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Sapacitabine oral capsules

(an investigational agent, not approved for human use)

November 19, 2013

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Sapacitabine Overview

Interferes with cancer cell repair via HR pathway

Oral; well tolerated; differentiated to current alternatives

- Convert AML → chronic disease

Significant market opportunity

- Front-line AML (SEAMLESS registration Ph. 3 under SPA)
- 2nd line MDS after hypomethylating agent failures
- Solid tumor activity in HR-deficient patients incl. gBRCA +ve

Exclusivity: Long patent life cycle to 2027-2030; orphan US & EU

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AML Unmet Medical Need since 1969

- **16,000** US prevalence; **14,590** US incidence 2013 est. *
- Elderly cannot sustain intensive chemo. Treatment mortality ↑ & survival ↓ with age ≥ 70 yrs. Need less intensive therapies

Treatment	*Fit for Intensive Chemo (20%)*	*Unfit/Refused Intensive Chemo (80%)*
Front line	7 + 3	*Clinical trial* **Sapacitabine**
Relapsed/ Refractory	*Clinical trial*	*Clinical trial*

** Source: American Cancer Society and Cyclacel-commissioned primary market research. Sapacitabine data on file.* ***AML is an older/elderly disease: 50% ≥ 70 yrs.****; median age: ~ 67 .*

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Sapacitabine Key Clinical Data

AML:

- SEAMLESS pilot/lead-in 60-day mortality & landmark analysis*

MDS:

- Phase 2 median OS ~ 9 months nearly doubled expected median OS in HMA failures ‡◊

Solid tumors:

- Phase 1 durable PRs in gBRCA breast, ovarian, pancreatic cancers° and Phase 2 durable PRs in NSCLC ◊

** Source: ASH '12. † Lancet Oncology 2012. ‡ Eighth Annual Hematologic Malignancies 2012. ° AACR 2013. ◊ Data pending.*

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"SEAMLESS" Phase 3 Design

(Untreated AML: front line; aged ≥ 70 years; n=485)

- ✓ Design in consultation with FDA under SPA; p=0.05; HR=0.725.
- ✓ DSMB reviews every 100 patients; futility after 212 events
- ✓ Ca. 50% enrolled in US; EU expansion; completion by YE14

A. Alt. sapacitabine + decitabine (n~243)

Primary Endpoint: overall survival

B. Decitabine (n~243)

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Elderly AML: Key Benchmark Data

Most elderly patients unable to sustain intensive chemotherapy

Treatment mortality increases and survival decreases with age ≥70 years

Treatment	*4-week death rate*	*8-week death rate*	*m OS*
Intensive Chemotherapy	26%	**36%**	~4.6 months*
Low-intensity Chemotherapy	9%	**20%**	~5.0 - 7.7 months† ‡
Best Supportive Care	17%	N/A	~3.6 months◊
Sapacitabine:			
Pilot Lead-in for SEAMLESS	4%	**13%**	~8.5 - 9.4 months @

** Kantarjian, et al, Blood, 2010. † Burnett, et al, Cancer, 2007, Kantarjian, et al, Blood , 2012 ◊ Harousseau, et al, Blood 2009. ‡ Kantarjian, et al, JCO, 2012. @ Ravandi F, et al, American Society of Hematology Annual Meeting Dec. 2012, Abstract #2630.*

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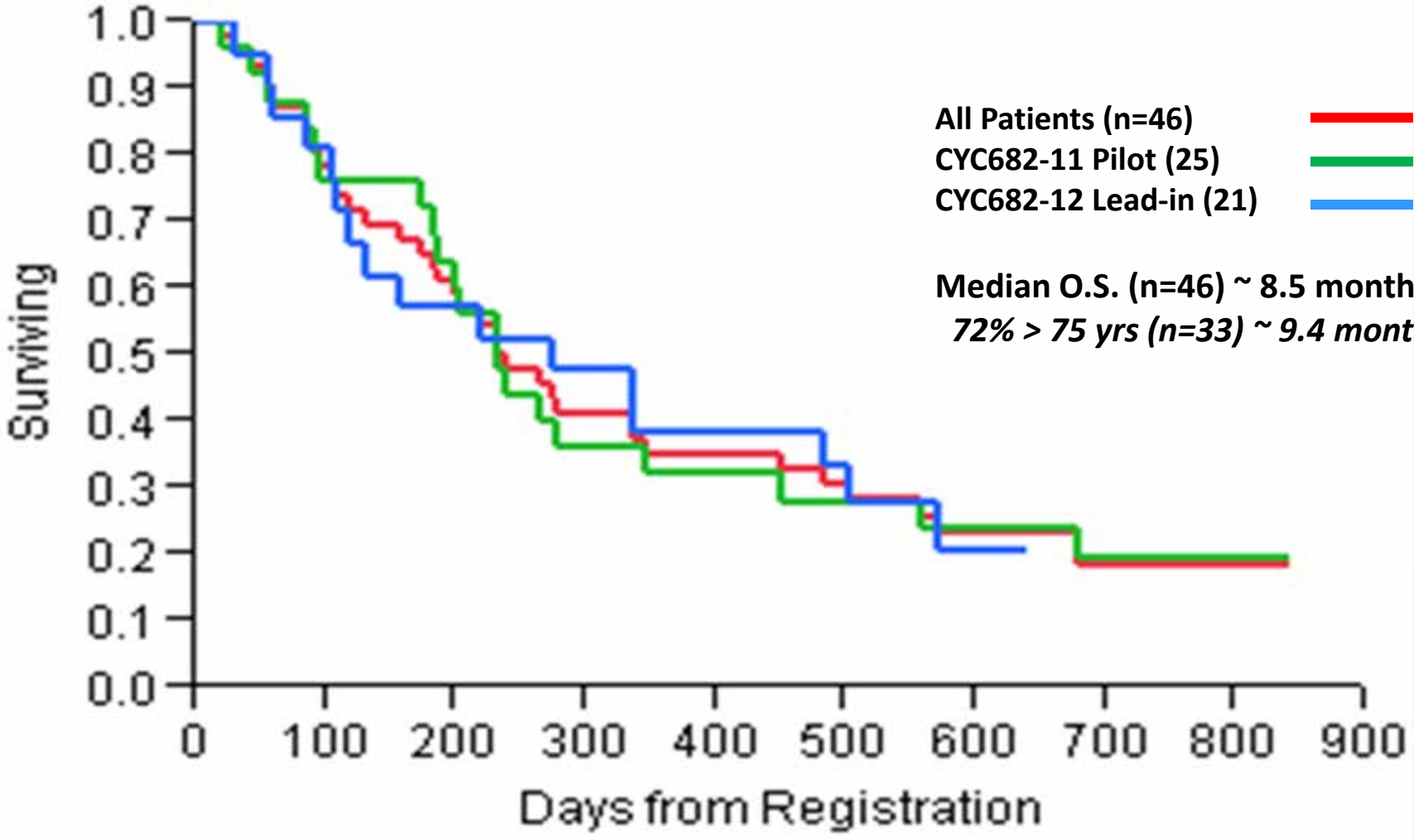
SEAMLESS Pilot/Lead-in Study

Kaplan-Meier Survival Plot



Median O.S. (n=46) ~ 8.5 months

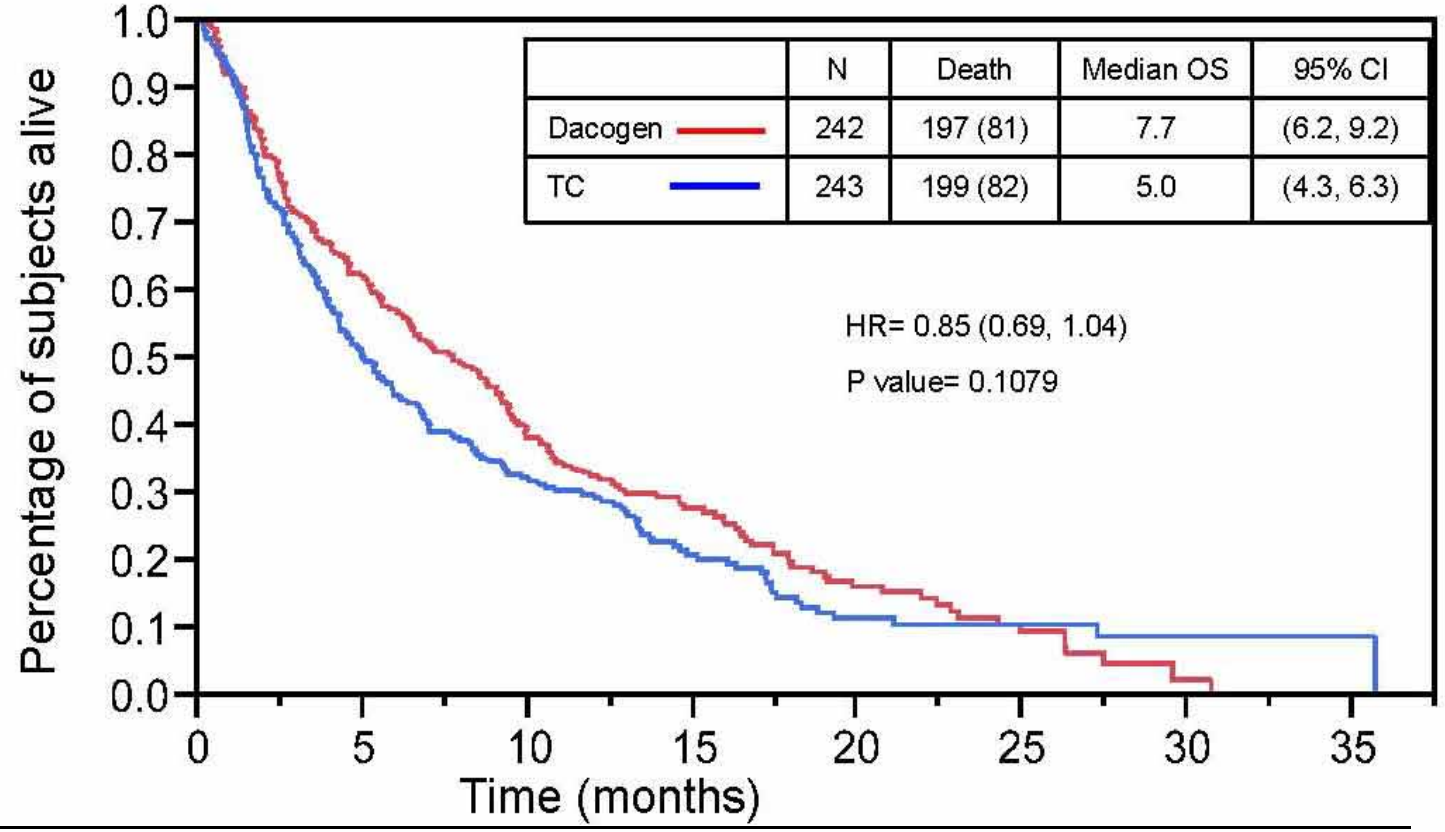
72% > 75 yrs (n=33) ~ 9.4 months

No. at risk	3M	6M	12M	18M	24M
	38 (83%)	**30** (65%)	**16** (35%)	**12** (26%)	not reached

** Source: Ravandi F, et al, American Society of Hematology Annual Meeting Dec. 2012, Abstract #2630.*

K-M Plot, Pre-specified OS final Analysis

(DACO-016: Cut-off Oct. 28, 2009)



	N	Death	Median OS	95% CI
Dacogen	242	197 (81)	7.7	(6.2, 9.2)
TC	243	199 (82)	5.0	(4.3, 6.3)

No. of subjects at risk		6M	12M	18M	24M	30M	36M
Dacogen	242	137	65	28	12	1	0
TC	243	107	55	19	07	4	0

** Source: FDA Briefing Document, Dacogen ODAC, February 9, 2012. Of 242 treated with decitabine 39% were aged 75 years or older.*

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Phase 3 Cross Study Comparison

Required reduction in risk of death: 27.5%

Landmark analysis vs. DACO-016: Non-inferior at all time points

60-day mortality:

Decitabine (DACO-016, > 65y, n=242): **20%** †

Sapacitabine/ Decitabine (ASH ’12, > 70y, n=46): **13%** *

Median Overall Survival (OS):

Decitabine (DACO-016 , > 75 years, n=95): **~ 6.3 mos.** †

Sapacitabine/ Decitabine (ASH ’12, > 75y, n=33): **~ 9.4 mos.** *

** Interim data from pilot, lead-in study of Arm A in SEAMLESS; subject to change. ASH 2012, Abs. 2630; 76% > 75 years.*
† Caveat: cross-study comparison. Kantarjian, et al, JCO, 2012.

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MDS Unmet Medical Need

*Est. 300K incidence in US & EU in 2008**

45,000 US Medicare patients (aged ≥65 years) filed claims for MDS in 2003*

Treatment	*Low Risk*	*High Risk*
1st line	***lenalidomide #***	***azacitidine#*** ***decitabine***
2nd line	*Clinical trial*	*Clinical trial* **Sapacitabine**

*…NCCN guidelines for 1st line hypomethylating agents**: 4-6 cycles** …‡*

*Median OS int-2/high-risk MDS after **treatment failure** of HM agents: **4.3-5.6 months**†*

** Source: Cyclacel est. & Golberg, S, et al, JCO, 2010. # Revlimid®, Celgene. Vidaza®, Celgene. & Dacogen®, Eisai. Dacogen and Vidaza are hypomethylating (HM) agents. ‡ NCCN Guidelines MDS v.2.2011 p. 19. † Prebet T, Gore S, et al, JCO 2011; Jabbour E, Garcia-Manero G, et al, Cancer 2010.*

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MDS HMA Failures: Key Benchmarks

MDS int-2 & high-risk IPSS experimental Standard of Care after frontline failure

Treatment	*m OS*	*1 year survival*
Azacitidine 2nd line	~5.6 months †	- †
Decitabine 2nd line	~4.3 months †	- †
Best Supportive Care	~4.1 months †	17% †
Sapacitabine:		
Phase 2 study 2nd, 3rd, 4th line	~ 10 months@	38% @

† Prebet T, Gore S, et al, JCO 2011 (95% CI, 14% to 26% on best supportive care; 29% on investigational agents).
@ ASH 2013 abstract 2752, November 7, 2013.

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Sapacitabine in Solid Cancers Phase 1 *

Sapacitabine may work best in HR-deficient tumors

All-oral sequential regimen with Cyclacel's seliciclib:

- durable clinical benefit (PRs & prolonged SD) in gBRCA +ve breast, ovarian, pancreatic cancers
- of which 55% ORR in PARP-naïve patients

…Opening new opportunities for line extensions…

** Source: Shapiro et al, AACR Proceedings, 2013, LB-202.*

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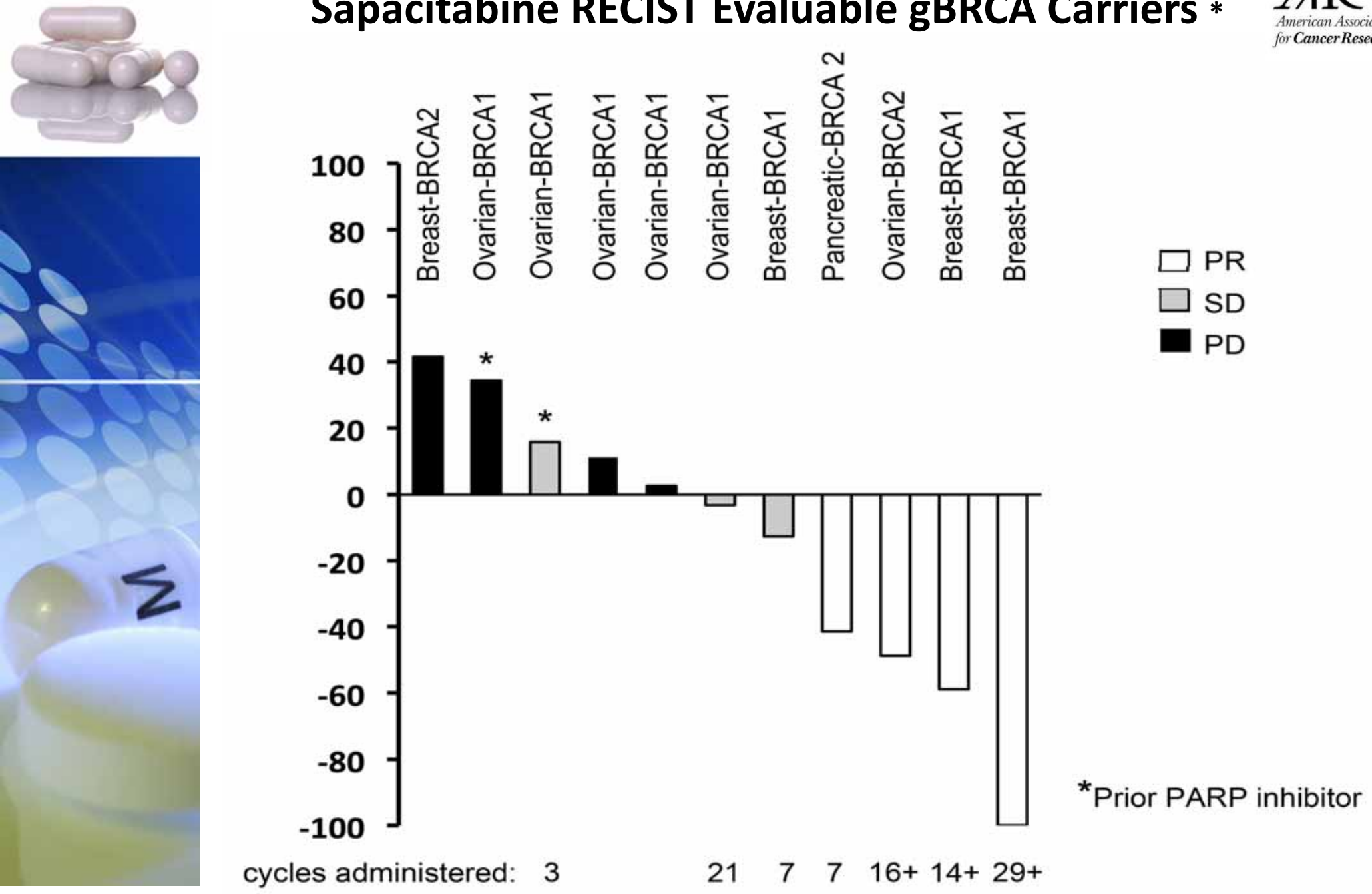
Sapacitabine RECIST Evaluable gBRCA Carriers *



** Source: Shapiro et al, AACR Proceedings, 2013, LB-202.*

Changing the Paradigm

"Sapacitabine is one of the most exciting drugs in development for AML since cytarabine, the current standard of care." †

Hagop Kantarjian, M.D.
Chairman & Professor, Leukemia Department

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
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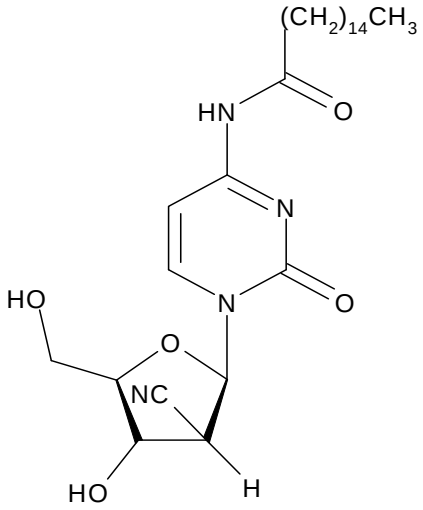

† *Source: CYCC Analyst Note 11/07, Lazard Capital Markets.*

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