belinostat

A Pan HDAC Inhibitor with Clinical Potential in both Hematological Malignancies and Solid Tumors

Discovery On Target Conference
HDAC Inhibitors

Dr Steven Butcher, TopoTarget
Dr Richard Penson, Massachusetts General Hospital

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Potential Conflicts of Interest (Dr Richard Penson)

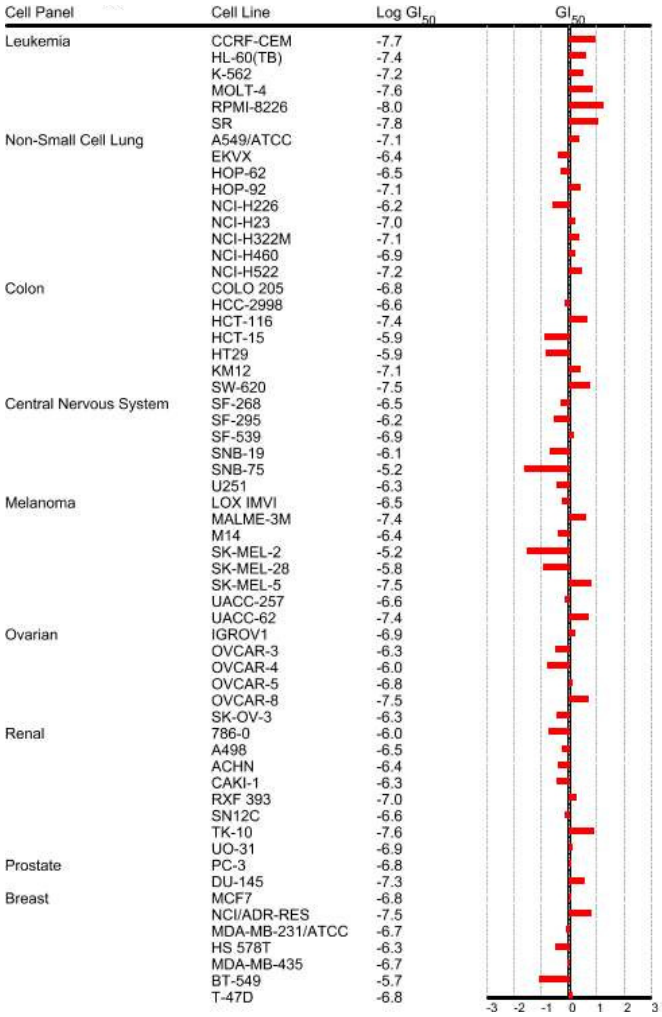
2004- Genentech, Inc. Research Funding.
2005-2007 DARA BioSciences™, Inc. Consultant.
2005- DARA BioSciences™, Inc. Research Funding.
2006-2008 MGI PHARMA, INC. Research Funding.
2006-2008 Lilly and Company. Consultant.
2006- Berlex Labs (Bayer HealthCare Pharmaceuticals). Research Funding.
2007-2008 GlaxoSmithKline. Scientific Advisory Board.
2005- CuraGen Corporation. Research Funding.
2007- PDL BioPharma, Inc. Research Funding.
2006- ImClone Systems, Inc. Research Funding.
2008 Abbott Laboratories. Scientific Advisory Board.
2008- Endocyte, Inc. Research Funding.
2009 AstraZeneca. Scientific Advisory Board.

Belinostat: Preclinical Profile

Selectivity of clinically advanced HDACi		
rhHDAC (Class)	**Belinostat EC_{50} (nM)**	**Vorinostat EC_{50} (nM)**
1 (I)	41	68
2 (I)	125	164
3 (I)	30	48
4 (I)	115	101
6 (II)	82	90
7 (II)	67	104
8 (I)	216	1524
9 (II)	128	107

- Belinostat is a pan HDACi that inhibits both class I and II HDACs
- Effective in multiple in vitro models inc. chemotherapy resistant cell lines
- Inhibits HDAC6 (tubulin substrate)
  - Basis for BelCaP efficacy?
- No additional toxicity issues compared to class selective HDACi

Belinostat
Average GI_{50} 1.78E-7



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Belinostat: Clinical Development Overview

- 24 trials in the overall clinical program
  - IV = 23 clinical trials (12 sponsored by TopoTarget; 11 sponsored by NCI)
  - Oral = 1 clinical trial sponsored by TopoTarget
- 694 pts treated with belinostat (as of 4th Sept 2009)
  - 448 pts treated in studies sponsored by TopoTarget
    - 339 pts in IV program and 109 pts in oral program
  - 246 pts enrolled in studies sponsored by NCI (IV administration)
- Treatment with belinostat is safe both with IV and oral administration
  - Large safety database; most frequent adverse events = low-grade nausea, vomiting and fatigue
  - Minor hematological toxicity using monotherapy, and no additional hematological toxicity in key chemotherapy combinations
  - No pericarditis or pericardial effusion
  - Independent evaluation of dedicated cardiac study: "the data show that there is no clear signal of any clinically relevant effect on heart rate, AV conduction, cardiac depolarization, morphology or cardiac repolarization"

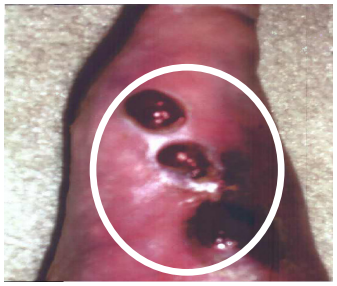
IV Belinostat: Monotherapy and Combination Efficacy

• Monotherapy

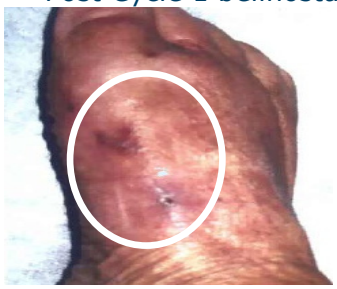
IV Schedule: 1000 mg/m^2 x 5 day

- Response rate 25% in PTCL inc 10% CR
- Durable CRs in CTCL
- ORs in solid tumors

Pre-belinostat



Post Cycle 1 belinostat



- 74-yr male with CTCL (CD30+ ALCL); extensive regional disease (R. foot-thigh; T2c)
- Previous CHOP therapy plus 4 courses of radiation; subsequent progressive disease
- Pt received 5 cycles of belinostat; PR 14 days and CR 36 days from treatment initiation, response duration ≥ 15 months

• Combination

BelCaP (belinostat + carboplatin + paclitaxel)

- Platinum Resistant Ovarian Cancer
  - 24% (RECIST) and 38% (RECIST + CA125) OR
  - 5.5 mo median PFS
- Bladder Cancer (after cis/gem)
  - 29% OR (n=14)

BelFU (belinostat + 5-FU; n=35)

- 26% SD inc. 6 pts with TTP of 12 - 41 weeks (median 3 prior regimens; majority ≥2 FU-based)

BelAza (belinostat + azacitidine)

- 2 CR, 1 PR & 4 hem. improvement (n=21)
- Expansion to randomised phase started by NCI

BelIda (belinostat + idarubicin)

- 2 CR & 3 CRi using IV or CIV (n=34)

BelDex (belinostat + dexamethasone)

- 44% ORR (2 PR, 2 MR; duration of 6 to +16w)
- 56% SD with duration up to 58w

Lymphoma study part ongoing d 1-14, q3w
- Currently at 1750mg QD

Oral Belinostat: Monotherapy Phase I

- Belinostat monotherapy multiple schedules defined in solid tumors
  - Continuous regimen; once daily (QD) or twice daily (BID)
    - Recommended dose = 250 mg BID continuous treatment
  - Discontinuous regimen; once (QD) or twice daily (BID) on days 1 – 14 in a 21 day cycle
    - Recommended dose = 750 mg QD*
  - Discontinuous regimen; once daily (QD) on days 1 – 5 in a 21 day cycle
    - Recommended dose = 2000 mg QD*

* intra-patient dose escalation possible if limited toxicity

ASCO 2009 solid tumors

- 92 pts, median age 59 (range 32-89)
- Most frequent treatment related AE (any grade) = fatigue, nausea and anorexia
- Mild hematological toxicity (one Gr3 thrombocytopenia in 92 pts treated)
- SD in 48 (64%) of 75 evaluable pts; 6 pts with ≥6 months treatment duration (e.g. 710d adenoidcystic, 551d bladder, 485d renal), and 9 pts with 3-6 months

ASCO 2009 lymphoma

- 15 pts, median age 53 (range 21 - 70)
- SD in 7 (70%) of 10 evaluable pts, incl. 3 of 3 pts with mantle cell lymphoma, 3 of 4 pts with Hodgkin's disease and 1 CTCL pt previously treated with vorinostat
- Median treatment duration pts with SD +77 days (range 62 to +282; 3 pts ongoing trt)
- Early tumor shrinkage of 43 to 49% in Hodgkin's disease and mantle cell lymphoma

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IV Belinostat: Monotherapy Phase II NCI Studies

- Thymoma/thymic carcinoma

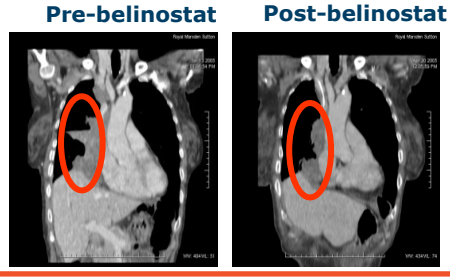
Key experts in the field

- G. Giaccone, Medical Oncology Branch, NCI, Bethesda, MD
- P. Loehrer, Indiana University, Indianapolis

Phase II Design

- Patients with recurrent disease progressing after platinum-based chemotherapy
- Belinostat IV at 1000mg/m^2/d on days 1-5, q3w (q4w after 12 cycles of therapy)
- ASCO 2009
  - 32 pts recruited (median 3 prior regimens)
  - Median of 4 belinostat treatment cycles (range 1 to +20)
  - 27 patients evaluable for response: 2 PR (13, 13+ m), 15 SD (3-15+ m) and 10 PD

Thymoma (from ph I mono, prolonged, 31 mo, minor response)



- Hepatocellular carcinoma

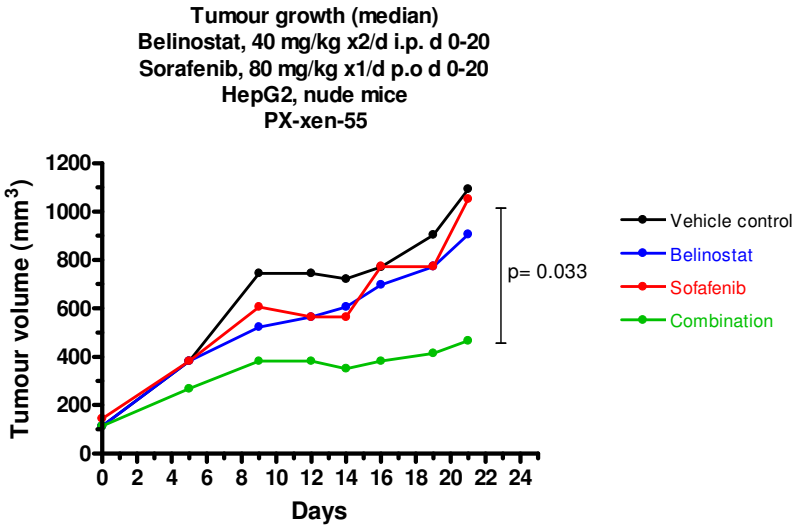
Phase I finalized

- Belinostat safely administered at higher doses than previously used in the standard day 1-5 IV schedule

Global phase II initiated

- Phase II portion using belinostat single agent dose of 1400 mg/m^2/day, days 1-5, q3w
- Sites in Hong Kong, Korea, Australia and US

Interesting possibility as monotherapy and/or in combination; e.g. combined with sorafenib



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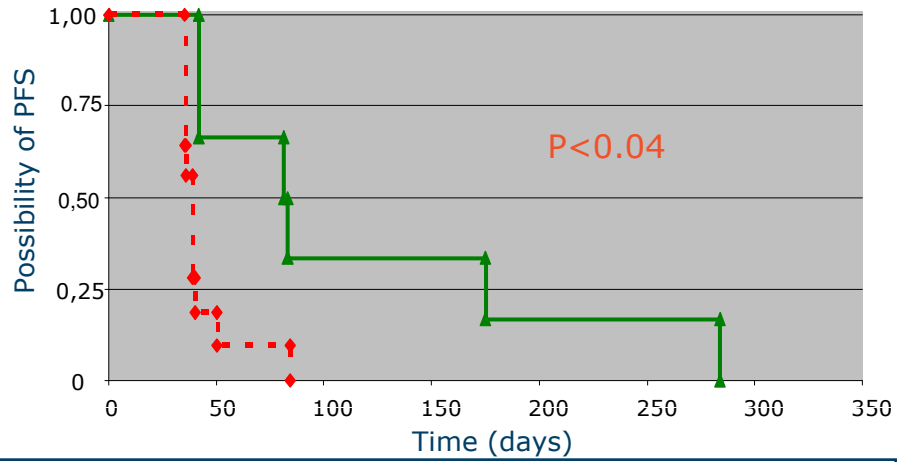
Belinostat:
Potential Patient Selection Marker in PBMCs

Maximum % change with belinostat (cycle 1) *versus* baseline thymidylate synthase (TS), dihydropyrimidine dehydrogenase (DPD), and p21 relative gene expression in patient PBMCs

Patient No Belinostat (mg/m²/day)	Study Trt outcome: No of trt Cycles/ Best Response	TS	DPD	p21
101-1 / 300	2 / PD	486%	136%	48%
101-2 / 600	2 / PD	190%	-74%	43%
101-3 / 600	8 / SD	-87%	-87%	88%
102-4 / 600	2 / PD	144%	-73%	-86%
102-5 / 600	2 / PD	NA	-13%	NA
101-4 / 1000	2 / PD	238%	547%	68%
102-6 / 1000	2 / PD	-51%	91%	972%
102-7 / 1000	2 / PD	NA	220%	-72%
102-8 / 1000	2 / PD	63%	169%	715%
101-5 / 1000	2 / PD	594%	-83%	62%
101-6 / 1000	4 / SD	250%	563%	156%
102-9 / 1000	2 / PD	NA	NA	NA
102-10 / 1000	2 / PD	NA	373%	43%
102-11 / 1000	2 / PD	NA	98%	-71%
101-7 / 1000	4 / SD	116%	-60%	-83%
101-8 / 1000	2 / PD	274%	160%	-86%
102-12 / 1000	2 / PD	NA	NA	NA
102-13 / 1000	1 / NE	NA	NA	NA
102-14 / 1000	14 / SD	-67%	-20%	74%
102-15 / 1000	4 / SD	214%	62%	-47%

BelFU; PFS by patient PBMC gene profile (6hr post D1)



PFS in pts with "2 of 3" PBMC marker pattern (n=6; green)
vs pts without "2 of 3" PBMC marker pattern (n=14; red)

Dynamic Biomarker (DBM)-signature for belinostat in combination with fluropyrimidines:

- TS down-regulation
- DPD down-regulation
- p21 up-regulation

Improved PFS in patients with specific PBMC gene expression pattern

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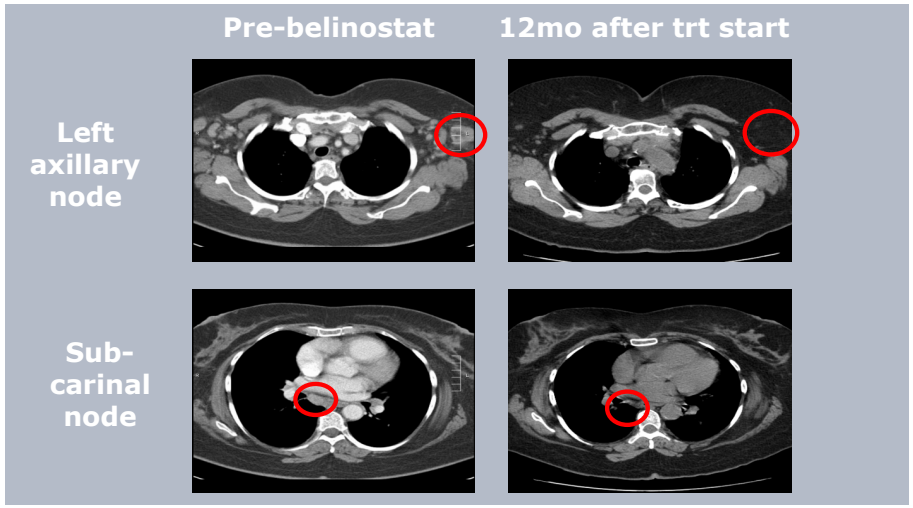
Belinostat: Clinical Development in PTCL

✓ Belinostat is supported by preclinical data
- *In vitro* efficacy in T-cell lymphoma lines

Cell Line	Bel (IC_{50} ; µM)
HH	0.12
HuT 78	0.42
SR-786	0.49
KARPAS-299	0.34

✓ Belinostat is supported by clinical data
- Clinical study PXD101-CLN-6 in patients with previously treated T-cell lymphoma



- 61-year old female patient with stage IIIA PTCL-unspecified
- Previous CHOP for 107 days; best response = PR; stopped due to PD
- Patient received 8 cycles of belinostat (166 days treatment duration)
- CR after 6 cycles of belinostat
- CR duration = 12.1 months
- Progression-free survival = 15.9 months

✓ SPA, Fast Track and Orphan Drug Designation with FDA

Belinostat:
PTCL: Phase II Trial Efficacy Population

Outcome measures important for FDA	**Result**
Response assessment according to IWG criteria Complete response = 2 pts (PTCLu IIIA and IIIB) Partial response = 3 pts (PTCLu IIIA, AITL IVB, ALCL IIA) Stable disease = 5 pts (PTCLu IB and IVB, NK/T-cell IIA and IVA, ALCL IIB)	Objective response rate 5 of 20 pts (25%)
Duration of Response (days), n=5 Median (2 ongoing) Range	 371 109 — +505
Duration of Stable Disease (days), n=5 Median (3 ongoing) Range	 +109 80 — +185

SPA for pivotal trial specifies final statistical target of 20% response rate
Response durability will also be an FDA consideration

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Why Develop BelCaP (belinostat/carboplatin/paclitaxel)?
Synergies based on mechanisms of action

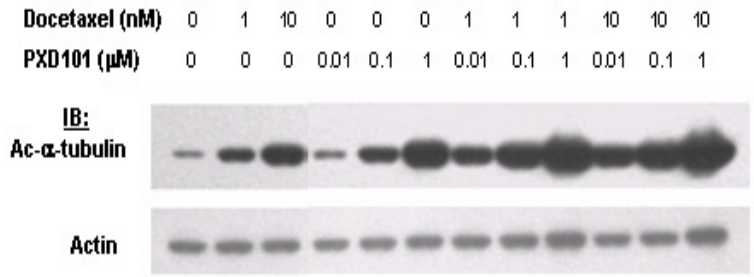
Synergy between platinum agents and belinostat

- HDACi relax DNA which may increase access for DNA-damaging chemotherapy agents
- HDACi impact DNA repair mechanisms, e.g. decreased expression of ERCC1, RAD51, and XPF in response to double strand breaks and inter-strand cross-links

Phosphorylation of H2AX is an early marker of DNA damage

Synergy between taxanes and belinostat

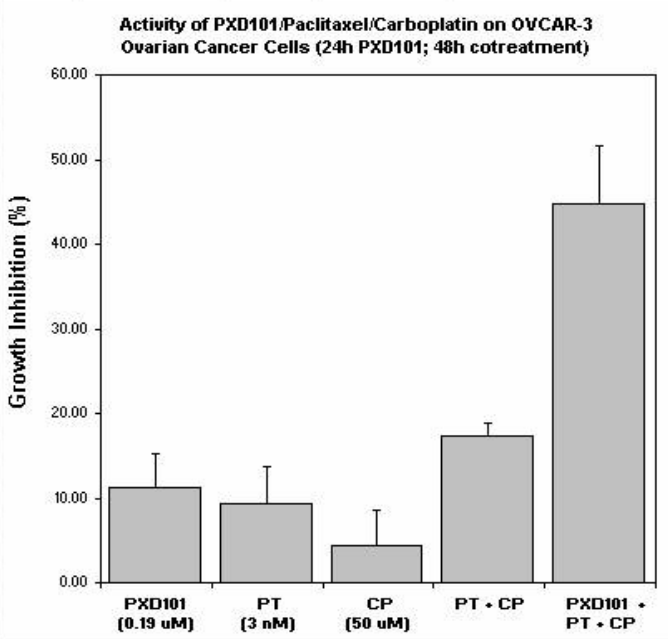
Enhanced tubulin acetylation alters microtubule dynamics



Stabilization of tubulin may lead to inhibition of mitosis and stimulation of apoptosis

Growth inhibition by belinostat in cancer cell lines

- Sub-micromolar IC_{50} on numerous cancer cell lines in vitro
- Synergistic activity combination with platinum and taxane agents in vitro
- Single agent and combination activity on platinum-resistant cancer cells in vitro and in vivo



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BelCaP (belinostat + carboplatin + paclitaxel) Clinical Data

BelCaP Phase I

- 23 patients treated; median of 4 cycles (range 1 – 32); with escalating doses of belinostat as a 30-min infusion (up to 1000 mg/m^2) daily for 5 days together with carboplatin (AUC 5, GFR by isotopic method) and/or paclitaxel (175 mg/m^2) delivered on day 3, every 3 weeks
    - Conclusion safety: No DLT observed. BelCaP is well-tolerated during prolonged treatment periods, presenting a safety profile consistent of that observed with carboplatin/paclitaxel alone. Hematological toxicity was not augmented by addition of belinostat.
    - Conclusion PK: Belinostat exposure using BelCaP similar to that observed with belinostat monotherapy. Belinostat does not alter excretion of paclitaxel or carboplatin

BelCaP Phase II in recurrent bladder cancer

- 14 evaluable patients with prior platinum-based therapy (range of prior regimens 1 - 3)
- Safety profile = similar to expected from carboplatin/paclitaxel alone
- Efficacy outcome = 29% OR (1 CR, 1 CRu (initiated RT), 2 PR) + 10 SD
    - No standard 2nd line treatment; recent phase III of vinflunine = 9% OR

BelCaP Phase II in recurrent ovarian cancer (following slides)

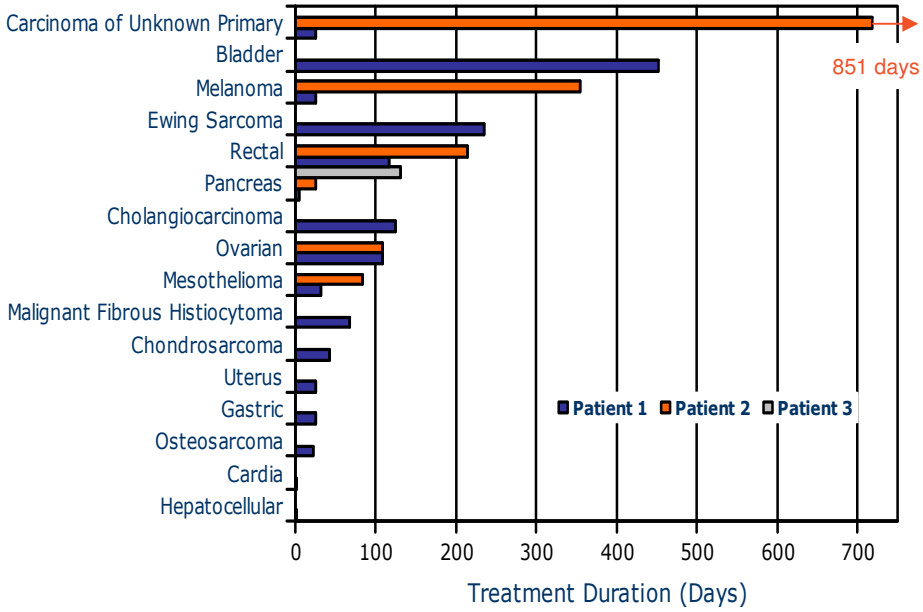
BelCaP Phase I in Solid Tumors

2 confirmed PRs:

- rectal cancer; previous 5-FU/irinotecan, oxaliplatin/capecitabine, and cetuximab/irinotecan; PR after 4 cycles of BelCaP, ongoing for five months when the patient elected to discontinue treatment.
- pancreatic cancer; previous gemcitabine; PR after 6 cycles of BelCaP, sustained for 2.5 months after end of treatment.

Additional 11 pts had SD for 2 to 32 cycles with 4 being stable for >10 cycles including:

- carcinoma of unknown primary; previous cisplatin/paclitaxel/gemcitabine (7.5 mo), capecitabine/oxaliplatin (3.9 mo), and carboplatin/paclitaxel/gemcitabine (5.6 mo); at PD liver mets start BelCaP, treatment duration 28 mo (32 cycles); dose of carboplatin reduced from cycle 7, paclitaxel stopped at cycle 11 due to neuropathy
- bladder cancer; previous cisplatin/gemcitabine and carboplatin/gemcitabine; belinostat with paclitaxel for 15 cycles followed by 5 cycles of belinostat monotherapy (treatment duration 14 mo)



Nine patients (39%), two with confirmed partial responses, one with a complete CA125-response, and six with sustained stabilization of disease and treatment durations beyond patients' most recent prior treatment,

- Carcinoma of unknown primary site
- Rectal cancer
- Pancreatic cancer
- Ovarian cancer
- Bladder carcinoma
- Soft tissue sarcoma
- Chondrosarcoma
- Ewing's sarcoma
- Melanoma

Key is the broad spectrum of diagnoses where positive impact is noted

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BelCaP Phase II in Recurrent Ovarian Cancer:
Study Design

Phase II, open label, non-randomized, multi-center study

- Primary objective: overall response rate by RECIST criteria
- ≤ 3 prior regimens for metastatic disease

BelCaP Treatment (21-day cycle)

- Day 1-5: belinostat 1000 mg/m^2/day IV over 30 minutes
- Day 3: Paclitaxel 175 mg/m^2 IV over 3 hours, 2-3 hours post belinostat followed by carboplatin (AUC of 5 IV over 30-60 minutes)

Tumor Response

- Primary end-point assessed by RECIST criteria (target and non-target lesions) every 2 cycles
- Secondary assessment of CA-125 response in patients with baseline CA-125 ≥ 2 x ULN

BelCaP Phase II in Recurrent Ovarian Cancer:
Baseline Characteristics

Baseline Characteristics	N = 35
Age, yr Median Range	 60 39 – 80
Race White/Caucasian African-American/Hispanic	 89% 11%
Duration of Ovarian Cancer* (yr) Median Range	 2.6 0.3 – 8.7
Number Prior Regimens Median Range	 3 1 – 4
Treatment-Free Interval (mo) Median Range	 1.8 0.3 – 38.3

* Histology = 80% serous papillary, 6% clear cell, 6% endometroid, 6% poorly/moderately diff adenocarcinoma, 3% mixed mesodermal

Platinum-Free Interval [1]	N (%)
Platinum Resistant [2] PFI < 6 months	21 (60%)
Platinum Sensitive [3] PFI ≥ 6 months	14 (40%)

[1]All patients received prior platinum-based therapy; 54% one, 31% two, and 14% three platinum-based regimens. Assessment of baseline platinum-free interval (PFI) based on most recent platinum exposure; time from last exposure of platinum until progression or start of new treatment

[2]Including 13 patients with PFI 0 - < 3 mo

[3]Including 6 patients with PFI ≥ 6 to < 12 mo

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BelCaP Phase II in Recurrent Ovarian Cancer:
Safety Population (n=35); Non-Hematological Toxicity

	Any Grade Treatment Related Adverse Events*	
	No of pts	Percentage
Nausea	29	83%
Fatigue	26	74%
Vomiting	22	63%
Diarrhea	13	37%
Alopecia	13	37%
Dysgeusia	11	31%
Constipation	9	26%
Peripheral sensory neuropathy	9	26%
Headache	8	23%
Anorexia	8	23%
Arthralgia	7	20%
Dizziness	7	20%
Myalgia	7	20%
Flushing	7	20%
Increased ALT (SGPT)	7	20%

Final Data Output

* Any grade non-hematological tox in ≥20% of patients

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BelCaP Phase II in Recurrent Ovarian Cancer:
Safety Population (n=35); Non-Hematological Gr3/4 Toxicity

Treatment related grade 3/4 non-hematological toxicity*	Grade 3	Grade 4	Total Grade 3/4	
	No of pts	No of pts	No of pts	Percentage
Fatigue	6	0	6	17%
Increased ALT (SGPT)	5	0	5	14%
Increased AST (SGOT)	5	0	5	14%
Nausea	2	0	2	6%
Vomiting	2	0	2	6%
Arthralgia	2	0	2	6%
Myalgia	2	0	2	6%
Anorexia	2	0	2	6%
Hypersensitivity (carboplatin)	2	0	2	6%

Final Data Output

* Worst grade per patient per preferred term including events experienced by more than one patient

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BelCaP Phase II in Recurrent Ovarian Cancer:
Safety Population (n=35); Hematological Toxicity

Adverse Events; irrespective of relationship	Grade 1	Grade 2	Grade 3	Grade 4
	No of pts (%)	No of pts (%)	No of pts (%)	No of pts (%)
Anemia	5 (14%)	15 (43%)	4 (11%)	0 (0%)
Neutropenia	0 (0%)	4 (11%)	6 (17%)	6 (17%)
Thrombocytopenia	4 (11%)	7 (20%)	3 (9%)	1 (3%)
Febrile Neutropenia	-	-	0 (0%)	0 (0%)

Final Data Output

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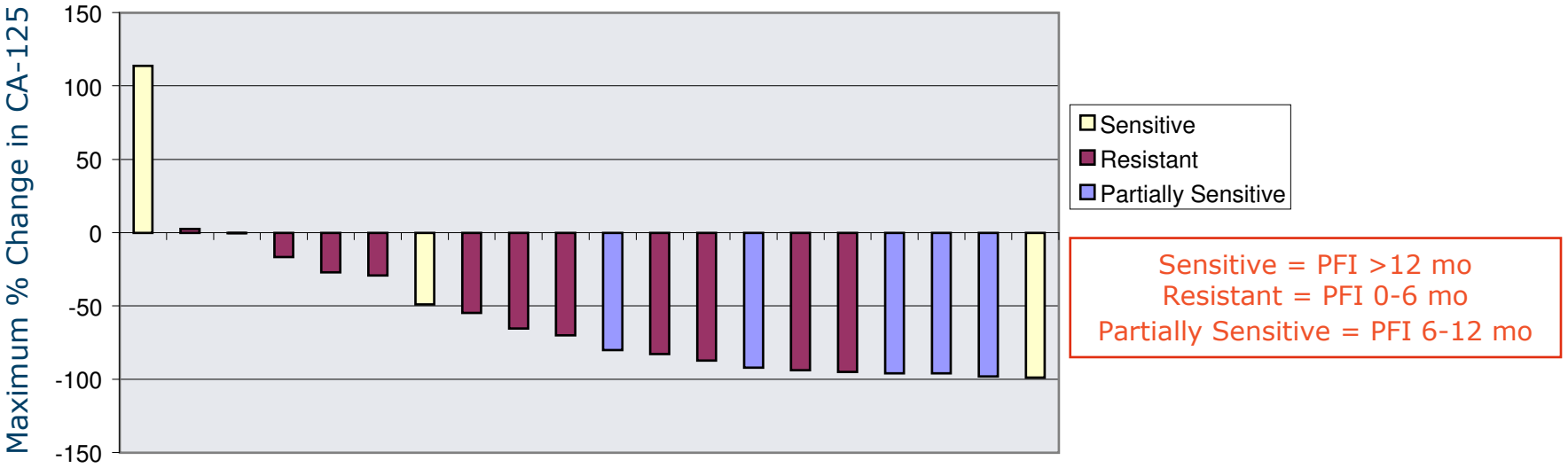
BelCaP Phase II in Recurrent Ovarian Cancer:
CA-125 Response

- 23 eligible patients = CA-125 value at baseline of >2x the upper limit of normal); median CA-125 = 339 U/mL (range 75-2040)
- 6x CR, 7x PR + 6x SD
- ORR = 57% in ITT population with eligible CA125 baseline

Maximum CA-125 % Change by Most Recent Platinum Sensitiveness - Evaluable Population*



*3 pts non-evaluable due to missing post-baseline value

- Definition of response = >50% decrease maintained for 28 days (with reference to Gynecologic Cancer Inter Group (GCIG) guidelines)

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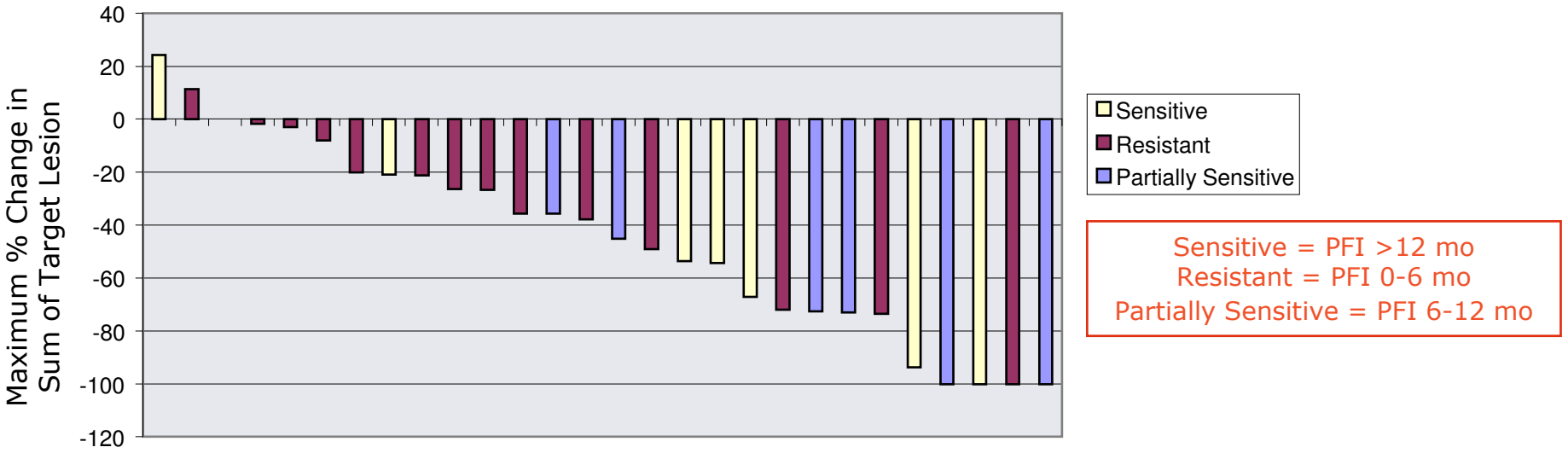
BelCaP Phase II in Recurrent Ovarian Cancer:
Tumor (RECIST) Response

- 3x CR, 12x PR + 13x SD
- ORR = 43% in ITT population

Maximum % Change in Sum of Target Lesion by Most Recent Platinum Sensitiveness – Evaluable Population*



Sensitive = PFI >12 mo
Resistant = PFI 0-6 mo
Partially Sensitive = PFI 6-12 mo

* 28 evaluable patients with assessable and comparable target lesion measures at baseline and at least one time point post-baseline.

* 7 non-evaluable pts: 3 pts due to new lesions, 3 pts due to no post baseline assessment; 1 pt due to PD/death (non related clinical deterioration)

- Definition of response = RECIST criteria

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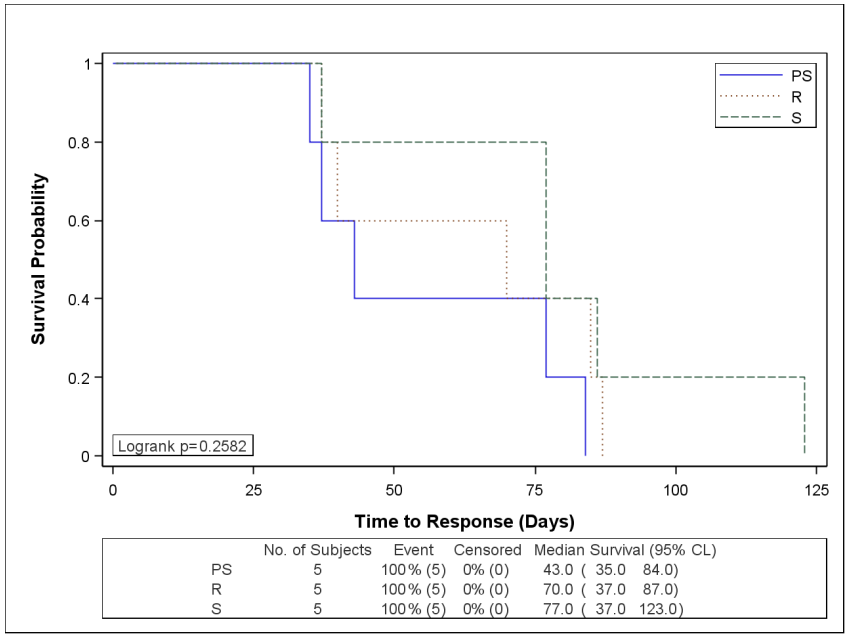
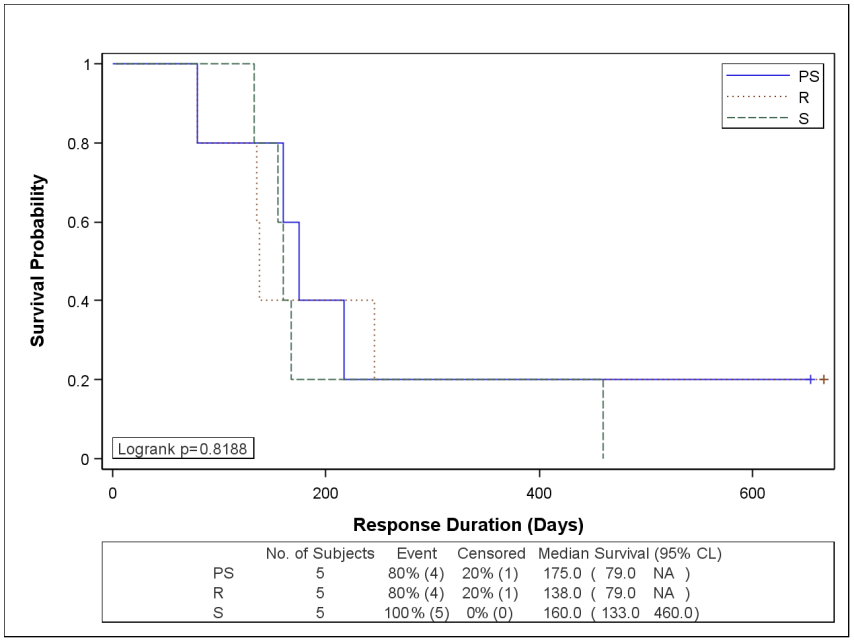
BelCaP Phase II in Recurrent Ovarian Cancer:
Time Related RECIST Outputs (by potential platinum sensitivity)

Time to Response



	No. of Subjects	Event	Censored	Median Survival (95% CL)
PS	5	100% (5)	0% (0)	43.0 (35.0 84.0)
R	5	100% (5)	0% (0)	70.0 (37.0 87.0)
S	5	100% (5)	0% (0)	77.0 (37.0 123.0)

Duration of Response



	No. of Subjects	Event	Censored	Median Survival (95% CL)
PS	5	80% (4)	20% (1)	175.0 (79.0 NA)
R	5	80% (4)	20% (1)	138.0 (79.0 NA)
S	5	100% (5)	0% (0)	160.0 (133.0 460.0)

Sensitive (S) = PFI >12 mo
Resistant (R) = PFI 0-6 mo
Partially Sensitive (PS) = PFI 6-12 mo

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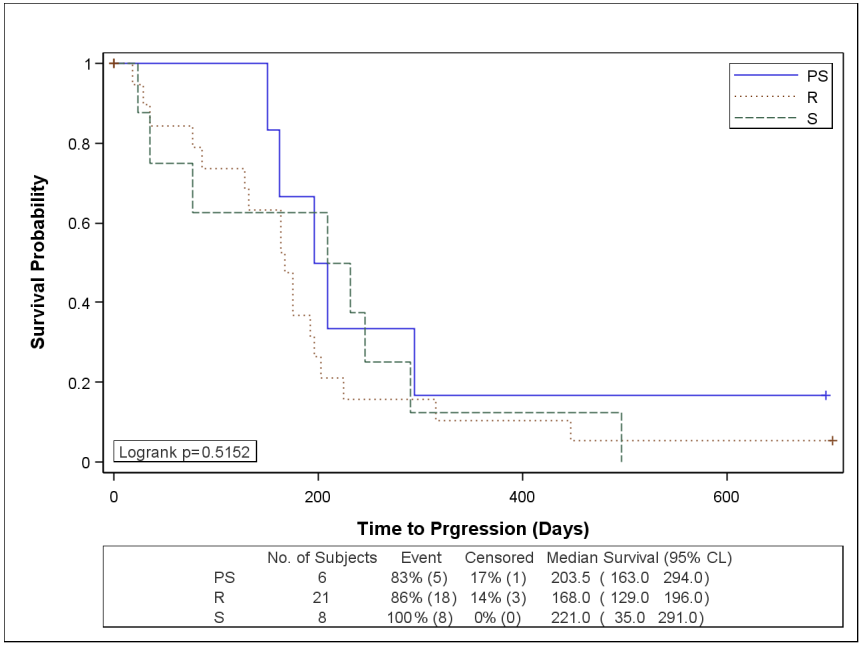
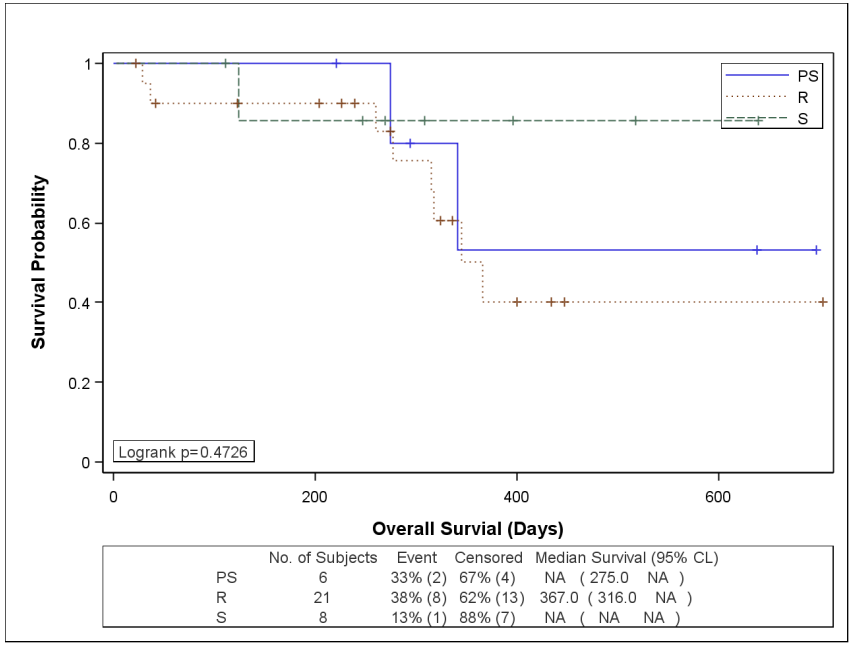
BelCaP Phase II in Recurrent Ovarian Cancer:
Time Dependant Outputs (by potential platinum sensitivity)

Progression Free Survival (PFS)



	No. of Subjects	Event	Censored	Median Survival (95% CL)
PS	6	83% (5)	17% (1)	203.5 (163.0 294.0)
R	21	86% (18)	14% (3)	168.0 (129.0 196.0)
S	8	100% (8)	0% (0)	221.0 (35.0 291.0)

Overall Survival (OS)



	No. of Subjects	Event	Censored	Median Survival (95% CL)
PS	6	33% (2)	67% (4)	NA (275.0 NA)
R	21	38% (8)	62% (13)	367.0 (316.0 NA)
S	8	13% (1)	88% (7)	NA (NA NA)

Sensitive (S) = PFI >12 mo
Resistant (R) = PFI 0-6 mo
Partially Sensitive (PS) = PFI 6-12 mo

TOPOTARGET

BelCaP Phase II in Recurrent Ovarian Cancer:
Efficacy Summary (by potential platinum sensitivity)

	Resistant PFI 0-6 mo	Partially Sensitive PFI 6-12 mo	Sensitive PFI > 12 mo
No of Patients	21	6	8
RECIST OR	23.8% (1 CR, 4 PR)	83.3% (2 CR, 3 PR)	62.5% (5 PR)
RECIST + CA-125 OR	38.1% (1 CR, 7 PR)	100% (2 CR, 4 PR)	62.5% (5 PR)
Median PFS	5.5 months (0.8 – 16.3 months)	6.7 months (2.8 – 22.9 months)	7.2 months (0 – 23.1 months)
% PFS at 6 months	37%	67%	63%

TOPOTARGET

BelCaP Phase II in Recurrent Ovarian Cancer:
Comparison with Doxil

	BelCaP PFI 0-6 mo RECIST		Doxil PFI 0-6 mo WHO[1]/RECIST[2]
No of Patients	21		130[1] 96[2]
RECIST OR	23.8% (1 CR, 4 PR)		12.3%[1] (1 CR, 15 PR) 8.3%[2] (1 CR, 5 PR)
Median PFS	5.5 months		2.1 months[1] 3.1 months[2]
Median Survival	12.0 months		8.2 months[1] N/A[2]

[1] Gordon et al J Clin Oncol (2001) 19, 3312
[2] Mutch et al J Clin Oncol (2007) 25, 2811

TOPOTARGET

Belinostat: Summary

Clinical Overview

- Over 690 patients treated
- Clinical efficacy in both hematological malignancies and solid tumors
- Manageable hematological & GI toxicity using both monotherapy and BelCaP combination

Potential in Platinum Resistant Ovarian Cancer

- Finalised Phase II in recurrent ovarian cancer using BelCaP
- Clinical effect in platinum-resistant disease