

**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): **November 25, 2013**

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
ID Number)

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

02494
(Zip Code)

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

Not Applicable
(Former name or former address, if changed since last report.)

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

- 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))

Item 7.01 Regulation FD Disclosure.

Celldex Therapeutics, Inc. (the "Company") intends to use a slide presentation during a conference call held on November 25, 2013. The slide presentation is attached hereto as Exhibit 99.1.

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, 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, 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 any of our drug candidates, including rindopepimut (CDX-110), CDX-011, 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, our ability to successfully complete research and further development and commercialization of rindopepimut, glemba and other drug candidates, our ability to obtain additional capital to meet our long-term liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the

clinical trials that we have initiated or plan to initiate; our ability to adapt our 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 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 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, 2012, and its Forms 10-Q and 8-K.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You 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

<u>Exhibit</u>	<u>Description</u>
99.1	Slide Presentation, dated November 25, 2013.

2

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.

CELLDEX THERAPEUTICS, INC.

Date: November 25, 2013

/s/ Avery W. Catlin

Avery W. Catlin, Senior Vice President and
Chief Financial Officer

3



Rindopepimut

Society for Neuro-Oncology (SNO) 2014 Update
November 25, 2013

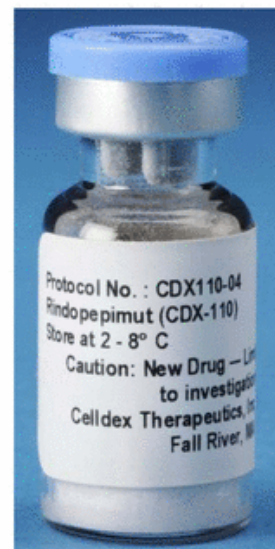
Forward Looking Statement

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 forward-looking 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.

Rindopepimut: A Phase 3 Immunotherapy Targeting EGFRvIII-expressing Glioblastoma

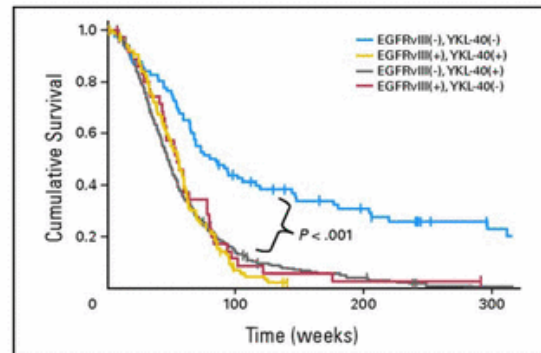
- Rindopepimut is the only vaccine in development targeting EGFRvIII (v3)
- EGFRvIII
 - Highly tumor specific, expressed only in tumors not normal tissues
 - Target has been validated, gaining importance as a tumor marker
 - Historical poor prognosis for vIII patients, historical median survival ~13-15 months, few survive two years
 - ~30% of GB express EGFRvIII (~4,000 EGFRvIII patients in US and ~8,800 in EU annually)
- Strong proprietary patent position
- Fast track U.S. granted
- Orphan Drug Status in US and EU (7 yrs. & 10 yrs.)



EGFR Mutation Variant III (EGFRvIII)

- Tumor-specific oncogene expressed in one-third of primary GBM, seldom expressed with IDH mutations but not in normal tissue
- EGFRvIII(+) cells may induce growth in EGFRvIII(-) cells via paracrine signaling, membrane-derived microvesicles and tumor stem cells¹⁻⁴
- Rindopepimut consists of EGFRvIII peptide conjugated to Keyhole Limpet Hemocyanin (KLH)
 - Generates a specific immune response against EGFRvIII-expressing GBM
 - "Off the shelf"
 - Delivered as intradermal injection of 500 µg rindopepimut with 150 µg GM-CSF as an adjuvant

EGFRvIII Linked To Poor Long Term Survival⁵



1. Inda, et al. Genes Dev. 2010;
2. Al-Nedawi, et al. Nat Cell Biol. 2008
3. Wong, et al. JCO. 2008

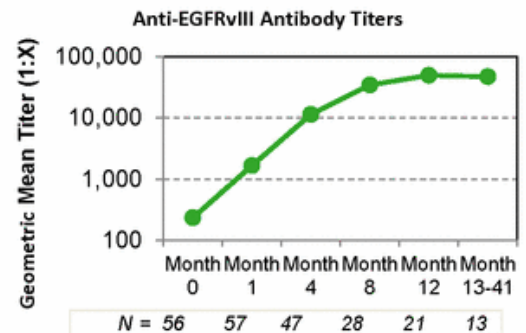
4. Fan, et al. Cancer Cell 2013
5. Pelloski, et al. JCO. 2007

Biology Supports Clinical Benefit

Rindo eliminates vIII from tumor cells

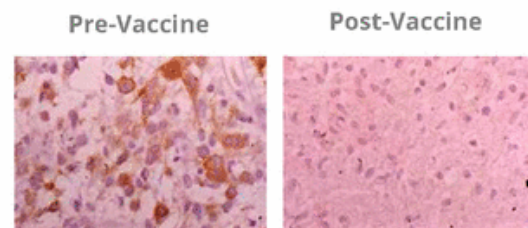
Induction of potent immune response to EGFRvIII

- 85% of patients developed significant anti-EGFRvIII antibody titers which increased with time on study
- Majority (67%) developed titers above 1:12,800
- Anti-EGFRvIII titers maintained for >6 months following cessation of treatment



Elimination of EGFRvIII expression

- EGFRvIII was selectively eliminated in recurrent tumors for 26/32 (81%) patients across three Phase 2 studies
- 15/15 control patients treated with TMZ/radiation (+/- CPT-11, bevacizumab or erlotinib) were EGFRvIII(+) at recurrence



Rationale for Rindopepimut Plus Bevacizumab in Recurrent GBM

- Compassionate use evidence suggest that rindopepimut may induce specific immune responses and regression in multifocal and bulky tumors
 - Marked tumor regression with rindopepimut in combination with standard treatments
 - Central review of ACT III patient scans
- Bevacizumab may optimize EGFRvIII-specific immune response²⁻⁴
 - VEGF may mediate immunosuppression (impairs DC maturation, alters tumor endothelium, potentially decreasing immune cell infiltration)
 - Bevacizumab shown to enhance immune-mediated anti-tumor effects in tumor models

Bevacizumab-experienced patients are historically difficult to treat

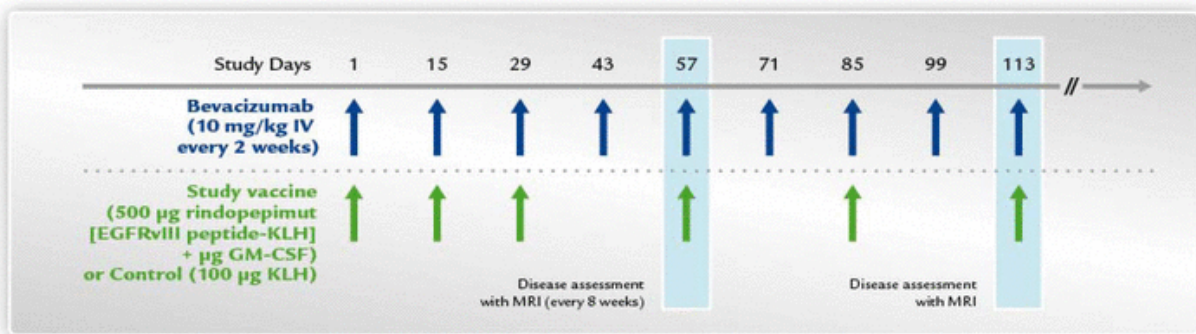
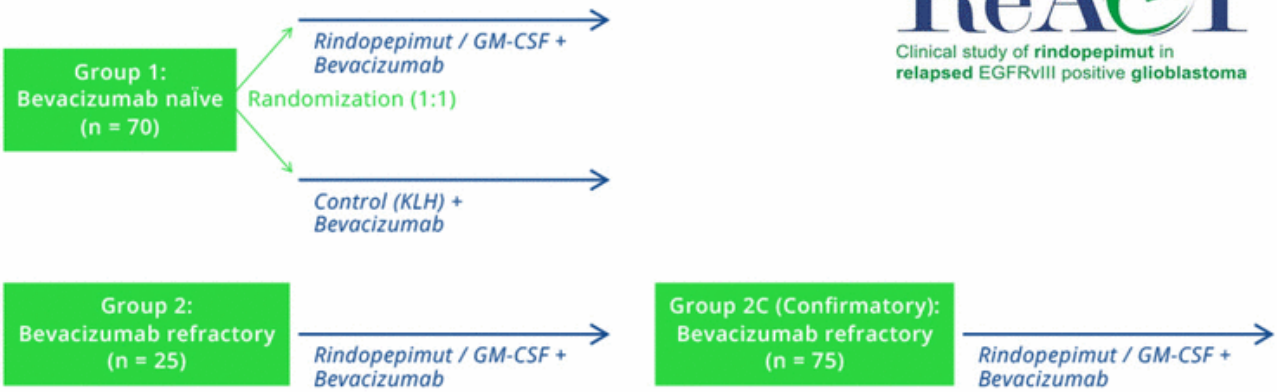
Treatment	ORR (%)	PFS6 (%)	Median PFS (months)	Median OS (months)
Bev + chemo ⁵	0	2	1.2	2.7
Bev + chemo ⁶	0	5	2.5	4.0
Bev + irinotecan ⁷	0	-	1.0	-
Bev + carboplatin & irinotecan ⁸	0	16	2.3	5.8
Bev + TMZ ⁹	0	0	0.9	2.9
Bev + etoposide ⁹	0	8	1.9	4.4
Bev + temsirolimus ¹⁰	0	-	1.8	3.5
MPC-6827 ¹¹	4	-	0.7	3.2
Bev + dasatinib ¹²	0	0	0.9	2.6

1. Sampson 2008
 2. Johnson 2007
 3. Shrimali 2010
 4. Osada 2008
 5. Quant 2009
 6. Chamberlain 2011

7. Kreisl 2009
 8. Reardon 2011
 9. Reardon 2011
 10. Lassen 2013
 11. Grimm 2010
 12. Lu-Emerson 2011



Phase II ReACT Study Design



Phase 2 ReACT Study Design cont.

Eligibility

- 1st or 2nd relapse of GBM
- EGFRvIII+ (as per centralized IDE-approved RT-PCR assay)
- Prior conventional radiation and temozolomide
- No radiation within 3 months of entry
- Systemic corticosteroid therapy \leq 4 mg of dexamethasone daily
- No metastatic disease, diffuse leptomeningeal disease, gliomatosis cerebri, or infratentorial disease
- No prior intracerebral agents (excluding diagnostic and imaging agents), antibody-based investigational therapy within 28 days, or non-protein based investigational therapy within 14 days of entry

Objectives

Exploratory study designed to estimate outcome for patients with relapsed EGFRvIII+ GBM treated with standard of care +/- rindopepimut

- Primary: Progression-free survival rate at 6 months
- Secondary:
 - Objective response rate (ORR, using RANO criteria¹), overall PFS, overall survival (OS)
 - Safety and tolerability
 - EGFRvIII-specific immune response

1. Wen, et al. JCO. 2010

ReACT Study Status

Bevacizumab-naïve

- Interim results available for the 1st 40 patients
 - 12 patients continue to receive treatment
 - A total of 27 patients continue to be followed for survival

Bevacizumab-refractory

- Enrollment to initial cohort is complete; 25 patients treated
 - 1 patient continues to receive treatment
 - A total of 6 patients continue to be followed for survival
- Expansion cohort (n=73) underway

Data Evaluation

- Investigator assessment of tumor response (according to RANO criteria) complete
- Cases with $\geq 25\%$ reduction in area of measurable disease reviewed by expert panel blinded to treatment assignment
- Formal third-party review of images by central review vendor to be performed at completion of follow up



Patient Characteristics

	Bevacizumab Refractory (n=25)	Bevacizumab Naïve	
		Rindopepimut + Bevacizumab (n=20)	Control (KLH) + Bevacizumab (n=20)
Age, years (median [range]) ≥50 years (n [%])	58 (39-79) 20 (80%)	60 (51-79) 20 (100%)	56 (30-75) 15 (75%)
Male (n [%])	16 (64%)	9 (45%)	11 (55%)
KPS (n [%])			
100	1 (4%)	0	3 (15%)
90	7 (28%)	7 (35%)	6 (30%)
80	6 (24%)	8 (40%)	7 (35%)
70	11 (44%)	5 (25%)	4 (20%)
<i>De novo</i> GBM (n [%])	25 (100%)	20 (100%)	19 (95%)
Time from diagnosis to first study vaccination, months (median [range])	16.0 (8.4-58.6)	8.6 (4.5-55.3)	12.0 (5.6-33.8)
Prior relapses (n [%])			
1	4 (16%)	18 (90%)	16 (80%)
2	21 (84%)	2 (10%)	4 (20%)
Time to relapse with prior bevacizumab, months (median [range])	4.8 (0.5-42)	-	-
Any surgery after last relapse (n [%])	4 (16%)	4 (20%)	5 (25%)
Gross-total Resection	3 (12%)	3 (15%)	3 (15%)
Partial resection/biopsy	1 (4%)	1 (5%)	2 (10%)
On steroids at study entry (n [%])	7 (28%)	11 (55%)	11 (55%)

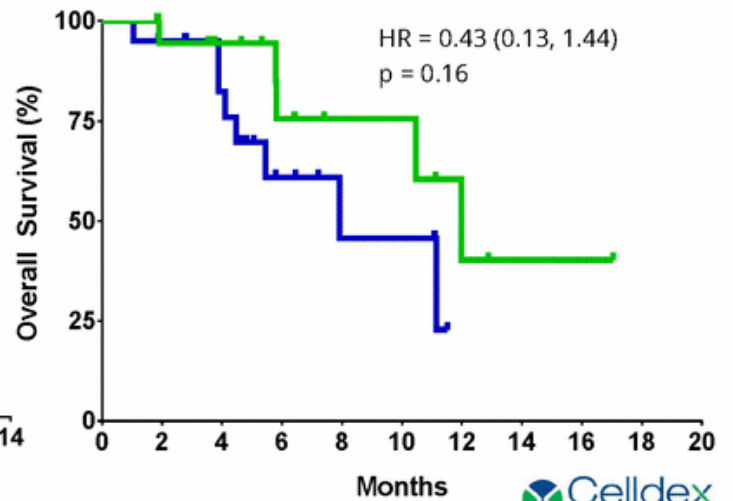
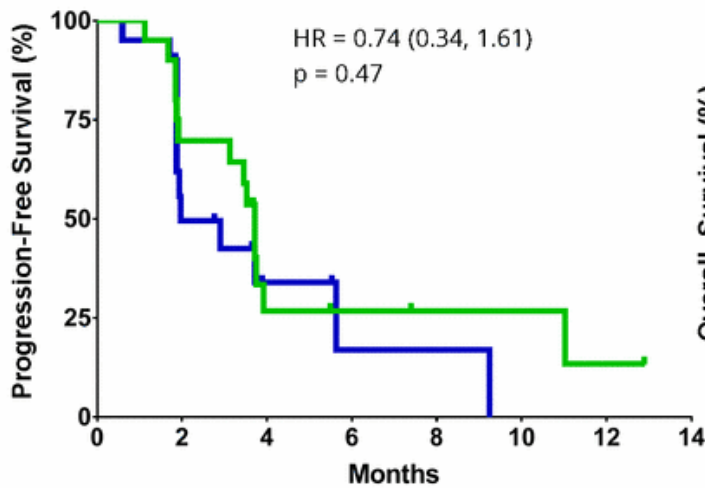
Group 1: Bevacizumab-Naive Recurrent GBM



Overall and Progression-Free Survival Bevacizumab-Naïve Recurrent GBM – Interim Data

	Median OS, Months (95% CI)	Median PFS, Months (95% CI)
 Rindopepimut + Bevacizumab (n=20)	12.0 (5.8, Not est.)	3.7 (1.9, 3.9)
 Control + Bevacizumab (n=20)	7.9 (4.1, Not est.)	2.0 (1.9, 5.6)

Median follow-up: 6.4 months for rindopepimut
5.8 months for control



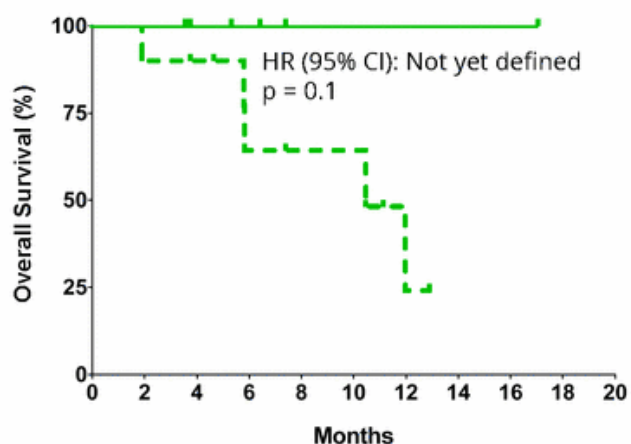
First Controlled Data for EGFRvIII Supports that EGFRvIII Patients Fare Worse than the General GBM population

	Median OS, Months	Median PFS, Months
Bevacizumab only (AVF3708g, all comers)	9.3	4.2
Bevacizumab only (ReACT Control , EGFRvIII only)	7.9	2.0

Early Anti-EGFRvIII Response Correlates with Survival in Recurrent GBM Treated with Rindopepimut + Bevacizumab

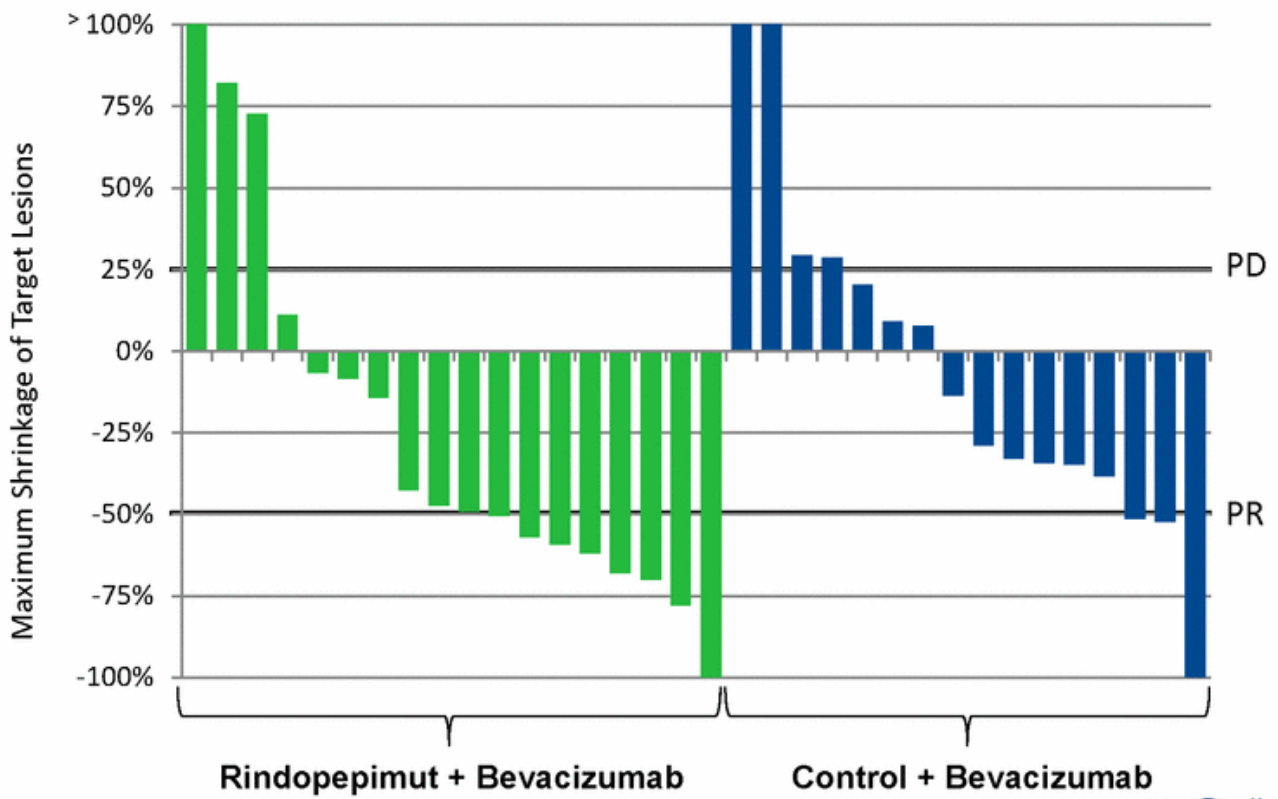
Bevacizumab-Naïve

	Median OS Months (95% CI)	6-Month OS (%)
Highest Titers* (n=8)	Not yet defined	100%
All others (n=10)	10.5 (1.9, Not est.)	64%



* Based on the generation of anti-EGFRvIII antibody titer $\geq 1:12,800$ by Day 57. Similar results observed at Day 29 as well as across a range of cut-off values (1:800 to 1:12,800).

Tumor Shrinkage: Bevacizumab-Naïve Recurrent GBM



Preliminary Analysis of Anti-Tumor Effect Bevacizumab-Naïve Recurrent GBM

	Rindopepimut + Bevacizumab	Control + Bevacizumab
Steroids initiated or increased (1 st adjustment)	1/20 (5%)	7/20 (35%)
ORR (confirmed CR/PR) ^{1,2}	3/19 (16%)**	2/16 (13%)**
Any response (≥50% shrinkage) including those not sustained at subsequent assessment ¹		
By Investigator review	7/19 (37%)	3/16 (19%)
By Expert Panel review	6/19 (32%)	4/16 (25%)
By Either review	9/19 (47%)	4/16 (25%)
Stable disease or better for ≥ 2 months	14/20 (70%)	11/20 (55%)

** Two additional patients receiving rindopepimut+bev and one patient receiving control+bev have experienced >50% shrinkage by either investigator or expert panel review, and are pending follow-up for confirmation of response.

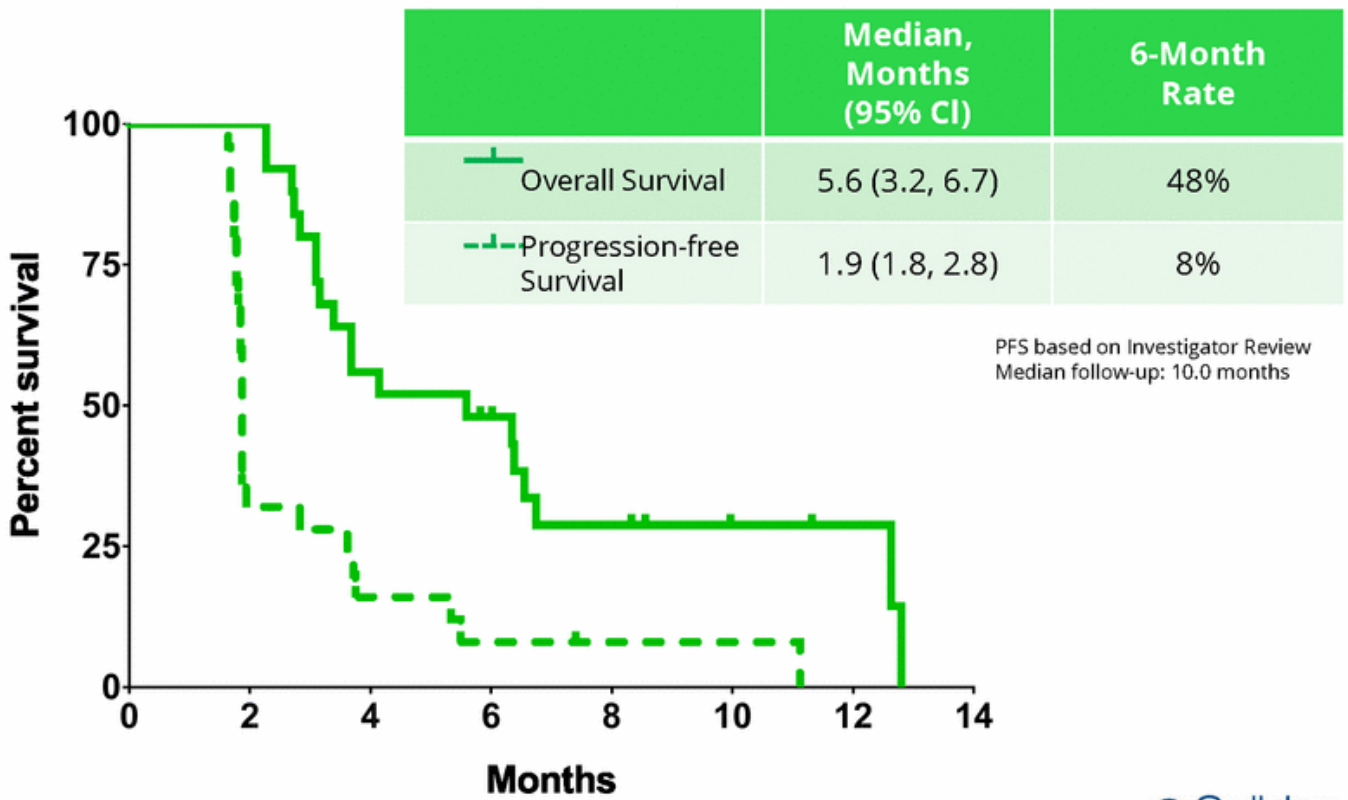
1. Response-evaluable patient subset with measurable disease

16 2. All concordant between investigator and expert panel review

Group 2: Bevacizumab-Refractory Recurrent GBM



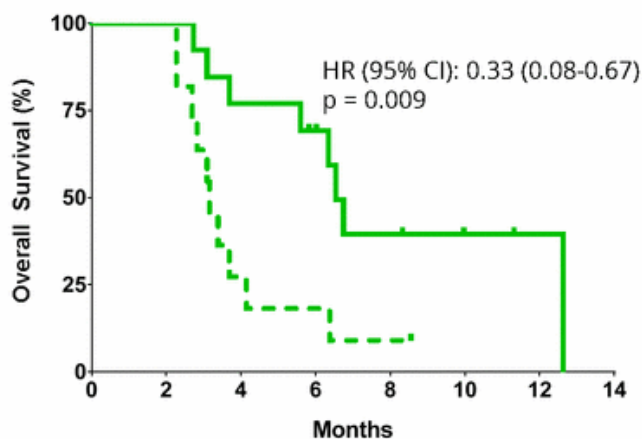
Progression-Free and Overall Survival Bevacizumab-Refractory Recurrent GBM



Early Anti-EGFRvIII Response Correlates with Survival in Recurrent GBM Treated with Rindopepimut + Bevacizumab

Bevacizumab-Refractory

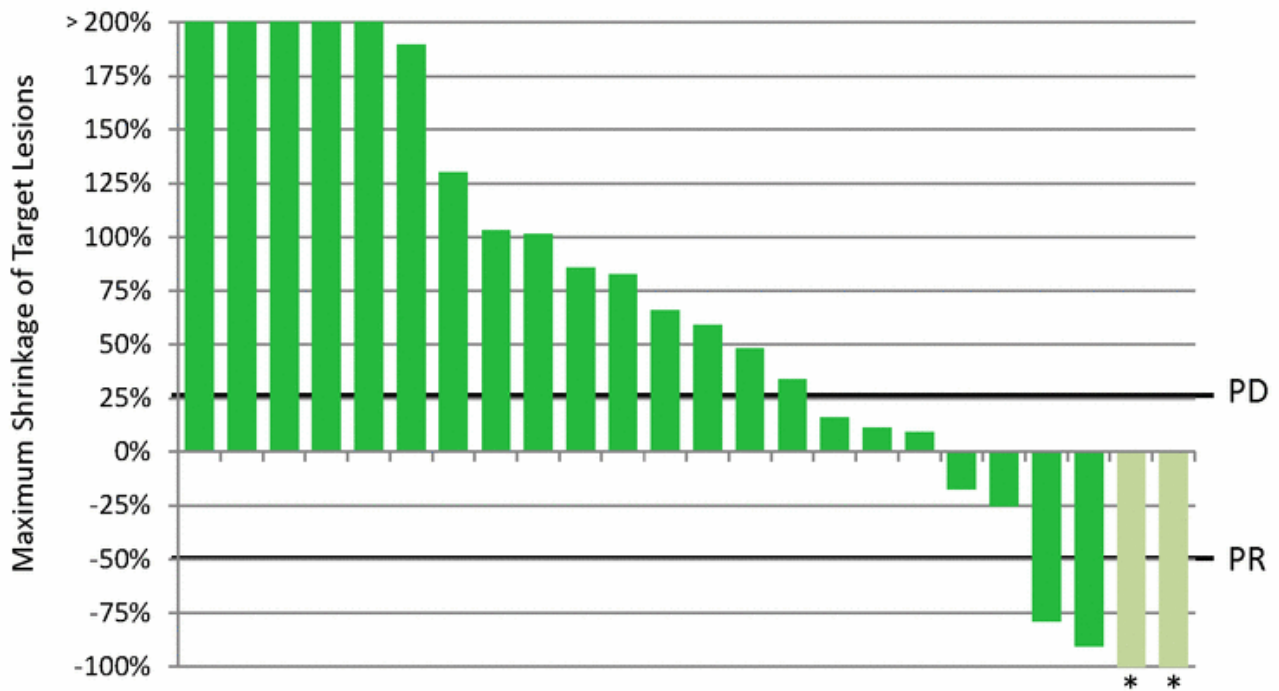
	Median OS Months (95% CI)	6-Month OS (%)
— Highest Titers* (n=13)	6.6 (3.7, 12.6)	69%
- - - All others (n=11)	3.2 (2.3, 4.1)	18%



* Based on the generation of anti-EGFRvIII antibody titer \geq 1:12,800 by Day 57. Similar results observed at Day 29 as well as across a range of cut-off values (1:800 to 1:12,800).

Tumor Shrinkage

Bevacizumab-Refractory Recurrent GBM



Data from Investigator Read

* Previously treated with bevacizumab but did not have progression within 2 months of discontinuation.



Anti-Tumor Effect

Bevacizumab-Refractory Recurrent GBM

- ITT analysis of primary endpoint: 2/25 (8%) patients receiving rindopepimut + bevacizumab were progression-free at 6 months
 - Study designed with an ambitious goal of PFS6=20%
 - No comparative data available to define expected outcome for EGFRvIII positive patients who have failed bevacizumab
- 8 (32%) with stable disease or better for > 2 months (range 2.8 – 11.1)
- Four patients with response
 - Two did not meet protocol-specified definition for refractory disease

Patient	Investigator Assessment	Expert Panel Review
1	PR (79% shrinkage)	SD*
2	90% shrinkage, not sustained	SD*
Patients with progression > 2 months after discontinuation of bevacizumab:		
3	CR (9.3 months duration)	SD*
4	100% shrinkage, not sustained	PR

* Enhancement judged not measurable, but thought to improve on treatment

Anti-Tumor Effect

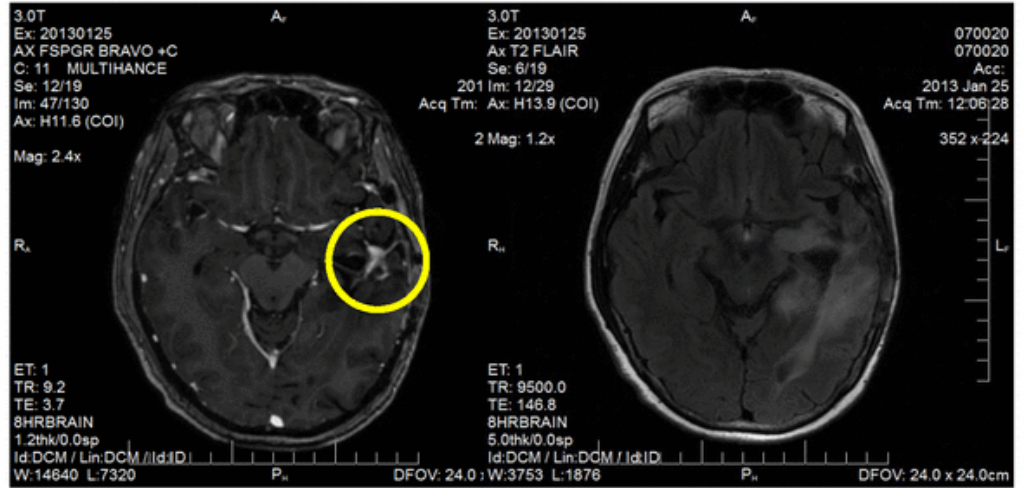
Bevacizumab-Refractory Recurrent GBM

1. One ongoing Partial Response (-79% shrinkage in measurable disease) by Investigator assessment; deemed Stable Disease due to lack of clearly measurable disease by expert panel
 - Patient continues treatment at 8.3 months
 - Prior treatments: partial resection, radiation and temozolomide with progression at 6.1 months post-diagnosis, bevacizumab with 2nd relapse at 3.5 months
2. One patient with -90% shrinkage in measurable disease by Investigator assessment; deemed Stable Disease due to lack of clearly measurable disease by expert panel
 - Response at 2 months was followed by progression at 4 months
 - Prior treatments: partial resection, radiation and temozolomide with progression at 3.7 months post-diagnosis, radiation, bevacizumab with 2nd relapse 4.6 months later

Tumor Response in Bevacizumab-Refractory Recurrent GBM

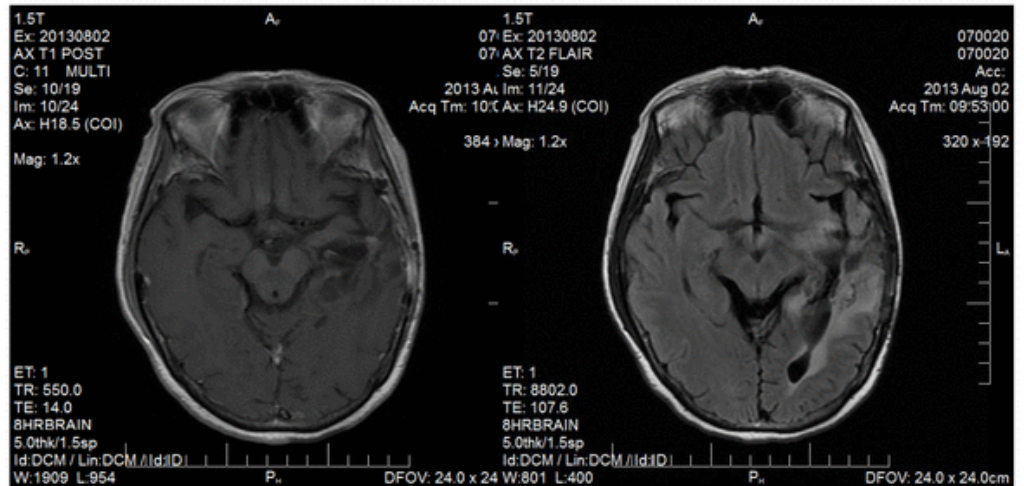
Pre-Rindopepimut

63 yr, female with PD after XRT/TMZ and 7 cycles of adjuvant TMZ; then 2nd PD after 3.5 months on BEV monotherapy



Ongoing response after 5 cycles of Rindopepimut + BEV

Patient continues to be progression free, currently at 8+ months of treatment with rindopepimut + BEV



Anti-Tumor Effect

Bevacizumab-Refractory Recurrent GBM cont.

Responses seen in both patients who had previously received bevacizumab, but did not meet strict definition of refractory per ReACT protocol

3. One Complete Response (9.3 months duration) by Investigator assessment; deemed Stable Disease due to lack of clearly measurable disease by expert panel
 - Patient experienced progression-free survival of 11 months
 - Prior treatments: Gross-total resection, radiation and temozolomide. Adjuvant bevacizumab was switched to temozolomide due to toxicity after 3 months. 1st relapse occurred 5.4 months later
4. One with -100% shrinkage in measurable disease by Investigator assessment; assessed as a robust Partial Response (4 months duration) by expert review panel
 - Patient experienced progression-free survival of 5.5 months
 - Prior treatments: Gross-total resection, radiation and temozolomide, with adjuvant bevacizumab and temozolomide. Bevacizumab was discontinued due to toxicity after 8 months and relapse occurred three years later

Safety



Safety: Bevacizumab-Refractory and Bevacizumab-Naïve Recurrent GBM

- Rindopepimut plus bevacizumab (dosing for up to 13 months) has been well-tolerated
 - No unexpected toxicity associated with concomitant bevacizumab administration
 - No treatment-related toxicity resulting in discontinuation of study treatment
- Treatment-related toxicity consistent with previous studies
 - Grade 1-2 injection site reactions (primarily erythema and pruritus) in the majority of patients
 - One grade 2 hypersensitivity reaction (dyspnea, throat tightness, chest pain)
 - Cerebral edema limited to one Grade 1 event

ReACT Conclusions

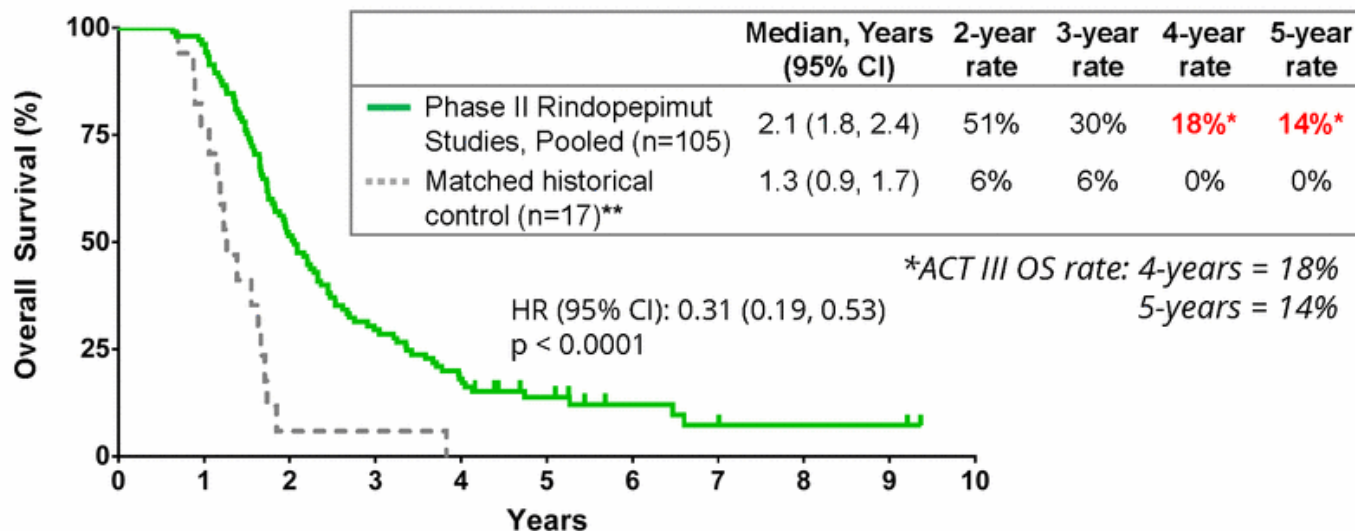
- Rindopepimut combined with bevacizumab was very well tolerated
- Remarkable frequency and level of anti-EGFRvIII immune responses were generated despite prior chemotherapy and growing tumor
- Encouraging tumor response and survival data
 - 48% OS rate at 6 months in refractory patients
 - Trend toward more frequent tumor shrinkage and improved survival in early/interim examination of naïve patients
 - The subjectivity of response evaluation in GBM continues to be a complex issue
- Early development of anti-EGFRvIII titer may be predictive of improved outcome
 - Improved survival associated with rapid generation of humoral response
- Refractory population expansion cohort (n=73) underway, accrual to naïve arm ongoing
- Results support the potential for efficacy in newly diagnosed patients
 - ACT IV trial data pending

Additional Updates



Rindopepimut: Long-Term Follow-up from Phase 2 Trials in *de novo* GBM

- Three Phase 2 Studies: ACTIVATE (n=18), ACT II (n = 22), ACT III (n=65)
 - Newly diagnosed, resected, EGFRvIII-expressing GBM
- Significant anti-EGFRvIII immunity in 85% of ACT III patients (67% > 1:12,800)
- EGFRvIII eliminated from 86% of recurrent tumors
- Very little toxicity
- International Phase 3 study ongoing



** Patients treated at M.D. Anderson contemporaneously to ACTIVATE, matched for major eligibility requirements, including EGFRvIII+ GBM, GTR and no PD through CRT.



ACT IV: Phase 3 Study in Newly-Diagnosed EGFRvIII-positive Glioblastoma

- Randomized (1:1), double-blind, placebo controlled study in up to 450 patients with newly diagnosed, surgically resected, EGFRvIII-positive glioblastoma (including 374 patients with minimal residual disease) (adaptive design); approx. 200 international sites in 20+ countries
- Rindopepimut/GM-CSF with standard of care (SoC) maintenance temozolomide vs blinded control (KLH) with SoC
- Study objectives - Overall survival (primary), PFS (RANO criteria), safety, immune response, QoL, elimination of EGFRvIII expression
- Includes sample size re-estimation and interim analyses where the trial may terminate early for futility or success



ACT IV Status Update

- In this adaptive design study, total accrual is dependent on the following variables:
 - Overall enrollment rate
 - Patients with minimal residual disease
 - Rate of events (deaths)
- 351 patients have been randomized to date
- Due to event rate and patient mix, enrollment will exceed 450 patients and is expected to continue to mid-year 2014
- First interim analysis anticipated late 2014/early 2015
- Further update on year-end call in February

Q&A

