Investor Day
November 2nd, 2006

Challenging cancer.

EU Regulatory Process and Brand Updates

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Safe harbor

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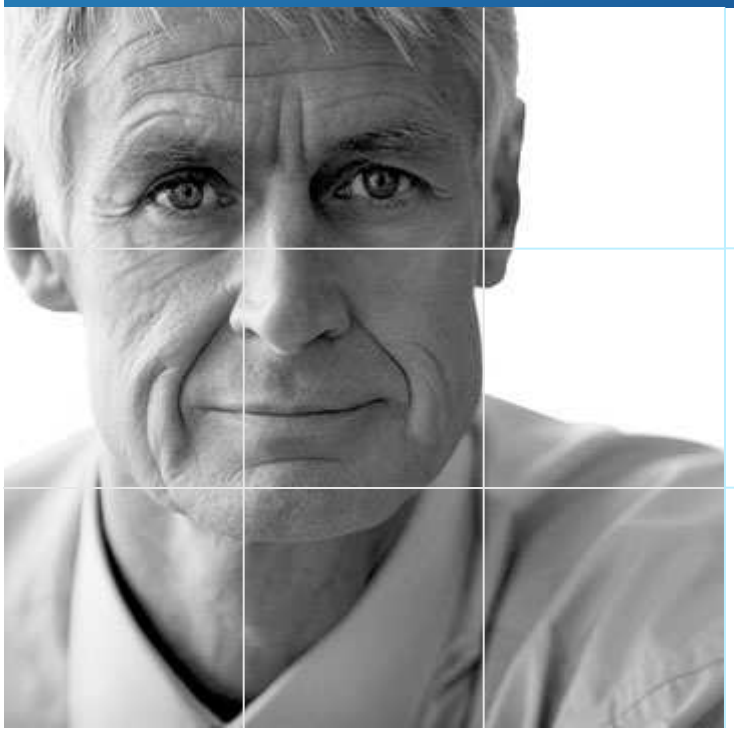
Today's discussion

- **EU regulatory overview**
- **EU regulatory strategy**
  - > Thalidomide
  - > Satraplatin
  - > Vidaza

Challenging cancer.

EU Regulatory Overview



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European Medicines Agency (EMEA)

- **Pan-European agency representing 25 countries**
- **Expertise contributed by national agencies**
- **Role:**
  - > Provide scientific advice
  - > Manage marketing authorizations
  - > Pharmacovigilance
  - > Inspection activities

Committee for Proprietary Medicinal Products (CHMP)

- **Scientific evaluation committee of the EMEA**
- **One representative from each member state agency**
- **Evaluation and opinion on medicinal products for human use**
  - > Evaluation of MAAs under the centralized procedure
  - > Development of guidelines
  - > Provision of scientific advice
  - > Pharmacovigilance issues

Centralized procedure for MAA

- **Compulsory for:**
  - > Biotech products
  - > Cancer and certain other diseases
  - > Orphan medicinal products
- **Single application to EMEA**
- **Assignment of rapporteur and co-rapporteur**
- **Pan-European approval within 210 days**
  - > Clock-stops can increase this timeframe
- **Single fee**

Centralized procedure timeline

Action	Procedure Day
Start of procedure	0
CHMP list of questions (clock-stop)	120
Responses to EMEA	
Clock re-start	121
CHMP discussion & decision on oral explanation. Clock-stop	180
Responses to questions	
Clock re-start & possible oral explanation	181
CHMP decision	210
Ratification by EU Commission (1-3 months)	

Orphan drugs in Europe

- **An orphan drug is intended to treat rare conditions**
- **Rare = less than five in 10,000 cases across EU**
- **Incentives:**
  - > 10 years market protection
  - > Fee reduction/waiver
  - > Protocol assistance
- **Apply for orphan status at any time before MAA**

New EMEA accelerated assessment procedure

- **To meet expectation of patients**
  - > Faster access to new medicines
- **Reserved for products of major therapeutic interest**
  - > Unmet clinical need
  - > Major change to medical practice
- **Request accelerated review prior to the CHMP meeting initiating the centralized procedure**
- **CHMP opinion within 150 days**

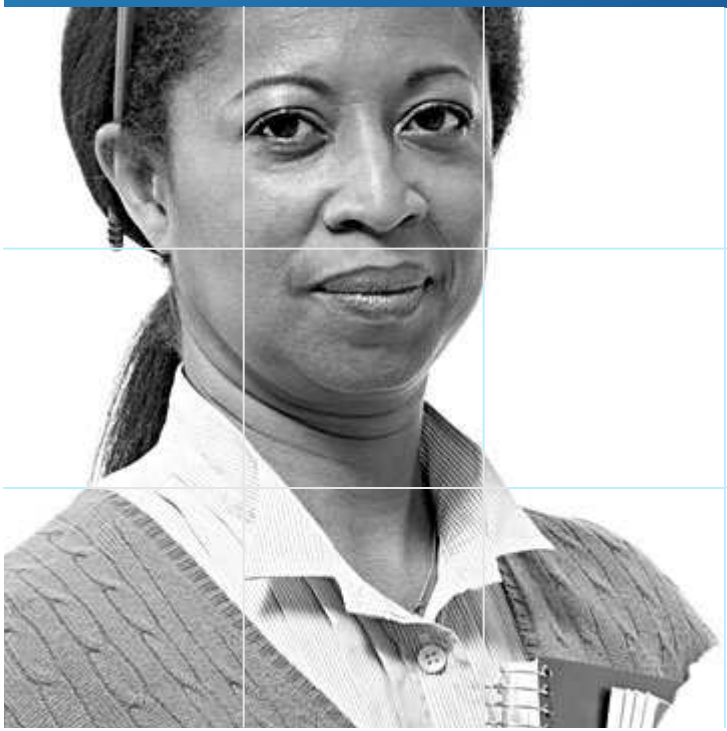
Pharmion portfolio

- **Thalidomide**
  - Orphan designation for multiple myeloma (MM)
  - Anticipate standard review time given drug history
- **Satraplatin**
  - No orphan designation because prostate cancer is not an orphan indication
  - Anticipate standard review time
- **Vidaza**
  - Orphan designation for MDS
  - Accelerated assessment possible if ongoing Phase III study demonstrates survival benefit

Challenging cancer.

Thalidomide

EU Regulatory Strategy and Development



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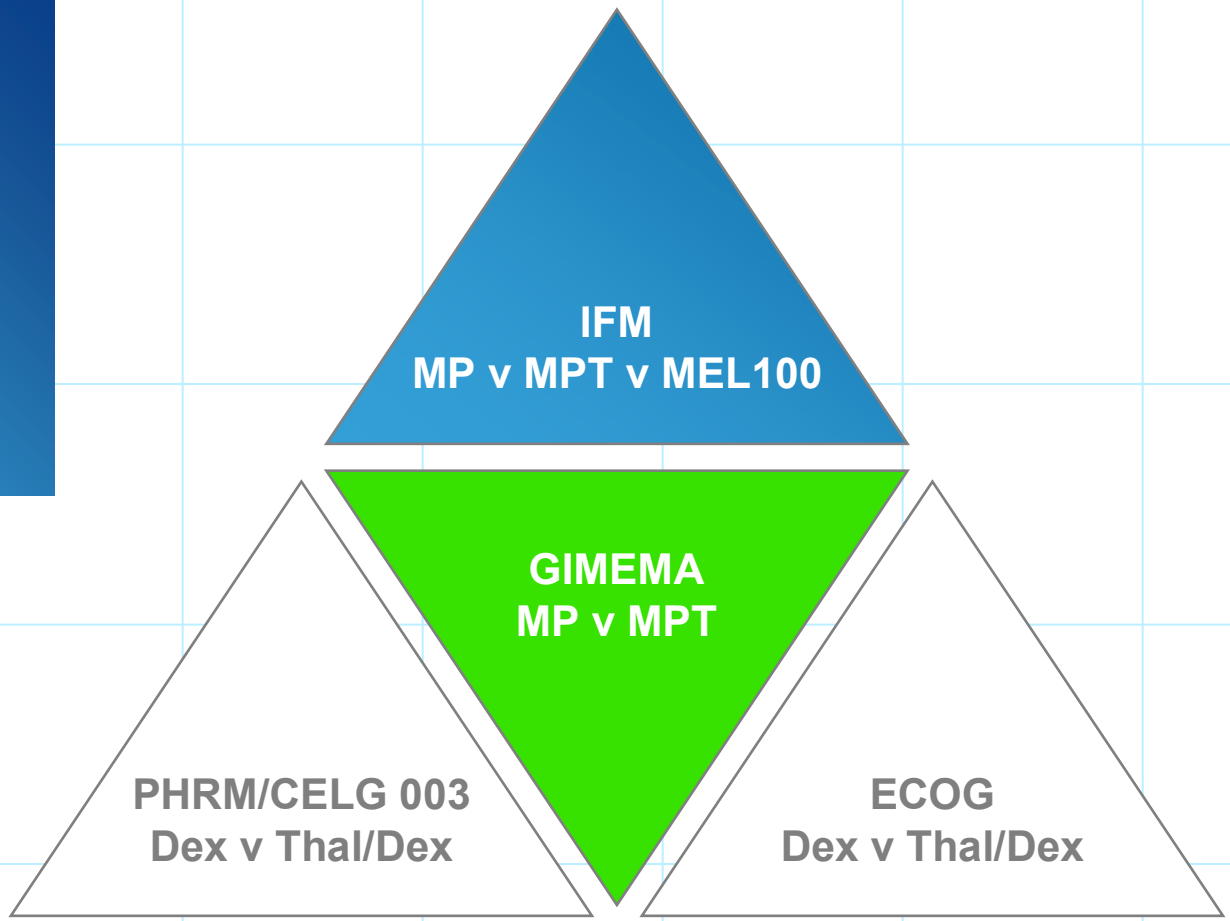
THALIDOMIDE PHARMION 50MG HARD CAPSULES

Creating an environment to support thalidomide's approval

- **Transparent relationships with:**
  - > Patient associations
  - > Victim associations
  - > Key opinion leaders
- **Frequent agency interactions with:**
  - > National agencies
  - > EMEA
  - > European Commission

First line MM marketing authorization application (MAA)

Clinical data package based on four studies and more than 1400 patients



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THALIDOMIDE PHARMION 50MG HARD CAPSULES

Seeking the first EU approval for newly-diagnosed MM

Proposed 1st line indications

- **"Thalidomide Pharmion in combination with melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma ineligible for high dose chemotherapy"** **(IFM; GIMEMA)**
- **"Thalidomide Pharmion in combination with dexamethasone and other standard induction therapies, prior to high dose chemotherapy and bone marrow transplant"** **(ECOG; MM03)**

Thalidomide Pharmion must be prescribed and dispensed with the Pharmion Risk Management Programme

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IFM study protocol: Newly diagnosed MM 65-75 years

THALIDOMIDE PHARMION 50MG HARD CAPSULES

MP	MPT	MEL100
MP 1	MP + **Thalidomide** ≤ 400 mg/d	VAD 1
MP 2		VAD 2
MP 3		Cyclophosphamide 3g/m^2 + granulocyte + PBSC harvest
MP 12		MEL 100 mg/m^2 + PBSC + granulocyte
		MEL 100 mg/m^2 + PBSC + granulocyte

Thalidomide average dose in study approx. 200 mg

Clodronate was given to all patients

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IFM study results

THALIDOMIDE PHARMION 50MG HARD CAPSULES

Survival Analyses: Median in Months

	MPT (n=124)	MP (n=191)	MEL100 (n=121)	Comparisons
OS	53.6	32.2	38.6	MPT v MP, p<0.001 MPT v ASCT, p=0.004
PFS	27.6	17.1	19.4	MPT v MP, p=0.001 MPT v ASCT, p=0.004

* Facon et al. data on file

GIMEMA study design: Newly diagnosed MM

Melphalan
4 mg/m2 on
days 1-7/month
for 6 courses

+

Prednisone
40 mg/m2
days 1-7/month
for 6 courses

+

Thalidomide
100 mg/d
continuously
until relapse

OR

Melphalan
4 mg/m2
days 1-7/month
for 6 courses

+

Prednisone
40 mg/m2
days 1-7/month
for 6 courses

* Palumbo et al. Lancet 2006;367:825-31.

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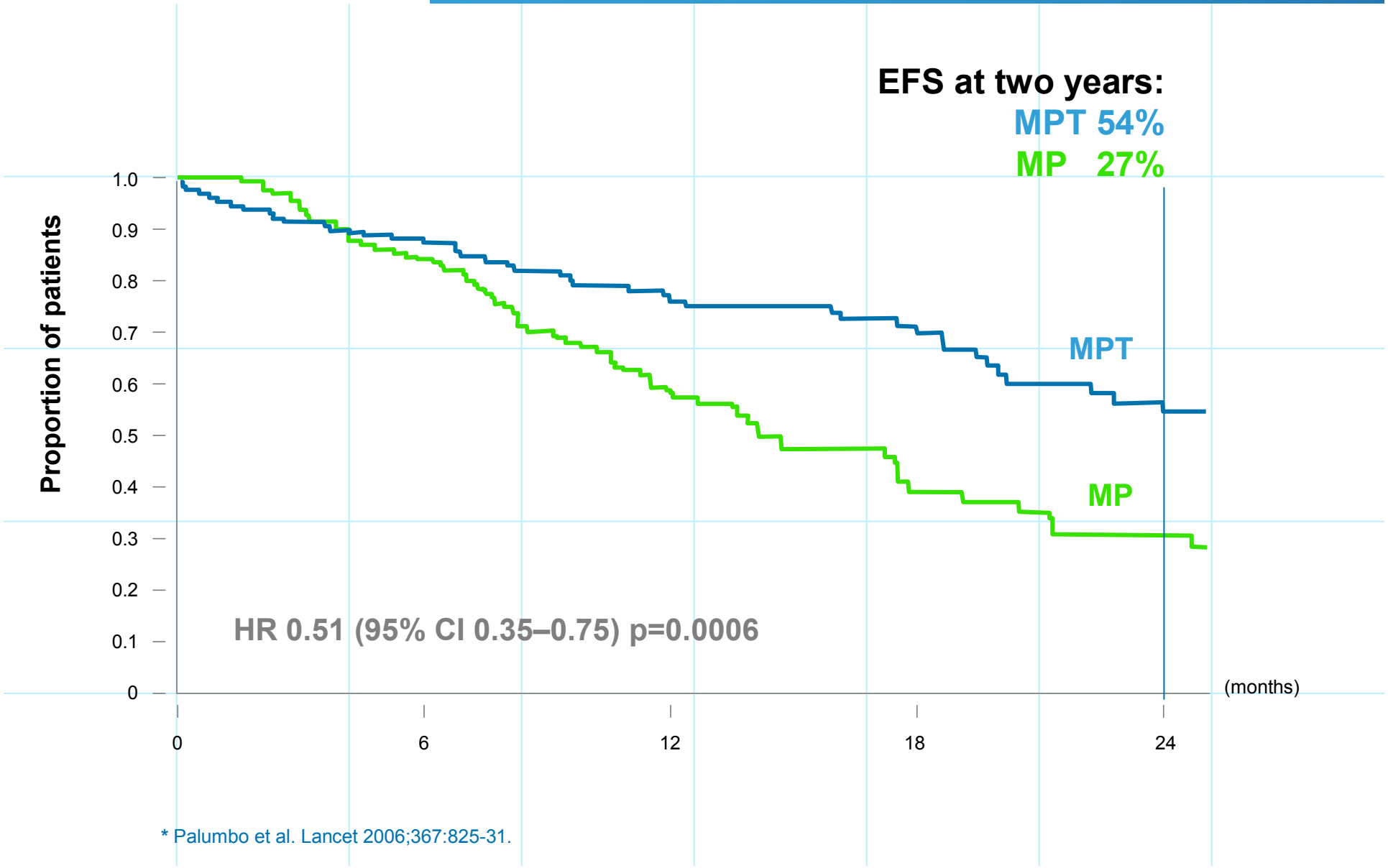
GIMEMA study results: Event-free survival



* Palumbo et al. Lancet 2006;367:825-31.

Pharmion and Celgene MM-003 study design: Newly diagnosed MM

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THALIDOMIDE PHARMION 50MG HARD CAPSULES

Thalidomide

50-200 mg PO daily, continuously†

+

Dexamethasone

40 mg/day 1-4, 9-12, 17-20 per cycle

VS.

Dexamethasone alone

40 mg/day 1-4, 9-12, 17-20 per cycle

Rajkumar et al. J Clin Oncol 2006;24 (18S):7517.

† Thal begun at 50 mg/d and titrated to 100 mg/d after 2 wks and to 200 mg/d at start of cycle 2.

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MM-003 study results

THALIDOMIDE PHARMION 50MG HARD CAPSULES

Primary Efficacy Endpoint	Thal/Dex (Months)	Dex alone (Months)	P value
	(n=235)	(n=235)	
TTP (95% CI)	17.4 (8.1 – DNE)	6.4 (5.6 – 7.4)	< 0.000065

- Rajkumar et al. J Clin Oncol 2006;24 (18S):7517.

ECOG study design: Newly diagnosed MM, pre-transplant

Dose

Thalidomide

- 200 mg PO daily, continuously

Dexamethasone

- 40 mg day 1-4, 9-12, 17-20 per cycle

All patients received pamidronate or zoledronic acid monthly

* Rajkumar et al. J Clin Oncol 2006;24:431-6.

ECOG study results

Efficacy Endpoint	Thal/Dex	Dex alone	P value
	(n=99)	(n=100)	
Best response*	63%	41%	0.0017
Complete response*	4%	0%	
Patients undergoing SC harvest	37% (29/79 patients)	38% (30/79 patients)	

*within four cycles using ECOG criteria
Rajkumar et al. J Clin Oncol 2006;24:431-6.

Pharmion Risk Management Programme (PRMP) in the EU

- Comprehensive safety and distribution program
- Equivalent to Celgene's S.T.E.P.S.® program in U.S., adapted for European and international markets
- Critical to compassionate use sales and ultimate marketing approval
- Important to Thalidomide victims' groups
- Available today in more than 20 languages

Thalidomide summary

Solid foundation in place for 1st line approval

- **Working with all interested parties with transparency and clarity toward an approval**
- **Data from four clinical studies support a solid submission**
- **Demonstrated survival advantage in 1st line MM**
- **Established commitment to safety through PRMP**

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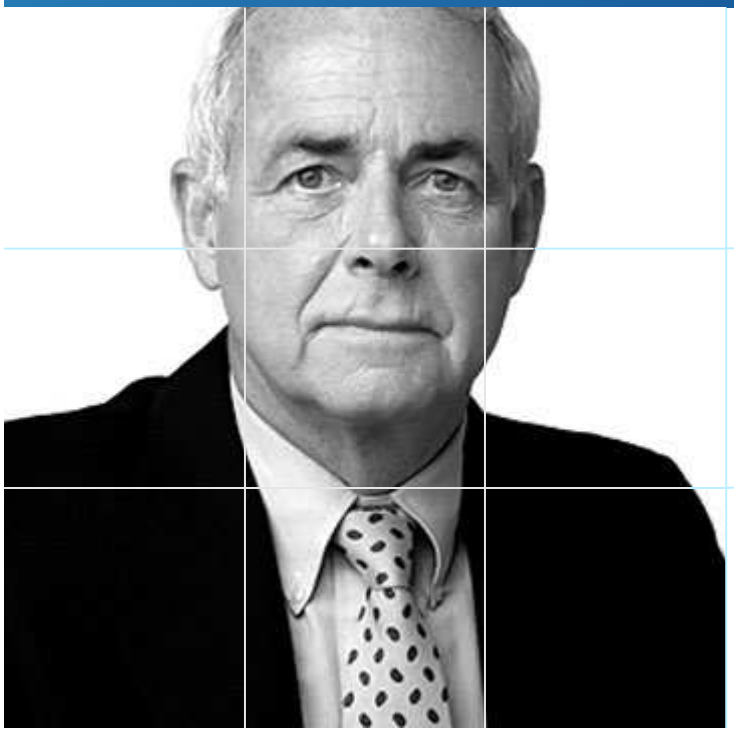
Satraplatin



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Satraplatin regulatory progress

On track for submission for 2nd line HRPC in H1 2007

- **Scientific advice procedure with EMEA completed Q1 2006**
  - > Confirmed ability to submit with PFS (700 events) and supportive data from overall survival in defined number of patients
- **EU national agencies approached for pre-submission meetings**
- **Panel of external experts identified to support filing and positioning strategy**

Satraplatin regulatory strategy

Positive top-line results support submission

- **Submit based on SPARC study**
  - > PFS
  - > Clinical benefit
- **Proposed indication: Satraplatin in combination with prednisone, for the treatment of hormone-refractory prostate cancer in patients who have failed or are ineligible for docetaxel therapy**
- **EU submission expected in H1 2007**

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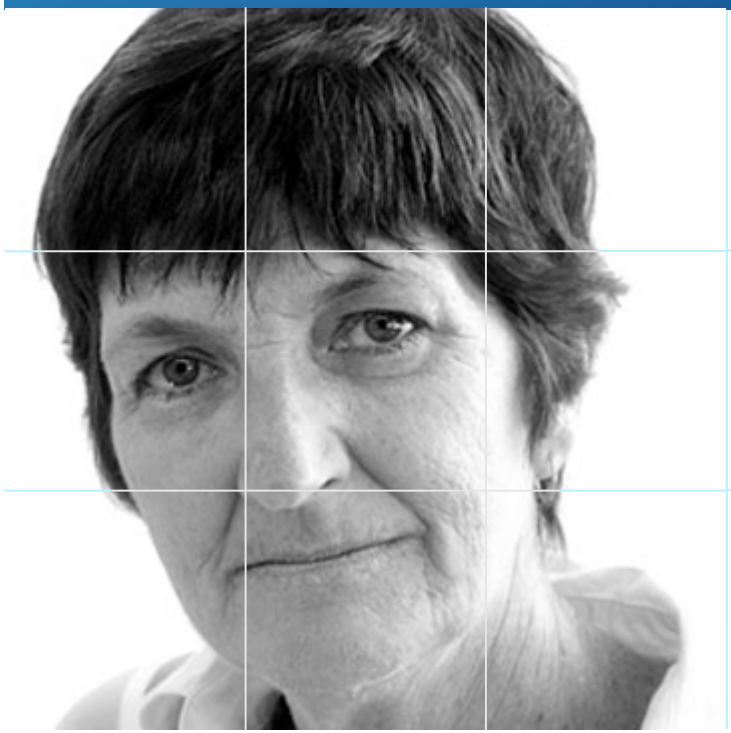
Vidaza



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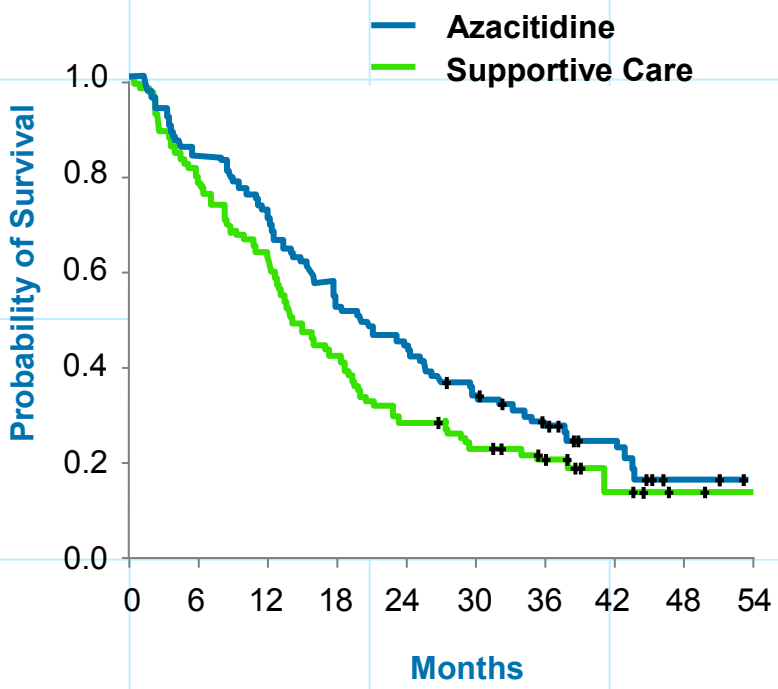
Vidaza regulatory strategy for EU

- **Survival study expected completion Q3 2007**
  - > High risk MDS
  - > Vidaza vs. standard of care comparators
  - > Enrollment complete: 358 patients
  - > Patient activity complete August 2007
- **Submission to EMEA for high-risk MDS expected Q4 2007**
- **Supportive data**
  - > CALGB study
  - > Alternate dose study

CALGB clinical study results



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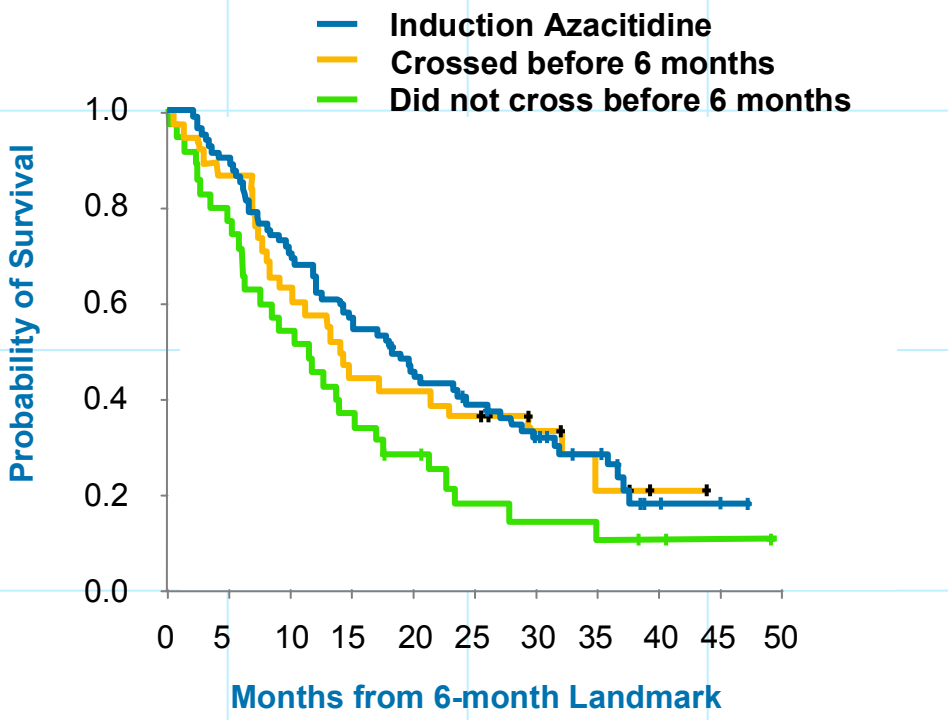

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Silverman L, et al. Randomized Controlled Trial of Azacitidine in Patients with MDS: A Study of the CALGB *J Clin Oncol* 2002. 18:2414-26. Reprinted with permission from the American Society of Clinical Oncology.

Survival study design

Vidaza® azacitidine for injectable suspension

Patient Randomized Into Study

Azacitidine 75 mg/m² x 7 days
Every 28 days x N cycles
defined in protocol*

Standard of care x N cycles
defined in protocol*

Options consist of:

- Best Supportive Care or
  1) Low dose Ara-C or
  2) Standard chemotherapy

* Time to leukemic transformation or death,whichever occurs first.

Vidaza survival study

- **Primary endpoint: survival**
- **Secondary endpoints:**
  - > Transfusion independence
  - > Response rate*
  - > Time to relapse after CR or PR, or disease progression*
  - > Time to transformation to AML
  - > Time to transformation or death from any cause

* According to IWG criteria

Vidaza regulatory strategy in US

- **FDA action on IV Vidaza sNDA imminent**
  - Change to labeling instructions re: route of administration
- **Oral formulation IND submission expected Q4 2006**
- **Survival study label expansion sNDA submission expected Q4 2007**

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