



***Celator***<sup>®</sup>  
***Pharmaceuticals***





**Celator's mission is to improve and extend the lives of patients with cancer by discovering and developing novel products based on our CombiPlex<sup>®</sup> technology.**



April 22, 2009



# Celator Pharmaceuticals: Overview

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- Strong, committed investor syndicate
- Broad intellectual property protection covering technology platform and novel products
- Two products with clinical data better than historical data
- Conducting two randomized Phase II AML studies with CPX-351
  - Interim data from both Phase II studies by Y/E 2009
- Seeking partner / external collaborations
- Organization focused on delivering clinical results, demonstrating the value of the technology platform, and increasing the value of the company

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## Celator Financing History

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- Aug 2000 – Feb 2002: \$2.6M Seed and Angel rounds
- Dec 2002: \$7.5M Series A
- Apr 2005: \$40.0M Series B
- Jul 2007: \$10.0M Series B follow-on
- Jul 2008: \$22.5M Series C
  
- Investors include:
  - Domain Associates LLC
  - Ventures West Management Inc.
  - Quaker BioVentures
  - TL Ventures
  - GrowthWorks Capital, Ltd.
  - BDC Capital

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# CombiPlex<sup>®</sup> Technology Platform: Overview

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- Proprietary method of producing novel product:
  - Identify drug combinations that exhibit synergistic ratio-dependent anti-tumor activity in vitro
  - Fix the desired synergistic ratio in an effective drug delivery vehicle
  - Deliver and maintain the synergistic drug ratio in vivo
    - Addresses random PK of existing drug combination therapy
- Numerous product opportunities based on combinations of non-proprietary and proprietary agents
  - Initial focus on known effective combinations
- Goal = Superiority versus conventional administration of the drugs
  - Improved efficacy and possibly safety

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# Technology & Intellectual Property

CombiPlex® Approach

Umbrella  
Patent

Antimetabolite +  
Topo I Inhibitor

Antimetabolite +  
DNA Crosslinker

Combination of  
Cytotoxics

Product  
Patents

Formulation “Toolbox” Technology

Enabling  
Patents

1

2

3

4

5

6

7

8

Etc.

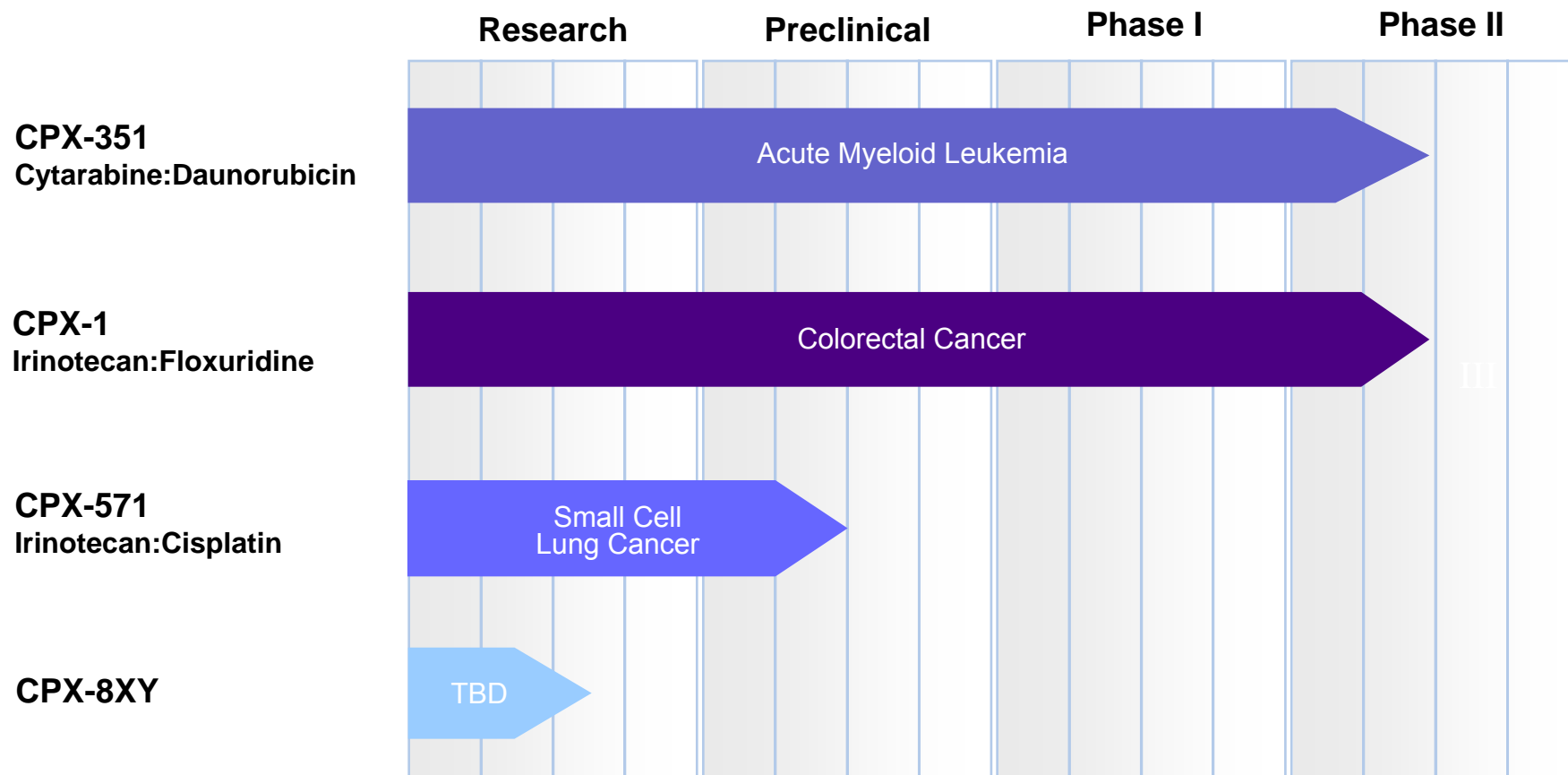
Multiple  
Patents per  
Product

- 8 Granted Patents, 81 Pending Patent Applications

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# Celator Product Pipeline



\*All products sourced from Celator's CombiPlex® technology platform.

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# CPX-351 (Cytarabine:Daunorubicin) Liposome Injection

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# Ratio-Dependent Synergy for Cytarabine:Daunorubicin

Cytarabine:Daunorubicin molar ratio of 5:1 maximizes synergy and minimizes antagonism in vitro

Cell Lines	Tissue	CI @ ED90				
		1:10	1:5	1:1	5:1	10:1
HCT-116	Colon	0.8	0.7	0.8	0.8	0.8
SW620	Colon	1.0	0.6	0.8	0.7	0.6
Nalm-6	Leukemia	1.8	1.6	1.1	1.1	1.1
P388	Leukemia	1.2	1.5	0.6	0.7	0.8
HL60	Leukemia	1.3	1.2	0.8	0.8	1.1
L1210	Leukemia	1.4	1.5	1.3	0.8	1.1
A253	Oral	1.1	1.0	1.1	0.8	0.9
BXPC-3	Pancreatic	1.1	1.1	1.2	1.0	0.9
IGROV-1	Ovarian	2.0	1.3	1.5	1.1	0.9
Capan-1	Pancreatic	1.0	0.9	1.0	0.9	1.6

Synergistic 

Additive 

Antagonistic 

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## CPX-351: Phase I Study in Patients with Advanced Leukemia

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- Data presented in December '08 at the American Society of Hematology
- Open label, dose escalating design in adult patients with advanced leukemia
- CPX-351 is a fixed synergistic 5:1 molar ratio of cytarabine:daunorubicin
- 1 unit = 1.0 mg cytarabine + 0.44 mg daunorubicin
- Induction: 90-minute infusion on Days 1, 3 & 5
- Up to 2 inductions and one consolidation
  - Induction is therapy designed to kill as many of the leukemia cells as possible and induce a remission, a state in which there is no visible evidence of disease and blood counts are normal
  - Consolidation is post-remission therapy designed to kill any remaining leukemic cells
- 4 centers in US (Cornell University; H. Lee Moffitt Cancer Center; North Shore University Hospital; Lombardi Cancer Center, Georgetown)

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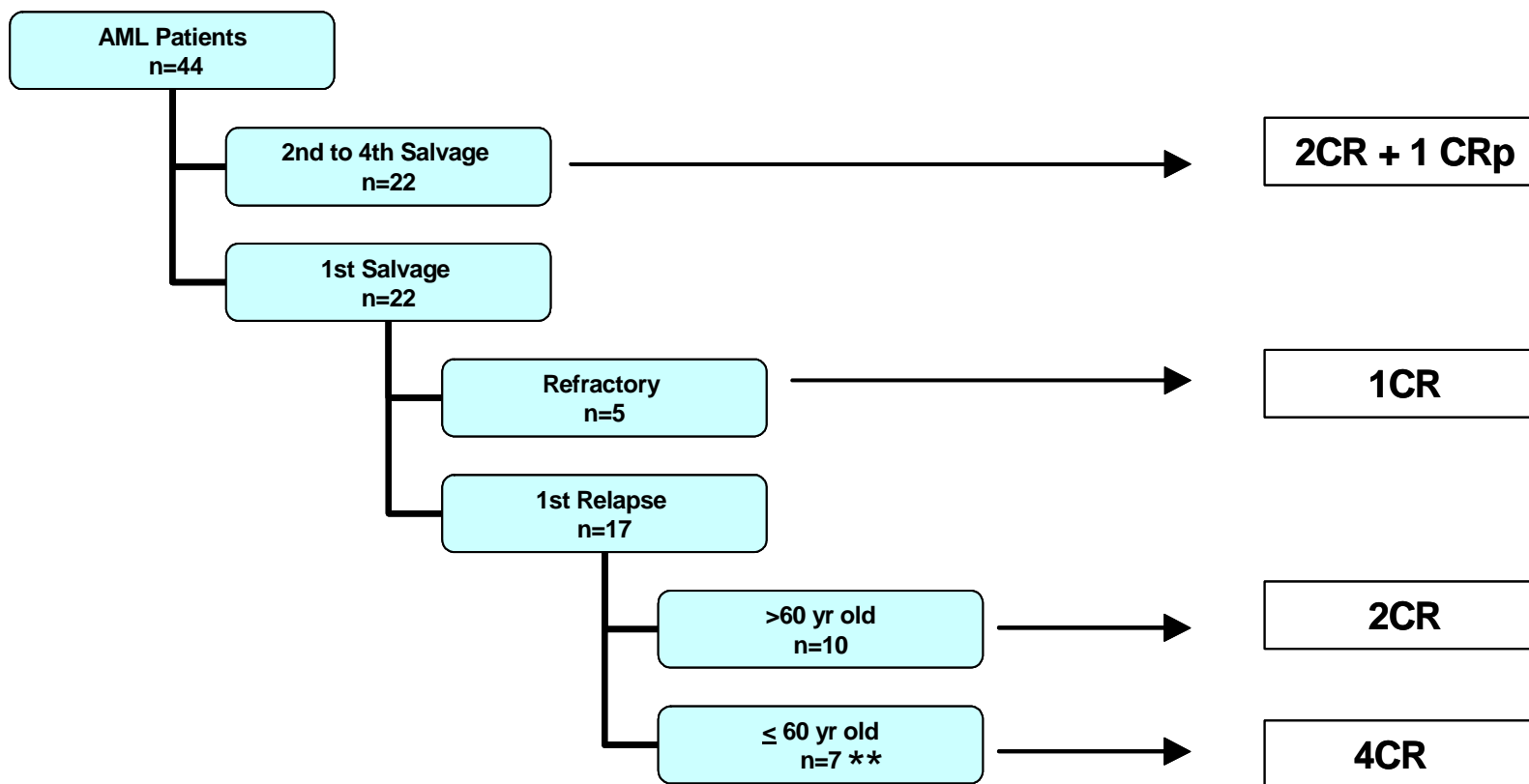


# CPX-351 Phase I Study: Summary

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- The MTD for CPX-351 is 101 u/m<sup>2</sup>
  - Results in ~300mg/m<sup>2</sup> cytarabine and ~135mg/m<sup>2</sup> daunorubicin which is less than conventional “7+3” (700mg/m<sup>2</sup> and 135-180mg/m<sup>2</sup>, respectively)
  - Greater ease of administration
    - Days 1, 3, & 5 vs 7 day continuous infusion and days 1, 2, & 3
- CPX-351 at the MTD had acceptable safety
  - Minimal mucositis and other non-hematological toxicities
- The CPX-351 formulation of cytarabine and daunorubicin:
  - Maintained the intended 5:1 molar ratio for >24 hours
  - Was fully bioavailable
  - Markedly prolonged the half-life of both cytarabine and daunorubicin
- CPX-351 had potent anti-leukemic efficacy:
  - CRs in patients with 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> relapse and refractory disease; patients with poor risk cytogenetics; patients >60 years old

# CPX-351 Phase I Study: Patient Disposition\*



\*47 patients enrolled of which 3 were with ALL.

\*\*1 patient lost to follow-up

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## CPX-351 Phase I Study: Efficacy Results

Dose Level	N	Aplasia	Responses	Observations
32 units/m <sup>2</sup>	4	2/4	CRp (5.4 m)	no DLT
43 units/m <sup>2</sup>	4	2/4	CR in ALL (0.5m) CR in AML (6.0m)	no DLT; 1 early death
57 units/m <sup>2</sup>	3	0/3		no DLT
76 units/m <sup>2</sup>	3	1/3	CR in AML (1.6 m)	no DLT
101 units/m <sup>2</sup>	5	3/5	PR in AML	no DLT; 2 early deaths
134 units/m <sup>2</sup>	6	4/6	CR in AML (13.0+ m) CR in AML (6.7 m)	3 DLTs; 1 early death
101 units/m <sup>2</sup> Expansion	4	2/4	CR in AML (7.1 m) CR in AML (9.8+ m) (T)	no DLT; 1 early death
101 units/m <sup>2</sup> Extension	10	8/10	CR in AML (7.4+ m) CR in AML (7.3 m) (T) CR in AML (3.8 m)	no DLT; 2 early deaths

As of: 10 February 2009

Early Death= died <60 days from start of study  
T=transplant

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# CPX-351: Phase I vs. Historical Data (AML only)

First Salvage	Historical DB	n	Expected CR	Observed CR
<u>1st CR Duration</u>				
No initial CR	0.15 CR/pt	5	0.75	1
<1 year	0.15 CR/pt	10	1.5	2
1-2 years	0.5 CR/pt	5	2.5	3
>2 years	0.75 CR/pt	1	0.75	1
Lost to Follow-up	N/A	1	N/A	N/A
		22	5.5	7CR
<b>Second-Fourth Salvage</b>				
<u>1st CR Duration</u>				
<1 yr or no initial CR	0 CR/pt	20	0	1CR + 1CRp
1-2 years	0 CR/pt	2	0	1
		22	0	2CR + 1CRp
		<b>44</b>	<b>5.5</b>	<b>9CR + 1CRp</b>

Estey E, et al. Blood 1996;88:756

# CPX-351 Randomized Phase II Study: Newly Diagnosed AML, Elderly (Open for Enrollment)

- Newly diagnosed AML
- Age  $\geq 60$  and  $< 76$  years
- Able to tolerate intensive chemotherapy
- High-risk and Intermediate-risk leukemia based on karyotype and AHD
- PS 0-2
- 30-40 Centers in North America

## Two arms, n=120 patients

**CPX-351 100 units/m<sup>2</sup> IV  
days 1, 3, 5  
Up to 2 induction/ 2 consolidations  
(80 pts)**

**“7+3” Regimen  
Cytarabine 100 mg/m<sup>2</sup> 7-day infusion  
Daunorubicin 45-60 mg/m<sup>2</sup>  
days 1, 2, 3  
(40 pts)**

- Endpoints
  - 1<sup>o</sup> endpoints - %CR
  - 2<sup>o</sup> endpoints - CR duration, time to treatment failure, survival at 12 months, and 30, 60, 90 day mortality

## Anticipated for Control Arm:

CR: 45%

CR duration: 8 months

Survival at 1 year: 20%

Induction Mortality: 25%

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# CPX-351 Randomized Phase II Study: AML, 1<sup>st</sup> Relapse in Patients ≤60 yo (Open for Enrollment)

## Two arms, n=120 patients

- 1<sup>st</sup> Relapse\*
- Initial CR ≥1 month
- Ages ≥18 and ≤60
- Stratified by EPI
- PS 0-2
- 30-40 Centers in North America

\* Relapse is the return of disease following an initial remission

**CPX-351 100 units/m<sup>2</sup> IV  
days 1, 3, 5  
(80 pts)**

**Control (40 pts) as per investigator  
choice of published salvage regimens,  
including:**

- High dose cytarabine +/- daunorubicin
- "7+3"
- MEC (mitoxantrone+etoposide+cytarabine)

- Endpoints
  - 1<sup>o</sup> endpoint – Survival at 1 year
  - 2<sup>o</sup> endpoints - %CR, CR duration, event-free survival, and 30, 60, 90 day mortality
- Supported through a partnership with The Leukemia and Lymphoma Society®

### Anticipated for Control Arm:

Breems *et al*

CR: 46%

Survival at 1 year: 29%

Giles *et al*

CR: 31%

Survival at 1 year: 28%

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## AML Market Opportunity

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- AML market is highly unsatisfied
  - Untreated AML progresses rapidly to death
- US incidence and mortality
  - 13,290 new AML cases in 2008
  - 8,820 deaths from AML in 2008
- Targeted group of physicians treating AML
- “7+3” (cytarabine plus an anthracycline) is standard first line treatment in patients suitable for intensive chemotherapy and has been for 30 years

## AML Market Opportunity

- 1<sup>st</sup> Line Treatment (Induction)

Regimen	US % of Pts	Europe* % of Pts	Japan* % of Pts
Cytarabine + anthracycline	42%	32%	68%
Cytarabine + anthracycline + other drugs	11%	12%	NA
Cytarabine	9%	14%	16%
Cytarabine + Other Drugs	6%	6%	NA%

\* Figures may underestimate usage; data collected for top 75% of usage

Source: IMS data MAT2Q2007, IntrinsiQ data Sept2007

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# AML Market Opportunity: Selected Drugs in Development

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## Newly Diagnosed AML <60 yo

- Laromustine + Cytarabine + Idarubicin
- Laromustine + Cytarabine + Daunorubicin
- Sorafenib + Cytarabine + Idarubicin

## Newly Diagnosed AML >60 yo suitable for induction chemotherapy

- Laromustine + Cytarabine
- Clofarabine +/- Cytarabine
- Azacitidine + Gemtuzumab Ozogamicin

## Newly Diagnosed AML >60 yo “unsuitable” for induction chemotherapy

- Laromustine
- Clofarabine
- Azacitidine
- Decitabine

## Relapsed or Refractory

- Laromustine + Cytarabine
- Clofarabine +/- Cytarabine
- Azacitidine + Cytarabine
- Azacitidine + Gemtuzumab Ozogamicin

Source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov) 24-March-09, drug name, AML, company listed as a sponsor, Phase II or later

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# AML Market Opportunity: Selected Drugs in Development

## Newly Diagnosed AML <60 yo

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**CPX-351**

## Newly Diagnosed AML >60 yo "unsuitable" for induction chemotherapy

- Laromustine
- Clofarabine
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## Relapsed or Refractory

- Laromustine + Cytarabine
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**CPX-351**

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# CPX-351: AML Revenue Projections

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- Indications –
  - For the treatment of elderly (>60 years) AML patients
  - For the treatment of AML patients who relapsed following initial CR
- Worldwide peak year revenue potential in excess of \$250M
  - Other patient populations could increase sales potential
- Potential utility in other AML populations, other hematologic malignancies (e.g. ALL, MDS, NHL), and stem cell transplant

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# CPX-1 (Irinotecan:Floxuridine) Liposome Injection

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## CPX-1: Phase II Study in Patients with Colorectal Cancer

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- Data presented in June '08 at the American Society of Clinical Oncology
- Phase II, multi-center, open-label
- Two groups of patients:
  - Irinotecan-naïve
  - Irinotecan-refractory
- CPX-1 is a fixed synergistic 1:1 molar ratio of irinotecan:floxuridine
- 1 unit = 1.0 mg irinotecan HCl + 0.36 mg floxuridine
- CPX-1: 210 u/m<sup>2</sup> over 90 minutes every 2 weeks

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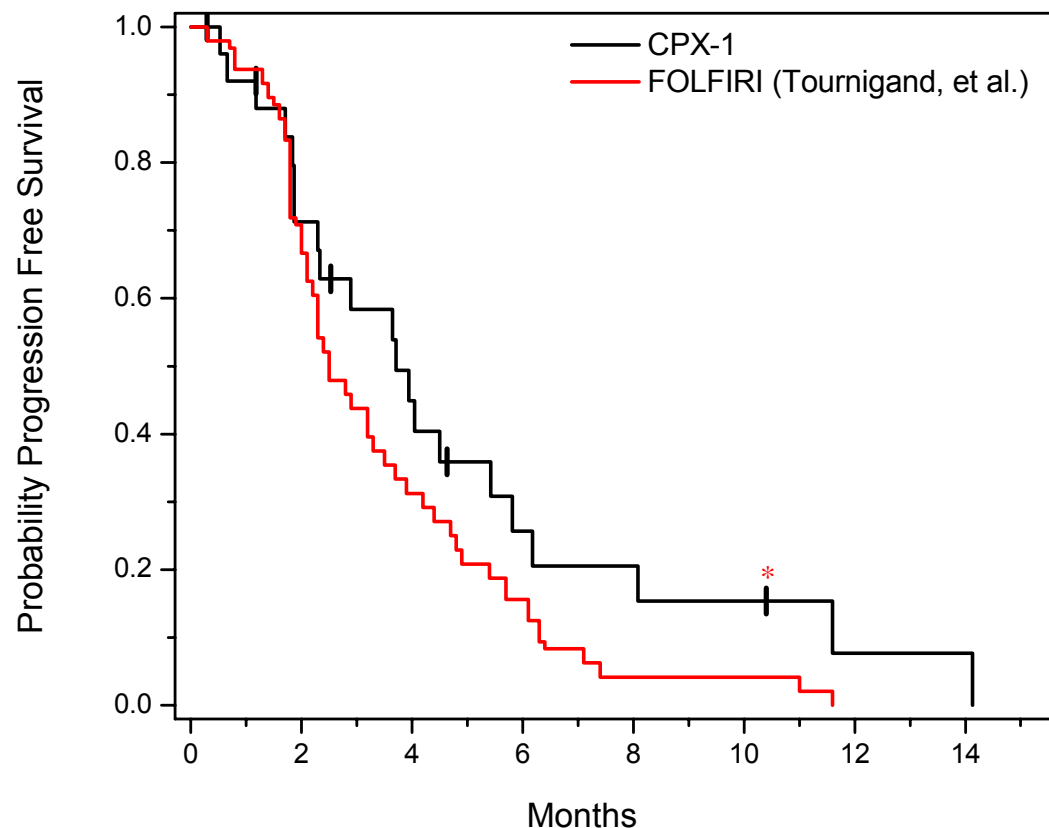
# CPX-1: Phase II Study in Patients with Colorectal Cancer

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- Irinotecan naïve (n=26) and irinotecan refractory (n=33)
  - Irinotecan naïve – median PFS = 3.7m, 6 patients PFS >6m
  - Irinotecan refractory – median PFS = 2.3m, 3 patients PFS >6m
- Results of CPX-1 alone compared to historical data
  - Irinotecan naïve:
    - Better results (ORR, DCR, PFS) than reported for irinotecan alone and for irinotecan + a fluoropyrimidine (FOLFIRI)
    - Comparable (DCR, PFS) to irinotecan + cetuximab
  - Irinotecan refractory:
    - Comparable / slightly better results (DCR, PFS) than approved drugs (cetuximab, panitumumab)
- Given the competitive landscape in CRC - conduct a randomized, clinical study with a biologic (e.g. Avastin<sup>®</sup>, Erbitux<sup>®</sup>, Vectibix<sup>®</sup>)

# CPX-1: Phase II – Irinotecan-Naïve vs FOLFIRI

## CPX-1 data compared to literature



### CPX-1 (n = 26)

Median PFS = 3.7 mo

Patients >6 mo PFS = 23%

ORR (CR+PR) = 8%

DCR (ORR+SD) = 58%

### FOLFIRI

Median PFS = 2.5 mo

Patients >6 mo PFS = 17%

ORR (CR+PR) = 4%

DCR (ORR+SD) = 35%

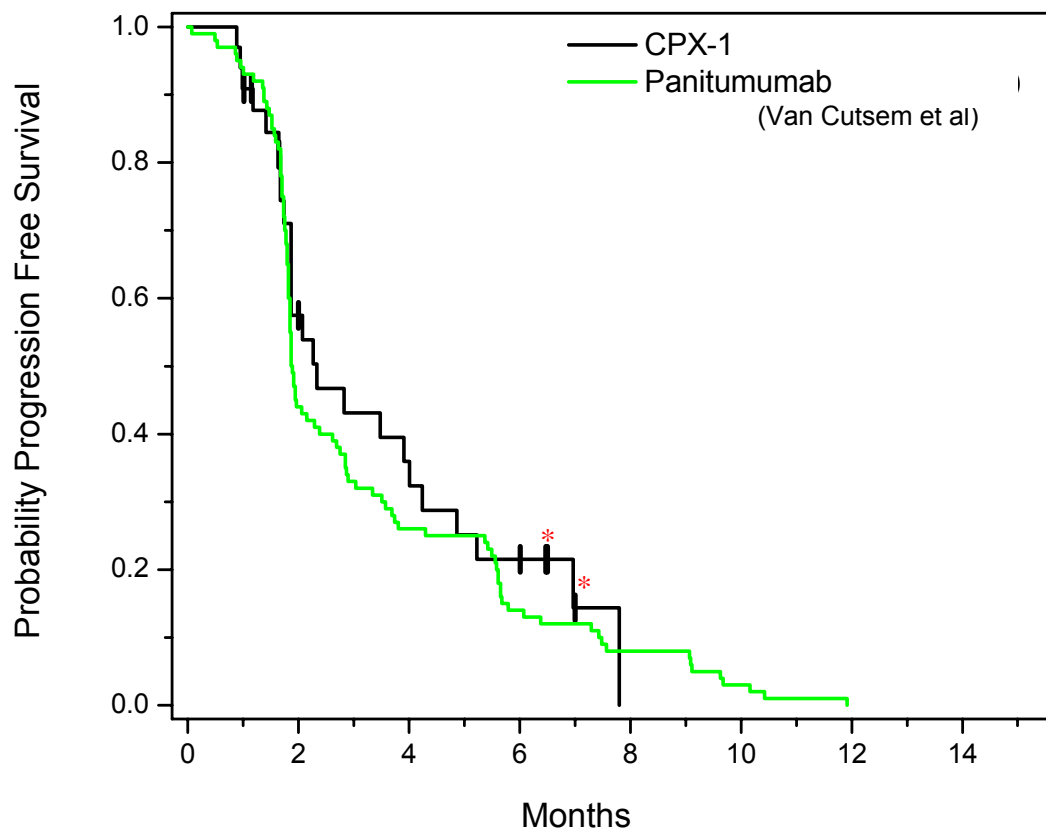
As of: 20 Jun 2008

\* Patient remains on-study

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# CPX-1: Phase II – Irinotecan-Refractory vs Panitumumab

## CPX-1 data compared to literature



### CPX-1 (n = 33)

Median PFS = 2.3 mo

Patients >6 mo PFS = 9%

ORR (CR+PR) = 0%

DCR (ORR+SD) = 45%

### Panitumumab

Median PFS = 1.8 mo

Patients >6 mo PFS = 13%

ORR (CR+PR) = 10%

DCR (ORR+SD) = 37%

As of: 20 Jun 2008

\* Patient remains on-study

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## Celator Pharmaceuticals: Completed 2008-2009 Goals

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- Raised Series C financing in excess of \$22.5M (July '08)
- CPX-351 Phase I study completed and presented at the American Society of Hematology meeting (December '08)
- Partnership with The Leukemia and Lymphoma Society for \$3.7M - funding in support of the first relapse AML study (January '09)
- Secured loan for \$3.5M (March '09)
- Initiated newly diagnosed AML study and first relapse AML study (November '08 and March '09)

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## Celator Pharmaceuticals: 2009-2011 Goals

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- Research collaboration with a pharma/biotech company (2Q09)
- Interim data analyses from both Phase II AML studies (4Q09)
- Complete enrollment of newly diagnosed, >60 yo, AML patient study (4Q09)
- Complete enrollment of first relapse, <60 yo, AML patient study (1Q10)
- Data analyses from both Phase II AML studies (4Q10)
- Strategic partnership completed for clinical asset(s) (2Q11)

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  - Interim data from both Phase II studies by Y/E 2009
- Seeking partner / external collaborations
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