

Sorrento Therapeutics



Next-Generation Cancer Therapeutics

December 2013

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Management Team

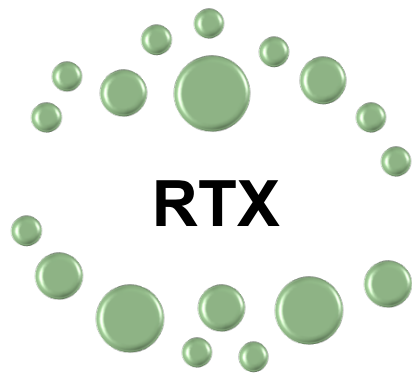
Henry Ji, Ph.D. President & CEO, and Director	<ul style="list-style-type: none">• Inventor of G-MAB[®] Technology• President & CEO of Stratagene Genomics• VP of CombiMatrix and Stratagene
Vuong Trieu, Ph.D. Chief Scientific Officer, and Director	<ul style="list-style-type: none">• Founder and CEO of IgDraSol• Co-inventor of IP covering Abraxane[®]• Instrumental in the approval of Abraxane[®]• Celgene acquired Abraxis Biosciences (Abraxane[®]) for > \$3 billion
George Uy Chief Commercial Officer	<ul style="list-style-type: none">• CCO of IgDraSol• Directed the launches of Abraxane[®], Xeloda[®] & Fusilev[®]• Built commercial infrastructures and organizations in startup companies
David (Zhenwei) Miao, Ph.D. Chief Technology Officer	<ul style="list-style-type: none">• President and CSO of Concoris BioSystems• Co-inventor of IP covering ADC technologies• Head of Chemistry at Ambrx
Richard Vincent EVP, CFO, and Director	<ul style="list-style-type: none">• \$430M sale of Elevation to Sunovion-Dainippon• Meritage Pharma option agreement with ViroPharma (\$90M upfront + milestones)• \$310M sale of Verus asthma program to AstraZeneca• Elan: various acquisitions and divestitures with aggregate values in excess of \$300M

Investment Highlights



Late Stage Oncology Drug with Exclusive US and EU Rights

- Addresses multi-billion dollar paclitaxel market
- Abbreviated regulatory pathway (“bioequivalence”) for approval
- Bioequivalence registration trial in 2014 (study direct costs ~ \$5M)
- Product launch expected in 1H 2016



Intractable Pain in Advanced Cancer

- Ongoing Phase 1/2 study
- Orphan drug status received
- Two potential drug products from same API (Resiniferatoxin)



Therapeutic Antibody Engine

- G-MAB® library generated using patented RNA-based technology
- First antibody drug candidate in clinic 1H 2015

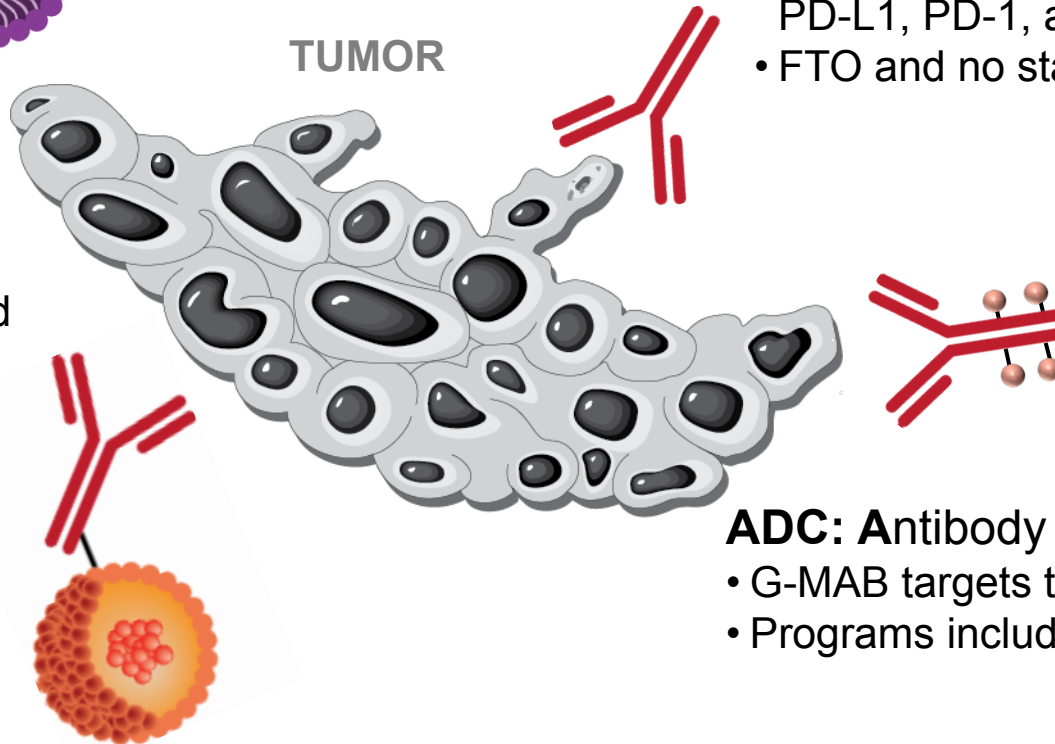
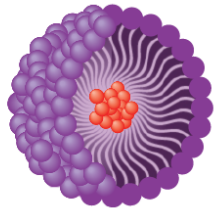
Targeted Drug Delivery (ADC)

- G-MAB® antibody as specific targeting warhead
- Proprietary toxins as potent tumor killing payload
- Proprietary linker/conjugation chemistry for homogenous ADC generation

Sorrento's Next-Generation Cancer Therapeutics

Cynviloq™

- Next-generation Abraxane®
- Bioequivalence (BE) pathway for approval
- Efficacy demonstrated
- US and EU rights



G-MAB®

- High-diversity human Ab library
- Lead mAb programs include PD-L1, PD-1, and CCR2
- FTO and no stacking royalties

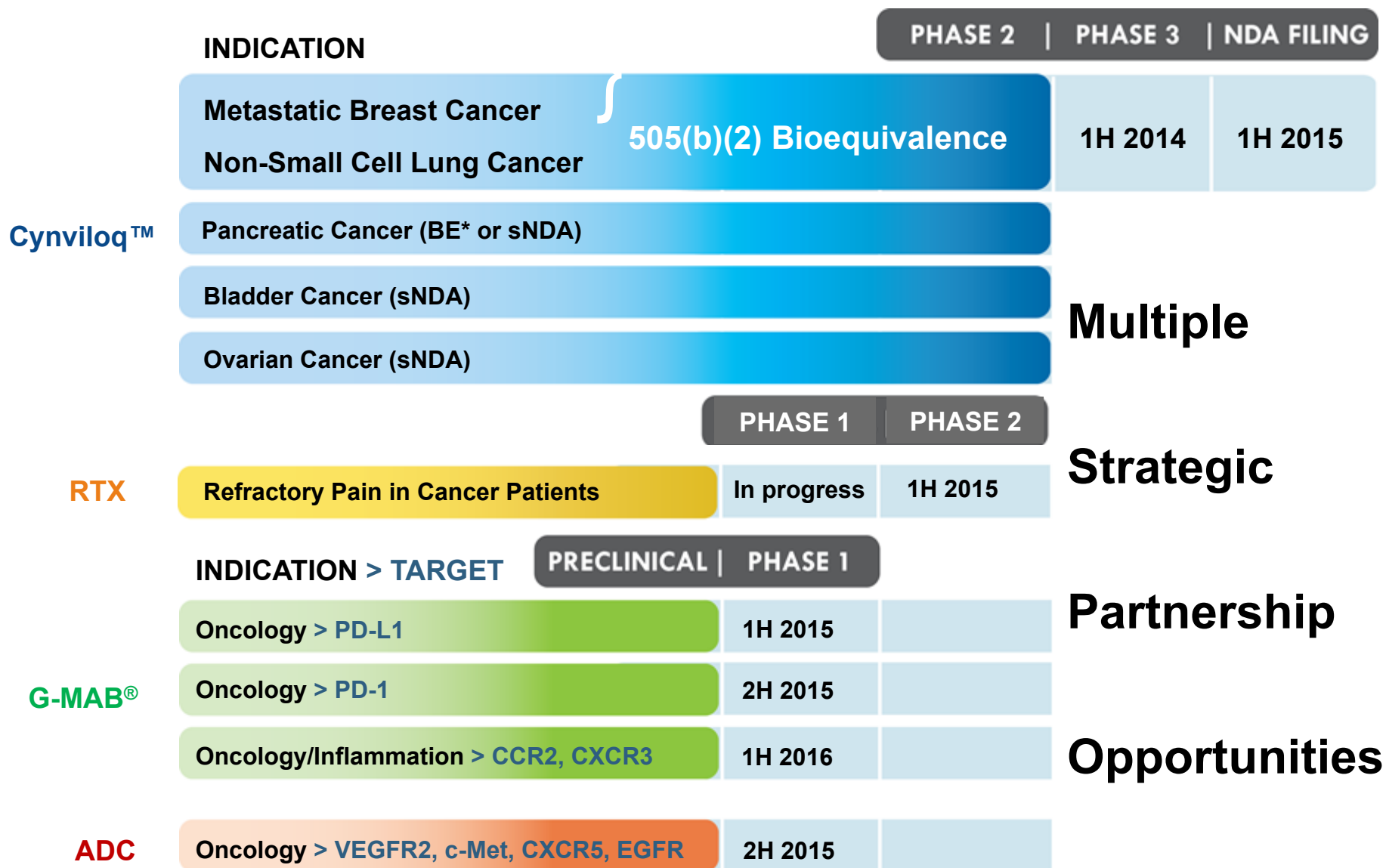
AfDC: Antibody formulated Drug Conjugate

- G-MAB targets approved chemotherapeutics to the tumor
- Effective against heterogeneous tumors

ADC: Antibody Drug Conjugate

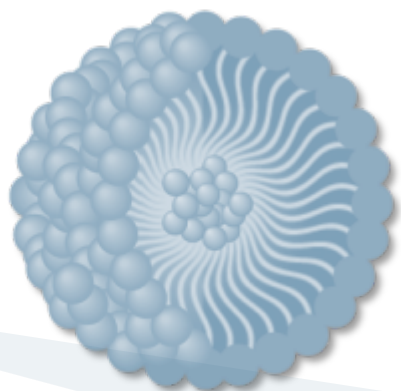
- G-MAB targets toxin to cancer cell
- Programs include VEGFR2, c-Met

Pipeline

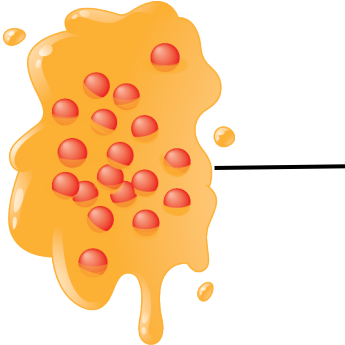
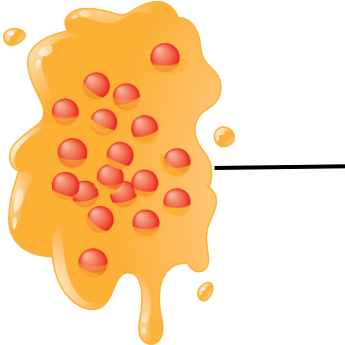
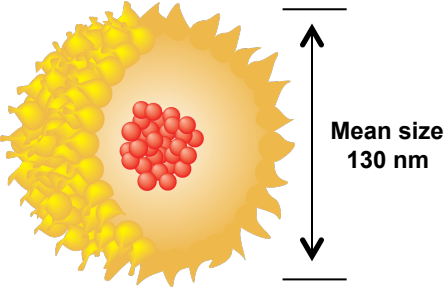
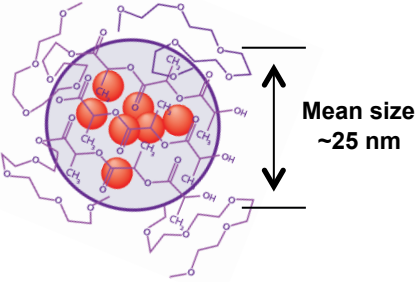


* Abraxane® orphan drug status (FDA approval, September 2013)

Lead Product Opportunity



Cynviloq is the 3rd Generation Paclitaxel Therapy

<u>Generation</u>		<u>Formulation</u>	<u>Maximum Tolerated Dose</u>	<u>Peak Product Sales</u>
1 st Taxol[®] paclitaxel		Cremophor EL excipient: Polyoxyethylated castor oil	175 mg/m²	~ \$1.6B (WW in 2000)
2 nd Abraxane[®] <i>nab</i> -paclitaxel	 Mean size 130 nm	Biological polymer: Donor-derived human serum albumin (HSA)	260 mg/m²	Est. ≥\$1.7B* (US) (\$430M in 2012)
3 rd Cynviloq[™] paclitaxel polymeric micelle	 Mean size ~25 nm	Chemical polymer: Poly-lactide and polyethylene glycol diblock copolymer	>300 mg/m² (up to 435 mg/m ²)	Conversion of Abraxane sales + new indications

*Analyst projection ; in MBC + NSCLC + PC

Cynviloq is a High Value Proposition

1. Exclusive US and EU Rights
2. Cynviloq efficacy demonstrated in Phase 2 and Phase 3 studies
 - a. Approved and marketed under brand name Genexol-PM in S. Korea
3. FDA concurred
 - a. Available data support pursuing 505(b)(2) regulatory pathway
 - b. Bioequivalence (BE) study sufficient for approval of indications in Abraxane label (MBC and NSCLC)
4. Large market opportunity
 - a. Abraxis (Abraxane) sold to Celgene for > \$3B
 - b. \$1.7B in projected US peak revenues for Abraxane

Clinical Efficacy & Safety Summary

Total number of patients across all trials: 1,260

Phase 1: Trials established higher MTD in US - Dana Farber Cancer Inst, Russia, & S. Korea (total n=80)

- >300 mg/m² (q3w) vs. 175 mg/m² (Taxol; weekly) and 275 mg/m² (Abraxane; q3w)

Phase 2: Completed trials in MBC, NSCLC, PC, OC, BC; in US - Yale Cancer Center, Russia, S. Korea (total n=259)

- Data suggestive of efficacy comparable to historic data for Abraxane and superior to historic Taxol data or Standard-of-Care
- Possible Phase 3 sNDA programs in these tumor types

Phase 3: Ongoing trial for MBC in S. Korea (total n=209; Cynviloq n=105)

- GPMBC301. An Open-label, Randomized, Parallel, Phase 3 Trial to Evaluate the Efficacy and Safety of Cynviloq compared to Genexol® (Paclitaxel with Cremophor EL) in Subjects with Recurrent or Metastatic Breast Cancer)
- Interim analysis suggests ORR superior to Taxol and comparable to historic Abraxane efficacy
- Efficacy and safety data supportive of 505(b)(2) BE submission

PM-Safety: Completed for MBC and NSCLC (total n=502)

- Efficacy and safety data supportive of 505(b)(2) BE submission

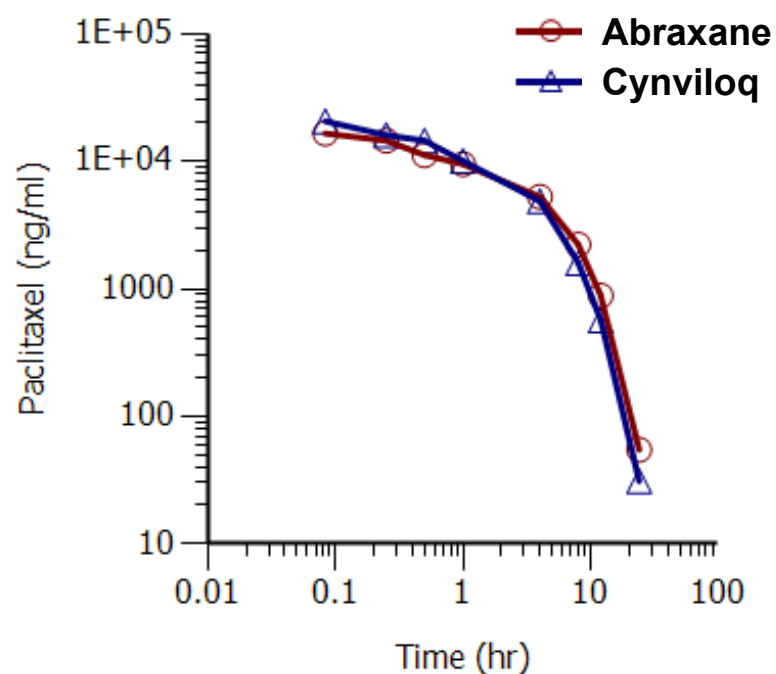
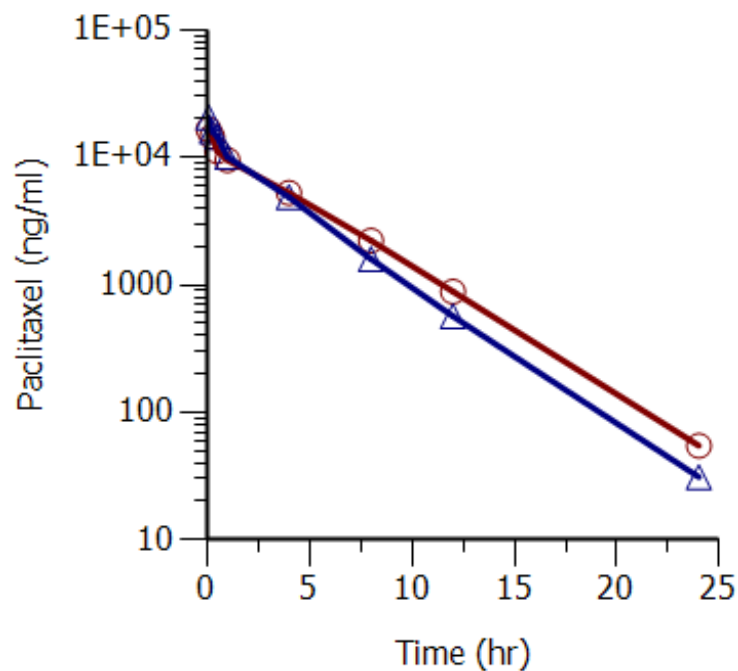
Phase 2b (IIS): Chemo-naïve Stage IIIb/IV NSCLC vs Taxol in S. Korea (total n=276; Cynviloq n=140)

- 230 mg/m² + cis (q3w) vs. Taxol 175 mg/m² + cis; non-inferiority established

Phase 2 (IIS): 1st line treatment of OC vs Taxol in S. Korea (total n=100; Cynviloq n=50)

- 260 mg/m² + carbo (q3w) vs. Taxol 175 mg/m² + carbo; non-inferiority established

Equivalent Pharmacokinetics in Mice



Drug	HL (h)	T max (h)	AUCinf (h*ng/mL)	Vz (mL/kg)	Cl (mL/h/kg)
Abraxane	2.99	0.08	61561.33	2103.71	487.32
Cynviloq	2.83	0.08	58151.31	2103.58	515.90

IV bolus at 30 mg/kg; n = 3

Comparable Pharmacokinetics in Human

Data from 2 separate studies
(3 h infusion, 135 mg/m² dose, n=3)

	C_{max} (ng/ml)	AUC_{inf} (ng/ml*h)	Half-Life (hr)	Cl (L/hr/m ²)
Cynviloq™	1357	5473	12.7	25.5
Abraxane®	1392	5654	12.9	27.4

Simulated PK Parameters Supportive of BE: Cynviloq vs. Abraxane

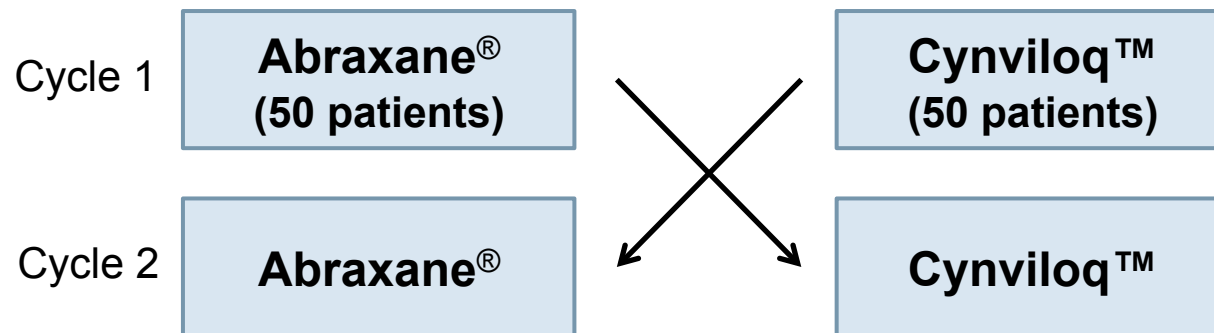
Comparison of mean non-compartmental pharmacokinetic parameters of **Cynviloq (T) and Abraxane (260 mg/m²) at 30 min infusion time:**

	Cmax (ng/mL)	Ratio Cmax(T)/Cmax(R)	AUCinf (ng*h/mL)	Ratio AUCinf(T)/AUCinf(R)
Cynviloq (Simulated PK)	19486	99.6%	22198	109.2%
Abraxane (Actual PK)*	19556		20324	

- PK BE was calculated as 95% confidence interval (CI)
- Ratio T/R (Cmax and AUCinf) within 80-125% (FDA Guidance for establishing BE)

Bioequivalence = Efficient Pathway to Market

- Bioequivalence registration study in breast cancer patients (2014)
 - 12 months of duration (including patient recruitment)
 - Direct trial cost ~\$5M



Key Parameters*:

- Dose: 260 mg/m²
- Infusion time: 30 min
- Duration: 3 weeks + crossover for 3 weeks
- Endpoints: AUC and C_{max} (90% CI)

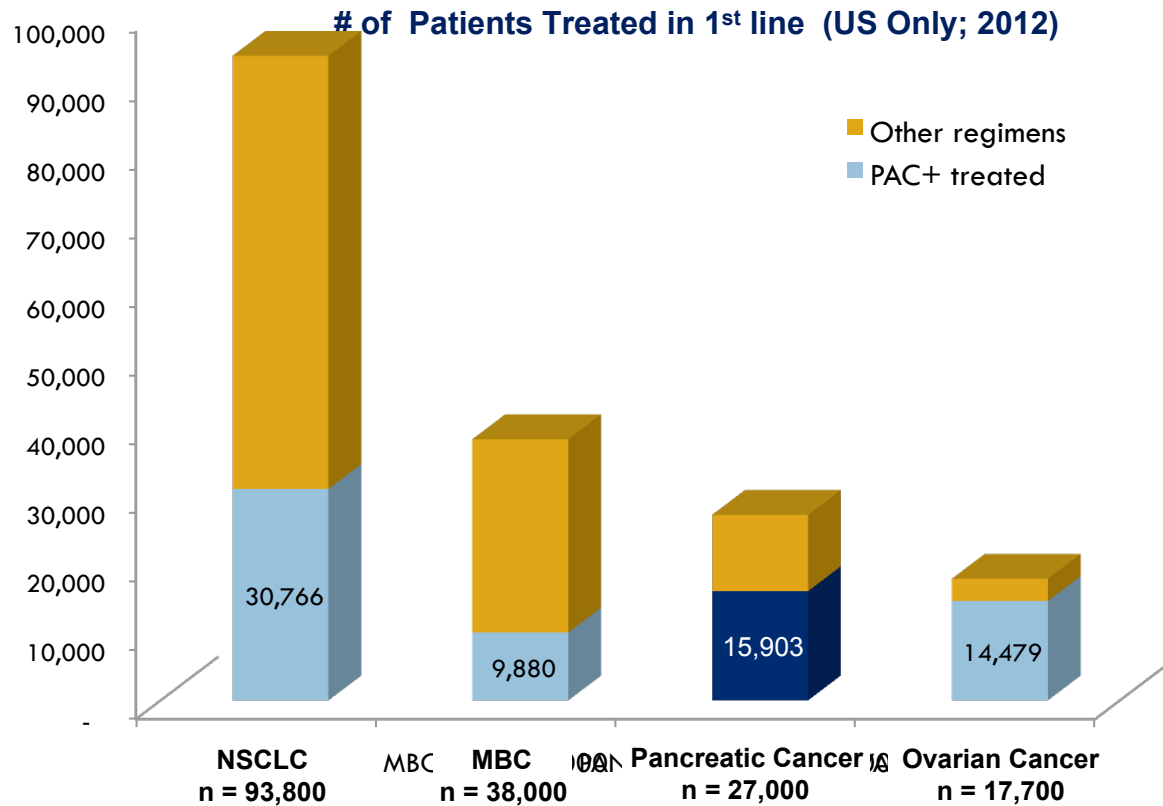
Cynviloq Advantages

	Cynviloq™	Abraxane®	Taxol®	Cynviloq Advantage
Maximum Tolerated Dose (mg/m ²)	>300	260	175	Potential for higher efficacy
Rapid reconstitution: no foaming concerns	●		●	Convenience for busy practices and pharmacies
No donor-derived human serum albumin (HSA)	●		●	No viral / prion concerns
Convenient storage conditions	●		●	No requirement for controlled temp storage
No microbial growth	●		●	Chemical polymer
Cremophor-free	●	●		Reduced side effects
Dosing	q3w	q3w* & weekly**	q3w & weekly	Exploits PK advantage @ higher dose

* = MBC; ** = NSCLC & PC

Cynviloq Market Opportunity

~70,000 patients treated with paclitaxel-based regimen in 1st line



~55,000 patients with paclitaxel as 1st line therapy in MBC, NSCLC & OC

15,903 PC patients eligible for treatment with Abraxane® + Gemcitabine combination

Note: In Pancreatic Cancer, the blue portion represents # patients treated with gem-based Rx in 2012

Sources: US information, SEER Annual Cancer Review 1975-2006; US Census; Mattson Jack; UHC and Medicare Claims; IntrinsiQ; Synovate Tandem. WHO mortality database 2008 <http://www.who.int/whosis/whosis/>. World Population Prospects. The 2008 Revision. UN Population Division 2009. <http://esa.un.org/unpp/>. Roche-Genentech Clinical, Patient Chart Audits. Total patient numbers represent treatable population. 1st Line patient estimates from IntrinsiQ 2012 Monthly LOT Diag Combo.

Potential to Expand Label Indications – For Example: 2nd Line Bladder Cancer

	Cynviloq Phase 2 (Korea)* 260-300 mg/m ² q3w n=34#	Best Supportive Care Phase 2 (Japan) **/ Phase 3 (EU)*** n=23** / n=108***
Overall Response Rate (ORR)	21%	- / 0%***
Progression Free Survival	2.7 M	- / 1.5 M***
Overall Survival	6.5 M	2.3 M** / 4.3 M***

Summary:

- High unmet need - no FDA-approved 2nd line drug
- Demonstrated clinical Overall Response Rate (ORR)
- Phase 3-ready for development as 2nd line chemotherapy in patients refractory to platinum-based therapy

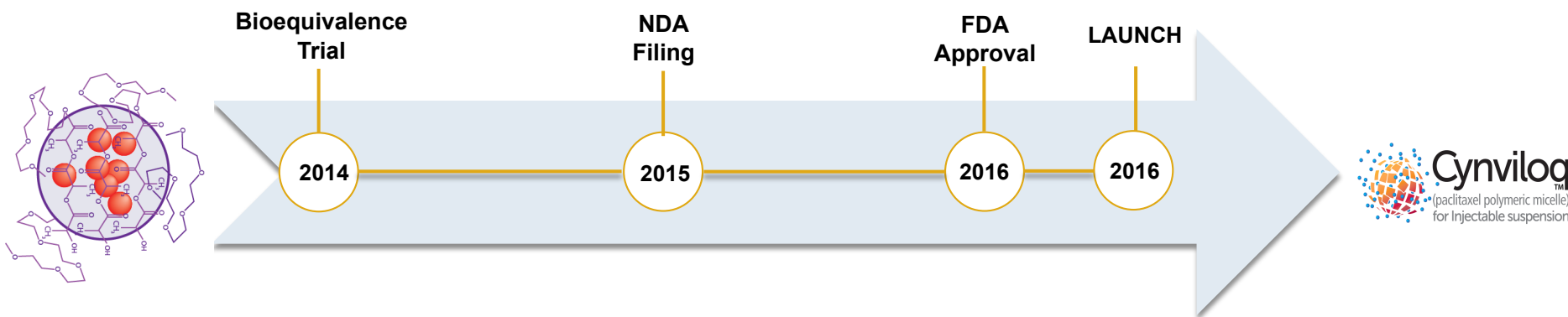
* Invest New Drugs (2012) 30:1984–1990

advanced urothelial carcinoma patients refractory to gemcitabine and cisplatin

** AUA- San Diego May 4th-8th; *** JCO (2009): 4454-61

Next Steps for Cynvilog

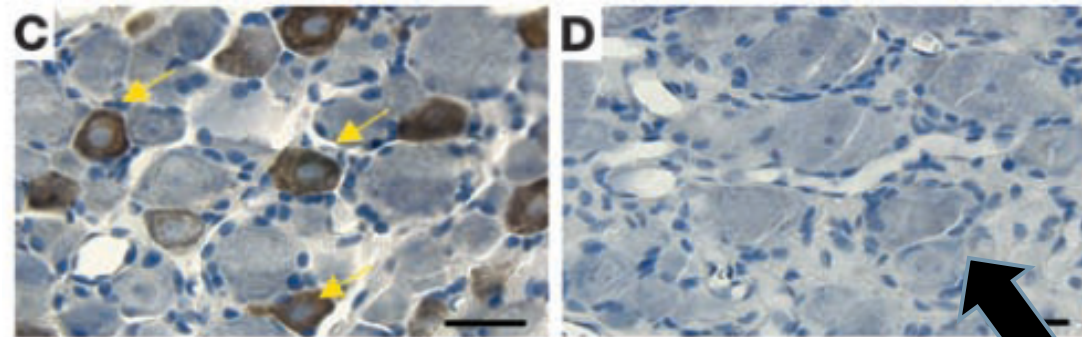
1. Bioequivalence (BE) trial: **2014**
2. NDA filing: **2015**
3. Approval: **2016**
 - a. MBC and NSCLC
 - b. Future Abraxane indications (Pancreatic cancer and Melanoma)
4. Product launch for MBC and NSCLC: **2016**
5. sNDA planning for label expansion into Bladder and Ovarian cancers



Expanded Clinical Pipeline with Multiple Opportunities



Resiniferatoxin (RTX): Non-opiate Drug Candidate for Treating Cancer Pain



Cross section of spinal cord after treatment*

Pharmacology:

- Ultra potent agonist of the TRPV1 receptor
- < 2 pM TRPV1 receptor binding

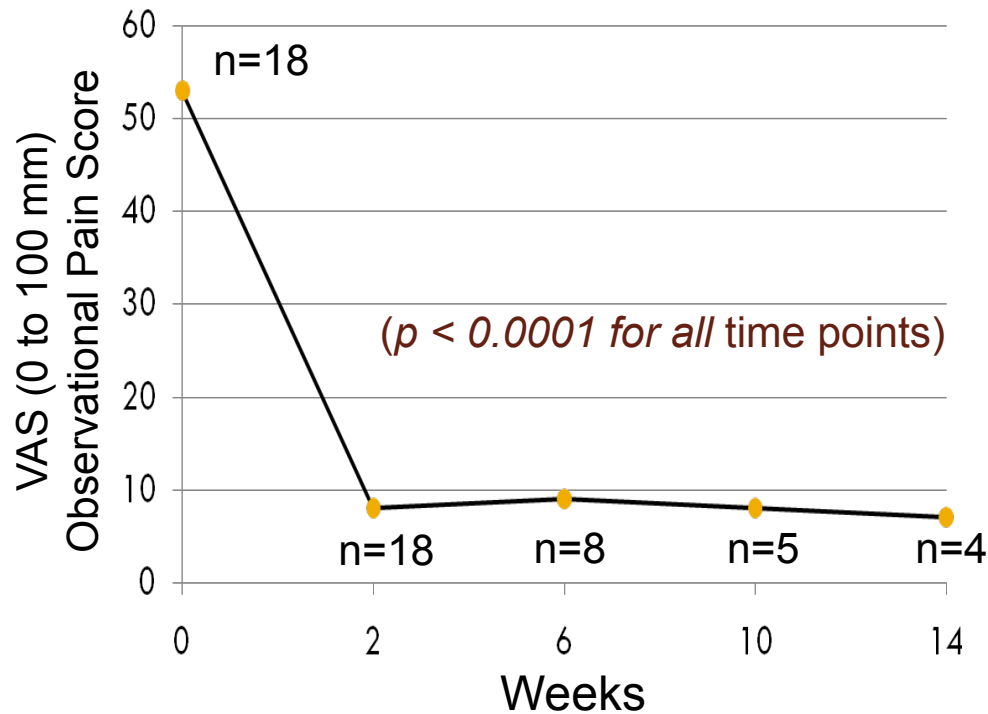
Binding in primate ex-vivo spinal cord

- dorsal root ganglion
resiniferatoxin $K_i = 309$ pM
- dorsal horn
resiniferatoxin $K_i = 349$ pM

RTX induces apoptosis of TRPV1-expressing afferent nerves.

“ADC”-like killing, but no antibody-mediated targeting needed

Single Injection Addresses Cancer Pain in Dogs



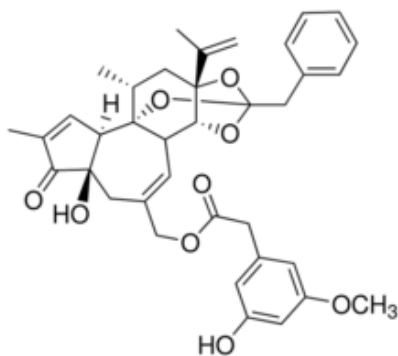
- Single intrathecal injection
- Permanent ablation of nerves
- Attractive Therapeutic Effect
 - All subjects responded
 - Personality & mood of animals visibly improved
 - No opioid-associated side effects

Veterinary Market: Strategic Partnership Opportunity

Next Steps for Dual Pathway of RTX Development

2014

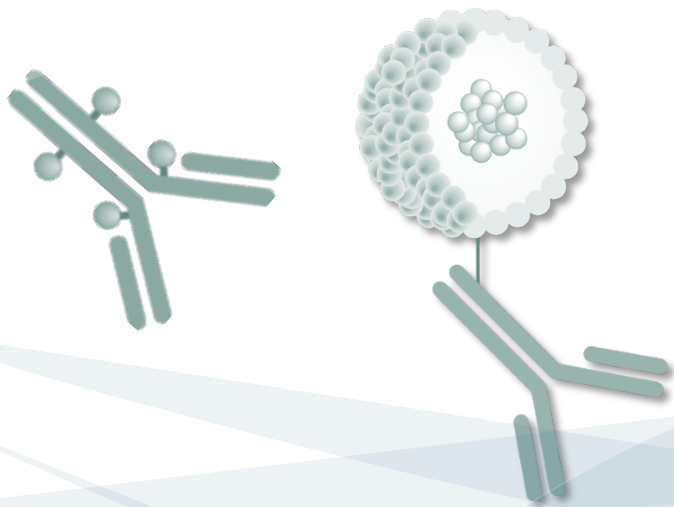
1. Intractable cancer pain clinical Phase 1/2 trial (**intrathecal injection**); n~40 patients
2. Phase 1/2 trial for **intraganglionic injection** (osteosarcoma); n~15 patients (under NIH CRADA)



~3 years for clinical development



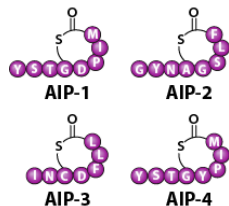
Pre-IND Immunotherapy Programs



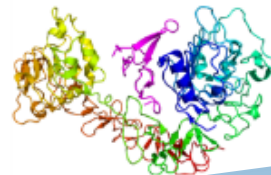
G-MAB[®]: Library of Therapeutic Antibodies

- Proprietary technology
 - RNA amplification used for library generation
 - Freedom-To-Operate
- No stacking royalties
- Very high library diversity: **2.1 x 10¹⁶** distinct antibodies
- Fully human antibodies
- High successful screening hit rate

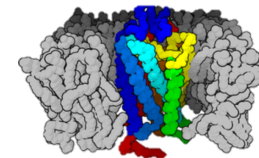
Difficult Targets:
Small Peptides



High Value Oncology Targets:
Immunomodulation: PD1 and PD-L1
Antibody Drug Conjugates: VEGFR2 and c-Met



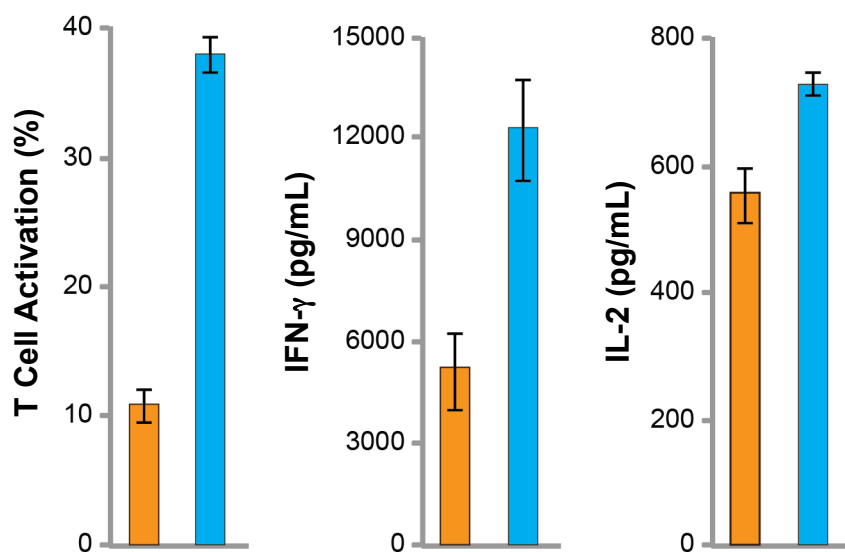
Most Difficult Targets:
G Protein-Coupled Receptors
(GPCRs)



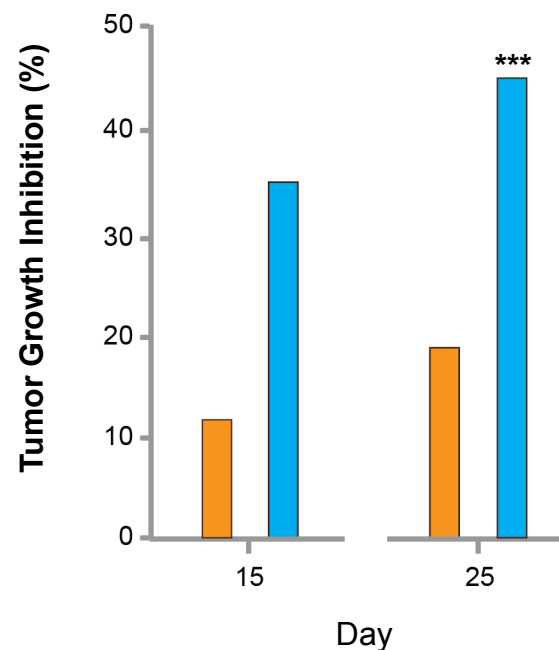
Size of Target Antigen

Anti-PD-L1 mAbs Exhibit Potent Activity

Immune Modulation*



Tumor Mouse Model**



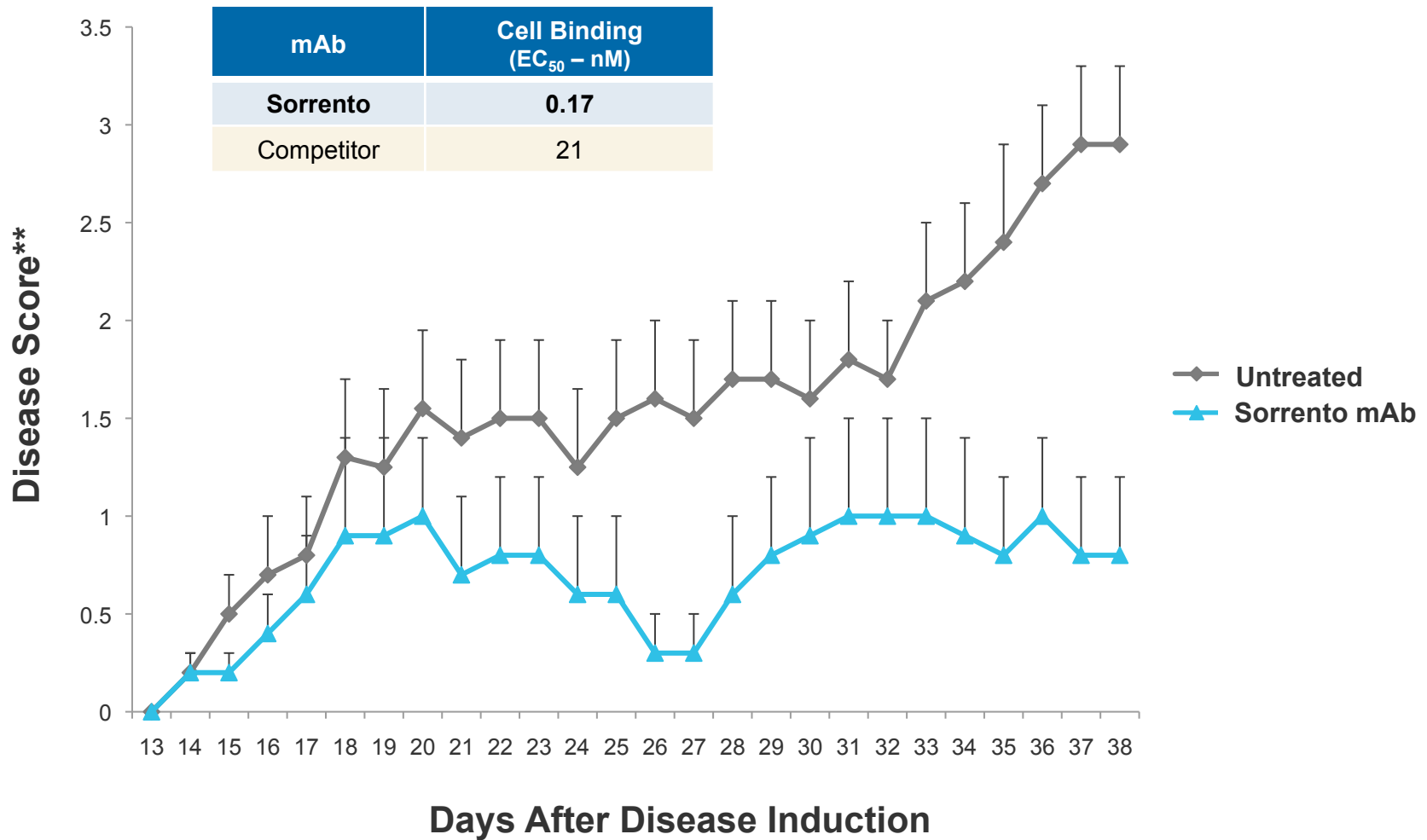
Competitor mAb
Sorrento mAb

* mAbs @ 0.05 mg/mL

** xenograft model using H1975 human NSCLC cells; % inhibition relative to control mAb treatment

*** $p < 0.05$, mean tumor volumes are significantly reduced in STI-A1010 group versus control groups as determined by Mann-Whitney u-test

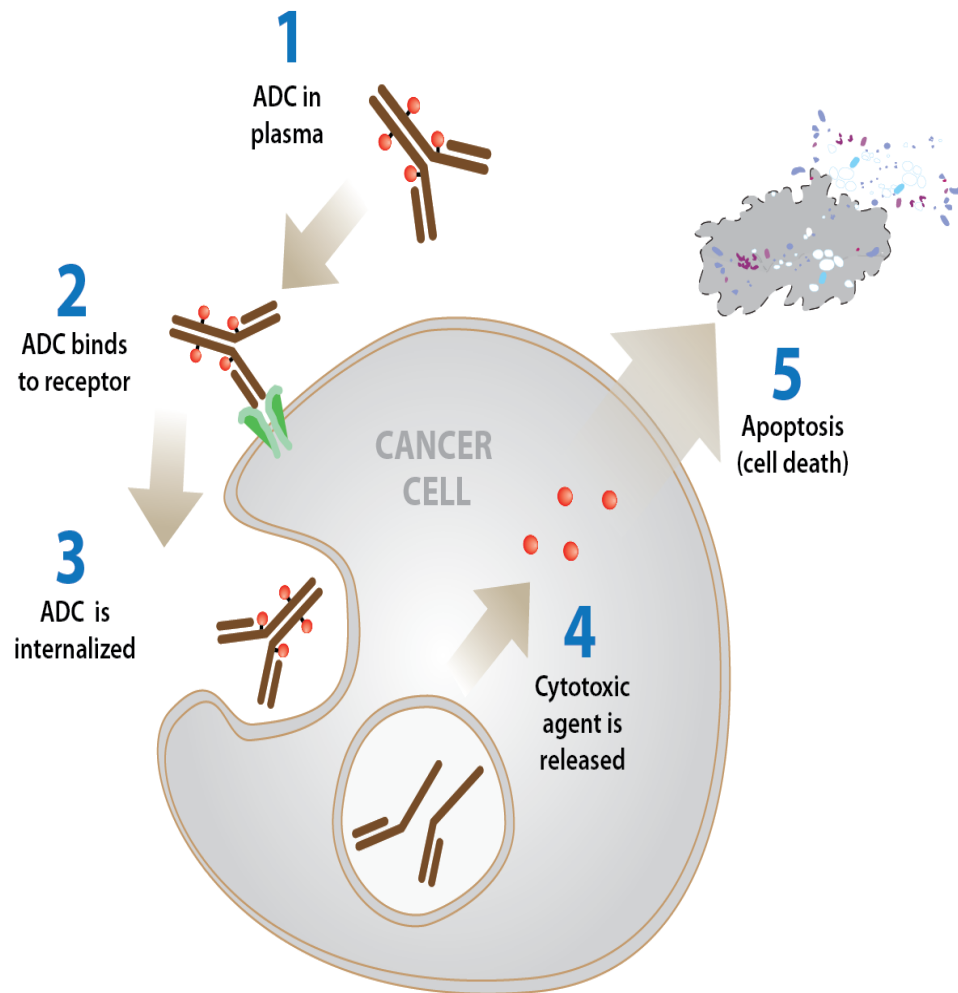
Potent Antibody against Difficult GPCR Target*



* Sorrento mAb against C-C Chemokine Receptor 2 (CCR2)

** Experimental Auto-immune Encephalomyelitis (EAE) = murine model of Multiple Sclerosis

Antibody Drug Conjugates (ADC)



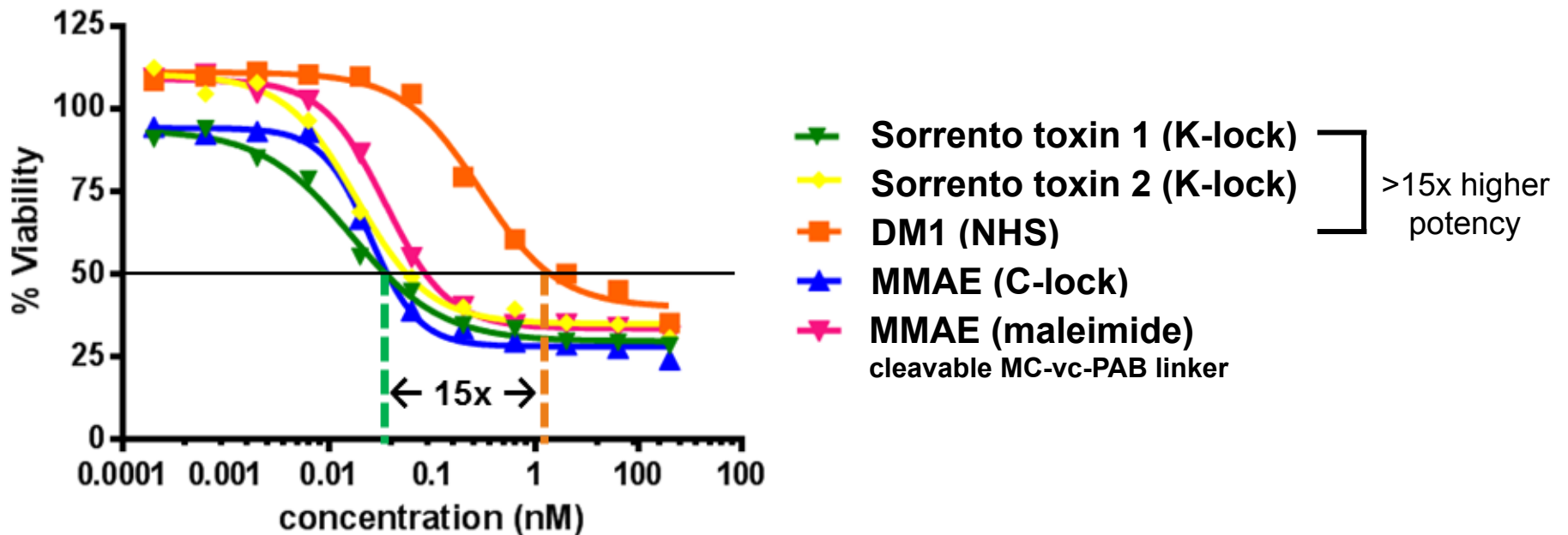
Key Components:

1. Target-specific internalizing antibody
2. Potent cytotoxic prodrugs
3. Linker and conjugation chemistries

Drug released in CANCER CELL

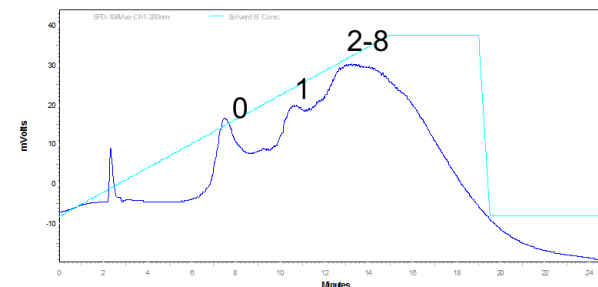
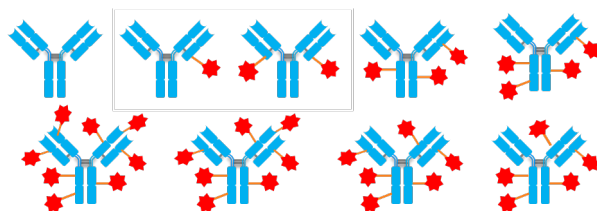
Proprietary Toxin Potency Higher than DM1

SKBR3
(Breast Cancer Cell Line)

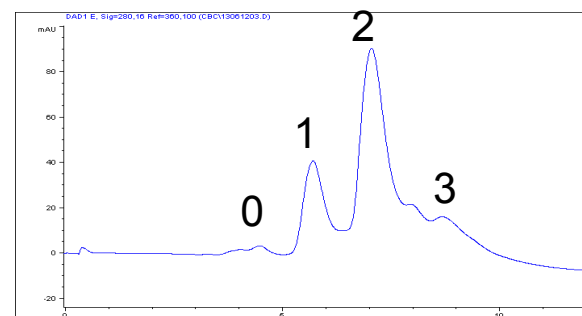


K-lock Conjugation Enables Homogeneous ADCs

Current industry standard chemistry

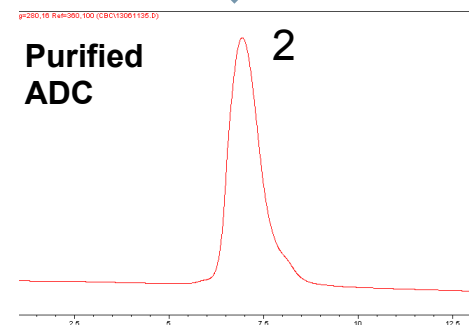
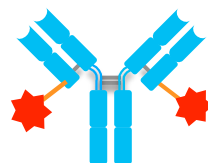


Sorrento's proprietary K-lock chemistry

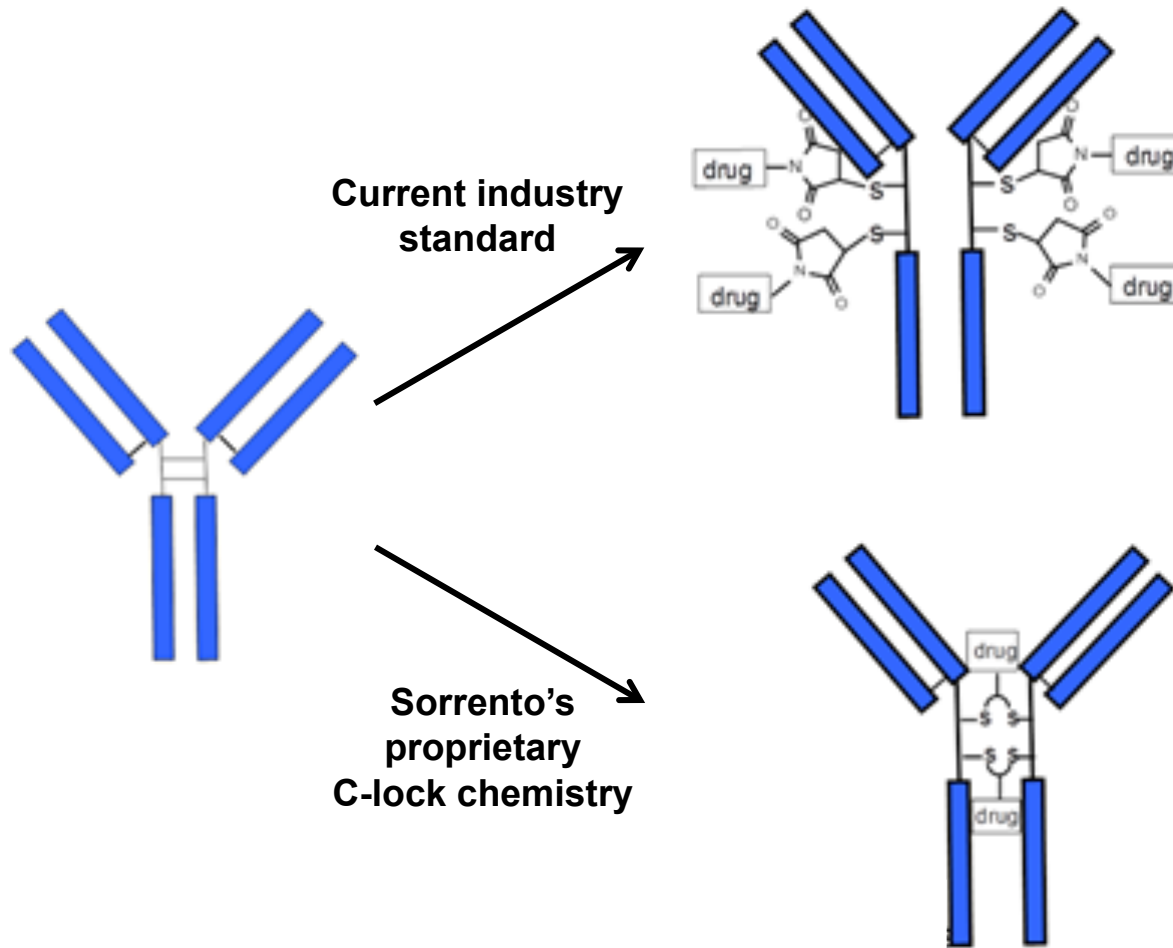


↓ purified

Sorrento's homogenous ADC



Irreversible C-lock-stabilized ADCs



Current industry standard

Sorrento's proprietary C-lock chemistry

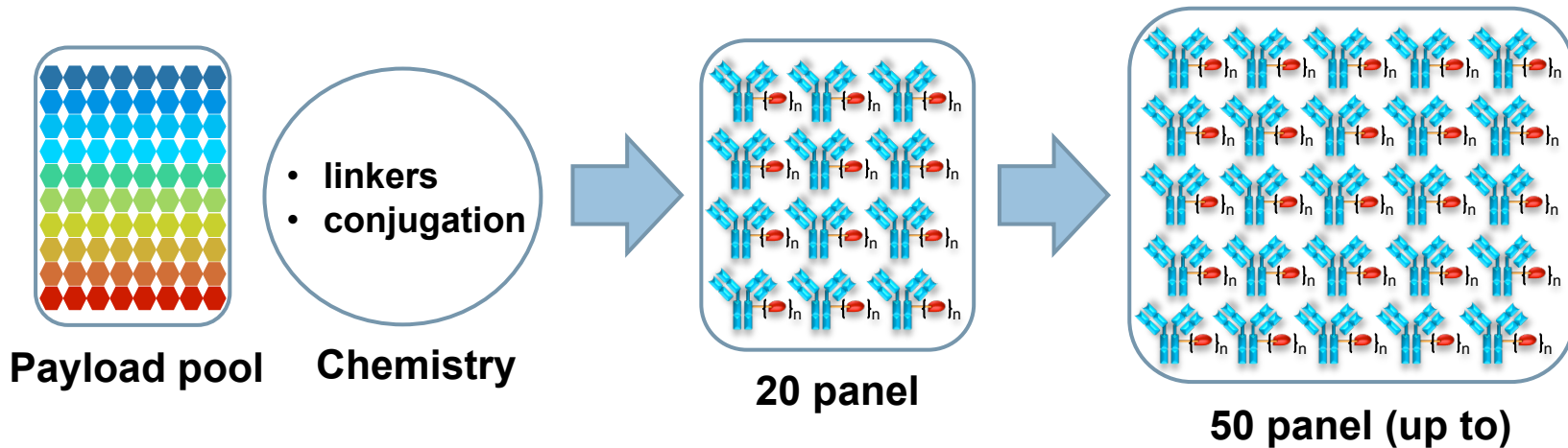
Maleimide conjugation

- ❑ Destabilizes antibody structure
- ❑ Reduced target specificity
- ❑ Altered PK profile
- ❑ Drug-antibody linkage not stable
- ❑ Off-target drug effects

C-lock conjugation

- ❑ Enhances ADC stability
- ❑ Prolongs PK profile
- ❑ Reduced off-target effects

Proprietary ADC Screening and Optimization Panels

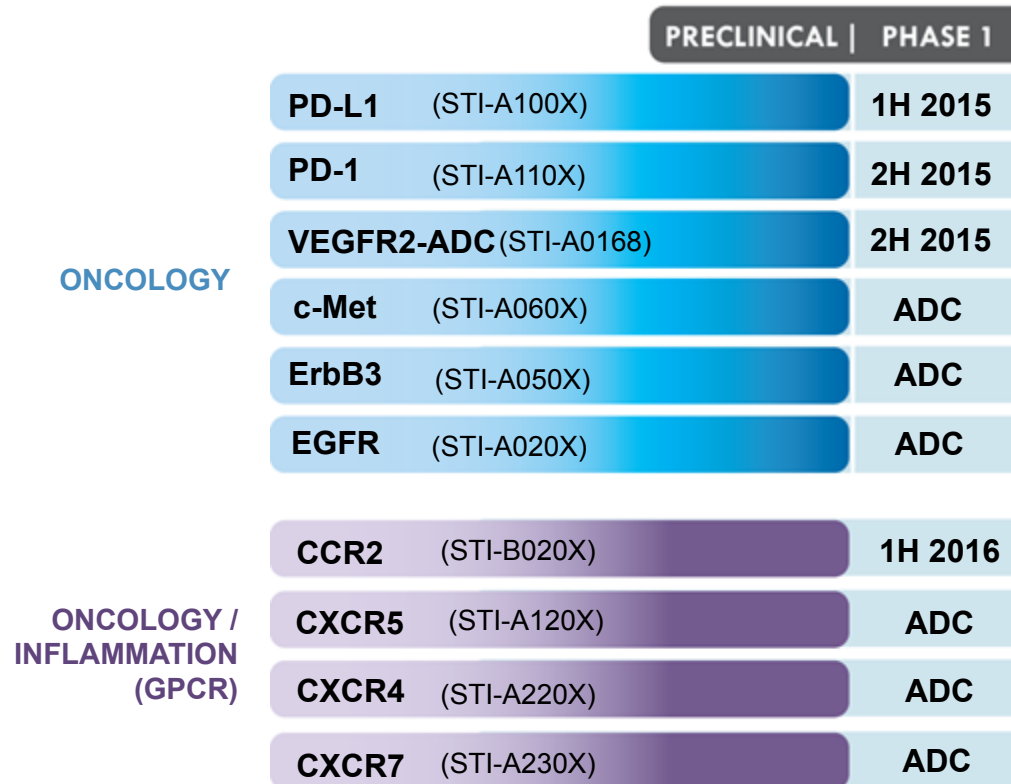


ADCs consist of many moving parts.

Identification of optimal linker, conjugation chemistry and drug payload combination essential for efficient and expedited development

- **Primary screen for discovery of lead ADCs (“20-panel”)**
 - Initial ADCs via rationale design with linker/conjugation technologies and payload pool
- **Advanced screen for generation of ADC product candidates (“50-panel”)**
 - Optimization of payloads, linkers and conjugation chemistries
 - Potential expansion to new mechanism of action (MOA) drug payloads

G-MAB[®] and ADC Pipeline



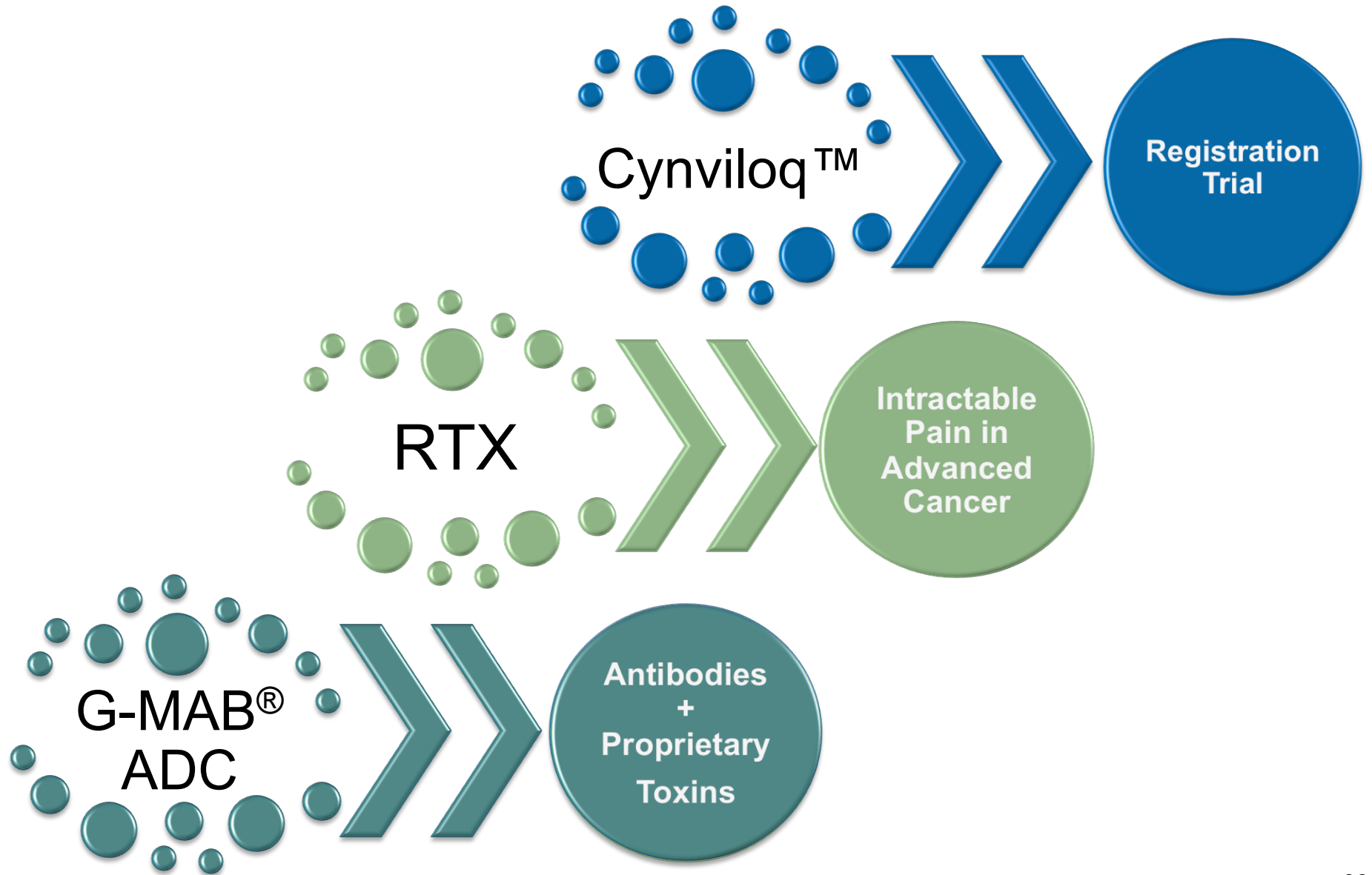
Multiple

Strategic

Partnership

Opportunities

Positioned to Become Oncology Leader



Small Molecule Oncology Drug, Antibody Library and ADC Company Valuations

Company	Small Molecule Oncology Drug	Antibody Platform	Targeted Drug Delivery	Mkt Cap*
Puma: PBYI Pre-revenue	MBC (Phase 3)			~\$1.2B
Clovis: CLVS Pre-revenue	NSCLC, MBC (Phase 1)			~\$1.6B
MorphoSys: MOR.DE Pre-revenue		Antibody Library		~\$1.6B
CAT: Acquired (2006) Pre-revenue		Antibody Library		~\$1.4B
Domantis: Acquired (2007) Pre-revenue		Antibody Library		~\$450M
Seattle Genetics: SGEN Product sales + royalty			ADC	~\$5.1B
ImmunoGen: IMGN Royalty only			ADC	~\$1.3B
Sorrento: SRNE	NSCLC, MBC (Ph3/Registration Trial)	Antibody Library	ADC & AfDC	~\$180M

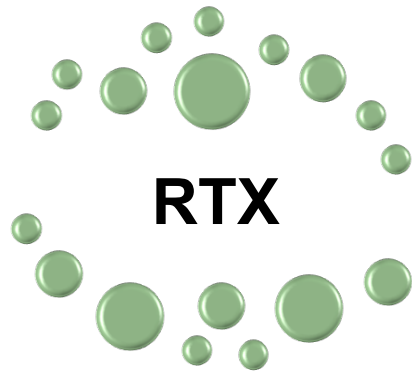
* based on publicly-available information (11/14/13)

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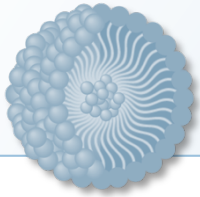


Therapeutic Antibody Engine

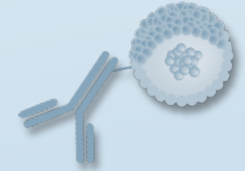
- G-MAB® library generated using patented RNA-based technology
- First antibody drug candidate in clinic 1H 2015

Targeted Drug Delivery (ADC)

- G-MAB® antibody as specific targeting warhead
- Proprietary toxins as potent tumor killing payload
- Proprietary linker/conjugation chemistry for homogenous ADC generation



Sorrento Therapeutics



Next-Generation Cancer Therapeutics

Contact:
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