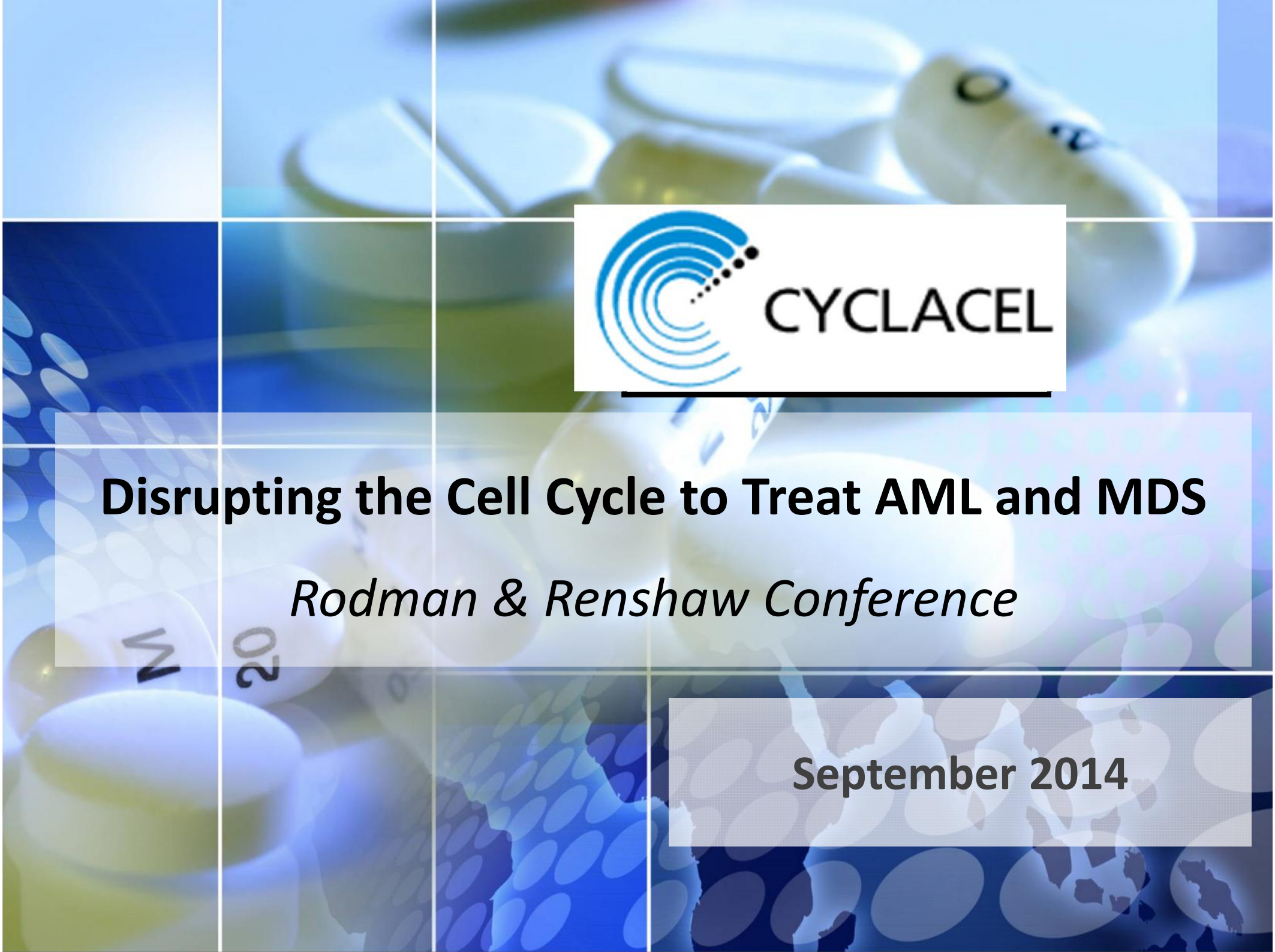

Disrupting the Cell Cycle to Treat AML and MDS

Rodman & Renshaw Conference

September 2014

Disclaimer

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Cyclacel Highlights

Sapacitabine in front-line AML in the elderly: SEAMLESS Phase 3

- Oral agent for elderly AML patients; minimal options today
- Interim analysis for futility expected late 2014/early 2015
- Complete enrollment 2014/15; top-line data 2H15

Sapacitabine in high-risk MDS after HMA failure

- "Impressive" Phase 2 survival data in 2nd/3rd Line MDS
- Phase 2b RCT planned to start in 2015

Strong financial position & earlier-stage pipeline

- Sufficient capital beyond SEAMLESS Phase 3 data readout
- Sapacitabine in solid tumors; CDK and PLK inhibitors

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Sapacitabine for AML

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AML Unmet Medical Need since 1969*

- Young AML patients: induction chemotherapy cocktail, then transplant
- Most elderly cannot tolerate Intensive chemo; need less intensive therapies
- Drug development goal: overall survival (OS) not necessarily remission (CR)

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

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

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Predicament of 70+ year old AML Patient

- Newly diagnosed AML: multigenetic, heterogeneous disease

- Old age, frailty and comorbid conditions

Options:

- 45-year old intensive chemotherapy regimen
- Investigational agent(s) in a clinical trial
- Hospice or terminal care at home

- Expected median survival of 3 - 6 months
- Mortality in first 2 months of ~ 20 - 36%

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Elderly AML Benchmark Data

Most elderly patients unable to sustain intensive chemotherapy

Treatment mortality ↑ and survival ↓ with age over 60 years

Treatment	*4-week death rate*	*8-week death rate*	*m OS*
Intensive Chemotherapy	26%	**36%**	~ 5 months*
Low-intensity Chemotherapy	9%	**20%**	~ 5 - 8 months† ‡
Best Supportive Care	17%	N/A	~ 4 months◊
Sapacitabine:			
Pilot Lead-in for SEAMLESS	4%	**13%**	~ 8 months @

** Kantarjian, et al, Blood, 2010. † Burnett, et al, Cancer, 200[illegible] 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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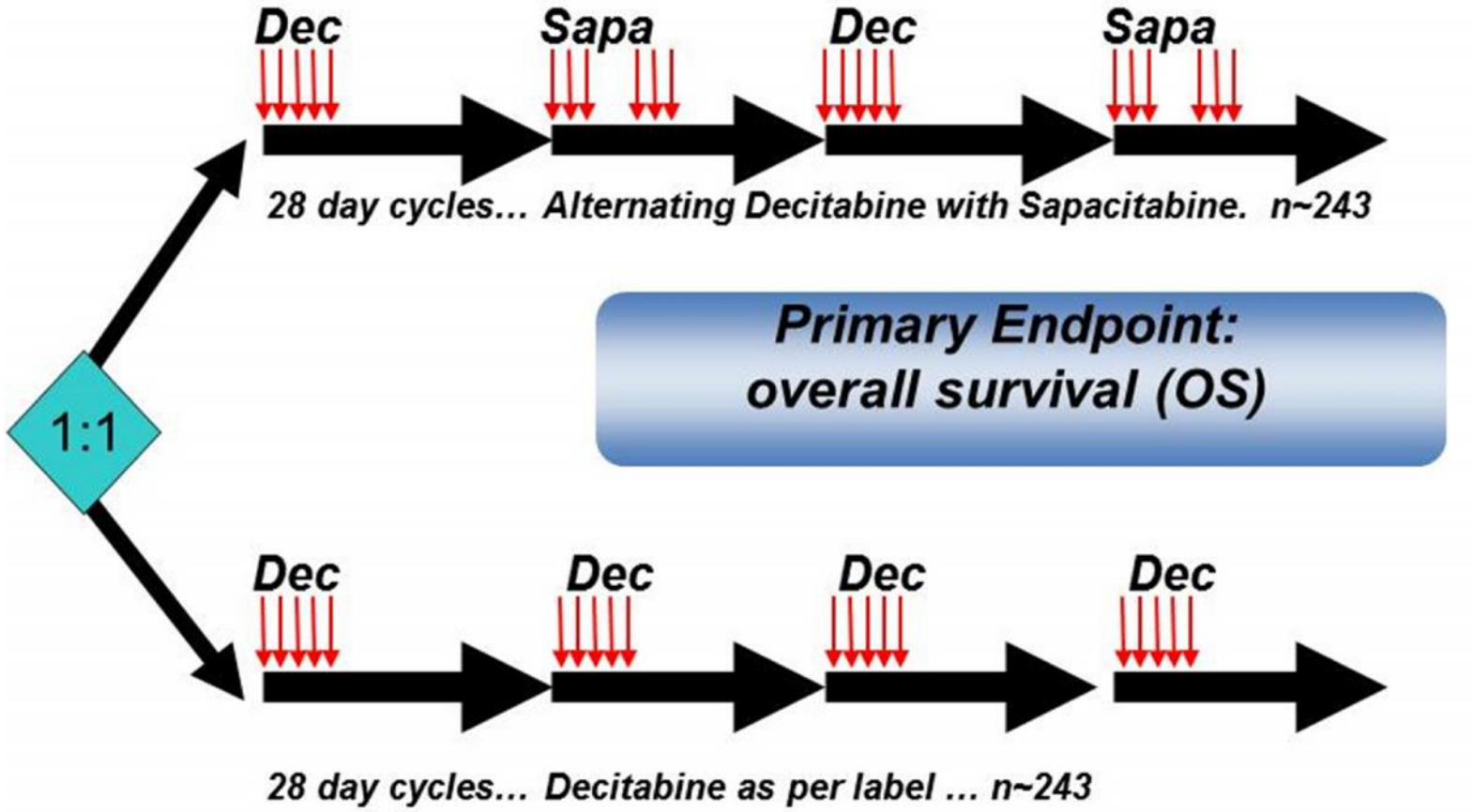
Rationale for Sapacitabine in AML

- Elderly AML patients are very frail
- How to control leukemia cell growth but not worsen the patient's immunity & quality of life?
- Sapacitabine-based Phase 3 "low-intensity" regimen balances those needs, resulting in ~ half the 60-day mortality vs. that reported with control regimen
- Hypothesis tested in SEAMLESS Phase 3 study under SPA:
  - Can the use of a sapacitabine-based less-intensive treatment regimen ↑ OS vs. active control

** Source: ASH 2012. Kantarjian et al, JCO, 2012.*

“SEAMLESS” Phase 3 Design

(Untreated AML: front line; ≥ 70 years; n=485; p=0.05; HR=0.725)



- ✓ In consultation with FDA under SPA enrolling at U.S. and European centers
- ✓ DSMB every 100 patients *(n=119; n=212*:“no safety or efficacy concerns”)
- ✓ Interim analysis for futility after 212 events (50% of required events)

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SEAMLESS Milestones

- DSMB review at ~ 300 patients: 2H14
- Interim analysis for futility: Late 2014/Early 2015
- Enrollment > 70%; completion: Late ’14/Early ’15
- Top-line data: 2H15

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Will SEAMLESS Phase 3 Succeed?

Required reduction in risk of death: 27.5%

Median Overall Survival (OS):

Decitabine (DACO-016 , > 75 years, n=95): **~ 6 mos.** †

Sapacitabine/ Decitabine (ASH ’12, > 75y, n=33): **~ 9 mos.** *

60-day mortality:

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

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

Complete enrollment around end of 2014

** 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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NDA Enabling Activities

- External consultant review of available NDA content
- Planning a potential “rolling NDA” submission
  - Biopharm section
  - CMC section
  - Clinical section would be last to be submitted
- Core dossier also to be used for MAA submission in EU

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Sapacitabine for MDS

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MDS Unmet Medical Need

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

…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†***

 # Revlimid®, Celgene. Vidaza®, Celgene. & Dacogen®, Otsuka. Dacogen & 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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Predicament of 60+ year old High-Risk MDS Patient

High risk MDS after failure of front-line drugs

- Already failed 1st line hypomethylating agents (HMAs): azacitidine (Vidaza®) and/or decitabine (Dacogen®)
- Higher risk from infections; transformation into AML
- Multigenetic, heterogeneous disease

Options:

- Investigational agent(s) in a clinical trial
- Hospice or terminal care at home

- Expected median survival of 4.3 - 5.6 months †

† Source: Prebet T, Gore S, et al, JCO 2011; Jabbour E, Garcia-Manero G, et al, Cancer 2010.

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Sapacitabine Phase 2 MDS Design: 682-06, Part 4

High-risk MDS: 2nd, 3rd or 4th line; ≥ 60 years; n=63; all arms 28-day cycles

- ✓ Intermed-2 or hi-risk IPSS after HMA failure; blasts 6% -19%
- ✓ Primary Endpoint: 1-year survival

G. Sapacitabine 200mg bid x 7d (n=21)

H. Sapacitabine 300mg qd x 7d (n=21)

I. Sapacitabine 100mg qd x 5d x 2w (n=21)

Source: Garcia-Manero et al, J. Clin. Oncol. 2012:30:Abs. 6520. HMA = hypomethylating agents.

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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	~ 6 months †	- †
Decitabine 2nd line	~ 4 months †	- †
Best Supportive Care	~ 4 months †	17% †
Sapacitabine:		
Phase 2 study 2nd, 3rd, 4th line	~ 9 months@	38% @

† Prebet T, Gore S, et al, JCO 2011 (95% CI, 14% to 26% on best supportive care; 29% on investigational agents). @ Garcia-Manero G et al, American Society of Hematology Annual Meeting Dec. 2013, Abstract #2752 (Arm G 1-year survival).

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Sapacitabine Phase 2 MDS Data

(High Risk MDS: 2nd, 3rd or 4th line; aged ≥ 60 years; n=63) *

	Total (63)	*Arm G (21)*	*Arm H (21)*	*Arm I (21)*
Prior Azacitidine	30	9	10	11
Prior Decitabine	15	4	3	8
Prior Aza + Decitabine	18	8	8	2
Median OS (days)	**260**	**291**	**290**	**227**
≥ 10% blasts in b.m.	*291*	*266*	*307*	*153*
60-day deaths	8	3	2	3
Responders	32	11	11	10

** Garcia-Manero G et al, American Society of Hematology Annual Meeting Dec. 2013, Abstract #2752. Response = CR/CRp, major HI, stable disease over 16 weeks.*

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Sapacitabine MDS Phase 2b RCT

Study Objectives

- Prolong overall survival
- Convenient outpatient treatment

Active control options

1. Low dose cytarabine (LoDAC)
   - Differentiated mechanism
   - Outpatient convenience
   - Activity in 1st line setting *
2. *Other HMA*
   - *Patients failed/progressed 1st line HMA*
   - *IV administration*
   - *HMA cross-treatment data inconclusive*

** Zwierzina H et al, Leukemia, 2005.*

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Rationale for Randomized Phase 2b RCT

- Limited knowledge
- Genetic heterogeneity & treatment complexity
- Sapacitabine Phase 2 clinical data encouraging
- Cyclacel approach
  - Review recent MDS trials
  - Confer with MDS KOLs
  - Conduct feasibility assessment
- Goal: determine path that may
  - Add to understanding of sapacitabine's role in the indication
  - If RCT data exceptional, discuss with regulators

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Phase 2b MDS RCT Design

(int-2 or high risk MDS after HMA failure: aged ≥ 60 years; n~250)

A. Alternating sapacitabine & LoDAC (n~125)

Primary Endpoint: overall survival (OS)

B. LoDAC* (n~125)

- ✓ Feasibility in over 100 US & EU sites
- ✓ Est. enrollment ~15 months , excl. lead-in stage
- ✓ Interim safety reviews at 100 & 200 patients

** LoDAC=low-dose cytarabine.*

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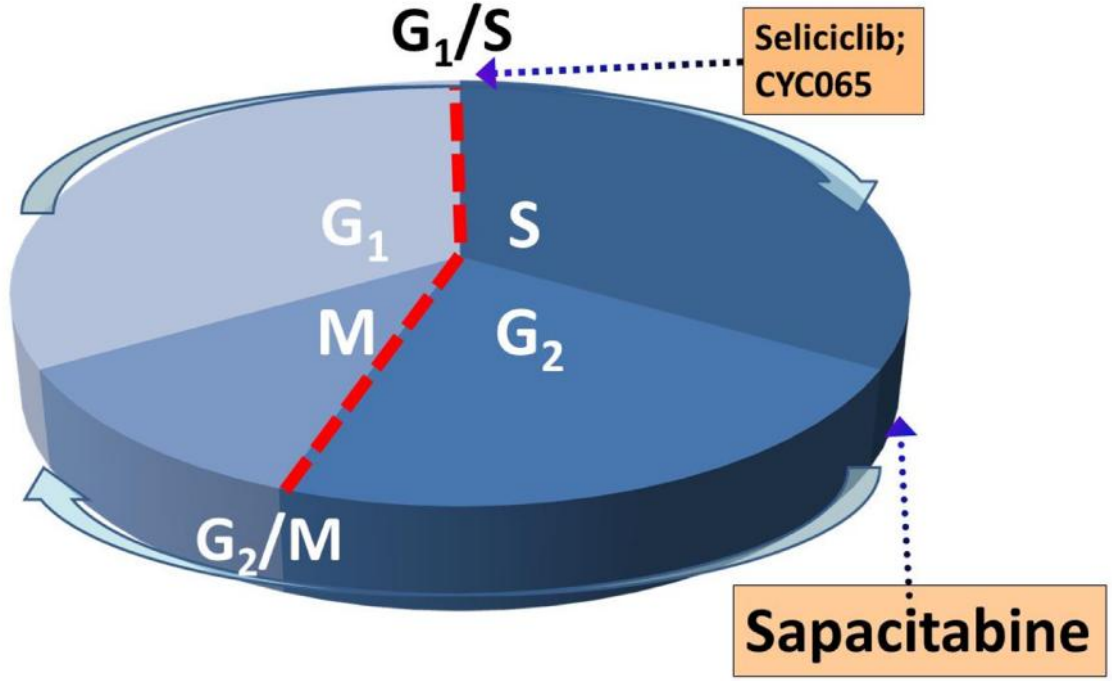
Sapacitabine Overview



Interferes with cancer cell repair via HR pathway

Therapeutic strategy: QOL maintenance vs. toxic cure attempt

- Oral administration; well-tolerated; administered over multiple cycles

Significant market opportunity beyond AML and MDS

- Solid tumor activity in HR-deficient patients incl. gBRCA +ve

Exclusivity: IP to 2027-30; Orphan Drug Status for AML & MDS

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Cyclacel Early-stage Pipeline

Candidate	*MOA*	*Use*	*Pre-clinical*	*Phase 1*	*Phase 2*	*Phase 3*
Sapacitabine + seliciclib	DNA synthesis inhibitor + CDK2,7,9 inhibitor	HR repair-deficient solid tumors	→	→		
CYC065	CDK2,5,9 inhibitor	Blood & solid tumors*	→			
CYC140	PLK1 inhibitor	Blood & solid tumors*	→			

**Both mainly funded by government grants.*

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Financial Position & Capitalization

Cash runway beyond SEAMLESS Phase 3 data

- ~$34 m cash & cash equivalents [1]
- Complete SEAMLESS ~ end of 2014; data read-out ~ 2H 2015 (costs to data readout ~ $12 m)
- Other R&D costs and G&A: ~ $8-9 m annually [3]

Fully diluted shares: ~ 25.3 million [1, 2]

No debt

1. *Company 10-Q June 30, 2014 . Common stock outstanding: 22.7 million.*
2. *Includes 1.1 million warrants and options with an exercise price > $10 per share.*
3. *Excludes cost of MDS Ph 2b RCT*

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Key Milestones

Sapacitabine

- SEAMLESS: 300-patient DSMB review
- SEAMLESS: interim analysis for futility
- SEAMLESS: complete enrollment
- MDS: open enrollment of Phase 2b after HMA failure
- Sapacitabine & seliciclib in patients with solid tumors: update Phase 1 data

Other

- Advance early-stage pipeline

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Summary

- **Sapacitabine opportunity in front line AML: SEAMLESS approaching completion**
- **Sapacitabine in MDS: Phase 2 data, high-reward**
- **Strong financial position: sufficient capital beyond SEAMLESS data read-out**
- **Early-stage pipeline addressing high-interest targets & mechanisms of action**

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Cyclacel Pharmaceuticals

Cell cycle pioneers

Improving patient lives

With orally-available

Innovative medicines

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