### 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 23, 2012

#### **CELLDEX THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**000-15006** (Commission File Number) **13-3191702** (IRS Employer Identification No.)

(State or other jurisdiction of incorporation)

Delaware

119 Fourth Avenue

**Needham, Massachusetts 02494-2725** (Address of principal executive offices) (Zip Code)

(781) 433-0771

(Registrant's telephone number, including area code)

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 7.01. Regulation FD.

On May 23, 2012, Celldex Therapeutics, Inc. (the "Company") issued a press release and held a webcast to announce the preliminary results from the Company's randomized Phase 2b EMERGE study of CDX-011 (glembatumumab vedotin) antibody drug conjugate in patients with glycoprotein NMB (GPNMB) expressing, advanced, heavily pre-treated breast cancer. A copy of the press release is attached hereto as Exhibit 99.1. The presentation is attached hereto as Exhibit 99.2. The Company undertakes no obligation to update, supplement or amend the press release or the presentation materials.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

This Current Report on Form 8-K, including exhibit 99.1 and 99.2, 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 CDX-011 or any of our other drug candidates, including rindopepimut (CDX-110), CDX-1135 (formerly TP10), CDX-1401, CDX-1127, CDX-301, Belinostat and any future action we or the FDA (or any other regulator) might take with respect to regulatory approvals. 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, future actions that the FDA and other regulators might take or not take with respect to CDX-011 or any drug candidate, the market for CDX-011 or any other drug candidate or assay, future clinical testing which will be necessary before FDA approval could be sought, our ability to obtain additional capital on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials that we initiated in 2011 and plan to initiate in 2012; our ability to adapt APC Targeting TechnologyTM 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 limited experience in bringing programs through Phase 3 clinical trials; our ability to manage research and development efforts for multiple products at varying stages of development; the timing, cost and uncertainty of obtaining regulatory approvals; the failure of the market for the Company's programs to continue to develop; our limited cash reserves and our ability to obtain additional capital on acceptable terms, or at all; our ability 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, 2011, and its Forms 10-Q and 8-K.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautions not to place undue reliance on any forward-looking statements, which speak only as of the date of this Current Report on Form 8-K. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

- 99.1 Press Release of Celldex Therapeutics, Inc., dated May 23, 2012.
- 99.2 Presentation of Celldex Therapeutics, Inc., dated May 23, 2012.

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#### SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be filed on its behalf by the undersigned hereunto duly authorized.

Celldex Therapeutics, Inc.

Dated: May 23, 2012

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

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Exhibit Index

99.1 Press Release of Celldex Therapeutics, Inc., dated May 23, 2012.

99.2 Presentation of Celldex Therapeutics, Inc., dated May 23, 2012.

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Anthony S. Marucci President and CEO Celldex Therapeutics, Inc. (781) 433-0771 Avery W. Catlin Chief Financial Officer Celldex Therapeutics, Inc. (781) 433-0771 IR@celldextherapeutics.com For Media: Brad Miles BMC Communications (646) 513-3125 bmiles@bmccommunications.com

### CELLDEX'S CDX-011 DEMONSTRATES HIGH RESPONSE RATES IN PATIENTS WITH METASTATIC BREAST CANCER EXPRESSING ELEVATED LEVELS OF GPNMB AND IN TRIPLE NEGATIVE DISEASE

—Webcast scheduled for 4:30 pm ET today—

**NEEDHAM, MA (May 23, 2012):** Celldex Therapeutics, Inc. (NASDAQ: CLDX) today announced preliminary results from the Company's randomized Phase 2b EMERGE study of CDX-011 (glembatumumab vedotin) antibody drug conjugate in patients with glycoprotein NMB (GPNMB) expressing, advanced, heavily pretreated breast cancer. Preliminary results suggest that CDX-011 induces impressive response rates compared to current, available therapies in patients with advanced, refractory breast cancers with high GPNMB expression (expression in  $\geq$ 25% of tumor cells). In this high expressing patient population, treatment with CDX-011 resulted in a 32% overall response rate (ORR; includes confirmed and unconfirmed responses), whereas treatment with Investigator's Choice (IC) single-agent chemotherapy resulted in a 13% ORR. CDX-011 also demonstrated strong response rates in patients with triple negative breast cancer across all levels of GPNMB expression (CDX-011 ORR of 21%; IC ORR of 0%), where treatment options are extremely limited. In addition, in patients with triple negative breast cancer who also highly express GPNMB, greater activity was observed (CDX-011 ORR of 36%; IC ORR of 0%). The ORR across all levels of GPNMB expression was 19% for the CDX-011 arm and 14% for the IC arm, and a direct, positive correlation was observed between increasing levels of GPNMB expression and increased CDX-011 response rates. Based on these data, the Company believes CDX-011 has significant promise as a targeted therapy for patients with breast cancer and high expression of GPNMB, and especially for those with triple negative disease.

While data in the study are not yet mature, in patients with high GPNMB in the CDX-011 arm, a trend of improvement in progression-free survival (PFS) has been observed. In patients with both triple negative breast cancer and high GPNMB expression, a statistically significant PFS benefit is currently observed (p=0.0032). Study data continue to mature and patients continue to be followed. The Company anticipates updating results in the fourth quarter of 2012.

"The correlation with GPNMB expression rates and clinical responses in this study confirms the role of GPNMB as a potentially new and important cancer target," said Linda Vahdat, MD, Professor of

— more —

#### 119 FOURTH AVENUE NEEDHAM, MA 02494-2725 USA 781-433-0771 FAX 781-433-0262 www.celldextherapeutics.com

Medicine, Chief of Solid Tumor Service and Director of the Breast Cancer Research Program at Weill Cornell Medical College and the lead investigator of the EMERGE study. "These results are promising in this heavily pretreated patient population for which there are few treatment options left. With continued positive results, CDX-011 has the potential to offer a possible new and important targeted therapy."

GPNMB has been associated with the migration, invasion, and metastasis of breast cancer. It is also highly expressed in triple negative breast cancers where it is associated with increased risk of recurrence. The Phase 2b EMERGE study required patients' tissue to have at least 5% of cells expressing GPNMB at entry and, based on the low threshold for marker positivity, 99% of patients screened for GPNMB expression met the entry requirement, allowing for a specific focus on expression pattern subgroups. A total of 122 patients were treated on the study, with 81 patients (81 evaluable) randomized to the CDX-011 arm and 41 patients (36 evaluable) to the IC single-agent chemotherapy arm. Greater than 98% of the patient population across both arms had Stage IV disease. Patients on the CDX-011 arm received a median of six prior courses of therapy and patients on the IC arm received a median of five prior courses of therapy. The study overall replicated previous data in all comers, but subgroup analyses show enrichment for improved outcome in triple negative and high expressing subsets. Adverse events prominent with the CDX-011 arm include rash and peripheral neuropathy.

#### **Preliminary Topline Results:**

#### Phase 2b EMERGE Preliminary Results: Activity of CDX-011 is Greatest in Patients with Triple Negative and ≥ 25% GPNMB-Expressing Disease (High)\*

	All Patien	ts	Triple Neg	ative	High GPNN Expression	/IB n	Triple Negati High GPN Expressio	ve and MB on
	CDX-011 (n=81)	IC (n=36)	CDX-011 (n=24)	IC (n=9)	CDX-011 (n=25)	IC (n=8)	CDX-011 (n=11)	IC (n=3)
% Response (% Confirmed)	19(12)	14(8)	21(8)	0	32(16)	13(13)	36(9)	0
Disease Control Rate	59	50	71	33	64	38	82	33
Any Tumor Shrinkage	50	46	54	33	57	38	64	33

<sup>\*</sup>Responses per RECIST 1.1; IC = Investigator's Choice; CDX-011 arm includes 15 patients who crossed over to receive CDX-011 treatment after progression on IC; Analysis of best response excludes patients who discontinued from study without evaluable post-baseline radiographic imaging (n = 15 for CDX-011 arm; n=5 for IC arm); Analysis of tumor shrinkage excludes additional patients without evaluable post-baseline imaging of all target lesions (n=5 for CDX-011 arm; n=1 for IC arm).

Thomas Davis, MD, Chief Medical Officer of Celldex Therapeutics, commented, "The data in all patients, which includes both low and high GPNMB expression levels, replicates our previous study and

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shows CDX-011 to have activity similar to drugs currently approved for advanced breast cancer. The results in triple negative and high expressing patient populations suggest these groups are a highly responsive patient subset for targeted treatment with CDX-011. This result is in contrast with other agents, which tend to have limited effects in these populations. With a defined patient population for targeted therapy established for CDX-011, we can now confidently discuss possible approval paths with the regulators to determine next steps."

Anthony Marucci, President and Chief Executive Officer of Celldex Therapeutics, concluded, "It is increasingly clear that targeted therapies will be needed to make meaningful progress in difficult to treat cancers like advanced and triple negative breast cancer. We have developed a reliable diagnostic assay that identifies GPNMB expression patterns and levels in breast cancer, and the results to date from the Phase 2b EMERGE study suggest we have clearly identified patient populations that have significant potential to benefit from CDX-011. Together, patients with  $\geq$ 25% GPNMB expression levels and patients with triple negative disease account for more than 35% of the total breast cancer patient population and we believe CDX-011 could play a vital role as a much needed treatment option for these patients."

#### Webcast Details:

The data will be presented in a webcast today, May 23, 2012, at 4:30 p.m. ET by Celldex management. Linda Vahdat, MD, Professor of Medicine, Chief of Solid Tumor Service and Director of the Breast Cancer Research Program at Weill Cornell Medical College and the lead investigator of the EMERGE study, will join Celldex on the webcast to discuss results to date from the study. Accompanying slides for the webcast will be made available on the Celldex website at the start of the call.

The conference call will be webcast live over the Internet and can be accessed by logging on to the "News & Events" section of the Celldex Therapeutics website at www.celldextherapeutics.com. The call can also be accessed by dialing 800-299-0148 (within the United States) or 617-801-9711 (outside the United States). The passcode for participants is 98560829.

A replay of the call will be available approximately two hours after the live call concludes through June 6, 2012. To access the replay, dial 888-286-8010 (within the United States) or 617-801-6888 (outside the United States). The passcode is 41731858. The webcast will also be archived on the Company's website.

#### About CDX-011:

CDX-011 (glembatumumab vedotin) is an antibody-drug conjugate (ADC) that consists of a fully-human monoclonal antibody, CR011, linked to a potent cellkilling drug, monomethyl-auristatin E (MMAE). The ADC technology, comprised of MMAE and a stable linker system for attaching it to CR011, was licensed from Seattle Genetics, Inc. The ADC is designed to be stable in the bloodstream. Following intravenous administration, CDX-011 targets and binds to GPNMB, a specific protein that is expressed in breast cancer and other tumor types, and which promotes the migration, invasion and metastasis of breast

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cancer. Upon internalization into the targeted cell, CDX-011 is designed to release MMAE from CR011 to produce a cell-killing effect. CDX-011 has been shown to be well tolerated and active, with observed objective responses in two positive Phase 1/2 trials in metastatic breast cancer and advanced melanoma. In May 2010, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to Celldex's CDX-011 for the treatment of advanced, refractory/resistant GPNMB-expressing breast cancer.

#### About Celldex Therapeutics, Inc.:

Celldex Therapeutics is the first antibody-based combination immunotherapy company. Celldex has a pipeline of drug candidates in development for the treatment of cancer and other difficult-to-treat diseases based on its antibody focused Precision Targeted Immunotherapy (PTI) Platform. The PTI Platform is a complementary portfolio of monoclonal antibodies, antibody-targeted vaccines and immunomodulators used in optimal combinations 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 CDX-011 or any of our other drug candidates, including rindopepimut (CDX-110), CDX-1135 (formerly TP10), CDX-1401, CDX-1127, CDX-301, Belinostat and any future action we or the FDA (or any other regulator) might take with respect to regulatory approvals. 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, future actions that the FDA and other regulators might take or not take with respect to CDX-011 or any drug candidate, the market for CDX-011 or any other drug candidate or assay, future clinical testing which will be necessary before FDA approval could be sought, our ability to obtain additional capital on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials that we initiated in 2011 and plan to initiate in 2012; our ability to adapt APC Targeting Technology<sup>TM</sup> 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 limited experience in bringing programs through Phase 3 clinical trials; our ability to manage research and development eff

Company's programs to continue to develop; our limited cash reserves and our ability to obtain additional capital on acceptable terms, or at all; our ability 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, 2011, and its Forms 10-Q and 8-K.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise.



### CDX-011 – EMERGE Topline Data May 23, 2012

# **Forward Looking Statement**

This communication contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "will," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future. These forwardlooking statements are subject to risks and uncertainties that may cause actual future experience and results to differ materially from those discussed in these forward-looking statements. Important factors that might cause such a difference include, but are not limited to, the timing, cost and uncertainty of obtaining regulatory approvals for product candidates; our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors; the validity of our patents and our ability to avoid intellectual property litigation, which can be costly and divert management time and attention; and the other factors listed under "Risk Factors" in our filings with the SEC, including Forms 10-K, 10-Q and 8-K.

Celldex does not undertake any obligation to release publicly any revisions to such forward-looking statement to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.



# The Target: GPNMB

- An internalizable glycoprotein expressed in ~40-75% of breast cancers, as well as other tumor types
- Promotes the migration, invasion, and metastasis of breast cancer
- Highly expressed in triplenegative breast cancers where it is associated with increased risk of recurrence

Patients with High GPNMB-Expressing Tumors Have Significantly Shorter Metastasis-Free and Overall Survival





# CDX-011: First-in-class, Next Generation Therapeutic Antibody

- Antibody drug conjugate designed to release MMAE upon internalization into GPNMB-expressing tumor cells
  - Celldex proprietary target and antibody
  - Toxin and linker licensed from Seattle Genetics
    - Same technology as Adcetris<sup>™</sup>





# **CDX-011: Consistent Clinical Experience**

- Phase 1/2 study in patients with heavily pre-treated metastatic melanoma (n=117), not selected for GPNMB expression
  - CDX-011 well tolerated; Phase 2 dose defined at 1.88 mg/kg
  - Exploratory analysis showed enrichment for tumor regression in patients with significant tumor GPNMB expression
- Phase 1/2 trial in advanced, heavily pre-treated breast cancer patients (n=42), not selected for GPNMB expression
  - Encouraging activity in patients with triple-negative disease (ER/PR/HER2 negative) where treatment options are limited
  - Data suggest that patients with significant GPNMB expression receive greatest benefit from CDX-011
- Preliminary results from randomized, Phase 2b EMERGE study again show very encouraging activity in patients with triple negative disease and in patients with significant GPNMB expression



### EMERGE: Phase 2b Randomized Study in **Advanced Breast Cancer**

- Advanced, GPNMB-expressing breast cancer patients refractory/resistant to approved therapies (targeted n=120)
- Study designed to examine whether anti-cancer activity of CDX-011 is dependent upon distribution/intensity of GPNMB expression
  - Endpoints: overall response rate [primary], progression-free survival, duration of response, safety, PK/PD
- Study initiated Sep 2010; enrollment completed Dec 2011



### EMERGE: Tissue Screening for GPNMB Expression

EMERGE patients were selected for GPNMB expression using validated, centralized IHC method

- Generally historical samples from prior resections (primary or metastatic)
- Of 338 screened patients, 99% were considered eligible  $(\geq 5\%$  of tumor or stroma cells expressing GPNMB)





#### **GPNMB Expression in Breast Cancer**



# EMERGE: Baseline Characteristics All Treated Patients

		CDX-011 (N=81)	Investigator's Choice (N=41)
Mean Age [Years (SD)]		56.4 (10.4)	55.8 (10.0)
Breast Cancer Stage [n (%)]	III	2 (2%)	0
	IV	79 (98%)	41 (100%)
Visceral disease (Liver or Lung) [I	n (%)]	67 (83%)	33 (80%)
Mean Duration of Metastatic or Locally Advanced Disease [Years	s (SD)]	4.0 (3.5)	3.0 (3.1)
PR Positive [n (%)] *		31 (38%)	20 (49%)
ER Positive [n (%)]		48 (59%)	26 (63%)
HER2 Positive [n (%)] **		9 (11%)	9 (22%)
Triple Negative [n (%)]		27 (33%)	11 (27%)
Prior Anticancer Regimens [Media	an (Range)]	6 (2-10)	5 (2-11)

SD = standard deviation; PR = progesterone receptor; ER = estrogen receptor; HER2 = human epidermal growth factor receptor 2; IC = Investigator's Choice



\* PR status is unknown for 2 CDX-011 patients.

\*\* HER2 status is unknown for 3 CDX-011 and 1 IC patient.

# EMERGE: Safety Summary All Treated Patients

	CDX-011 (n = 96)			IC (n = 41)		
	All Grades	Grade 3	Grade 4	All Grades	Grade 3	Grade 4
Hematologic				8.		12
Neutropenia/Neutrophil count decreased	25 (26%)	12 (13%)	6 (6%)	16 (39%)	7 (17%)	3 (7%)
Leukopenia/White blood cell count decreased	9 (9%)	2 (2%)	1 (1%)	11 (27%)	6 (15%)	0
Thrombocytopenia/Platelet count decreased	4 (4%)	0	1 (1%)	6 (15%)	1 (2%)	0
Non-hematologic						
Rash (maculopapular, pruritic, erythematous, etc.)	36 (38%)	3 (3%)	0	1 (2%)	0	0
Fatigue	31 (32%)	6 (6%)	0	17 (41%)	2 (5%)	0
Nausea	29 (30%)	3 (3%)	0	14 (34%)	0	0
Alopecia	22 (23%)	0	0	6 (15%)	0	0
Decreased appetite	17 (18%)	1 (1%)	0	4 (10%)	1 (2%)	0
Peripheral neuropathy	17 (18%)	2 (2%)	0	3 (7%)	0	0
Vomiting	15 (16%)	1 (1%)	0	3 (7%)	0	0
Constipation	13 (14%)	0	0	7 (17%)	0	0
Stomatitis	9 (9%)	1 (1%)	0	6 (15%)	1 (2%)	0
Dehydration	7 (7%)	3 (3%)	0	2 (5%)	1 (2%)	0

IC = Investigator's Choice

CDX-011 arm includes 15 patients who crossed over to receive CDX-011 treatment after progression on IC.



Table presents treatment-related adverse events with incidence  $\geq$ 15% overall, or  $\geq$ 3% at Grade 3-4 severity, in either study arm. No Grade 5 treatment-related adverse events were reported.

# EMERGE: Activity of CDX-011 is Greatest in Patients with Triple Negative and GPNMB-Expressing Disease

	All Patients		Triple Negative		High GPNMB Expression (≥25% Tumor Cells)		Triple Negative and High GPNMB Expression	
	CDX-011 (n=81)	IC (n=36)	CDX-011 (n=24)	IC (n=9)	CDX-011 (n=25)	IC (n=8)	CDX-011 (n=11)	IC (n=3)
Partial Response	19%	14%	21%	0%	32%	13%	36%	0%
Confirmed PR	12%	8%	8%	0%	16%	13%	9%	0%
Disease Control Rate	59%	50%	71%	33%	64%	38%	82%	33%
Any Tumor Shrinkage	50%	46%	54%	33%	57%	38%	64%	33%

Responses per RECIST 1.1; IC = Investigator's Choice; PR = Partial Response; CDX-011 arm includes 15 patients who crossed over to receive CDX-011 treatment after progression on IC.

Analysis of best response excludes patients who discontinued from study without evaluable post-baseline radiographic imaging (n=15 for CDX-011 arm; n=5 for IC arm).

Analysis of tumor shrinkage excludes additional patients without evaluable post-baseline imaging of all target lesions (n=5 for CDX-011 arm; n=1 for IC arm).



# EMERGE: Correlation of Response and GPNMB Expression





Low GPNMB expression is defined as expression in <25% of tumor cells, while high GPNMB expression is defined as expression in  $\geq$ 25% of tumor cells.

\* Including confirmed and unconfirmed PR

# EMERGE: Triple-Negative Patients Correlation of Response and GPNMB Expression



#### Tumor Cells Expressing GPNMB



Low GPNMB expression is defined as expression in <25% of tumor cells, while high GPNMB expression is defined as expression in  $\ge$ 25% of tumor cells.

\* Including confirmed and unconfirmed PR

### EMERGE: Early Progression-Free Survival in Triple Negative and GPNMB-Expressing Breast Cancer





### **EMERGE:** Current Standard of Care Therapies Produce Low Response Rate in GPNMB+ Patients

 Over half (54%) of the patients randomized to Investigator's Choice arm in EMERGE received Halaven<sup>®</sup> or Ixempra<sup>®</sup>

	<b>Prior Studies</b>	EMERGE Experience			
	in Treatment- Refractory Breast Cancer	All Patients	GPNMB expression in ≥ 25% of Tumor Cells		
Halaven <sup>®</sup> (Eribulin)					
Partial Response		0% (0/13)	0% (0/6)		
Confirmed PR	<b>12-13%</b> <sup>1</sup>	0% (0/13)	0% (0/6)		
Ixempra® (Ixabepilone)					
Partial Response		14% (1/7)	0% (0/1)		
Confirmed PR	11-18% <sup>2</sup>	0% (0/7)	0% (0/1)		

PR = Partial Response



1. Cortes J, et al. Lancet. 2011 2. Perez, et. al. JCO, 2007

### Preliminary EMERGE Results Consistent with Previous Data in Similar Population

- Promising activity in triple-negative breast cancer (TNBC), where treatment options are limited
  - CDX-011 response rate of 21% in TNBC compared to 0% for Investigator's Choice (IC) therapy
- Significant tumor expression of GPNMB associated with greater activity
  - CDX-011 response rate of 32% compared to 13% for IC
  - High GPNMB expression seen in 39% of patients with TNBC; in these patients, CDX-011 response rate of 36% and progression-free survival advantage of 130% (p=0.0032)
- Celldex will explore possible registrational paths in these patients with significant unmet medical need
  - Additional Phase 2 development possible in other GPNMBexpressing tumor types (melanoma, lymphoma, lung cancer)





For additional information, please visit: www.celldextherapeutics.com