

MARSHALL EDWARDS INC

Safe anti-cancer drugs – a contradiction?

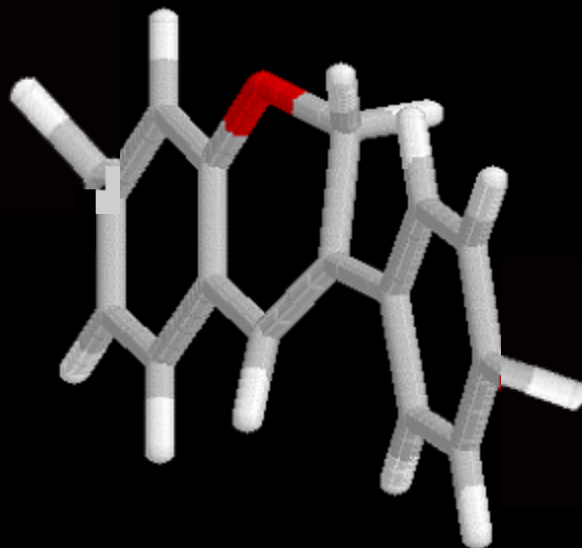
A new approach to anti-cancer therapeutics...

lessons from nature and the evolutionary process

A technology platform yielding safe but effective therapeutics...

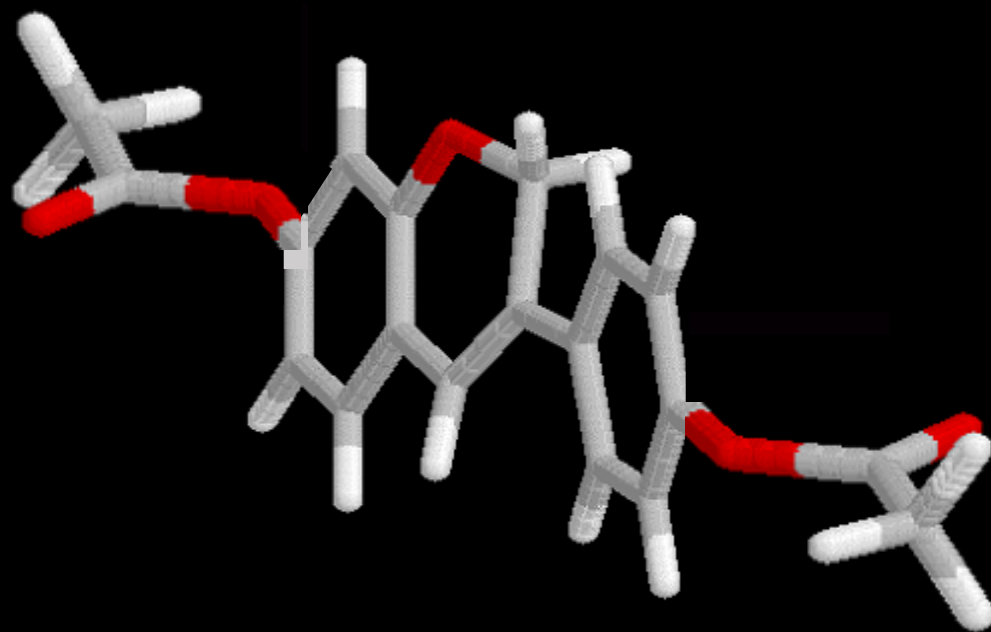
novel structures based on isoflavonoid scaffold

Phenolic drug scaffold
(isoflavone as found in plants)



Safe, Low activity

Novel chemical synthesis builds an enhanced molecule



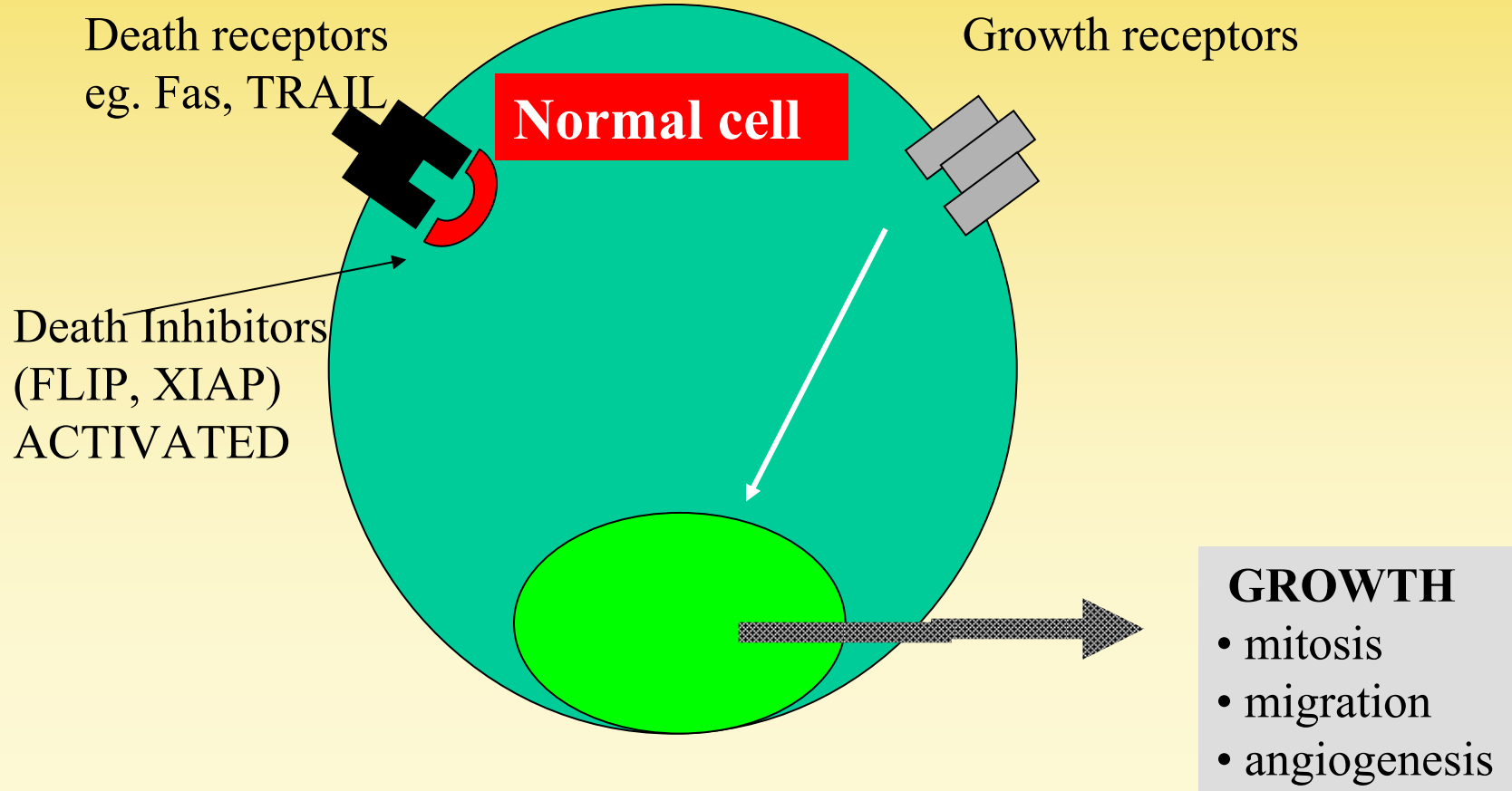
Safe, High activity

Phenoxodiol

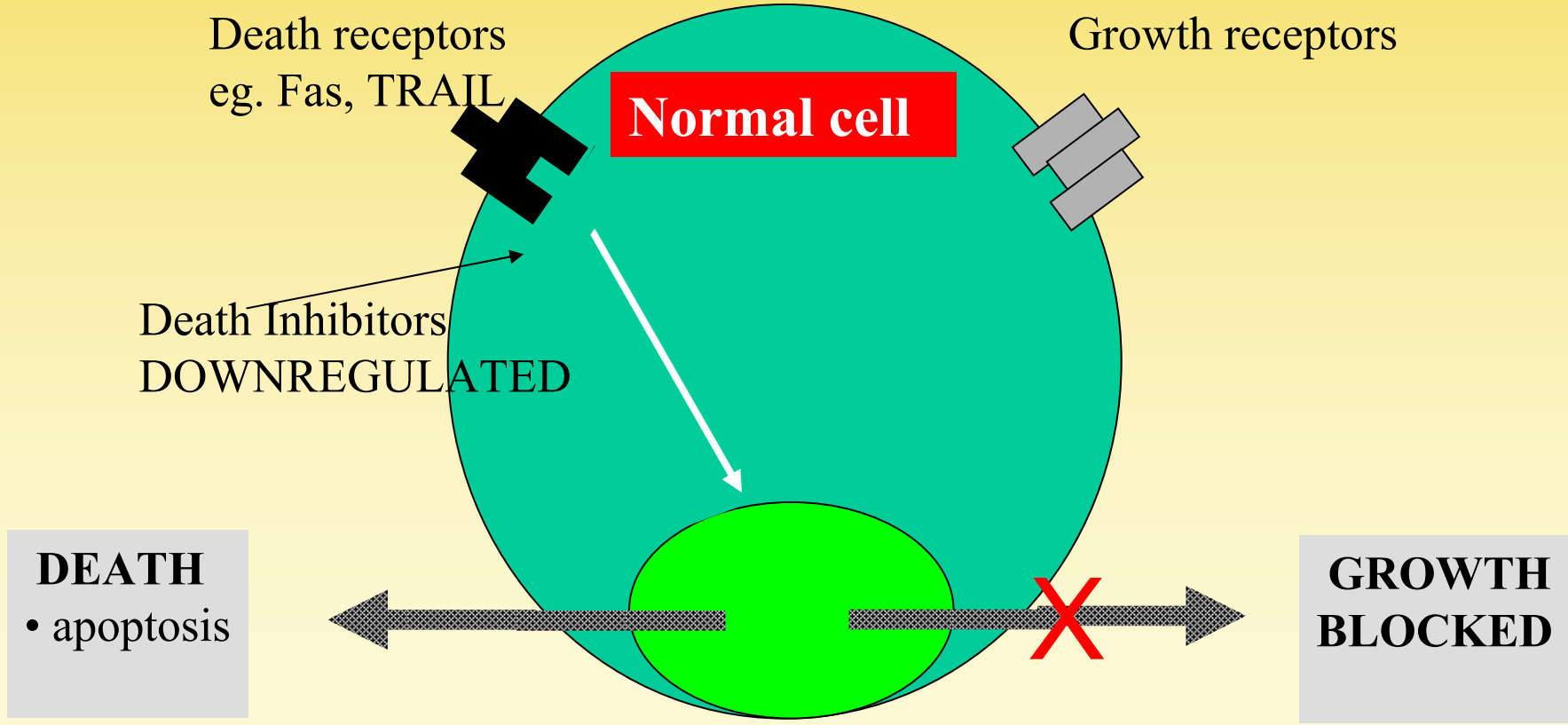
- Safe but effective
- Active in broad range of major cancers
- Current targets: ovarian, prostate and cervical



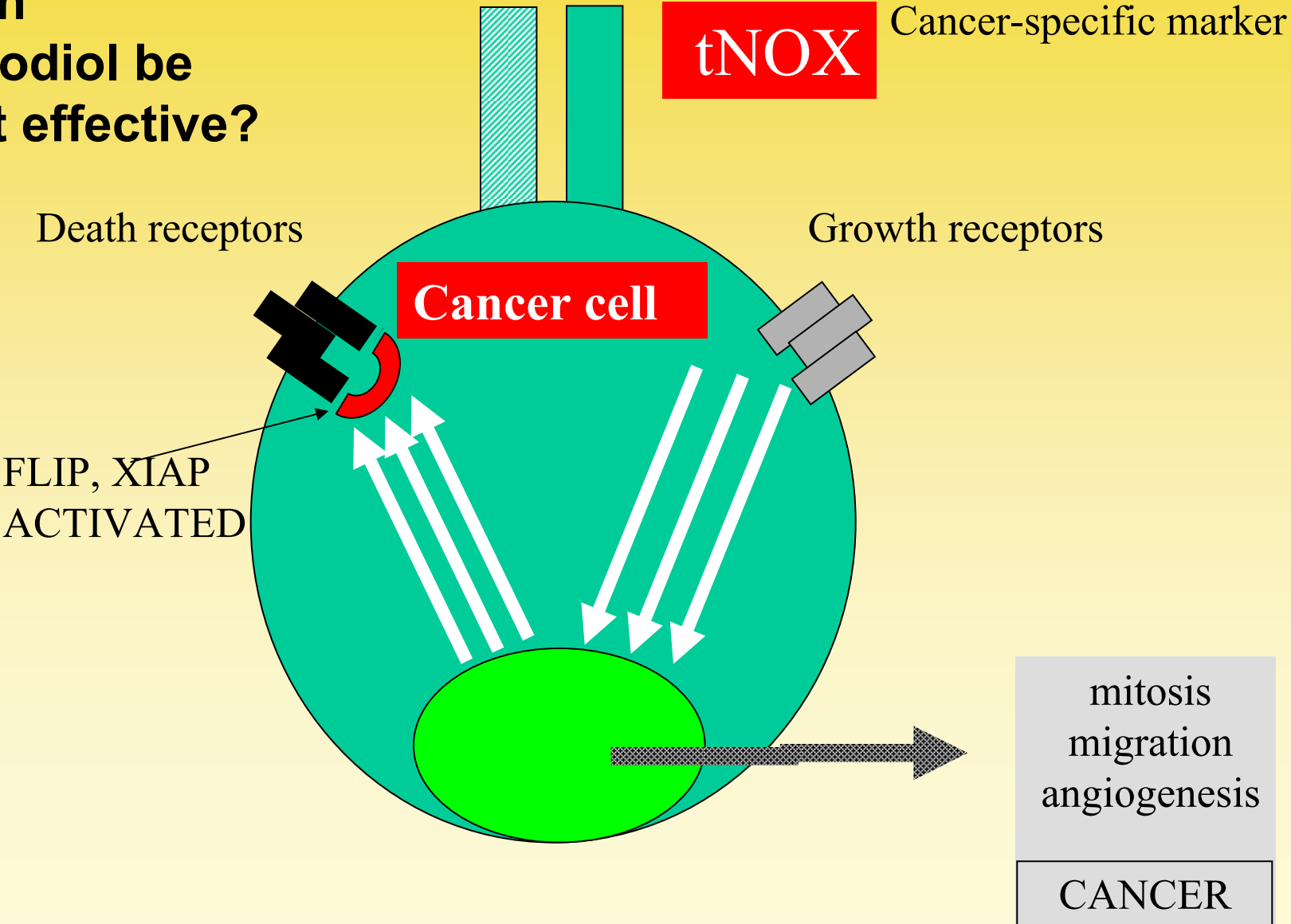
Normal Cell- Growth Phase



Normal Cell-Death Death Phase



How can phenoxodiol be safe yet effective?



Phenoxodiol

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How can phenoxodiol be safe yet effective?

tNOX

Cancer-specific marker (inactivated by Phenoxodiol)

Death receptors

Growth receptors

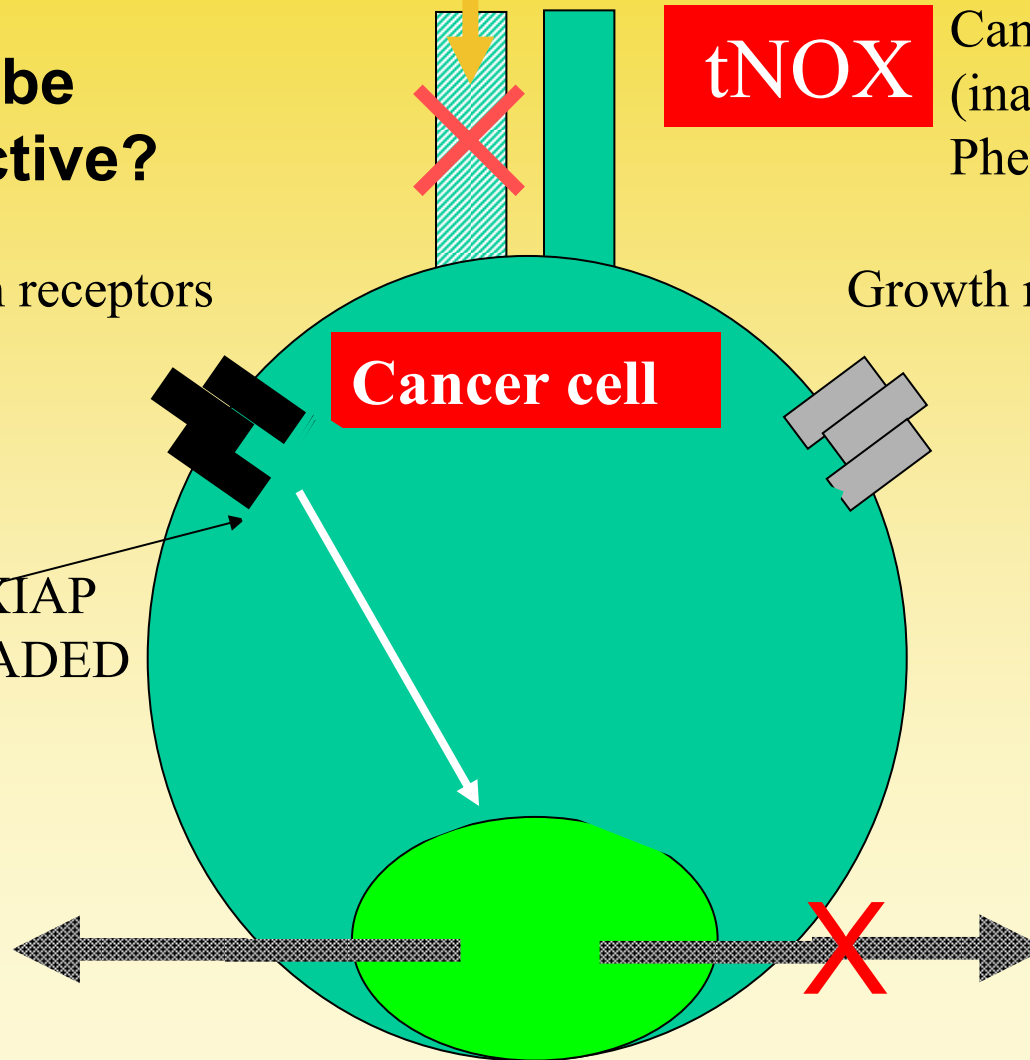
Cancer cell

FLIP, XIAP
DEGRADED

DEATH

• apoptosis

mitosis
migration
angiogenesis



Phenoxodiol

- On basis of current trial data, FDA approved Fast Track Status for
 - ovarian cancer refractory to chemotherapy
 - hormone refractory prostate cancer
- For ovarian cancer, Phase III OVATURE study, CRO appointed, trial site selection in progress
- Joint study with Sanofi-Aventis in combination therapy for chemoresistant ovarian cancer at Yale

Phase II: Ovarian Cancer Combination Therapy

NV-0037 (Yale University Hospital, Royal Womens Hospital, Melbourne)
Multi-Center Study: Phenoxodiol as a Chemosensitizing Agent for
Platinum and Taxane in Ovarian Cancer in Refractory/Resistant
Patients

5 treatment groups –

IV phenoxodiol + paclitaxel

IV phenoxodiol + cisplatin

paclitaxel run-in then IV phenoxodiol + paclitaxel

carboplatin run-in then IV phenoxodiol + carboplatin

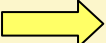
carboplatin run-in then oral phenoxodiol + carboplatin

Dose: 3 mg/kg/injection, administered by bolus intravenous infusion on
Days 1 and 2 of each week of each treatment cycle. Other two
chemotherapies: platinum 40 mg/m²; paclitaxel 80 mg/m²
administered as a weekly dose over 3 weeks each cycle

Fast Track by FDA on basis of preliminary data from this trial

Phase II: Ovarian Cancer Combination Therapy**Preliminary Results Announced 24 March 2006, SGO Meeting**

Best Response (RECIST)	Cisplatin + PXD	Paclitaxel + PXD
No. patients	21	19
CR	0	1
PR	6	2
ORR	29%	16%
SD	10	11
PD	5	5
Disease Control Rate	76%	74%

 = Progression Free Survival?

Phase II: Ovarian Cancer Combination Therapy

Preliminary Results Announced 24 Oct. 2005:

- Median survival:

PXD+cisplatin arm = 62 weeks *

PXD+paclitaxel arm = 48 weeks *

At 75 weeks, 35% of patients in the PXD+paclitaxel alive

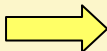
At 72 weeks, 35% of patients on the PXD+cisplatin alive.

* This compares with median survival reported for patients on standard therapy of only 28 to 40 weeks
(*Ann. Oncol.* 15:100-103, 2004)

- The PXD and cisplatin or paclitaxel combinations were well tolerated, with no unexpected toxicities encountered

Phase II: Ovarian Cancer Combination Therapy**Preliminary Results Announced 24 March 2006, SGO Meeting****Cisplatin Group Subset Analysis by Time Since Last Rx**

Best Response (RECIST)	<6 months	≥ 6 months
No. patients	10	11
CR	0	0
PR	3	3
ORR	30%	27%
SD	5	4
PD	2	4
Disease Control Rate	80%	64%

 = Progression Free Survival?

Phase III: OVATURE STUDY: Ovarian Cancer Combination Therapy

Proposed study plan:

Treatment Group: PXD oral 400mg tid (1200 mg total daily dose) + weekly carboplatin

Control Group: Weekly carboplatin

N = 235/ Group

Primary endpoint: Progression free survival

Secondary endpoint: Tumour response, overall survival

Interim analysis when all patients recruited and 97 events recorded

Phase II: Prostate Cancer Oral Dose Form

Monash Medical Centre, Sir Charles Gairdner Hospital, Aust.: Oral Phenoxodiol in patients with late stage hormone-refractory prostate cancer. **Data presented at AACR 18/11/05:**

Dose	n	PSA Response	PSA Doubling Time (wks)	Time to Progression (wks)
20	6	0	14	13
80	6	0	22	17
200	5	1	66*	55*
400	9	2	39**	42**
*One patient remaining on PXD therapy with stable PSA levels at 92 weeks				
** Four patients remaining on PXD therapy with stable PSA levels at 42, 74 and 82 weeks				

**Phase III: COMPACT STUDY: PXD Oral in Hormone Refractory
Prostate Cancer**

To address role of PXD in resensitizing HRPC patients who have not responded to docetaxel.

Proposed study plan

Treatment #1: PXD oral (400 mg PXD tid)

Treatment #2: PXD oral (400 mg PXD tid) + docetaxel (30
mg/m² weekly)

Phase I: Cervical Cancer Oral Monotherapy (Yale University)

Patient Number	Dose	Change in tumor size (RECIST)	Classification
01	50	+ 8%	SD
02	50	+ 7%	SD
03	50	+ 34%	DP
04	50	+ 13%	SD
05	50	- 1%	SD
06	50	unchanged	SD
11	200	+ 8%	SD
12	200	+ 16%	SD
13	200	- 20%	SD
14	200	unchanged	SD
15	200	- 9%	SD
16	200	- 2%	SD
18	200	- 19%	SD
19	200	+ 10%	SD

5 of 6 patients SD

8 of 8 patients SD

13/14 SD despite relatively short treatment time (28-day)

No phenoxodiol-related toxicity was observed in any patients

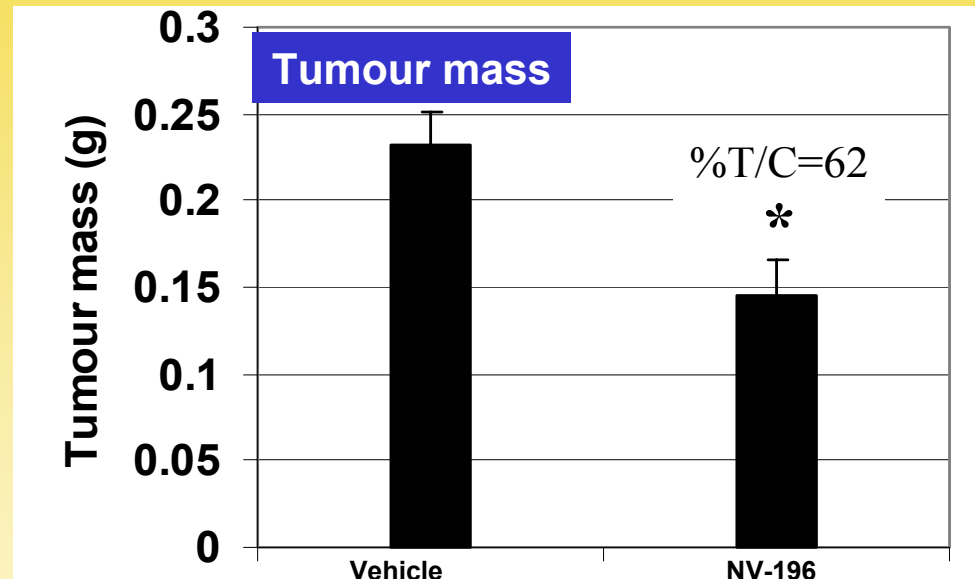
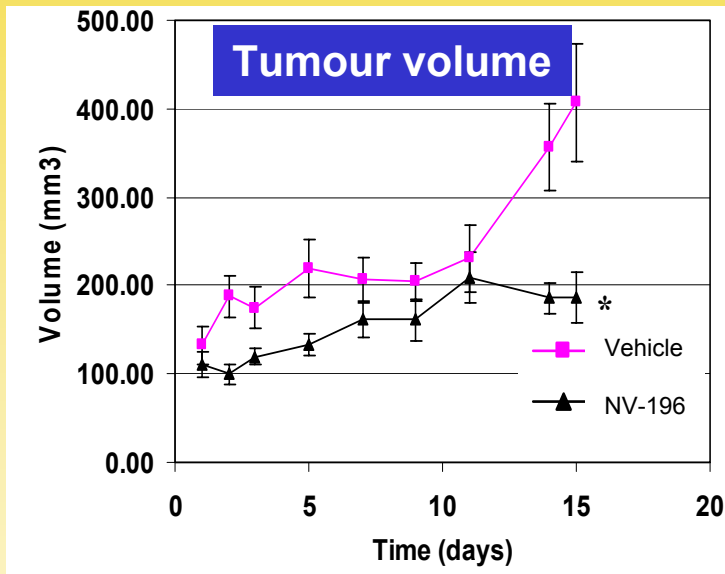
Study continues at 400 mg per dose

Anti-cancer Pipeline Compounds

- Novogen (NVGN) holds 87% equity in MSHL
- MSHL has first and last refusal rights over any Novogen oncology compound at entry to clinical phase development
- Novogen synthetic chemistry program has produced over 190 novel isoflavonoid compounds

NV-196 : Targets: pancreatic cancer, cholangiocarcinoma

NV-196 in vivo Efficacy in HPAC tumour bearing mice



100 mg/kg, p.o.Qdx15

Phase Ia - Bio-availability, Pharmacokinetic and Acute Safety

NV18-0001 (St. George Hospital, Sydney) Phase Ia Bio-availability, Pharmacokinetic and Acute Safety Study of Both Oral and Intravenous Dosage Forms of NV-196 in Patients with Solid Tumors

Clinical Progress Summary

		Preclinical	Phase I	Phase II	Target
MSHL	Phenoxodiol				Ovarian, prostate, cervical, renal cancers
	Ovarian Cancer				
	Prostate Cancer				
	Cervical Cancer				
	Renal Cancer				
NOVOGEN	NV-196				Pancreatic cancer, cholangiocarcinoma
	NV-128				Lung, breast cancer
	NV-143				Melanoma

Corporate Profile

- NASDAQ: MSHL
– market cap \$ US 310 million
- 87% owned Novogen Limited (NVGN)

**Novogen Limited
NVGN**

Pharmaceutical

- **Novogen Research Pty Ltd:**
Australia
USA

**Marshall Edwards, Inc.
MSHL**

- **Anti-cancer company**
conducting clinical trials of Phenoxodiol
- **NASDAQ (MSHL)**

Consumer Products

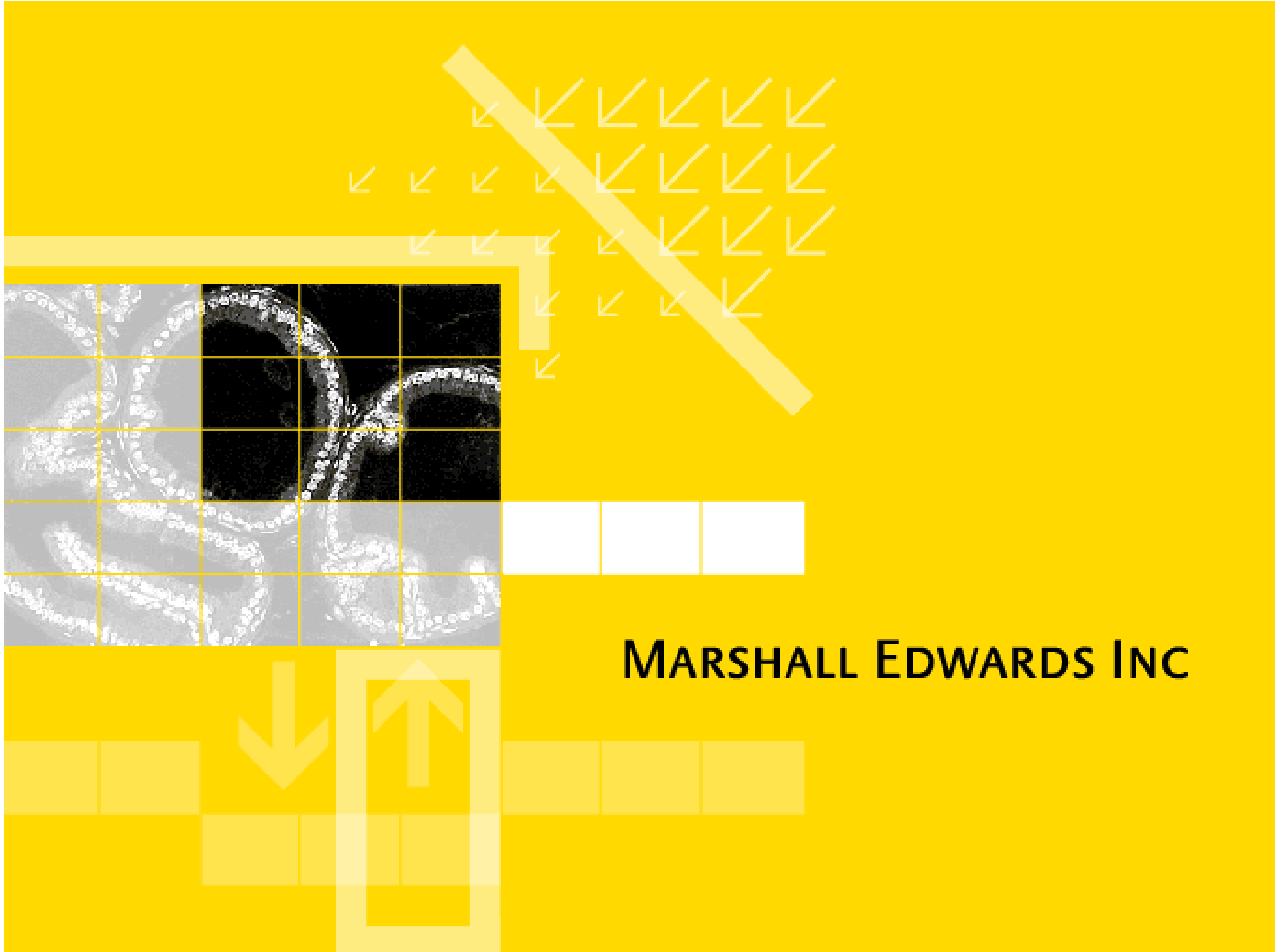
- **OTC Division:**
 - Australia
 - UK
 - USA
 - Canada
 - Netherlands
 - + Production

Glycotex, Inc.

- **Glucan wound healing technologies**

- Cash at December 31 2005 \$US 17.7 M *
- R&D Spend half-year to December 2005 \$US 1.5 M *
- Discovery
- R&D
- Manufacturing
- Clinical Trials
- Outlicensing

* excludes license fee payable to Novogen \$ 4m paid 31-01-06



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