



Vion is committed to extending and improving the quality of lives of cancer patients worldwide by bringing innovative cancer treatments to market

**Rodman & Renshaw
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Corporate Overview

- **Cloretazine[®] is lead product**
 - **Registration focus is in AML**
 - **Phase III trial in relapsed AML underway**
 - **Pivotal Phase II trial in elderly *de novo* poor-risk AML underway**
 - **Fast Track status in two AML indications**
 - **Orphan Drug status for treatment of AML (US and EU)**
 - **Additional activity in small cell lung cancer and brain tumors**
- **Clinical trials of second clinical compound Triapine[®] ongoing under NCI sponsorship**
- **Resubmission of IND for third clinical compound VNP40541 planned for 2007**
- **All commercialization rights retained by Company in major markets**
- **Patents for Cloretazine[®] provide coverage through 2015**
- **Management team has significant collective experience in pharmaceutical management at large pharmaceutical companies**

Ongoing Clinical Development

Cloretazine® Hematologic Malignancies		Phase I	Phase II	Phase III
First Relapse AML	Combination with cytarabine	—————●		
Elderly <i>de novo</i> Poor-Risk AML	Single Agent	—————●		
Relapsed/Refractory Leukemia	Combination with temozolomide	—————●		
Cloretazine® Solid Tumors		Phase I	Phase II	Phase III
Small Cell Lung Cancer	Single Agent	—————●		
Pediatric Glioma*	Single Agent	—————●		
Vion Pipeline		Phase I	Phase II	Phase III
Triapine®	Single Agent/Combination Studies**	—————●		
VNP40541 (KS119)	Preclinical	●		
Hydrazones	Preclinical	●		
TAPET®	Preclinical	●		

* Investigator Initiated

** NCI Sponsored

Vion Management

- **Alan Kessman**, Chief Executive Officer: Entrepreneur, formerly CEO of Executone Information Systems
- **Howard Johnson**, President & CFO: Entrepreneurial financial management at several technology firms and Investment Banking at Paine Webber
- **Meg Fitzgerald**, Chief Business Officer: formerly Senior Director in Strategic Planning at Pfizer
- **Ann Cahill**, Vice President, Clinical Development: formerly in project management at Schering-Plough
- **Dr. Ivan King**, Vice President, Research & Development: formerly in R&D at Schering-Plough
- **Aileen Ryan**, Vice President, Regulatory Affairs: formerly Head of Global Regulatory, Oncology at Bayer
- **Karen Schmedlin**, Vice President, Finance and Chief Accounting Officer: Over twenty years experience in public company accounting

Cloretazine[®]

Vion's Lead Anticancer Agent

- **Novel alkylating agent**
- **In two pivotal trials for AML**
 - Phase III trial completion of patient accrual expected late 2007
 - Phase II trial completion of patient accrual expected mid-2007
- **Phase II single agent data in elderly AML from 14 sites worldwide demonstrated 32% response rate overall, 50% response rate in de novo patients**
- **Initial data in solid tumors suggests activity in small cell lung cancer and brain tumors**
- **Licensed from Yale University**
- **Patent extends to 2015**

Cloretazine[®]

Biology and Pharmacology

- Preferential O⁶ alkylation
- Forms DNA cross-links
- In contrast to BCNU
 - No hydroxylating, aminoethylating, or vinylating activity
 - Produces a methylisocyanate versus chloroethylisocyanate
- Methylisocyanate group is thought to contribute to cytotoxicity
- Alkyl-guanine transferase (AGT) believed to be major mechanism of resistance
- Does not inhibit glutathione reductase
- Crosses blood-brain barrier
- Orally active

Cloretazine[®] Phase I Trials

Study	Pt Population	N	Dose Range	Schedule	DLT	Activity
Single agent	Solid tumor	26	3-305 mg/m²	q4w → q6w	Thrombocytopenia	CA-125 decrease in ovarian CA
Single agent	Solid tumor	23	80-155 mg/m²	w x 3 q4w → w x 3 q6-8w	Thrombocytopenia and neutropenia	SD with regression in head and neck, small B-cell lymphoma
Single agent	Advanced heme	38	220-708 mg/m²	q4-8w	Prolonged myelosuppression	CR MDS; CR AML
+IVCI HDAC	Advanced heme	41	200-600 mg/m²	AraC d1-4 or d1-3 Cloretazine[®] d2	Ileus, colitis and prolonged myelosuppression	At doses ≥400 mg/m², CR/CRp 32%

Clotretazine[®] Clinical Regulatory Strategies

Hematologic Indications		Regulatory Approval Considerations
Elderly <i>de novo</i> Poor-Risk AML (CLI-033 and CLI-043)	Single agent	<ul style="list-style-type: none">• Pivotal Phase II underway• Fast Track Designation• Orphan Drug Designation (US and EU)
First Relapse AML (CLI-037)	Combination with cytarabine	<ul style="list-style-type: none">• Pivotal Phase III underway• Fast Track Designation• Orphan Drug Designation (US and EU)



Cloretazine[®]
Acute Myelogenous Leukemia:
Elderly Poor-Risk Induction Therapy

Registration Indication

Elderly AML Induction Therapy

Current Treatment Patterns:

- **70% of patients best supportive care/palliation**
- **10-20% pts receive standard "3+7" anthracycline/cytarabine**
- **Investigational therapy for patients ≥ 60 years according to NCCN/ESMO guidelines**

Treatment Challenges:

- **Leukemia Biology**
 - **Unfavorable cytogenetics**
 - **Increased MDR expression**
 - **Increased secondary AML**
- **Clinical Baseline**
 - **Increased Age**
 - **Decreased functional status**
 - **Medical Comorbidities (cardiac, hepatic, pulmonary)**

CLI-033: Cloretazine[®] Phase II trial

- Cloretazine[®] 600 mg/m² IV *Day 1*
- Stratum A
 - Elderly AML (no prior cytotoxic treatment)
 - High Risk MDS ≥ 60 yrs (no prior cytotoxic treatment)
- 107 patients treated overall, 104 evaluable
- Median age: 72 (range: 60-84)
- 44% de novo AML patients; 45% secondary AML patients; 15% high-risk MDS patients
- No favorable risk cytogenetics; 55% intermediate cytogenetics; 45% unfavorable cytogenetics

CLI-033: Cloretazine® Phase II Trial

Stratum A: Clinical Outcome

Clinical Response			
Disease	CR/CRp	Overall Response (n)	% Response
<i>de novo</i> AML (44)	20/2	22	50
Secondary AML (45)	5/0	5	11
MDS (15)	4/2	6	40
Total (104)	29/4	33	32

Cytogenetics: *de novo* Patients (n=22 responders)

14 patients intermediate cytogenetics 52% CR

8 patients unfavorable cytogenetics 47% CR

CLI-033: Cloretazine® Phase II Trial

Stratum A: Distribution of Risk Factors

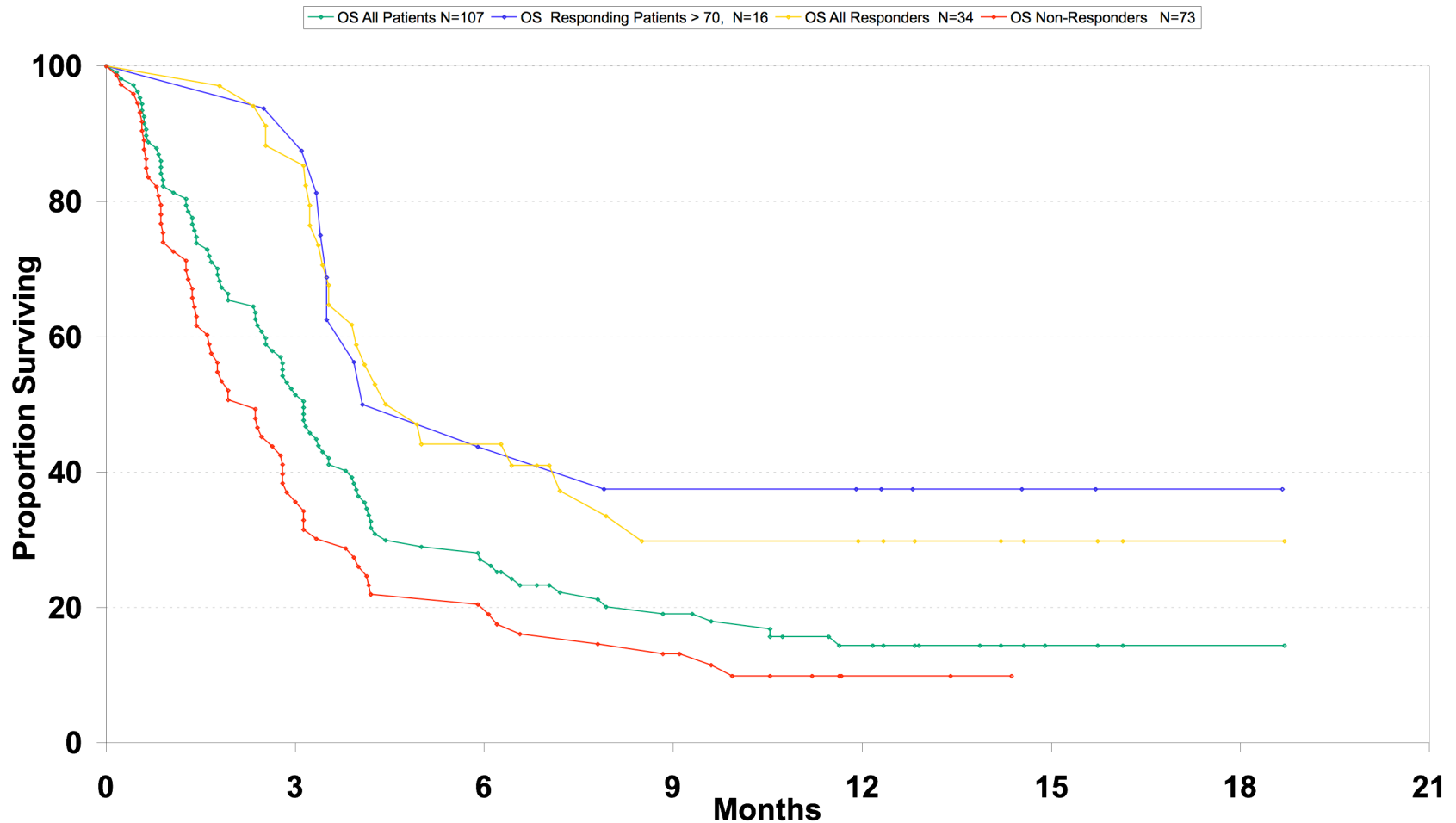
# Risk Factors	# of patients	Unfavorable cytogenetics N (%)	Secondary AML N (%)	PS 2 N (%)	Organ dysfunction N (%)
Age+0	12	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Age+1	20	4 (20%)	9 (45%)	0 (0%)	8 (40%)
Age+2	43	23(53%)	22 (51%)	11 (26%)	27 (63%)
Age+ ≥ 3	29	19 (66%)	14 (48%)	20 (69%)	29 (100%)

CLI-033: Cloretazine[®] Phase II Trial Stratum A: Response by Risk Factors

# Risk Factors	# of patients	CR/CRp (N=33)	CR/CRp (%)
Age+0	12	7	58%
Age+1	20	7	35%
Age+2	43	9	21%
Age+ ≥ 3	29	10	34%
All	104	33	32%

CLI-033: Cloretazine[®] Phase II Trial

Stratum A: Overall Survival



CLI-033: Cloretazine[®] Phase II Trial

All Adverse Events

EVENT	Worst Grade per Patient*					TOTAL N	(%)
	1-2	3	4	5			
Infusion-related symptoms**	60	5	2	0		67	26%
Gastrointestinal disorders	53	4	0	0		57	22%
Non-infectious pulmonary disorders	20	6	1	0		27	10%
Infection including febrile neutropenia	7	14	6	1		28	11%
Constitutional Disorders	19	4	1	0		24	9%
Skin/Rash	14	3	0	0		17	6%
Cardiac disorders	7	0	1	1		9	3%
Neurologic dysfunction	6	2	0	0		8	3%
Metabolic changes	5	2	0	0		7	3%
Eye Disorders	5	0	0	0		5	2%
Hepatic Disorders	0	2	2	0		4	2%
Renal Dysfunction	1	2	1	0		4	2%
Vascular Disorders	3	0	0	0		3	1%
Musculoskeletal Disorders	2	0	0	0		2	1%
N	202	44	14	2		262	
%	77%	17%	5%	1%		100%	

Majority of toxicity was grade 1-2.
Grade 3/4 toxicity: myelosuppression -induced infection.

* Based on an analysis of 104 patients

** Infusion-related events occurred in 32 (31%) of patients only after 1st cycle treatment

Outcomes in AML Therapy

	Age (yrs)	CR rates (%)	Induction deaths (%)
Bennett et al Cancer (1997)	<60	70	10
	61-69	55	20
	>70	35	39
CLI-033 <i>de novo</i> AML	72 (60-84)	50	17

- Encouraging activity
- Reasonable toxicity profile
- Acceptable induction death mortality

***CLI-043:
Pivotal Phase II Trial of Cloretazine®
for Elderly Patients with de novo Poor
Risk Acute Myeloid Leukemia***

Registration Indication First Relapse AML Therapy

Current Treatment Patterns

- **No current standard of care**
- **Most patients receive cytarabine-based therapy**
- **Prognosis depends on age and length of first remission**

CLI-043: Cloretazine Pivotal Phase II Trial in Elderly de novo Poor Risk AML

- **Initiated May 2006; to be conducted in ~25 sites worldwide**
- **Study Design**
 - Open label Phase II design following FDA discussion
 - Cloretazine® 600mg/m² IV induction therapy D1, repeat induction if necessary
 - AraC consolidation post remission
- **Patient Eligibility**
 - ≥ 60 years old with at least one additional risk factor
 - Adverse cytogenetics
 - ECOG PS=2
 - Age ≥ 70
 - Cardiac or Pulmonary or Hepatic Dysfunction
- **Primary Objective**
 - Complete Response
- **Secondary Objective**
 - Progression-free survival
 - Leukemia-free survival
 - Overall survival
 - Toxicity Spectrum
- **Statistical Design**
 - N=85
 - 2 stage optimal min max
 - > 8/42 CRs to open 2nd stage



Cloretazine[®]
Acute Myelogenous Leukemia:
First Relapse Therapy

CLI-037: Cloretazine: Phase III AML 1st Relapse

- **SPA January 2005**
- **Study Treatment**
 - **Cloretazine[®] 600 mg/m² + araC 1500 mg/m²/d CIV x 3d**
vs.
placebo + araC 1500 mg/m²/d CIV x 3 d
 - **Second induction allowed; consolidation after response**
- **Eligibility**
 - **First CR \geq 3 and $<$ 24 months duration**
 - **Age \geq 18 years old**
 - **ECOG performance status 0-2**

CLI-037: Cloretazine[®]: Phase III AML 1st Relapse

Study Design

- **Randomized double-blind, placebo-controlled trial**
 - **2:1 randomization**
 - **Primary endpoint - CR/CRp**
 - **Secondary endpoints- response duration, PFS, survival**
 - **Stratified for duration CR1 and age**
- **60+ sites in North America and Europe**
- **Target accrual 420 patients over 30 months**
 - **First patient enrolled March 2005**
 - **210 patients expected to be enrolled as of late 2006**
 - **Interim analysis in 1Q07**
 - **Full accrual expected late 2007**

Cloretazine® in Solid Tumors

PHASE II SMALL CELL LUNG CANCER	PHASE I PEDIATRIC GLIOMA PEDIATRIC BRAIN TUMOR CONSORTIUM	PHASE II ADULT GLIOMA DUKE UNIVERSITY
Objectives <ul style="list-style-type: none"> ➤ Determine complete and partial response rate in sensitive relapse and resistant SCLC patients 	Objectives <ul style="list-style-type: none"> ➤ Determine MTD in two cohorts of pediatric patients 	Objectives <ul style="list-style-type: none"> ➤ Efficacy/tolerability in gliomas
Dosing <ul style="list-style-type: none"> ➤ Cloretazine® 125 mg/m² weekly x 3 weeks ➤ Reduced to 100 mg/m² weekly x 3 weeks 	Dosing	Dosing <ul style="list-style-type: none"> ➤ 300mg/m² q 6 wks
Experience to date <ul style="list-style-type: none"> ➤ N=36 ➤ 32% response rate in sensitive relapsed disease (n=19) 	Experience to Date <ul style="list-style-type: none"> ➤ Data to be released 	Experience <ul style="list-style-type: none"> ➤ Initial data released in May 2005; update expected
Plans <ul style="list-style-type: none"> ➤ Trial ongoing 	Plans <ul style="list-style-type: none"> ➤ To be determined 	Plans <ul style="list-style-type: none"> ➤ To be determined

Cloretazine[®] Market Opportunity

- **Cloretazine[®] may be used in both frontline and relapsed AML settings**
- **AML Market in U.S.**
 - Estimated to be 11,960 frontline patients each year
 - Patients over 60 years of age represent over half of the frontline population
 - Estimated to be 8,000 relapsed patients each year
- **High-risk MDS Market in the U.S.: Some estimates are that this population could represent an additional 5-8,000 patients**
- **Opportunity in solid tumors (gliomas and small cell lung cancer investigation already underway)**
- **Opportunity in other settings where alkylating agents have been used in the past**

Sources:

1. **American Cancer Society, Cancer Facts and Figures 2006**
2. **Industry research reports and company filings**

Triapine[®]

- **Ribonucleotide reductase targeting M2 subunit**
- **More potent than hydroxyurea**
- **Under development as a single agent, combination therapy, and radiosensitizer**
- **4 trials underway with NCI, additional trials to be initiated, 8 trials completed**
- **Phase II clinical study in metastatic pancreatic cancer with gemcitabine yielded 8 month median survival**
- **Phase I evaluation of oral formulation expected to start in 2006**

VNP40541

- **Novel alkylating agent selectively activated in hypoxic conditions**
- **Planned clinical development in solid tumors known to be particularly hypoxic**
 - Pancreatic
 - Head and Neck
 - Glioma
- **IND to be resubmitted in 2007**

Vion by the Numbers

- Cash and Investments (as of 6/30/06): \$41.4 Million
- Market Capitalization (as of 11/06/06): \$102 Million
- Shares Outstanding (as of 6/30/06) 68.2 Million
 - Options 4.5 Million
 - Warrants 9.2 Million
- Total Shares Outstanding 81.9 Million

Conclusions

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