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for such product candidate as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; decisions by Pfizer concerning the timing, scope and progress of research, development and commercialization of the product candidate, which decisions are outside of our control; and competitive developments.

A further description of risks and uncertainties can be found in Celldex's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and in its reports on Form 10-Q and Form 8-K.

**CELLDEX CONTACT:**

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Jack Cox  
212-733-5017

<http://www.celldextherapeutics.com>

[http://www.Pfizer.com /](http://www.Pfizer.com/)

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## Celldex Therapeutics Announces CDX-1307 Clinical Data at 45<sup>th</sup> Annual ASCO Meeting

- Novel vaccine strategy targeting dendritic cells in combination with TLR agonists shows favorable safety profile and strong immune responses in Phase 1 study -

ORLANDO—(Business Wire)—June 1, 2009—Celldex Therapeutics, Inc. (NASDAQ: CLDX) today announced that promising clinical data from two Phase 1 studies of CDX-1307 were presented at the 45<sup>th</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO) in Orlando, Florida. CDX-1307 is a dendritic cell targeted immunotherapy designed to stimulate an immune response against hCG Beta (hCG-β), a target antigen frequently expressed in epithelial tumors.

The comprehensive Phase 1 studies include over 70 patients and were designed to investigate the safety and immunogenicity of CDX-1307 using different routes of administration and in combination with immunostimulants, including GM-CSF and toll-like receptor agonists (poly-ICLC/Hiltonol or R848/resiquimod). CDX-1307 was well tolerated with no dose limiting toxicity to date. Robust immune responses were generated, and 7 patients with breast, colorectal and pancreatic cancers experienced disease stabilization for 2.2+ to 6.5+ months.

“We have made good progress with this innovative approach that combines multiple agents from both our proprietary immunotherapy platform and recently in-licensed assets,” said Anthony Marucci, President and Chief Executive Officer at Celldex Therapeutics. “We intend to enter CDX-1307 into Phase 2 clinical trials in the second half of 2009.”

CDX-1307 is in early-stage development for the treatment of colorectal, pancreatic, bladder, ovarian and breast cancers that express the beta chain of human chorionic gonadotropin (hCG-β), an antigen often found in these tumors but not in most normal tissues. CDX-1307 is a fusion protein composed of the hCG-β antigen attached to a human monoclonal antibody that specifically targets the mannose receptors on dendritic cells. This antibody-vaccine is designed to deliver the antigen hCG-β directly to dendritic cells, activating the patient’s immune system against cancers that express hCG-β. This targeted approach contrasts with earlier generation vaccines that required dendritic cells to find and ingest passive vaccines.

### About Celldex Therapeutics, Inc.

Celldex Therapeutics is an integrated biopharmaceutical company that applies its comprehensive Precision Targeted Immunotherapy Platform to generate a pipeline of candidates to treat cancer and other difficult-to-treat diseases.

Celldex’s immunotherapy platform includes a complementary portfolio of monoclonal antibodies, antibody-targeted vaccines and immunomodulators to create novel disease-specific drug candidates. For more information, please visit <http://www.celldextherapeutics.com>.

**Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995:** *This release contains “forward-looking statements” made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including those related to the Company’s strategic focus and the future development and commercialization of the Company’s CDX-1307 vaccine program. Forward-looking statements reflect management’s current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct and you should be aware that actual results could differ materially from those contained in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, the successful integration of the businesses, multiple technologies and programs of the two companies (Celldex and AVANT) that merged together in 2008 to form our Company; our ability to adapt APC Targeting Technology™ to develop new, safe and effective vaccines against oncology and infectious disease indications; our ability to successfully complete product research and further development of our programs; the uncertainties inherent in clinical testing; our ability to manage research and development efforts for multiple products at varying stages of development; Pfizer’s and our strategy and business plans concerning the continued development and commercialization of CDX-110; the timing, cost and uncertainty of obtaining regulatory approvals; the failure of the market for the Company’s programs to continue to develop; the inability to obtain additional capital; the inability to protect the Company’s intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company’s products; and other risks detailed from time to time in the Company’s filings with the Securities and Exchange Commission, including the Company’s Form 10-K for the fiscal year ended December 31, 2008, and its Forms 10-Q and 8-K.*

### CELLDEX CONTACT:

Thomas Davis, Chief Medical Officer of Celldex Therapeutics, Inc., +1-908-454-7120; or Dan Budwick of BMC Communications Group, +1-973-271-6085, [dbudwick@bmccommunications.com/](mailto:dbudwick@bmccommunications.com/)

# Phase I clinical results of an APC-targeted hCG $\beta$ vaccine (CDX-1307) with TLR agonists.

**Michael Morse**<sup>1</sup>, Robert Chapman<sup>2</sup>, John Powderly<sup>3</sup>,  
Kimberly Blackwell<sup>1</sup>, Ding Wang<sup>2</sup>, Tibor Keler<sup>4</sup>,  
Lizhen He<sup>4</sup>, Venky Ramakrishna<sup>4</sup>, Laura Vitale<sup>4</sup>,  
Timothy Clay<sup>1</sup>, Jennifer Green<sup>4</sup>, Thomas Davis<sup>4</sup>

<sup>1</sup>. Duke University Medical Center, Durham, NC

<sup>2</sup>. Henry Ford Health System, Detroit, MI

<sup>3</sup>. Carolina BioOncology Institute, Huntersville, NC

<sup>4</sup>. Celldex Therapeutics, Inc., Phillipsburg, NJ

# Disclosure Slide

- Michael Morse
  - No disclosures related to this presentation

# Challenges in Immunotherapy

- Choosing target antigens to which tolerance may be broken
- Efficient delivery of antigen to APCs
- Presentation to CD8<sup>+</sup> and CD4<sup>+</sup> T cells
- Providing “danger signals” to APCs that lead to enhanced activation of T cells

## Targeting Ag to APC with Mannose Receptor-Binding Ab

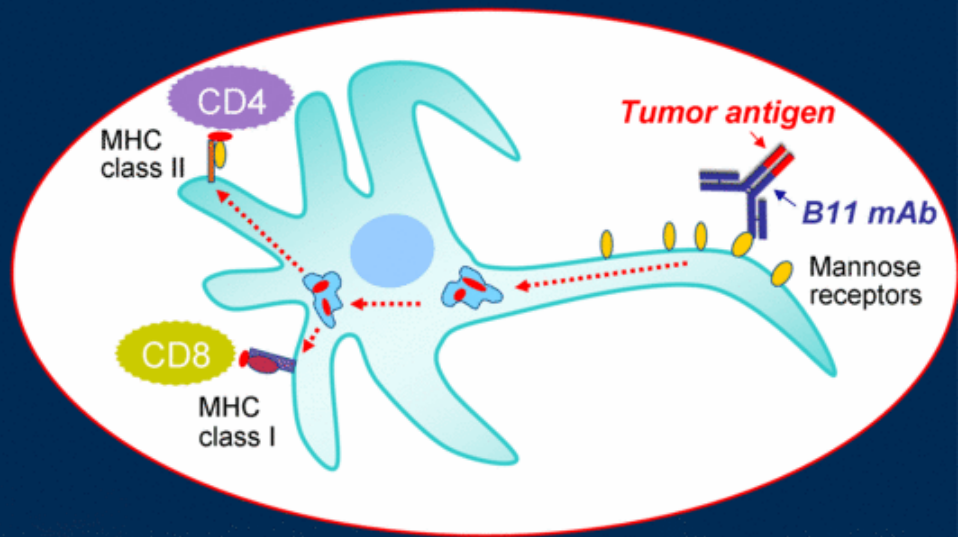
➤ Tumor antigen delivered to dendritic cells and macrophages

➤ Efficient uptake

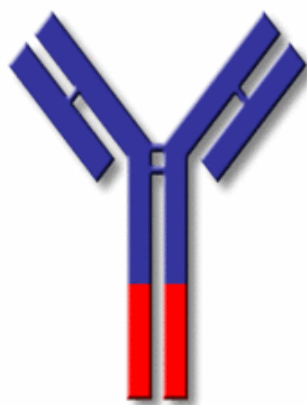
➤ Presentation of multiple epitopes (MHC-I and -II)

➤ Antibody and T cell immune responses

➤ Allows potential access to a larger APC population compared to standard protein vaccination strategies



## CDX-1307: APC-targeted hCG $\beta$ vaccine



B11 (fully human antibody to mannose receptor on APCs)

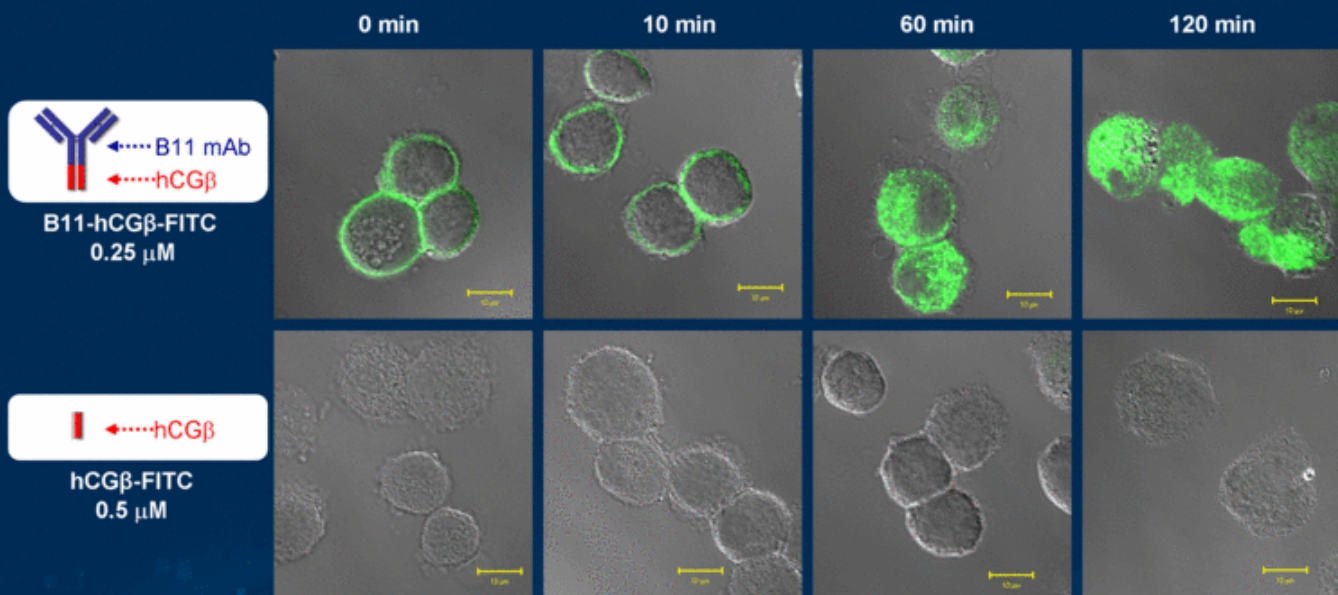
hCG $\beta$  (tumor antigen)



# Rationale for targeting hCG $\beta$ in cancer immunotherapy

- overexpressed by common cancers; few normal tissues<sup>1</sup>
- Implicated in survival and growth of cancer cells
- Elevated expression associated with poor prognosis
- Anti-hCG $\beta$  Ab response associated with improved survival<sup>2</sup>
- Tolerance to hCG $\beta$  may be broken
  - specific cytotoxic T cells can be generated from PBL of healthy donors and cancer patients

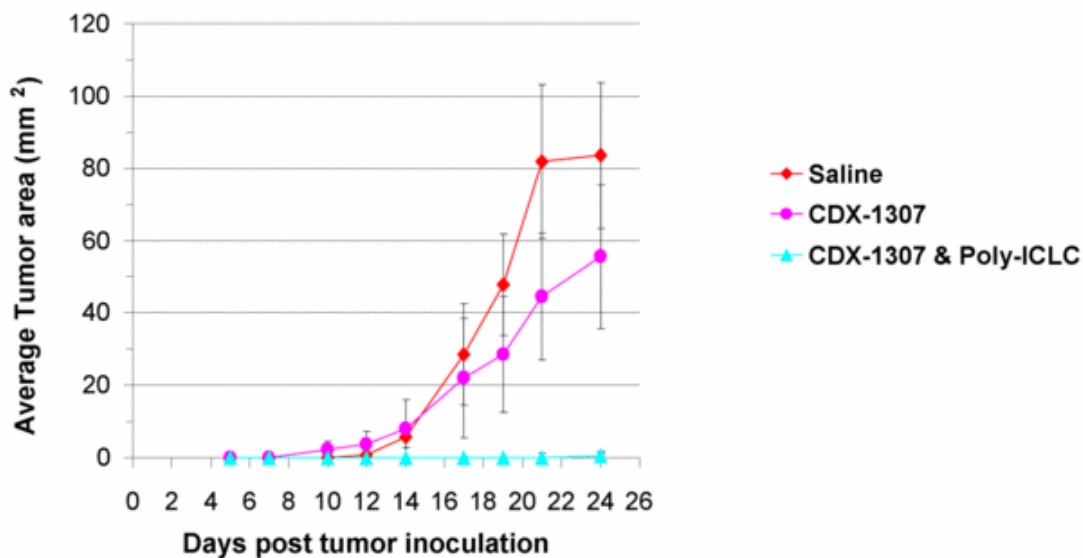
# *In vitro* targeting of B11-hCG $\beta$ (CDX-1307) to human dendritic cells



## Adjuvants provide additional signals for APC activation

- **GM-CSF**
  - Local recruitment and maturation of DCs
  - Up-regulation of mannose receptors
- **TLR agonists**
  - Trigger maturation and activation of APCs
  - enhance co-stimulatory signals and release of cytokines
    - **Poly-ICLC (Hiltonol: Oncovir, Inc.):** ds RNA with poly lysine and carboxymethylcellulose; activates TLR3
    - **Resiquimod/R848 (3M):** synthetic, imadazoquinoline; activates TLR7/8

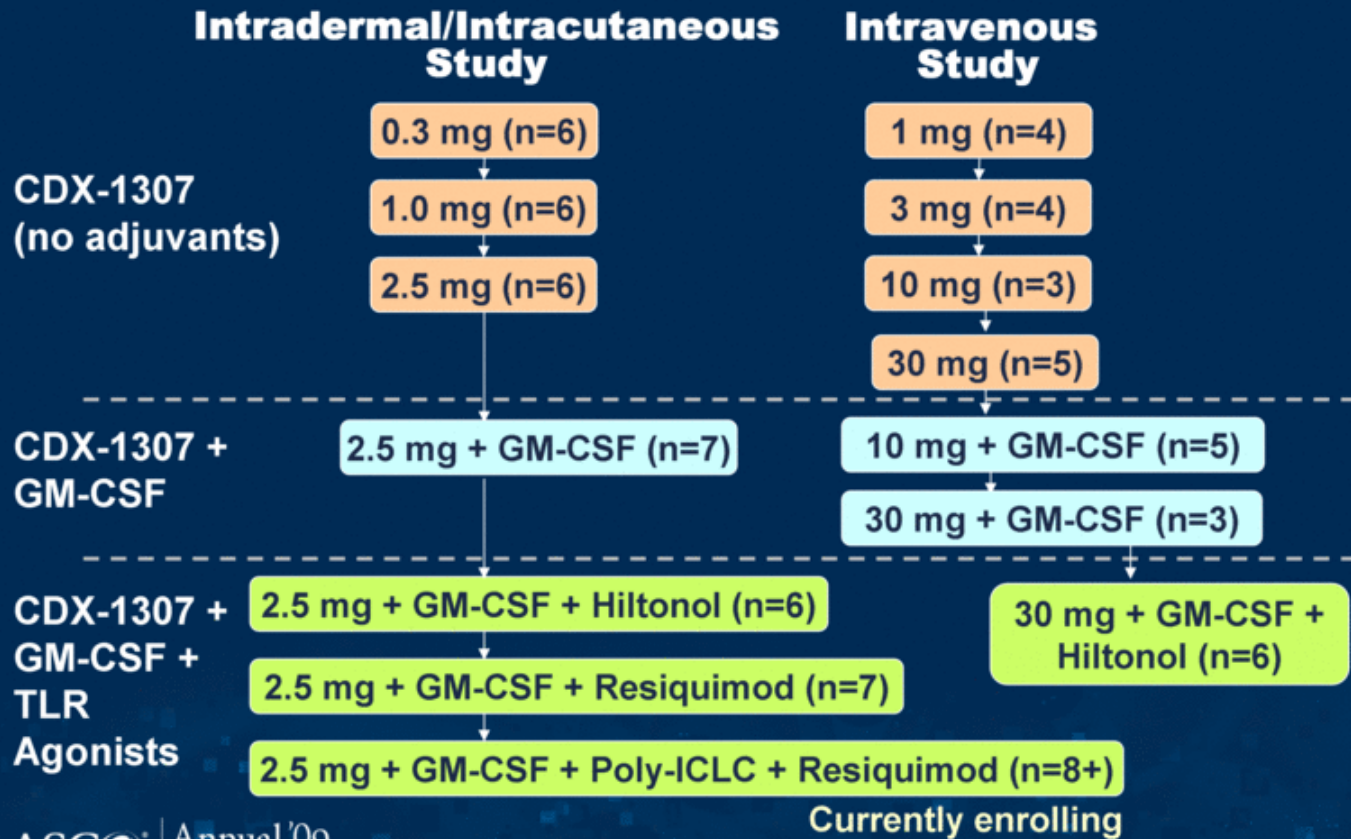
# Combination with TLR-Agonists Generates Anti-Tumor Immunity



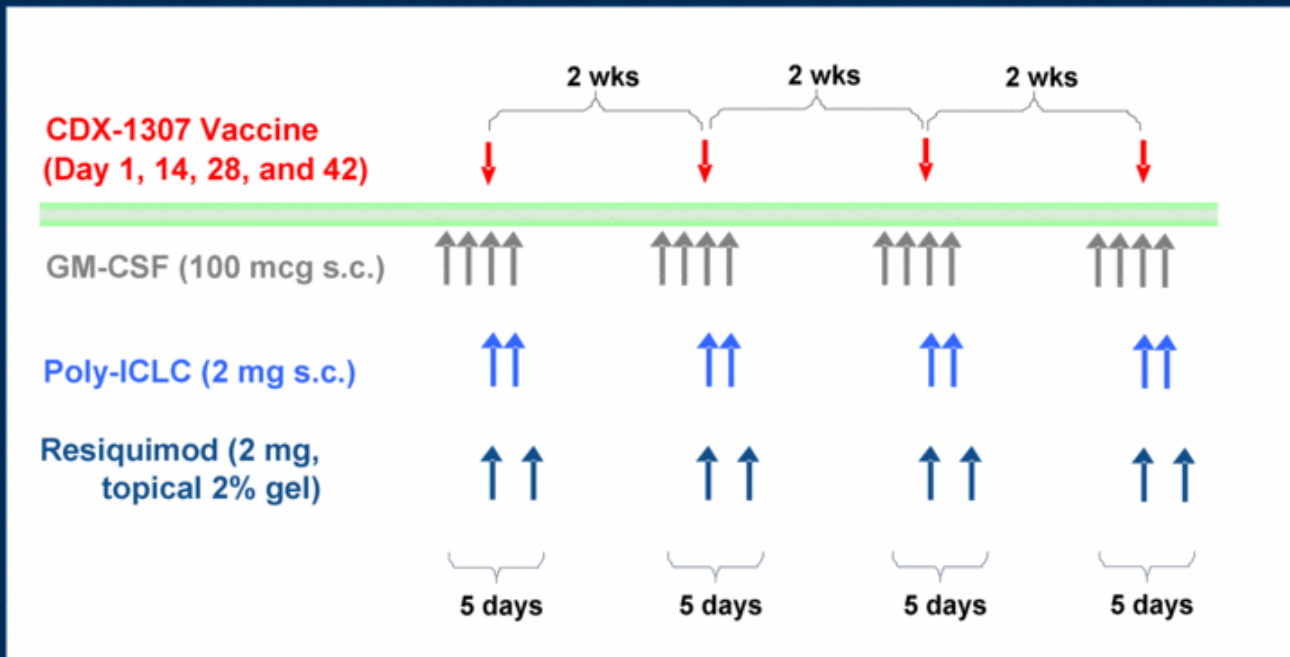
## CDX-1307: Clinical Studies

- Two Phase I studies:
  - Intravenous vs. intradermal delivery
- Advanced breast, colorectal, pancreatic, ovarian or bladder cancer
- Objectives:
  - Safety and tolerability;
  - Immune responses
  - Clinical activity (ORR, TTP)

# Clinical Study Cohorts



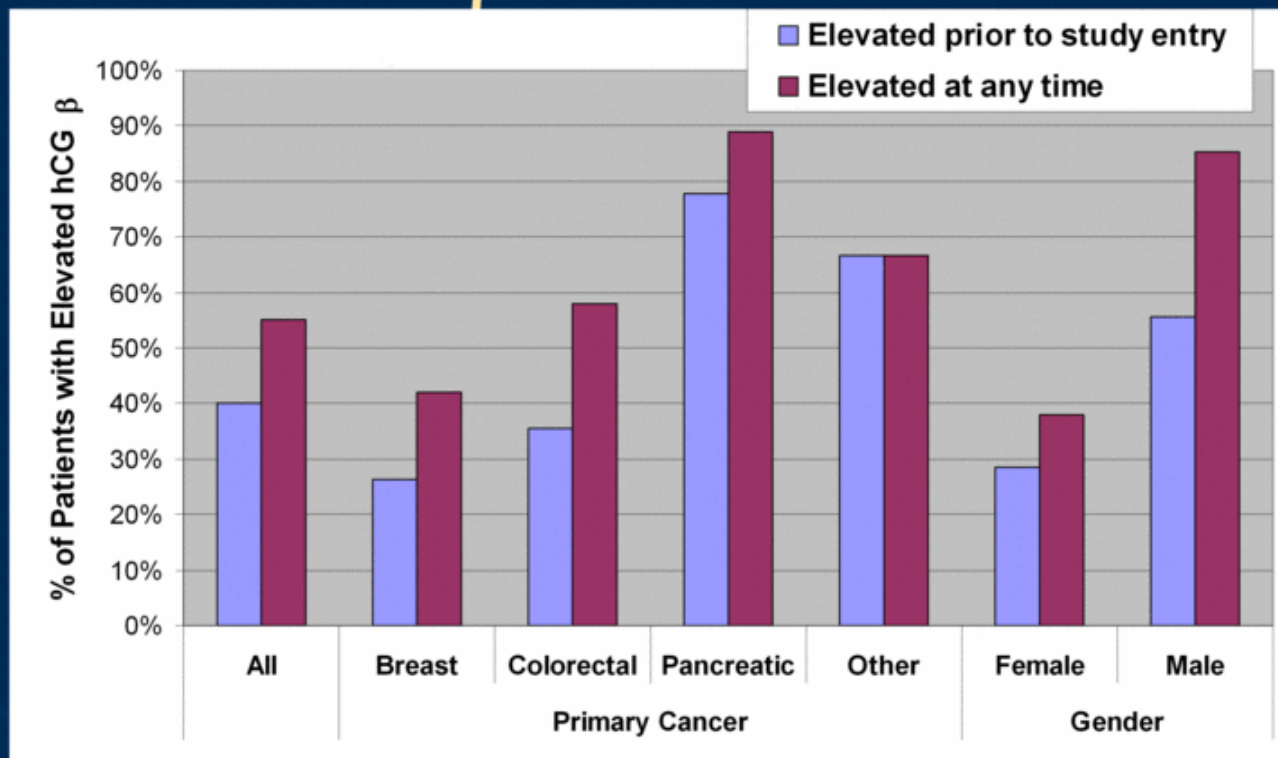
# Treatment Regimen



# Baseline Characteristics

Characteristic	All Patients (n=68)
Median age (years [range])	60 (35-81)
Male	40%
ECOG Performance Status	
0	49%
1	50%
2	1%
Primary Cancer	
Pancreatic	13%
Colorectal	46%
Breast	37%
Other	4%
Number of prior chemotherapy regimens (Mean)	4.5
Received prior radiotherapy	59%
Elevated Serum hCG-β	42%

# Serum hCG $\beta$ Measurements

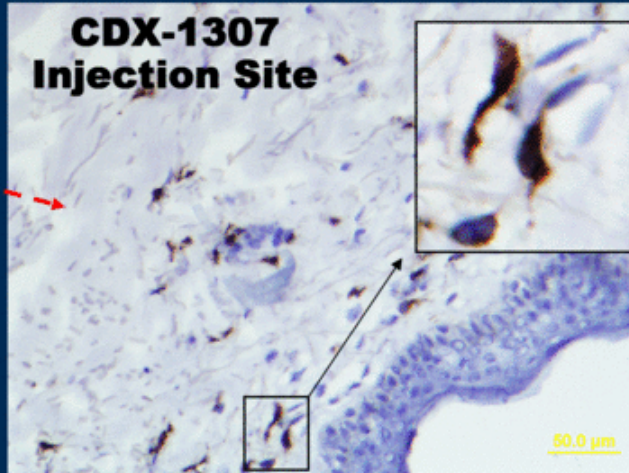
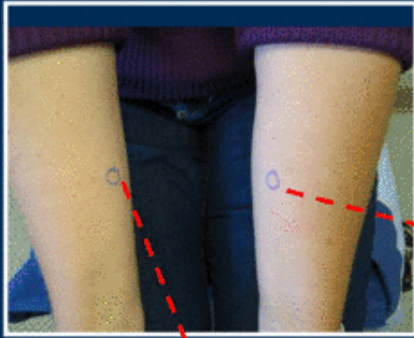


- Elevated hCG $\beta$  found commonly in cancer patients

## CDX-1307 Tolerability & PK

- No DLTs or treatment discontinuation due to toxicity
- 4 patients treated with 2<sup>nd</sup> cycle
- Treatment-related AEs:
  - G1-2 administration site reactions (23%)
    - CDX-1307 locally (17%); addition of adjuvants (55%)
  - G1-3 fatigue (21%), G1 flu-like illness (10%), G1 diarrhea (6%), G1 myalgia (6%), G1 pyrexia (6%)
- No significant circulating levels of CDX-1307 at doses below 30 mg
  - 30 mg dose IV ~ 1  $\mu$ g/ml at 2 hr post infusion

# Accumulation of hCG $\beta$ in dermal dendritic cells and macrophages



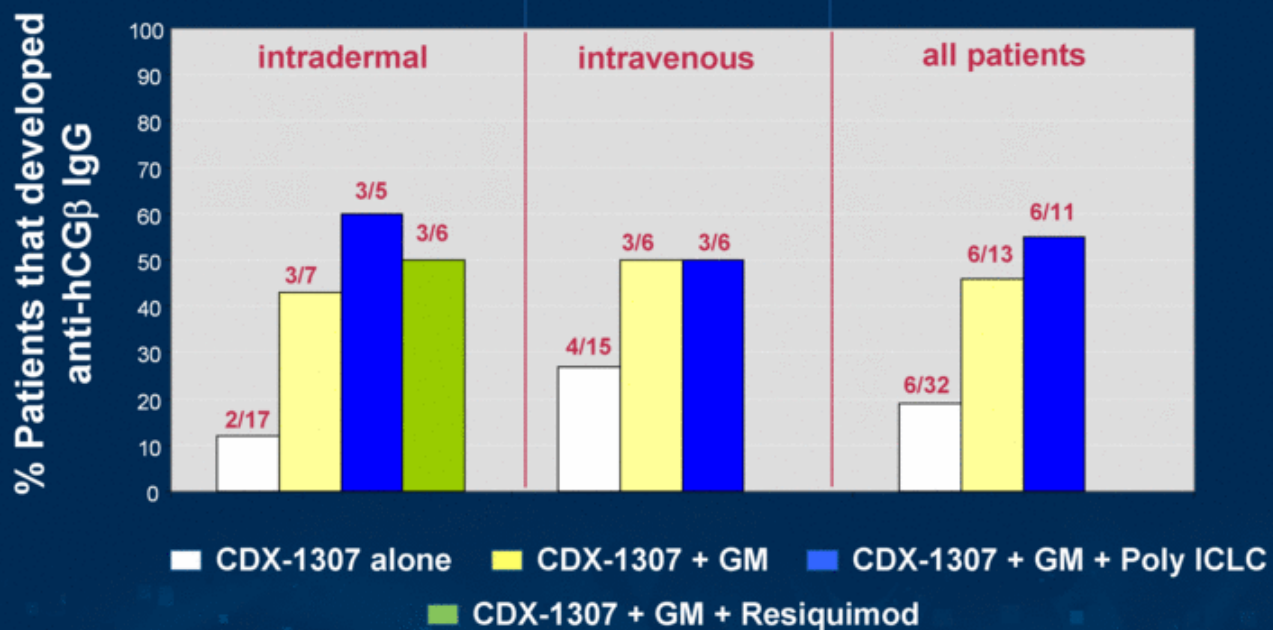
**CDX-1307  
Injection Site**

**Control arm**

**Skin punch-biopsies taken from  
injection site and opposite limb  
48 hrs post CDX-1307 (1 mg, i.d.)**

**IHC - rabbit anti-hCG $\beta$**

# Humoral Immune Responses



- Similar outcome with i.d. and i.v. administration

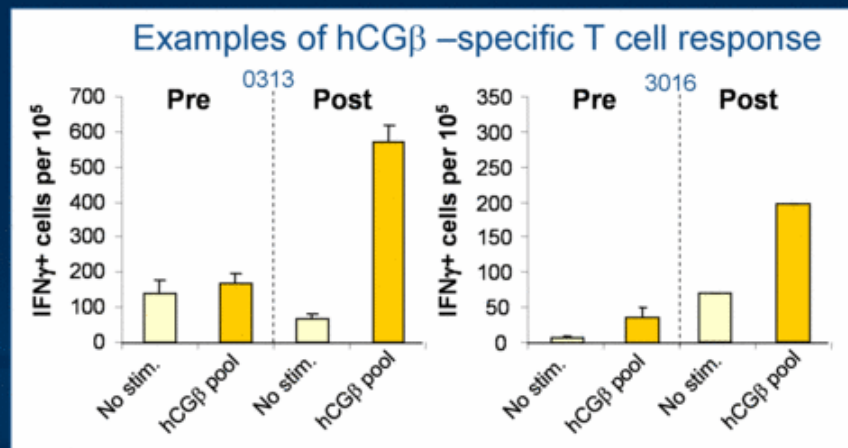
## Correlates of Anti-hCG-β Immune Response

- Highest titers in GM + TLR combination
  - Titers ranged to > 1/200,000
- Similar response in males (44%) and females (52%)
- Anti-hCGβ response despite elevated serum hCGβ
- Anti-hCGβ response in 3 of 4 patients receiving retreatment
- In adjuvant groups
  - 75 % (9/12) of breast cancer patients had Anti-hCGβ response
  - 36% (5/14) of colorectal Ca patients had Anti-hCGβ response



# Cellular Immune Responses

- Analysis not complete
  - Monitored from 90ml blood samples
  - In vitro re-stimulation to expand T cells
  - Analysis by ELISPOT with hCG $\beta$  peptide pool
- Enhanced T cell responses observed in some patients



ASCO Annual '09 Meeting

## Emerging data: CDX-1307 plus combined TLR agonists

3 of 3 with + humoral immune response

d1



d3



d4



Enhanced local response with combined TLR agonists

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# Clinical Outcomes

- Tumor response:
  - 1 mixed response seen in Pancreatic Cancer
  - 7 patients with SD for 2.2+ to 6.5+ months (5 breast cancer, 1 colorectal, 1 pancreatic)
- Tumor markers
  - Robust humoral response in 1 colon cancer patient - coinciding with decrease in CEA
  - Second patient (testicular cancer) with humoral immune response had improvement in AFP

# Summary/Conclusions

- CDX-1307 is designed for delivery of hCG- $\beta$  to APCs
- Administration of CDX-1307 is well tolerated
- hCG- $\beta$  localization in APCs demonstrated
- Anti-hCG $\beta$  immune responses observed in combination with adjuvants
- No clear differentiation between systemic and local administration
- 1 mixed response and 7 patients with stable disease
- Combination of TLR agonists may prime for additional anti-tumor activity

# Acknowledgements

- Duke University:
  - Amy Hobeika, PhD
  - Takuya Osada, MD
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  - Karrie Comatas
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  - Liz Anderson, RN, BSN, OCN
- Carolina BioOncology Institute:
  - Bryan Greene, PhD
  - Sonja Carabello
  - Lori Lipocky
  - Paola Pena
  - Bethany Skaggs, PA
  - Reena Yajnik
- Henry Ford Health System
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  - Nikki Adams, RN
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