

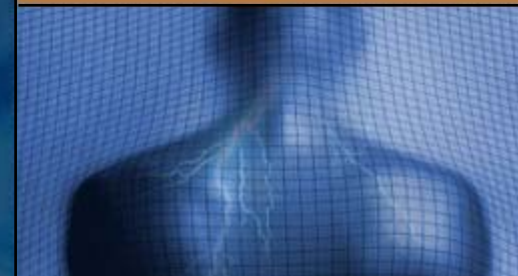
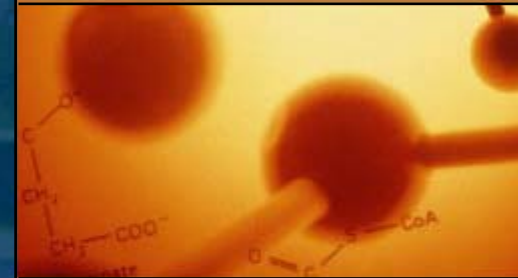


# ...EPICEPT

C O R P O R A T I O N

## Corporate Presentation

BIO Europe  
November 3, 2009



# Forward-Looking Statements

*This presentation contains forward looking statements that involve risks and uncertainties regarding the operations and future results of EpiCept. You should review the company's filings with the Securities and Exchange Commission, including without limitation the company's Form 10-K and Forms 10-Q, which identify specific factors that may cause actual results or events to differ materially from those described in the forward looking statements. The content of this presentation contains time sensitive information that is accurate only as of the date of the presentation. The company undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this conference call.*

# Company Description

**A specialty pharmaceutical company  
focused on the development of  
pharmaceutical products for the  
treatment of cancer and pain**

# Investment Highlights

- Product candidates address large, growing markets with unmet clinical needs in cancer and pain
- Ceplene® approved as remission maintenance drug for AML;
  - European partner discussions ongoing
  - Available on Named Patient Basis through Idis for all major markets (ex-US)
  - NDS filed
  - NDA filing anticipated Q1 2010
  - Approval decisions in North America anticipated H2 2010
  - Label expansion efforts to commence in 2009 with MDS trial
- NP-1 partnering discussions commenced
- Crinobulin combination trial with other chemotherapeutics in preparation

# Deep Late Stage Development Pipeline

Product	Initial Indication	Phase I	Phase II	Phase III	Registration	Marketing
<b>Cancer Portfolio</b>						
Ceplene®	AML	EUROPE				
		US/Canada				
Azixa™	Brain cancer					
Crinobulin	Solid tumors					
<b>Pain Portfolio</b>						
EpiCept™ NP-1	Neuropathic pain PHN, CIN, DPN					



*Reducing the Risk of Relapse in AML*

# Ceplene®: Product Profile

<b>Indication</b>	<b>Acute Myeloid Leukemia Remission Maintenance Therapy</b>
<b>Target Population</b>	<b>EU 16,000 patients; US 13,000 new patients annually Total EU 47,000+ all patients</b>
<b>Description</b>	<b>Histamine Dihydrochloride + Interleukin-2 (Proleukin®)</b>
<b>Dosage and Administration</b>	<b>Ceplene®: 0.5 mg, bid, sub-q + IL-2: 16,400 IU/kg, bid, sub-q Treatment comprises 10 cycles 3 cycles comprised of 3 weeks of treatment, followed by 3 weeks of rest 7 cycles comprised of 3 weeks of treatment, followed by 6 weeks of rest</b>
<b>Adverse Reactions</b>	<b>Well tolerated with mild flushing, headache and fatigue Ceplene® + IL-2 self-administered at home</b>
<b>Experience</b>	<b>International, multi-center, randomized Phase III trial in 320 patients with AML</b>
<b>Regulatory Status</b>	<b>US/Canadian regulatory approval decisions expected in 2010</b>

# Ceplene<sup>®</sup>: Acute Myeloid Leukemia

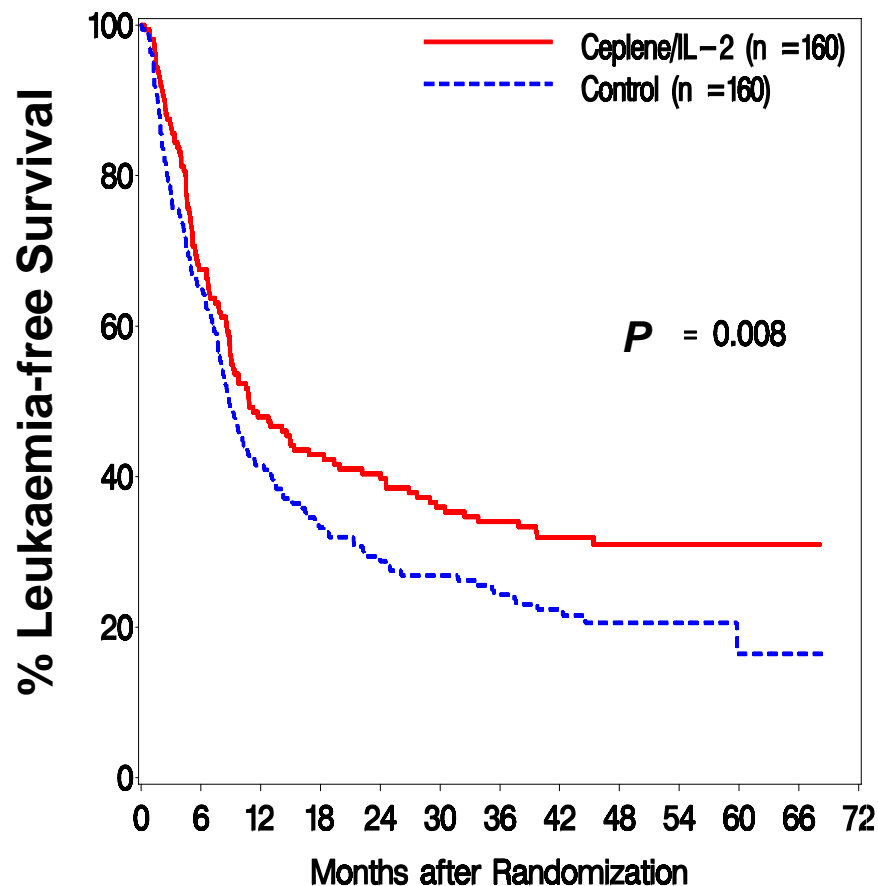
- Most lethal form of leukemia, overall mortality is very high, approximately 80%
- Complete remission (CR) achieved in approximately 50%-60% of patients
- Relapse from first complete remission approximately 75%
- Poor survival prognosis after relapse:
  - **Median survival of approximately 6-9 months**
  - **5%-15% of patients alive at 5 years**

## Ceplene®: EU Indication

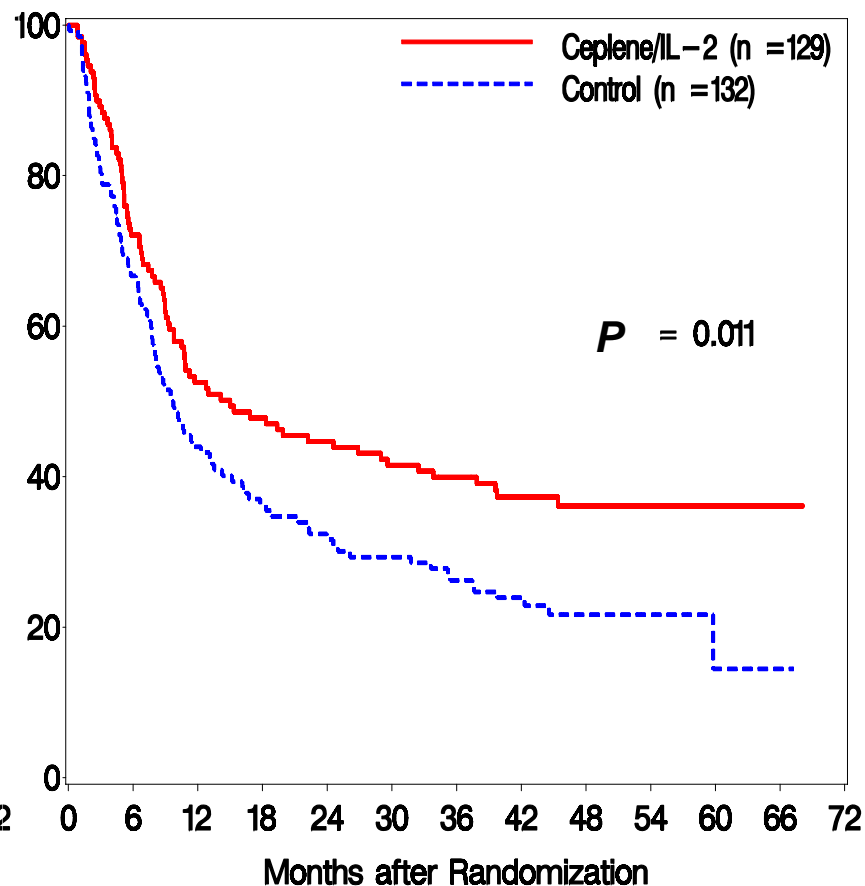
***“Ceplene®, administered in conjunction with interleukin-2, is indicated for maintenance of remission in adult patients with acute myeloid leukaemia in first remission to prolong the duration of leukaemia free survival.”***

# Results of the Ceplene® 0201 Study: Clinically and Statistically Compelling

## Overall Population



## CR1 Population



# Rationale for the Use of Ceplene® with IL-2

## IL-2

Activates and expands  
T and NK cells

## Ceplene® (HDC)

Protects T and NK cells  
against inactivation and  
apoptosis



Elimination of leukemic cells and  
protection against relapse

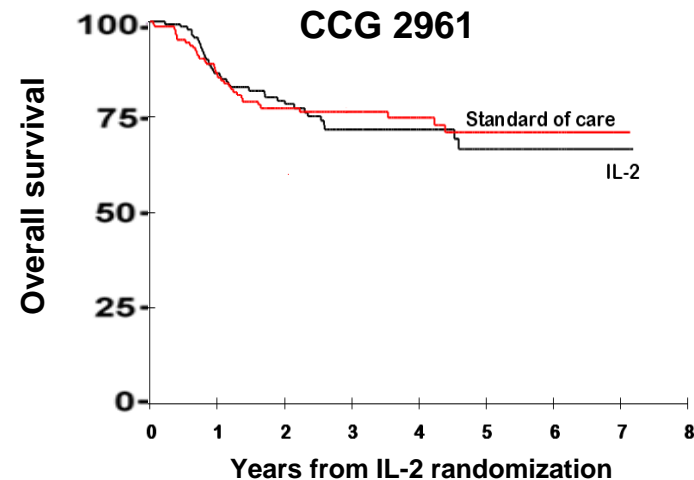
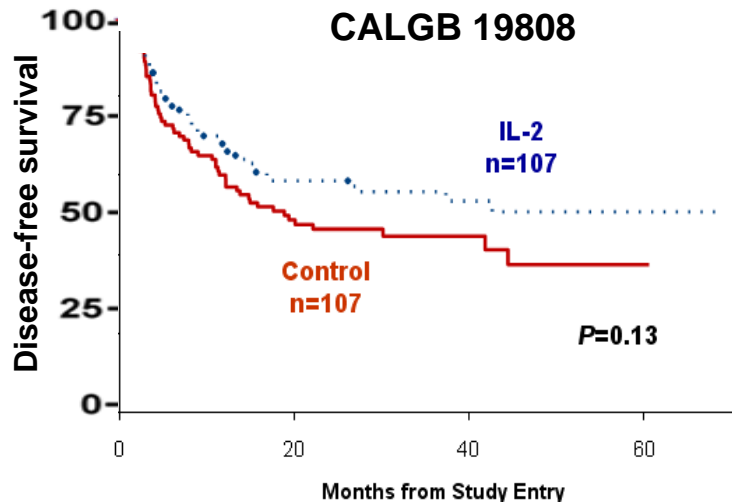
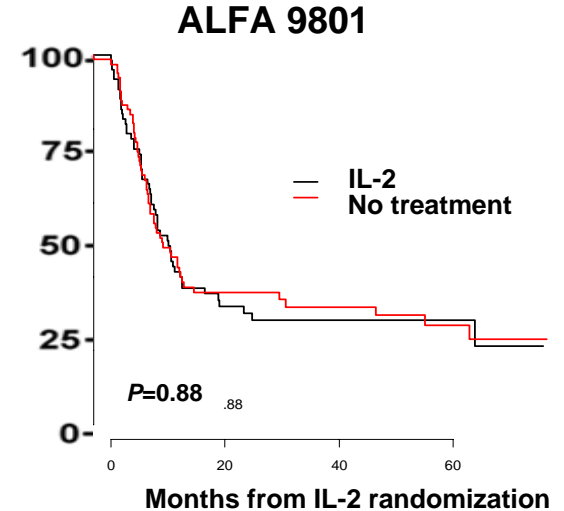
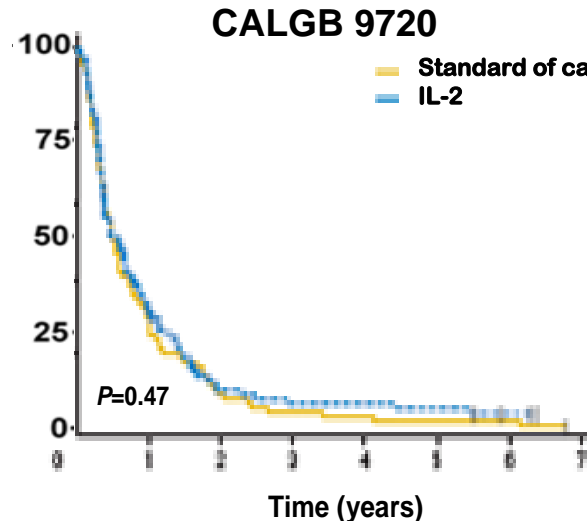
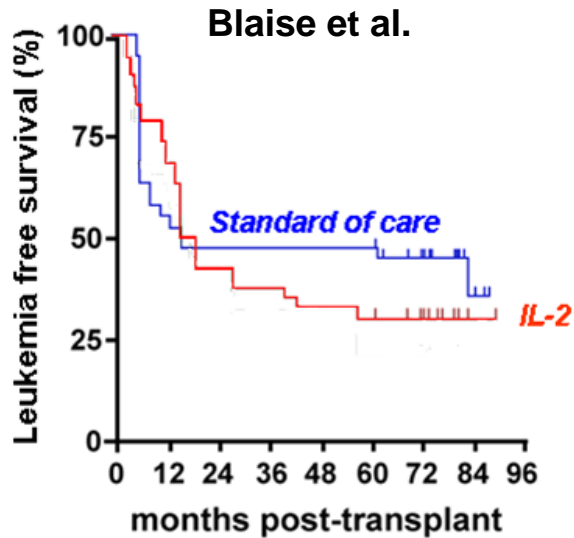
# Ceplene®: 0201 Study as the Single Pivotal Study

- An adequate and well controlled study was conducted in 320 well-characterized AML patients in remission
- 261 patients in CR1 were randomized to Ceplene®/IL-2 vs. standard-of-care, and balanced for risk factors
- 100 sites, stratified within 10 countries, GCP compliant
- Ceplene®/IL-2 s.c. twice daily regimen in three week cycles for up to 18 months, over the period of highest risk for relapse
- Increase in leukemia-free survival from 26% to 40% with Ceplene®/IL-2 over control arm at 3 years (51% relative increase)
- Well-tolerated regimen, good safety profile, and no major impact on QoL or function

# Efficacy of IL-2 Alone as Remission Maintenance Therapy in AML

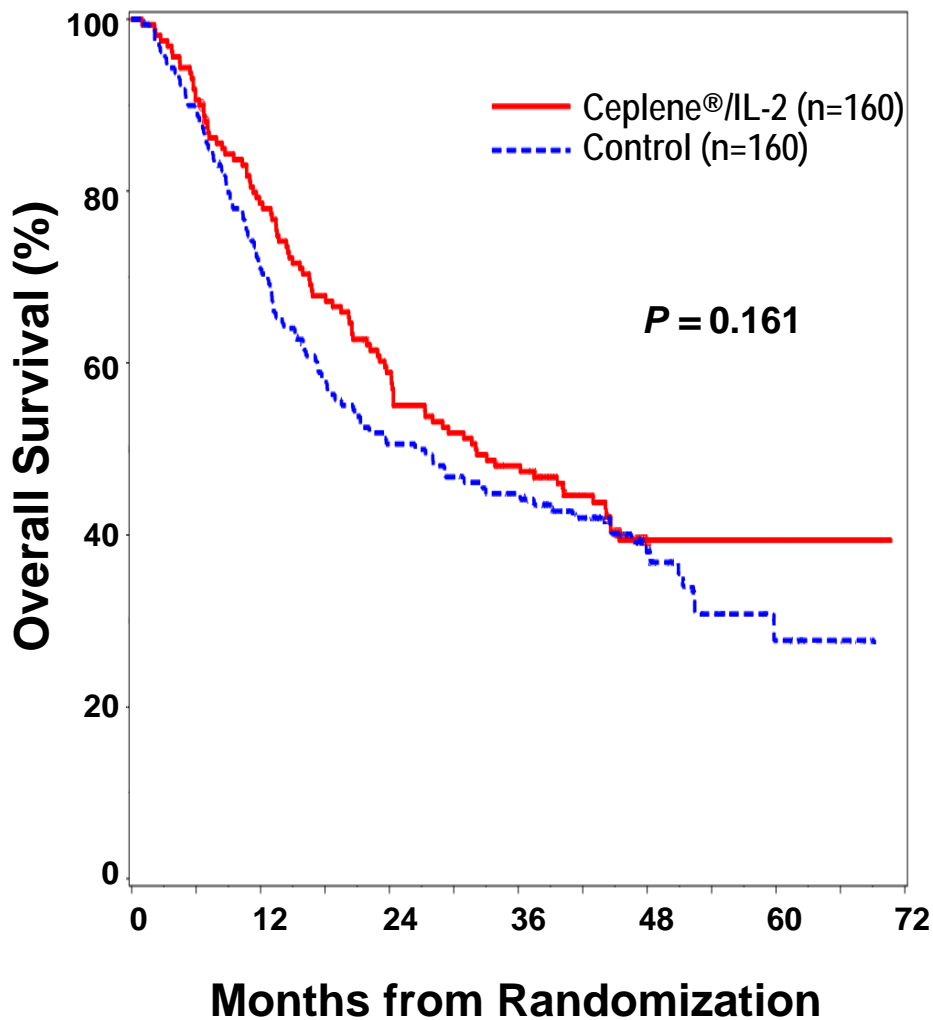
- Five randomized trials (n=899) have assessed IL-2 alone for prevention of first relapse in AML
- Several age groups were included in these trials, and a wide range of IL-2 regimens used
- Trials indicated no beneficial findings of IL-2 alone for any efficacy parameter
- Lack of efficacy of IL-2 in AML considered resolved by the CHMP

# IL-2 Monotherapy vs. Standard of Care for Remission Maintenance

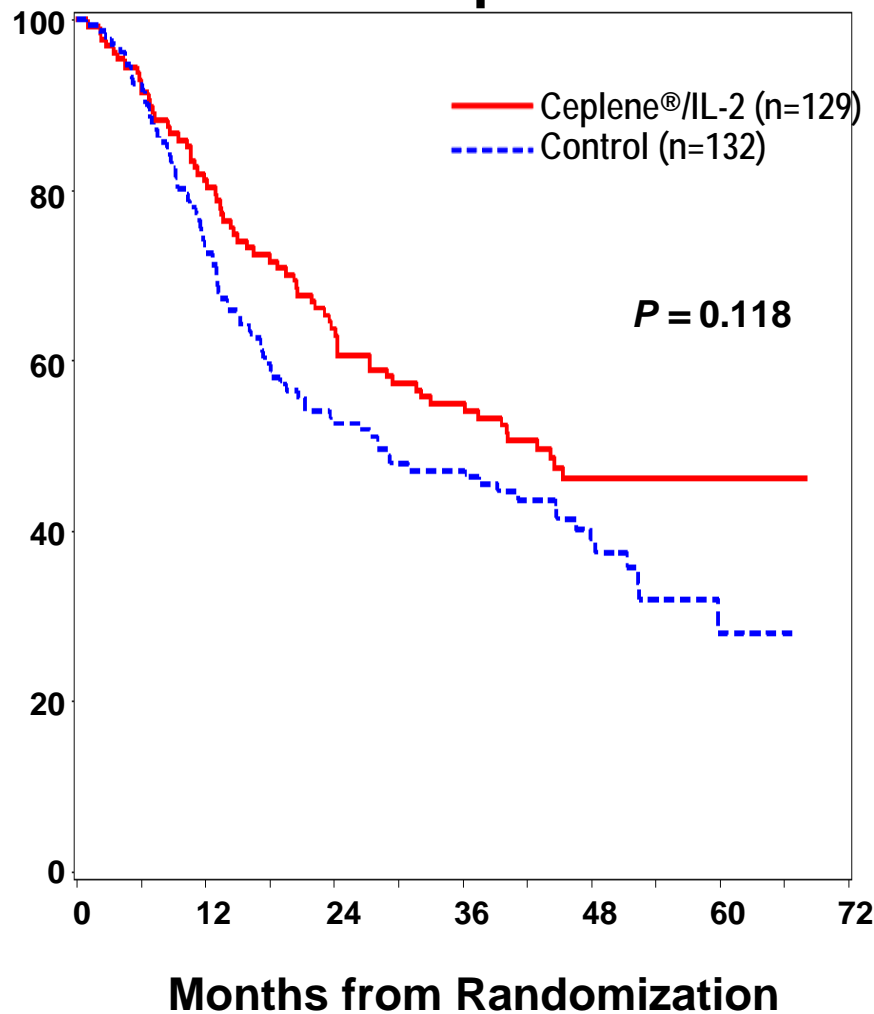


# Overall Survival Analysis

## Overall Population



## CR1 Population



# Overall Survival Analysis

- A positive trend in OS was observed
- Median prolongation in overall survival was 64 weeks in the CR1 population
- The Phase 3 pivotal trial was not powered to detect a statistically significant OS benefit
- Given the strong correlation between LFS and OS observed in the analysis of Ceplene®/IL-2 data, LFS can be considered an acceptable primary endpoint

# Anticipated Label Expansion

- Myelodysplastic syndrome (MDS)
  - 10,000-12,000 cases/year in US
  - Phase II Clinical trial to commence in 2<sup>nd</sup> half 2009
- Chronic myelogenous leukemia (CML)
  - 5,000 cases/year in US

# Ceplene® Summary

- Ceplene®, in conjunction with low-dose IL-2 (Ceplene®/IL-2), is a novel therapeutic regimen to fulfil an unmet clinical need to prevent relapse and prolong LFS in AML patients in first remission
- The Ceplene®/IL-2 benefit of prolonged LFS is both statistically significant and clinically relevant for AML patients in remission
- Cycles of daily Ceplene®/IL-2 s.c. injections at home are well-tolerated and are not an impediment to AML patients' QoL or functional status

# EpiCept™ NP-1: Product Profile

<b>Indication</b>	<b>Relief of pain associated with neuralgia due to diabetes, chemotherapy or shingles in adults</b>
<b>Target Population</b>	<b>15+ million patients</b>
<b>Description</b>	<b>4% amitriptyline and 2% ketamine cream</b>
<b>Dosage and Administration</b>	<b>4mL topical cream twice daily</b>
<b>Adverse Reactions</b>	<b>Mild sensitivity at application site</b>
<b>Experience</b>	<b>Over 1,300 patients treated in seven clinical trials</b>
<b>Regulatory Status</b>	<b>Completed Phase II; commence Phase III with partner</b>

# EpiCept™ NP-1: Product Profile

Reformulation of existing drugs in new dosage forms can create exciting new growth opportunities (e.g., Duragesic®, Lidoderm®, etc.)

- Ketamine and amitriptyline have been marketed for many years for systemic use and have been shown to be safe and effective
- The combination of amitriptyline 4%/ketamine 2% in a topical cream has been shown in several Phase II studies to be effective in patients with PHN and DPN
- The combination has been shown to be clinically superior to the individual ingredients given alone
- Skin irritation is comparable to placebo; fatigue and drowsiness are seen in a small percentage and is mostly mild
- NP-1 cream is effective and well tolerated chronically as demonstrated by the continuous use by patients from 6 months to one year
- NP-1 represents a large commercial opportunity with relatively low risk

# Crinobulin (EPC2407)

- Small molecule, vascular disruption agent (VDA), disrupts newly formed vascular cells and blood flow to tumor
- Superior anti-tumor (apoptotic) activity compared to other VDAs
- Enhanced efficacy in combination with Cisplatin or other chemotherapeutics
- Active on multi-drug resistant cells
- Strong intellectual property position

# Azixa™ (MPC-6827): Myriad Pharmaceuticals

- Small molecule, apoptosis inducer with VDA activity, concentrates in the CNS
- Discovered using ASAP technology
- Two Phase I studies completed in brain cancer: primary and metastatic
- Treatment schedule: Once a week for 3 weeks on 28 day cycle
- Reported Phase I results
  - Reached Maximum Tolerated Dose (MTD)
  - Signs of efficacy, measurable reduction in tumor size in primary glioblastoma and patients with secondary metastases
- Two Phase II trials dosing in primary and metastatic brain cancer
- Phase II trial(s) to complete late 2009

# Upcoming Milestones

- Ceplene® Canadian NDS filing action date
- Ceplene® licensing
- Ceplene® US NDA filing
- NP-1 licensing
- Azixa Phase II melanoma results
- Final Crinobulin monotherapy oncology trial results
- Crinobulin Phase Ib combination trial commences



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**Commercially Focused  
with a Discovery Edge**

