

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 26, 2024

CORBUS PHARMACEUTICALS HOLDINGS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37348
(Commission File Number)

46-4348039
(IRS Employer
Identification No.)

500 River Ridge Drive
Norwood, Massachusetts
(Address of Principal Executive Offices)

02062
(Zip Code)

Registrant's Telephone Number, Including Area Code: (617) 963-0100

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	CRBP	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On January 26, 2024, Corbus Pharmaceuticals Holdings, Inc. (the “Company”) issued a press release announcing data from the ongoing Phase 1 clinical trial for SYS6002 (CRB-701) conducted by the Company’s development partner, CSPC Pharmaceutical Group, that is being presented at the 2024 American Society of Clinical Oncology Genitourinary Cancers Symposium (the “2024 ASCO GU”) on January 26, 2024. A copy of the press release is attached hereto as Exhibit 99.1.

The Company also updated its presentation used by management to describe its business. A copy of the presentation is furnished as Exhibit 99.2 and is incorporated herein by reference.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibits 99.1 and 99.2, is being furnished to the Securities and Exchange Commission (the “SEC”), and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01 Other Events.

On January 26, 2024, the Company announced data from the ongoing Phase 1 clinical trial of SYS6002 (CRB-701) conducted by the Company’s development partner, CSPC Pharmaceutical Group, that is being presented at the 2024 ASCO GU on January 26, 2024.

The Phase 1 dose escalation study is being conducted in China and is enrolling patients with metastatic urothelial cancer as well as patients with other solid tumors prospectively confirmed to have nectin-4 positive tumors. The study opened for enrollment in January 2023 and the data presented is through December 2023 from the first eighteen patients reflective of the first six dose cohorts (0.2-3.6 mg/kg).

Safety

- CRB-701 was well-tolerated with the majority of adverse events being grade one or two and reversible.
- No adverse events above grade three were observed.
- There have been no dose discontinuations or reductions in the study to date. There has been a singular participant that experienced a temporary dose interruption.
- The dose escalation is ongoing at cohort 7 (4.5 mg/kg).
- No cases of drug-related peripheral neuropathy or skin rash have been reported to date.

PK

- Single dose PK suggested that TAB, ADC and MMAE increase in a dose proportional manner.
- No obvious accumulation was observed on cycle 3, day 1.
- When compared to the exposures achieved with enfortumab vedotin (EV) at 1.25 mg/kg Q1W x21 days, CRB-701 (SYS6002) consistently demonstrated lower free MMAE concentrations.

Efficacy

- Dose level 5 (2.7 mg/kg and above) represents the predicted therapeutically relevant doses based on allometric scaling.
- A mixed tumor population (n=7) receiving doses of 2.7 mg/kg or 3.6 mg/kg demonstrated an ORR of 43% (3 partial responses - 2 unconfirmed and one non responding participant with no-nectin-4 expression) and a disease control rate of 71%.
- The longest observed response to date is 11 cycles (~10 months) and ongoing.
- All nectin-4 positive mUC and cervical patients at doses \geq 2.7 mg/kg that were assessable at the time of the December 2023 data-cut off demonstrated levels of disease control and represent the CRB-701 (SYS6002) responsive population to date.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated January 26, 2024
99.2	Investor Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Corbus Pharmaceuticals Holdings, Inc.

Date: January 26, 2024

By: */s/ Yuval Cohen*
Name: Yuval Cohen
Title: Chief Executive Officer

CRB-701 (SYS6002) A Next Generation Nectin-4 Targeting Antibody Drug Conjugate Demonstrates Encouraging Safety and Efficacy in Patients with Nectin-4 Positive Tumors in First-In-Human Study Presented at ASCO-GU 2024

- Q3W schedule of CRB-701 (SYS6002) demonstrates a 43% ORR and 71% DCR at predicted therapeutically relevant doses
- All assessable nectin-4 positive study participants with mUC and cervical cancer treated at or above this dose demonstrated some level of disease control
- No dose limiting toxicities (DLTs) have been observed to-date up to 3.6 mg/kg (cohort 6) with further escalation at 4.5 mg/kg ongoing
- No cases of peripheral neuropathy or skin rash have been observed to date
- Cohort 6 is the first cohort selected for dose expansion

Norwood, MA, January 26, 2024 (GLOBE NEWSWIRE) -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), today announced that data from the first-in-human clinical study of CRB-701 (SYS6002) is being presented as a poster by the Company's development partner CSPC Pharmaceutical Group at the *2024 American Society of Clinical Oncology Genitourinary Cancers Symposium* (ASCO GU). The Phase 1 dose escalation study is being conducted in China and is enrolling participants with metastatic urothelial cancer (mUC) as well as participants with other solid tumors prospectively confirmed to have nectin-4 positive tumors. The study opened for enrollment in January 2023 and data through December 2023 from the first eighteen participants reflective of the first six dose cohorts (0.2-3.6mg/kg) will be shared.

The poster is titled Phase 1 Dose Escalation of SYS6002(CRB-701), a Next Generation Nectin-4 Targeting Antibody Drug Conjugate by DingWei Ye, et al and is being presented today at the poster session between 11:30 am-1pm PST. The poster will also be available on the Corbus website at the start of the poster presentation.

Safety

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- No adverse events above grade three were observed.
- There have been no dose discontinuations or reductions in the study to date. There has been a singular participant that experienced a temporary dose interruption.
- The dose escalation is ongoing at cohort 7 (4.5 mg/kg).
- No cases of drug-related peripheral neuropathy or skin rash have been reported to date.

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-

Efficacy

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- The longest observed response to date is 11 cycles (~10 months) and ongoing.
- All nectin-4 positive mUC and cervical patients at doses \geq 2.7 mg/kg that were assessable at the time of the December 2023 data-cut off demonstrated levels of disease control and represent the CRB-701 (SYS6002) responsive population to date.

Dr. Yuval Cohen Chief Executive Office of Corbus commented, "CRB-701 with its novel antibody and next generation linker technology, appears to have a differentiated PK profile compared to EV, with a current safety profile devoid of peripheral neuropathy and skin rash, both dose limiting toxicities for EV. This could translate into meaningful benefits for mUC patients and other nectin-4 positive solid tumors such as cervical cancer." In reviewing the emerging profile of CRB-701 with one of the preeminent experts in GU cancers, Dr Daniel P. Petrylack M.D., Professor of Medicine and Urology at Yale School of Medicine, Dr. Petrylack shared that "the clinical responses in nectin-4 positive mUC and cervical cancer patients are encouraging and the early clinical safety provides the first evidence that CRB-701 has clinical activity in multiple nectin-4 expressing tumors. This justifies further investigation into the safety and efficacy of this promising compound." Dr. Cohen concluded, "As the current clinical study continues to progress in China with our partner CSPC, we at Corbus are looking forward to commencing our clinical study in the US in Q1 2024 under an already open IND. We are grateful to CSPC for the work that has gone into conducting this ongoing study and to the clinicians and study participants."

Dose escalation and expansion are ongoing and additional data presentations are planned for later this year.

About CRB-701

CRB-701 (SYS6002) is a next-generation antibody-drug-conjugate (ADC) targeting nectin-4, that contains a site-specific, cleavable linker and a homogenous drug antibody ratio of 2, using MMAE as the payload. Nectin-4 is a clinically validated, tumor-associated antigen in urothelial cancer. The Nectin-4 ADC PADCEV® (enfortumab vedotin-ejfv) is approved for use in late metastatic urothelial cancer and recently received an expanded label under an accelerated approval from the Food and Drug Administration for use in combination with KEYTRUDA® for patients with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy.

About Corbus

Corbus Pharmaceuticals Holdings, Inc. is a precision oncology company with a diversified portfolio and is committed to helping people defeat serious illness by bringing innovative scientific approaches to well understood biological pathways. Corbus' pipeline includes CRB-701, a next generation antibody drug conjugate that targets the expression of Nectin-4 on cancer cells to release a cytotoxic payload, CRB-601, an anti-integrin monoclonal antibody which blocks the activation of TGF β expressed on cancer cells, and CRB-913, a highly peripherally restricted CB1 inverse agonist for the treatment of obesity. Corbus is headquartered in Norwood, Massachusetts. For more information on Corbus, visit corbuspharma.com. Connect with us on Twitter, LinkedIn and Facebook.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's restructuring, trial results, product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors on our operations, clinical development plans and timelines, which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

All product names, logos, brands and company names are trademarks or registered trademarks of their respective owners. Their use does not imply affiliation or endorsement by these companies.

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Managing Director
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Connecting Innovation to Purpose

Corporate Presentation
January 26 2024

Forward-Looking Statements

This presentation contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's restructuring, trial results, product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions. These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors, including the potential impact of the recent COVID-19 pandemic and the potential impact of sustained social distancing efforts, on our operations, clinical development plans and timelines, which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this presentation. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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A diversified pipeline with differentiated clinical risk profiles



Next Generation Nectin-4 targeting ADC				
CRB-701 Next generation Nectin-4 targeting ADC	Nectin-4 positive solid tumors	CSPC (China)	Dose Escalation Cohorts 1-6 completed Cohort 7 added and recruiting	Dose Confirmation / Expansion Cohort 6 expanding
		Corbus (US + Europe)	Dose Escalation On schedule for Q1 2024 End Q2 2024	Dose Confirmation / Expansion Start Q3 2024
Anti-Integrin mAb				
CRB-601 Anti- α v β 8 mAb <i>(TGFβ-targeting)</i>	α v β 8 enriched solid tumors	IND Cleared as of January 2024		
Highly peripherally-restricted CB1R inverse agonist				
CRB-913 CB1R inverse agonist	Obesity and related conditions	IND Q4 2024		



A decorative graphic on the right side of the slide, consisting of a network of interconnected nodes and lines, resembling a molecular structure or a network diagram. The nodes are represented by circles of varying sizes, and the lines are thin and light blue.

CRB-701

Next Gen Nectin-4 Targeting ADC



Designed to offer improved therapeutic index over Padcev®



Ph1 dose escalation ongoing in Nectin-4 tumors with first data release Q1 2024



Emerging clinical data supports differentiated ADC profile



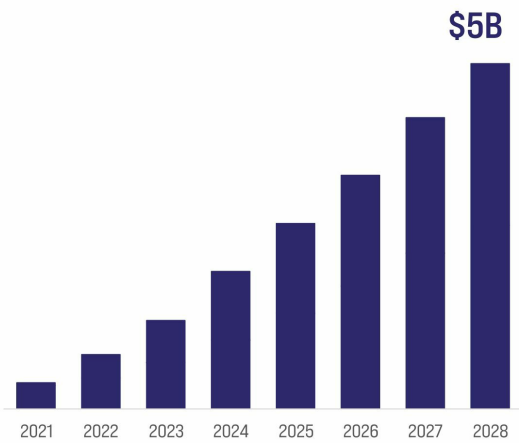
Latest Padcev® Q3 revenues ¹

(dollars in millions)	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	% Change	2023	2022	% Change
Total Net Product Sales	\$ 571	\$ 428	33 %	\$ 1,583	\$ 1,243	27 %
ADCETRIS	\$ 246	\$ 219	13 %	\$ 751	\$ 601	25 %
PADCEV	\$ 200	\$ 105	89 %	\$ 479	\$ 329	46 %
TUKYSA	\$ 102	\$ 88	16 %	\$ 289	\$ 267	8 %
TIVDAK	\$ 23	\$ 16	40 %	\$ 64	\$ 45	42 %

22nd October 2023 ²

Groundbreaking EV-302 Trial Significantly Extends Overall Survival and Progression-Free Survival in Patients Treated with PADCEV® (enfortumab vedotin-ejfv) and KEYTRUDA® (pembrolizumab) in First-Line Advanced Bladder Cancer

PADCEV® Global Projected Revenues in UC/Bladder³



Does tolerability for Padcev® impact clinical adoption?



PADCEV® Prescribing Information

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PADCEV safely and effectively. See full prescribing information for PADCEV.

PADCEV® (enfortumab vedotin-ejfv) for injection, for intravenous use (NDA 201-123-01)

WARNING: SERIOUS AND LIFE-THREATENING

- PADCEV may cause severe and fatal autoimmune adverse reactions, including hypoxic pulmonary edema (HPE) and interstitial lung disease (ILD).
- Immunotherapy-related HPE and ILD are not clearly defined and may occur at any time during or after treatment with PADCEV.
- Patients should be monitored for symptoms of HPE or ILD, such as cough, shortness of breath, and chest pain.
- Patients should be monitored for symptoms of HPE or ILD, such as cough, shortness of breath, and chest pain.

ADVERSE REACTIONS

See full prescribing information for complete adverse reaction monitoring.

INDICATIONS AND USAGE

PADCEV is a human monoclonal antibody with antineoplastic activity indicated as a single agent for the treatment of adult patients with locally advanced or metastatic urothelial cancer who:

- have previously received a programmed death receptor-1 (PD-1) or programmed death ligand-1 (PD-L1) inhibitor and platinum-containing chemotherapy; or
- have previously received one or more prior lines of therapy.

DOSE AND ADMINISTRATION

- For intravenous infusion: 1.25 mg/kg as a single agent or in combination with other antineoplastic products.
- The recommended dose of PADCEV as a single agent is 1.25 mg/kg on Days 1, 8, and 15 of a 21-day cycle with dose progression or discontinuation on Day 22.
- The recommended dose of PADCEV in combination with platinum-based chemotherapy is 1.25 mg/kg on combination days 1, 8, and 15 of a 21-day cycle with dose progression or discontinuation on Day 22.

HOW SUPPLIED AND STORAGE

For injection, 10 mg and 20 mg of enfortumab vedotin-ejfv are supplied in a single-dose vial for intravenous use.

Revised: 4/2023



Duration of Response
~5 months

47%
Rate of Serious Adverse Events (SAEs)

<p>→</p> <p>61%</p> <p>Dose interruptions</p>	<p>→</p> <p>34%</p> <p>Dose reductions</p>	<p>→</p> <p>17%</p> <p>Dose Discontinuations</p>
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EV-301: The safety of PADCEV was evaluated as a single agent in EV-301 in patients with locally advanced or metastatic urothelial cancer (n=296) who received at least one dose of PADCEV 1.25 mg/kg and who were previously treated with a PD-1 or PD-L1 inhibitor and a platinum-based chemotherapy



A Black Box warning¹

WARNING: SERIOUS SKIN REACTIONS

- PADCEV can cause severe and fatal cutaneous adverse reactions including Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN), which occurred predominantly during the first cycle of treatment, but may occur later.
- Closely monitor patients for skin reactions.
- Immediately withhold PADCEV and consider referral for specialized care for suspected SJS or TEN or severe skin reactions.
- Permanently discontinue PADCEV in patients with confirmed SJS or TEN; or Grade 4 or recurrent Grade 3 skin reactions [see *Dosage and Administration* (2.2), *Warnings and Precautions* (5.1) and *Adverse Reactions* (6.1)].

- **Greater than 25% of PADCEV® discontinuations are linked to peripheral neuropathy²**
- **PADCEV + Keytruda patients who experienced neuropathy:**
 - 13% complete resolution
 - 87% patients had residual neuropathy (45% had Grade ≥2)¹

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Source(s): 1. PADCEV® Prescribing Information Dec 2023. 2. Rosenberg et al., 2020

Adverse Events (% of patients)

	PADCEV® monotherapy ¹		PADCEV® + Keytruda ¹	
	All Grades	≥ Gr 3	All Grades	≥ Gr 3
Skin Reactions	58%	14%	70%	17%
Peripheral Neuropathy	53%	5%	67%	7%

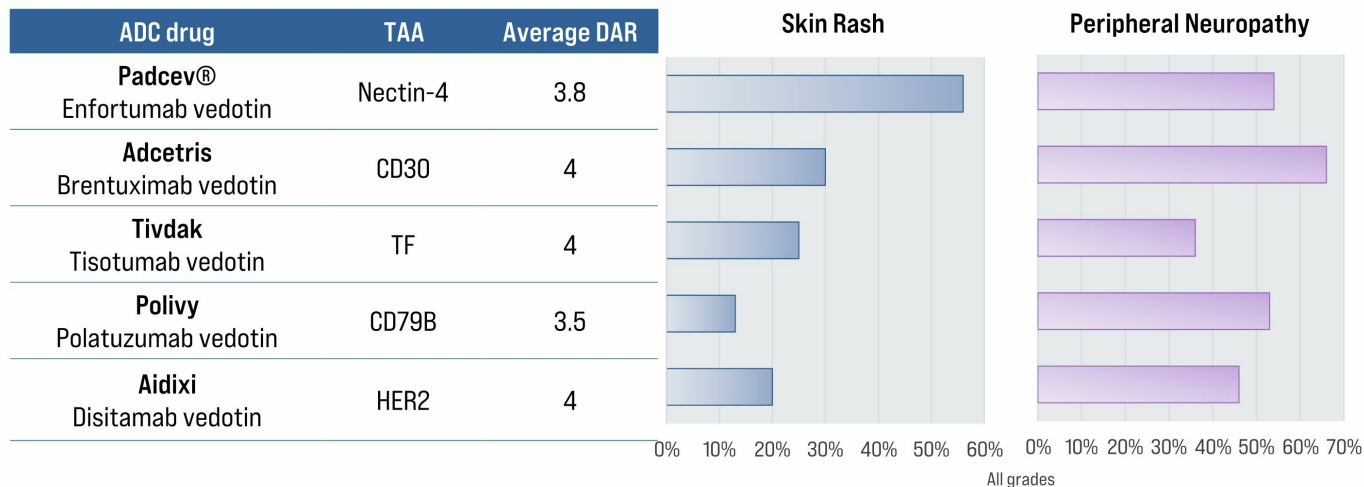
NR = not reported

Is the 2nd generation Seagen linker the cause?



Similar dose limiting toxicities seen across divergent ADCs that share same constellation of 'linker + payload'

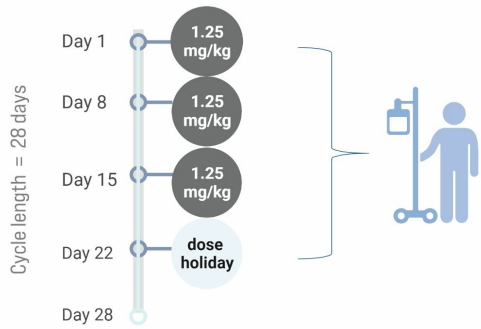
Val-Cit linker + vedotin (MMAE) payload



9 Padcev Val-Cit linker + payload = mc-VC-PABC = Maleimidocaproyl-L-valine-L-citrulline-p-aminobenzyl alcohol p-nitrophenyl carbonate
 Source(s): 1. Fu et al., Science, 2023 doi: 10.1016/j.isci.2023.107778. Padcev® Prescribing information, Adcetris® Prescribing Information, Tivdak® Prescribing Information, Polivy® Prescribing Information, Shi et al., 2022
<https://doi.org/10.1080/10717544.2022.2069883> Aidixi® <https://www.adcreview.com/drugmap/disitamab-vedotin>



Monotherapy Padcev®



6 months of therapy =
~ 54 hours of total clinic time / patient

Real-world use, dose intensity, and adherence to Padcev®

Metric	Result (N = 416)
EV use	
Number of cycles (median, IQR)	5 (2,8)
EV dose intensity	
Treatments per patient month (mean [SD])	2.6 [0.6]
Dosing frequency; treatments per cycle (mean [SD])	2.4 [0.5]
Dose (mean, mg/kg [SD])	1.1 [0.2]
Change in average dose (mg) from baseline (%)	-9.6 [20.2] %
EV treatment adherence	
Received on average > 2 treatments per cycle (%)	58.8 [34.4] %



Limitation	Padcev®	BT8009	9MW-2821
Upper dose limit	1.25 mg/kg ¹	5 mg/m ² ⁴	1.25 mg/kg ³
Schedule	D1, D8, D15 /28 days	Q1W	D1, D8, D15 /28 days
≥ Grade 3 AE rate	51% (n=155) ²	65% (n=20) ⁶	35% (n=85) ³
Peripheral Neuropathy	38%	30%	17%
Skin reactions	25%	10%	18%
Neutropenia (Gr 3)	5% ³	10% [#]	19%
Dose reduction	34%	16%	3.5%
Dose interruptions	64%	24%	28%

11 1 Rosenberg, et al., "EV-101 JCO, 2020 Apr 1; 38(10): 1041-1049, 2. Powles et al., EV-3012021, 3. Zhang et al., ESMO 2023, 4 Rigby et al., 2023, 6 Bicycle corporate deck Nov 2023_# - combined frequency of Grade 3 neutropenia/ low neutrophil count



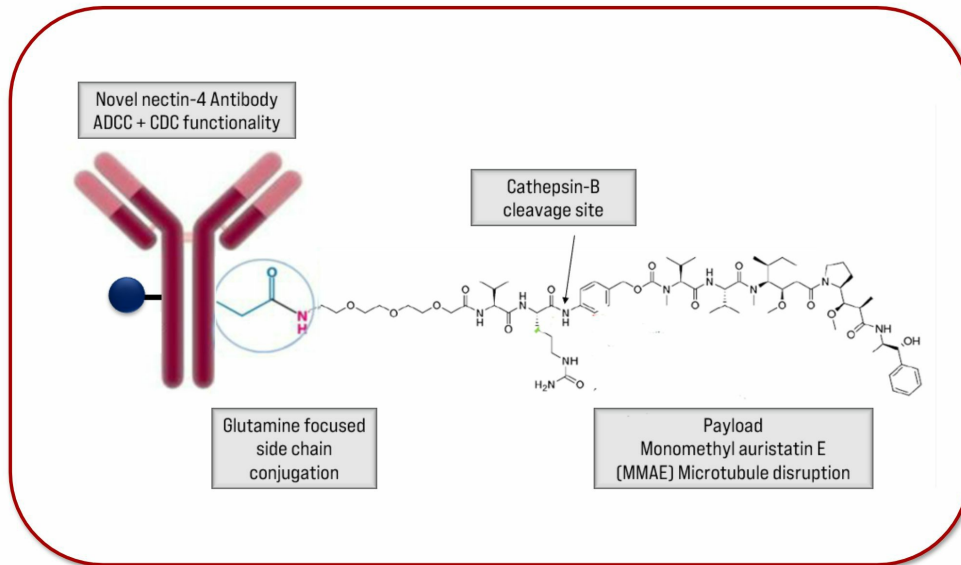
Toxicity: 3rd gen ADC with stable linker → Reduce free circulating MMAE



Compliance: Extend ADC half-life → Reduce dosing frequency



Efficacy: Lower DAR + longer half-life → Dose higher than Padcev®



13

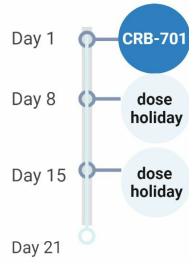
MMAE = Monomethyl auristatin E ADCC = antibody-dependent cellular cytotoxicity
CDC = complement dependent cytotoxicity DAR = Drug Antibody Ratio

Source(s): Modified image from Corbus data on file; Corbus data on file

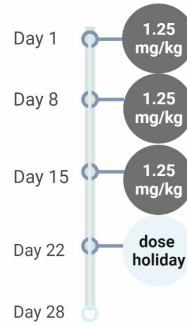


Clinical cycle comparison

CRB-701



Padcev®



Patient / physician
convenience

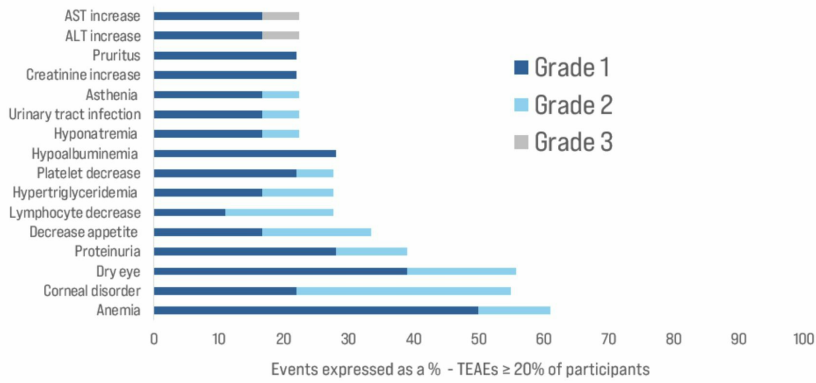
Combination flexibility



<p>KEY ELIGIBILITY</p> <p>Age \geq18 years Advanced urothelial carcinoma or Nectin-4 positive Advanced solid tumors ECOG 0-1 Adequate organ function No uncontrolled diabetes No active CNS metastasis</p>	<p>ESCALATION DESIGN</p> <p>Bayesian Optimal Interval (BOIN) design with accelerated titration at DL-1 IV Q3W over a 21-day cycle</p> <p>0.2 mg/kg 0.6 mg/kg 1.2 mg/kg 1.8 mg/kg 2.7 mg/kg 3.6 mg/kg 4.5mg/kg (recruiting)</p>	<p>KEY END POINTS</p> <ul style="list-style-type: none">• Safety / tolerability• Pharmacokinetics• Anti tumor activity
		<p>NEXT STEPS</p> <ul style="list-style-type: none">• Continue escalation• PK expansion at 3.6mg/kg• MTD or RP2D• Specific expansion



Characteristic	Value	Characteristic	Value
Median Age (Range)	58 (35-76)	Primary tumor type	n=18
Sex (M/F)	5/13	Urothelial	7
ECOG PS of 1	18 (100%)	Cervical	6
Weight in kg (Range)	55 (36-84)	Breast	4
Prior therapy (Range)	5 (1-10)	TNBC	3 of 4
Creatine Cl <60 μmol/L	7 (39%)	CRC	1
Visceral metastasis	15 (83%)	HbA1C levels ≤ 6.5%	18 (100%)



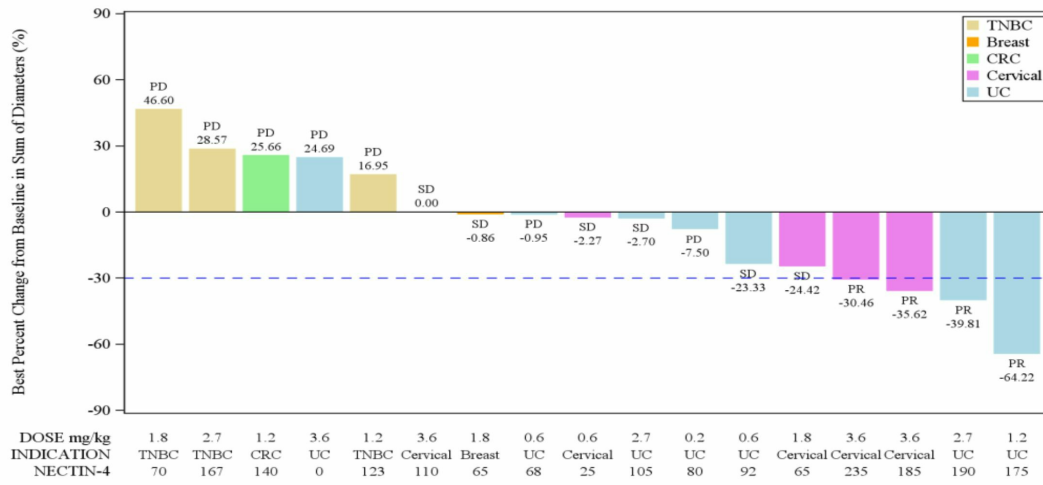
Dose Modifications (n=18)	Value
Discontinuations	0
Reductions	0
Interruptions	1 (5.5%)

- SYS6002 (CRB-701) was well tolerated with mainly grade 1 or 2 AEs
- No DLTs or Grade 4 or 5 AEs have been observed to-date
- Anemia and eye related adverse events were the most common treatment emergent AEs (TEAE)
- Four subjects reported 7 SAEs, 3 of which were considered probably related to SYS6002 (CRB-701)
 - Two Grade 3 SAEs (ILD and pulmonary infection) were reported in a single participant
 - 1 Grade 3 (ALT increase) reported in a separate participant
- To-date no cases of skin rash or peripheral neuropathy have been observed



21 Day PK	Comparison	% ADC		% Free MMAE	
		C _{max}	AUC _{21d}	C _{max}	AUC _{21d}
Enfortumab vedotin (EV) 1.25 mg/kg Q1W x3	EV benchmark	100%	100%	100%	100%
SYS6002 (CRB-701) 1.2 mg/kg Q3W	Matched ADC dose	79%	106%	33%	29%
SYS6002 (CRB-701) 2.7 mg/kg Q3W	Matched MMAE dose	177%	183%	79%	68%

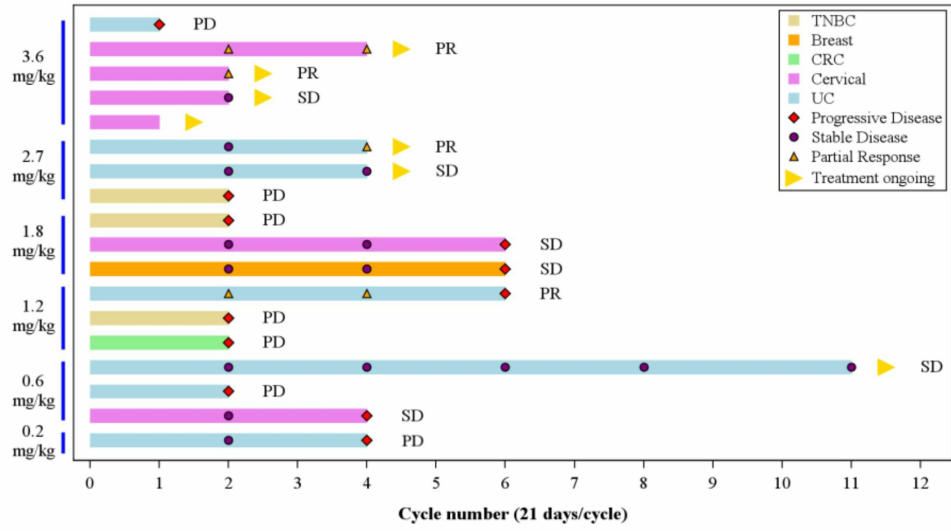
- After single IV infusion of SYS6002 (CRB-701), the exposure of TAb, ADC and MMAE generally increased in a dose proportional manner
- Clearance and volume of distribution were similar across doses
- The half-lives of TAb, ADC and MMAE were 4-6 days, 4-5 days and 5-10 days, respectively.
- No obvious accumulation was observed on C3D1
- Time to peak concentration of MMAE was about 3-7 days
- When compared to EV exposures SYS6002 (CRB-701) consistently demonstrates lower free MMAE



Efficacy for 3.6 mg/kg and 2.7 mg/kg doses:

ORR 43%

DCR 71%



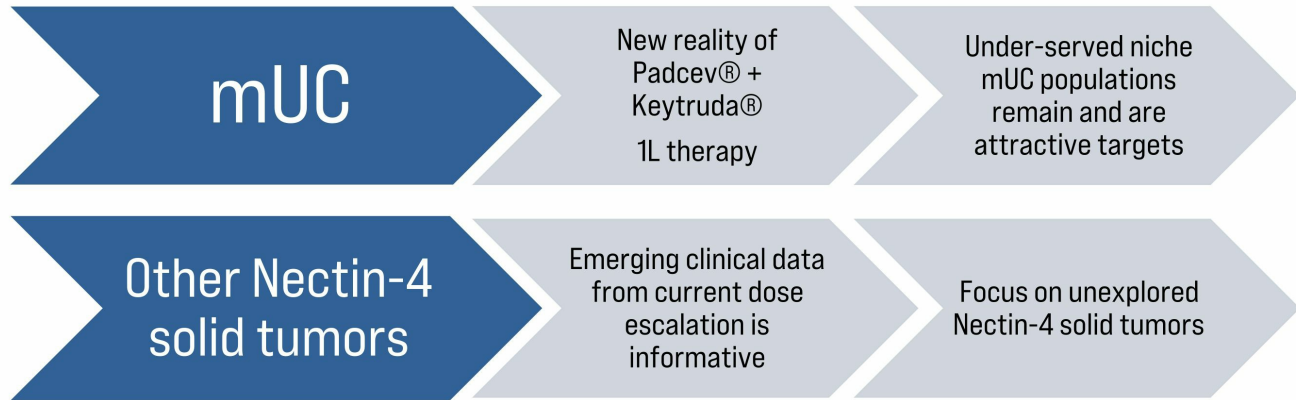
Note: Of the 4 PRs reported; 2 PRs are confirmed and 2 remain unconfirmed

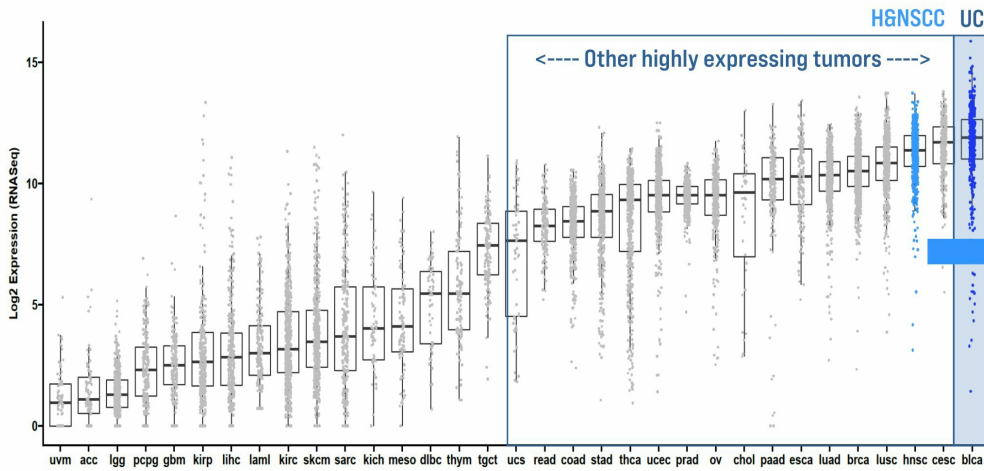


Predicted therapeutically relevant doses in Ph 1 study	Seven patients treated at 2.7mg/kg and 3.6 mg/kg on Q3W schedule
Objective Response Rate	43% - 3 out of 7 patients with PR's (2 unconfirmed)
Disease Control Rate	71% - 5 out of 7 patients
Tumor shrinkage across all nectin-4 positive mUC and cervical patients in study	9 out of 10 patients
Dose for first observed SD	0.6 mg/Kg
Dose for first observed PR	1.2 mg/Kg
Longest observed response duration to-date	11 cycles (still ongoing)
Participants still on CRB-701	7/18 (38%)
First expansion dose chosen	3.6 mg/Kg (cohort 6)



Proprietary insights are driving indication selection for CRB-701





PADCEV
enfortumab vedotin-ejfv
Injection for IV infusion: 20 mg & 20 mg vials

H&NSCC

Parameter	Patients (N=46)
Confirmed ORR	11 (23.9%)
CR	1 (2.2%)
PR	10 (21.7%)
SD	15 (32.6%)
mPFS	3.94 months

2023 **ASCO**
ANNUAL MEETING

Elevated Nectin-4 expression: urothelial, breast, ovarian, cervical, colorectal, rectal, esophageal, gastric, lung, thyroid, prostate, cholangiocarcinoma, pancreatic cancer, testicular cancer

Clinical Status: Non-clinical / Clinical Development plan



Updated planning
Nov 2023

Non-clinical

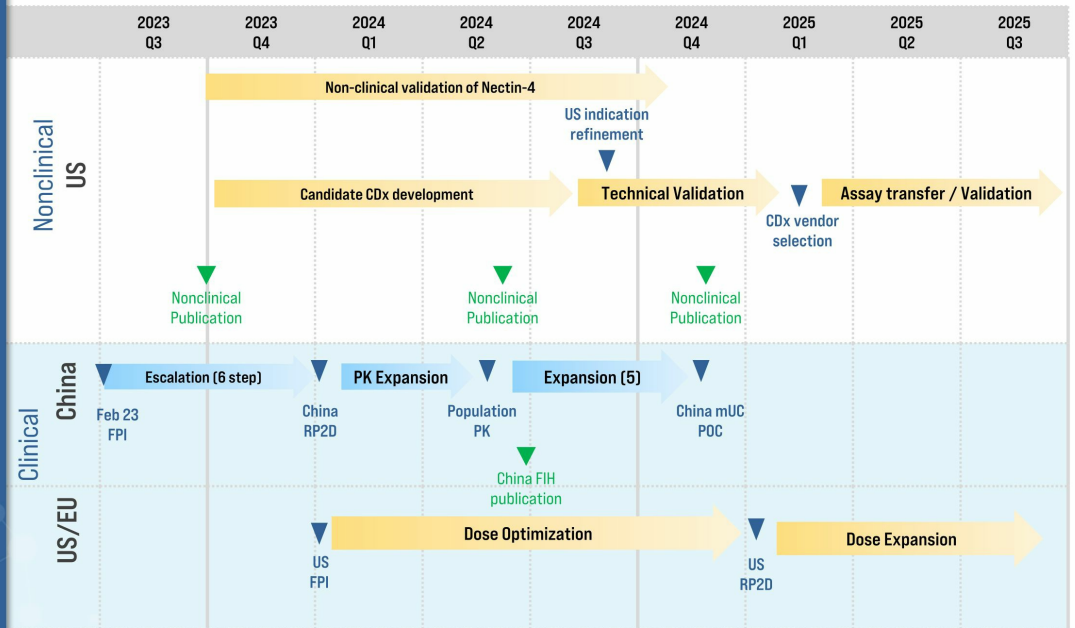
1. Clinical differentiation
2. Translational validation
3. CDx development

Clinical

1. Exploring doses beyond PADCEV®
2. Dose escalation complete Q4 2024
3. CRB-701 bridging Q1 2024
4. PK/safety /E modeling



CRB-701 Development Timeline





Emerging clinical safety and efficacy-potential for superior therapeutic index



Dose expansion has started (China); dose escalation in US Q-1 2024



3rd generation ADC with improved linker stability-reduces MMAE in circulation



CRB-913: oral cannabinoid type-1 inverse agonist for superior incretin therapy in obesity



NASDAQ: CRBP • CorbusPharma.com • @CorbusPharma



But...

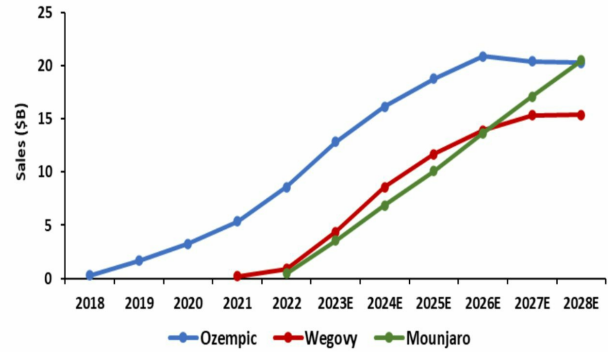
Muscle loss

Tolerability

Accessibility

→ Long-term compliance is ~ 27%

Sales (2018-2022) and sales estimates (2023-2028) for Ozempic, Wegovy, and Mounjaro reflect significant uptake and expectations





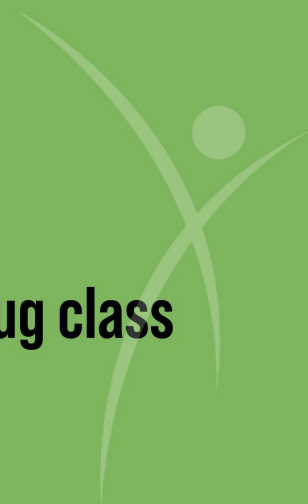
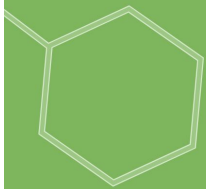
Muscle loss: Degree of weight loss → Quality of weight loss



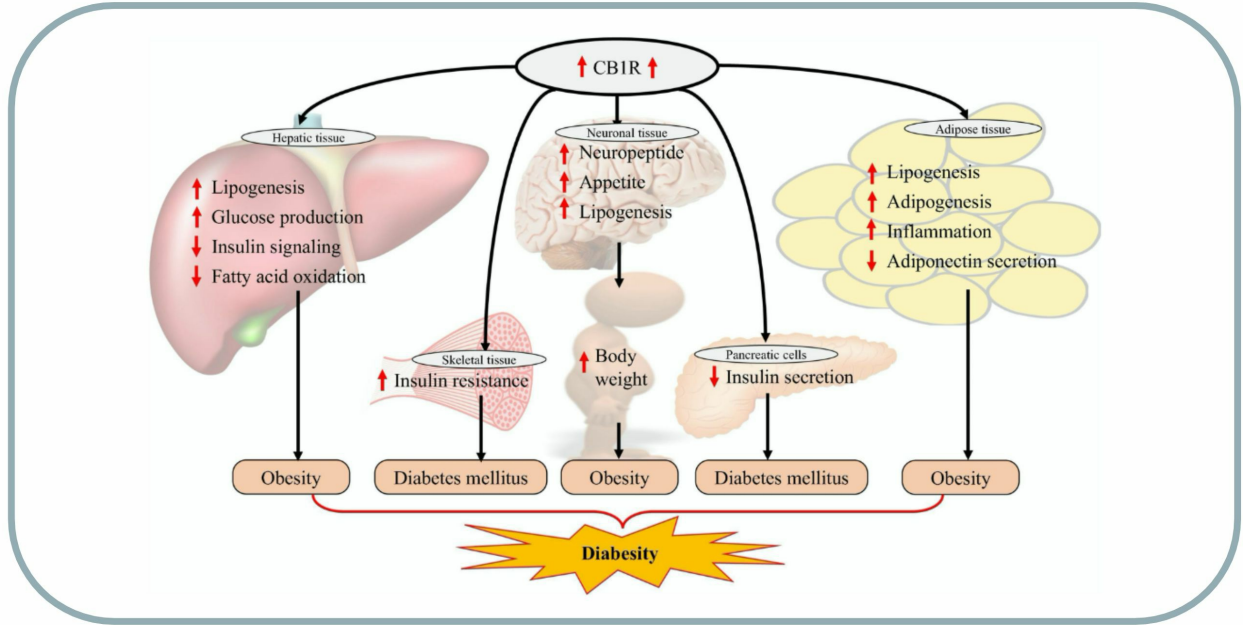
Tolerability: Single MOA → Multiple orthogonal MOAs



Accessibility: Injectables → Oral small molecules



CB1 inverse agonism: The return of a clinically-validated obesity drug class



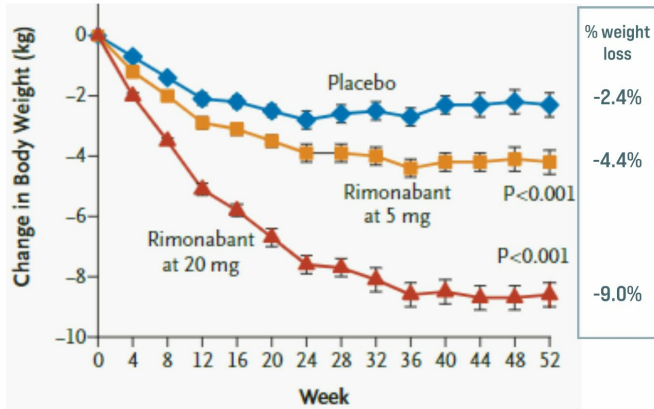
The CB1 MOA is clinically validated in obesity: data from 1st gen drugs



SANOFI
Rimonabant¹

RIO-Lipids Phase 3 study
Placebo (n=342);

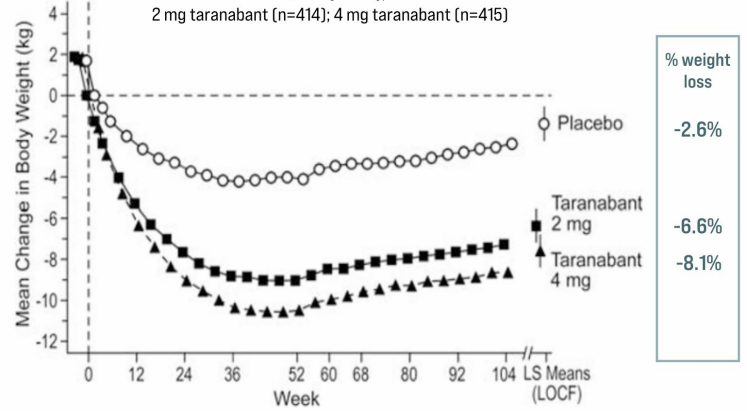
5 mg rimonabant (n=345); 20 mg rimonabant (n=346)



MERCK
Taranabant²

Completed Phase 3 studies (2 and 4 mg) (2 yr)
Placebo (n=417);

2 mg taranabant (n=414); 4 mg taranabant (n=415)



Phase 3 RIO study DEXA-scanned subgroup (n=146)

	Total body mass	Total fat mass	Fat mass/body mass	Lean mass
Rimonabant vs placebo	↓	↓	↓	Unchanged

Body composition was measured with body DEXA in a subset of patients in RIO Lipids. Decreases in the rimonabant 20 mg group relative to placebo were observed in the total body mass ($p < 0.001$), the total body fat mass ($p = 0.001$) and the fat mass/total body mass ratio ($p = 0.007$). There was no statistically significant difference between the 20 mg and the placebo groups in lean mass loss between groups.

Rimonabant NDA (page 21)



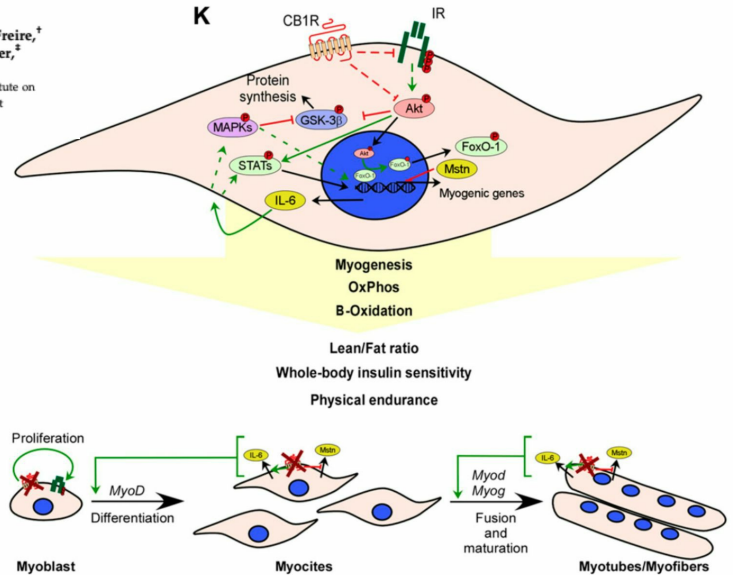
Muscle cannabinoid 1 receptor regulates Il-6 and myostatin expression, governing physical performance and whole-body metabolism

Isabel González-Mariscal,^{*,1} Rodrigo A. Montoro,^{*} Jennifer F. O'Connell,^{*} Yoo Kim,^{*} Marta Gonzalez-Freire,[‡] Qing-Rong Liu,^{*} Irene Alfaras,[‡] Olga D. Carlson,^{*} Elin Lehmann,[‡] Yongqing Zhang,[‡] Kevin G. Becker,[‡] Stéphan Hardivillé,[§] Paritosh Chosh,^{*} and Josephine M. Egan^{*,2}
^{*}Laboratory of Clinical Investigation, [‡]Translational Gerontology Branch, and ¹Laboratory of Genetics and Genomics, National Institute on Aging, National Institutes of Health, Bethesda, Maryland, USA; and ²Unité de Recherche 8576-Unité de Glycobiologie Structurale et Fonctionnelle (UCSF), Centre National de la Recherche (CNRS), Université Lille, Lille, France

Key finding:

Muscle-CB1 KO mice...

- Increase in muscle mass and strength
- Increase in biomarkers of muscle growth
- Increase in mitochondrial metabolism
- Increase in energy expenditure
- Increase in calorie consumption w/o weight gain
- Increase in fat metabolism
- Enhanced insulin sensitivity in muscle tissue
- Reduction in body fat content
- Reduction in sleep






1st gen (2000-2007)

- Designed to target the brain with high BBB penetration → FDA rejection due to safety concerns (2007)

 Rimonabant

 Otenabant

 Bristol Myers Squibb[®] Ibipinabant

 MERCK Taranabant

Next gen (2020 onwards)

- Designed to be peripherally restricted with minimal BBB penetration → avoid safety issues



INV-202

 CORBUS
PHARMACEUTICALS

CRB-913

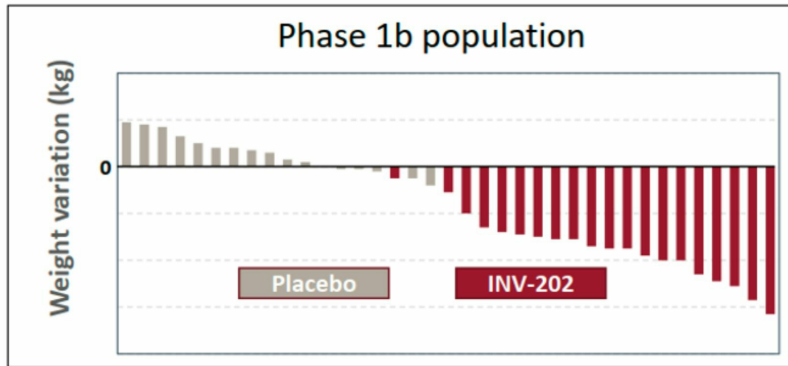


BIOTECH

STAT+

Novo acquires Inversago for up to \$1 billion, spotlighting troubled weight loss approach

Aug. 10, 2023



1. Single-dose INV-202 (25mg QD)
2. N = 37
3. Adults with metabolic syndrome
4. Weight loss: -3.50 kg (INV-202) vs +0.55Kg (placebo)



CRB-913: oral CB1 inverse agonist for combination therapy with incretins

OBESITY SYMPOSIUM
Obesity Biology and Integrated Physiology

Obesity THE OBESITY SOCIETY WILEY
A Research Journal

Novel cannabinoid receptor 1 inverse agonist CRB-913 enhances efficacy of tirzepatide, semaglutide, and liraglutide in the diet-induced obesity mouse model

Marshall Morningstar | Andrew Kolodziej | Suzie Ferreira | Tracy Blumen | Rachael Brake | Yuval Cohen

Nov. 2023



Design goals:



Best-in-class peripheral restriction



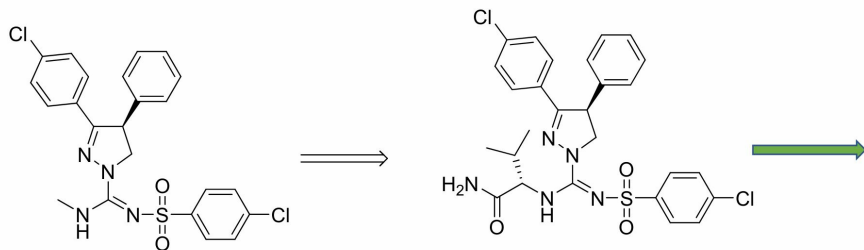
Protect lean mass (muscle)



Retain 1st gen efficacy



Enhance efficacy of incretin analogs



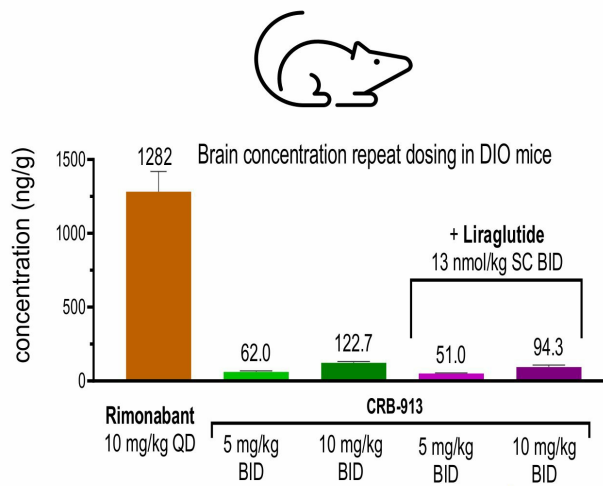
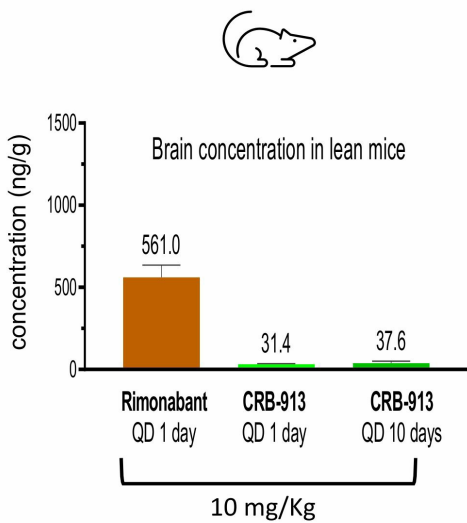
Ibipinabant
(2004-2008)

JD-5037 (2012-2018) /
CRB-4001 (2018-2021)

CRB-913

- Completed Phase IIb (Solvay/BMS)
- Small, lipid soluble molecule
- High BBB penetration
- Oral
- CRB-4001 (JD5037) licensed from Jenrin in 2018
- Extensive pre-IND studies carried out
- PK didn't support TPP
- Oral
- New IP published –patent coverage through 2043
- PK profile optimized for TPP
- Favorable multi-species bioavailability (>50%)
- Lower mfg. cost vs. Incretins
- Oral

CRB-913: marked peripheral restriction vs. rimonabant in both lean and obese mice



Co-administration with incretin analog does not affect brain penetration for CRB-913

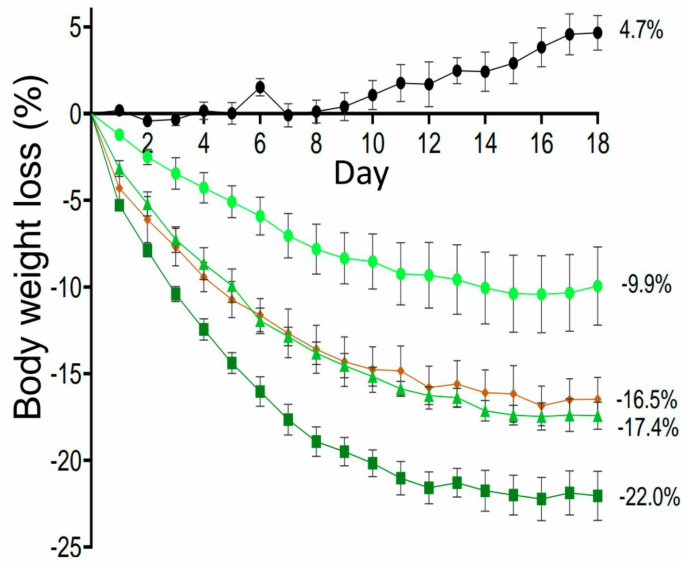
Source(s): Morningstar et al 2023

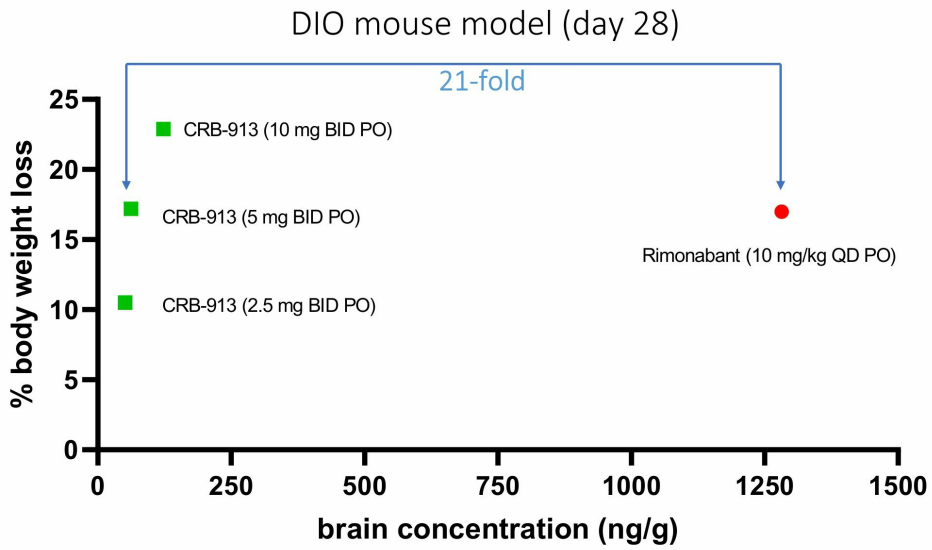


Brain concentration (ng/g)			
single acute dose	CRB-913 (lean mice)	INV-202 (lean mice)	Rimonabant (lean mice)
10 mg/Kg	26*	319**	561*

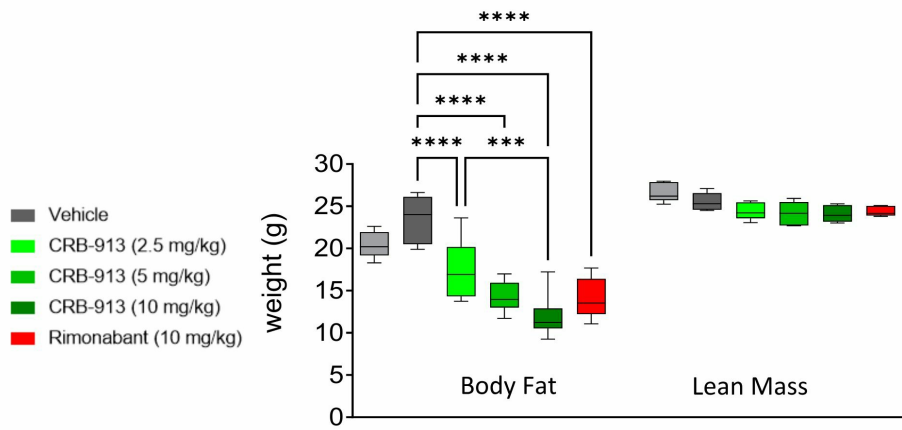


CRB-913: similar weight loss vs rimonabant at same daily doses in DIO mice



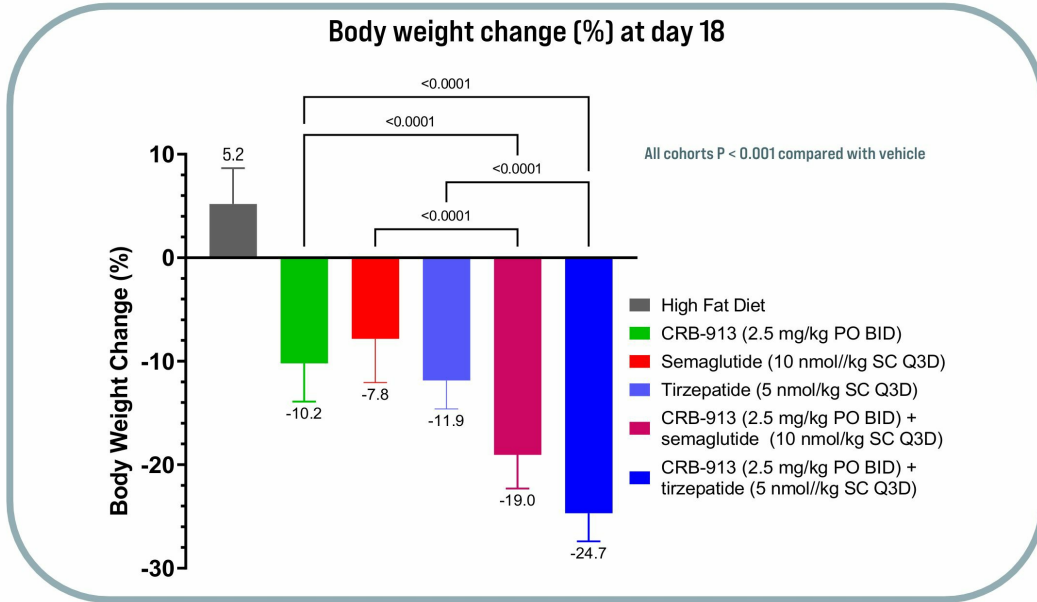


- DIO mouse model with C57BL6/N mice (n=10) fed a continuous high fat diet for 22 weeks prior and during 28 days of treatment
- Brain collected 1 h post final dose (C_{max})

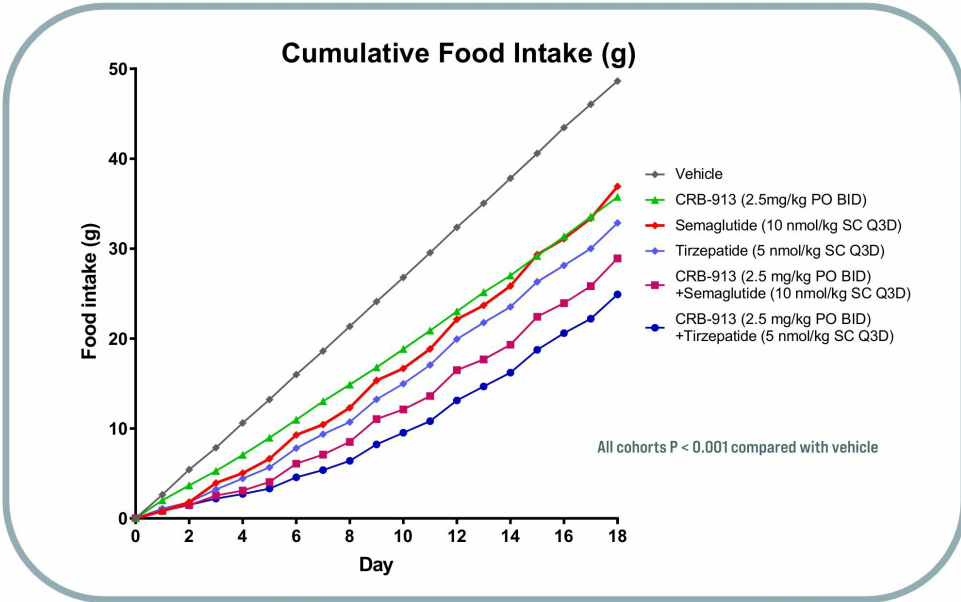


- DIO mouse model with C57BL6/J mice (n=10) fed a continuous high fat diet for 22 weeks prior
- Body fat by MRI determined on Day 20

Source(s): Morningstar et al 2023



DIO mouse model with C57BL6/J mice (n=10) fed a continuous high fat diet for 22 weeks prior and during 18 days of treatment
 (Similar effect also seen when CRB-913 was combined with liraglutide)



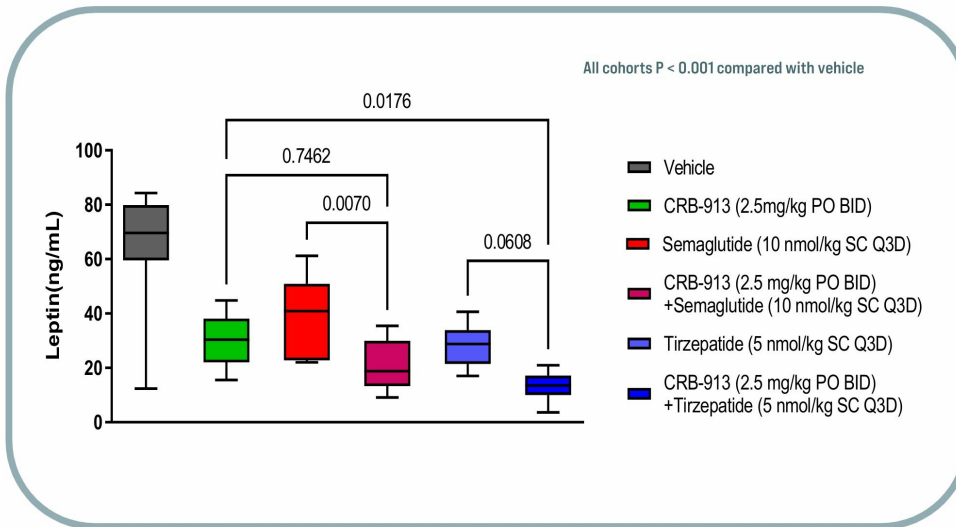
Food Consumption

- CRB-913, semaglutide and tirzepatide each results in food intake reductions
- Significant further reductions in food consumption when CRB-913 is combined with semaglutide or tirzepatide (p=0.001)



The Role of Leptin

- The hormone leptin regulates food intake
- Normally, leptin signals satiety (feeling “full”)
- In obesity, resistance to leptin develops and hunger persists despite high leptin levels (“leptinemia”)
- A reduction in leptin levels is believed to be important for weight loss¹

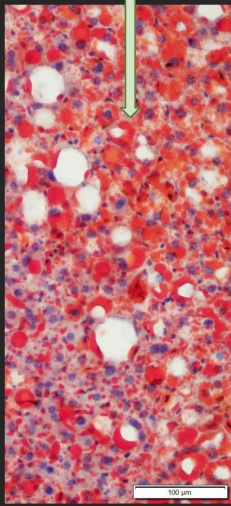


- DIO mouse model with C57BL6/J mice (n=10) fed a continuous high fat diet for 22 weeks prior
- Leptin measured at Day 28 of treatment

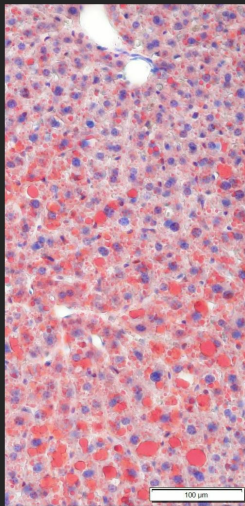
CRB-913 reduces liver fat alone and in combination with semaglutide or tirzepatide



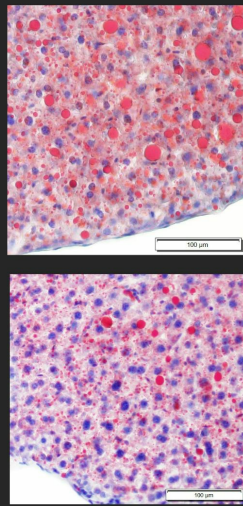
Liver fat



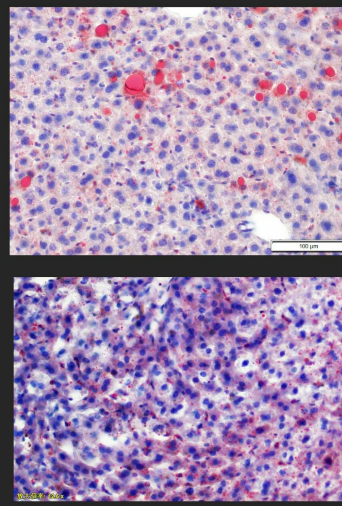
vehicle



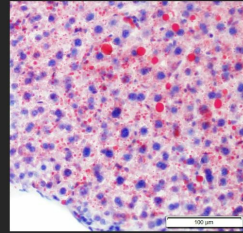
CRB-913
(2.5 mg/kg)



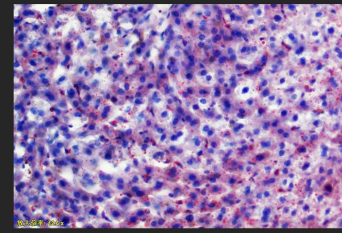
semaglutide
(10 nmol/kg)



CRB-913 (2.5 mg/kg) +
semaglutide (10 nmol/kg)



CRB-913 (2.5 mg/kg) +
tirzepatide (5 nmol/kg)



47

*liver oil red stain

Source(s): Company data on file.



Potential clinical applications:



Incretin analog therapy insensitive/intolerant/high-risk patients



Combination with oral incretin agonists →enhance efficacy OR improve tolerability



“Induction/maintenance” model: maintain weight loss post incretin analog therapy



Best-in-class peripheral restriction



Protect lean mass (muscle)



Retain 1st gen efficacy



Enhance efficacy of incretin analogs





Leadership Upcoming catalysts Financials



Yuval Cohen, PhD

Chief Executive Officer, Director

Corbus co-founder and Chief Executive Officer since 2014. Previously the President and co-founder of Celsus Therapeutics from 2005.



Sean Moran, CPA, MBA

Chief Financial Officer

Corbus co-founder and Chief Financial Officer since 2014. Prior senior financial management experience in emerging biotech and medical device companies.



Rachael Brake, PhD

Chief Scientific Officer

Expert in developing and executing innovative drug discovery and clinical development oncology programs at several leading pharmaceutical companies.



Christina Bertsch

Head of Human Resources

Accomplished senior human resource executive providing strategic HR consulting services to both large and small businesses across a variety of industries



Amb. Alan Holmer Ret.
Chairman of the Board

More than two decades of public service in Washington, D.C. including Special Envoy to China; Former CEO of PhRMA.



Anne Altmeyer, PhD, MBA, MPH
Director

20 years of experience advancing oncology R&D programs and leading impactful corporate development transactions; currently President & CEO of Tigenix.



Avery W. (Chip) Catlin
Director

More than 25 years of senior financial leadership experience in life science companies; Former CFO and Secretary of Celldex Therapeutics.



Yuval Cohen, PhD
Chief Executive Officer, Director

Corbus co-founder and Chief Executive Officer since 2014. Previously the President and co-founder of Celsus Therapeutics from 2005.



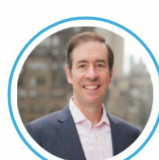
Rachelle Jacques
Director

More than 25-year professional career, experience in U.S. and global biopharmaceutical commercial leadership, including multiple high-profile product launches in rare diseases; CEO of Akari Therapeutics. (NASDAQ: AKTX)



John K. Jenkins, MD
Director

Distinguished 25-year career serving at the U.S. FDA, including 15 years of senior leadership in CDER and OND.



Pete Salzmann, MD, MBA
Director

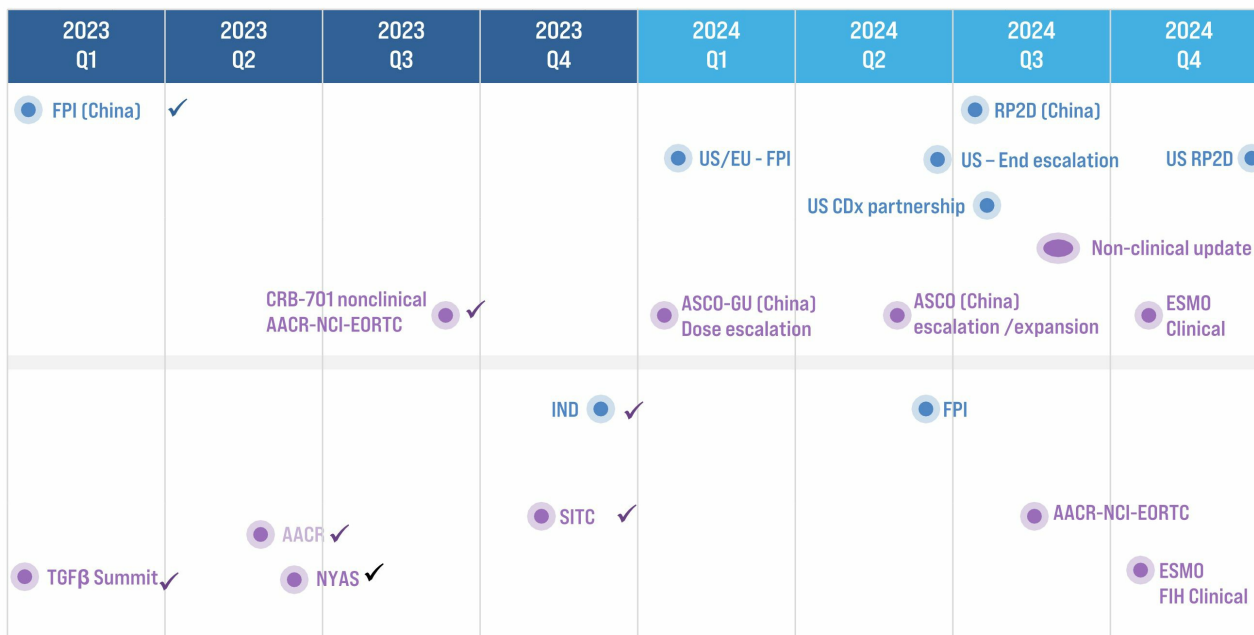
20 years of industry experience and currently serves as Chief Executive Officer of Immunovant (NASDAQ: IMVT), a biopharmaceutical company focused on developing therapies for patients with autoimmune diseases.



Yong (Ben) Ben, MD, MBA
Director

25 years of oncology R&D experience across industry and academia. Held two industry CMO positions, most recently at BeiGene (BGNE).

2023 - 2024 Catalysts



53

Clinical milestone

Conference presentation PK = Pharmacokinetics CDx = Companion Diagnostic RP2D = Recommended Phase 2 Dose FPI = First Patient In



Focus on developing precision oncology + differentiated assets



Clinically developing a next generation Nectin-4 targeting ADC



Move CRB-913 into clinic with IND in H2 2024



Advancing anti- $\alpha v \beta 8$ integrin program into clinic-IND cleared

CRBP
Ticker

\$29 Million

Cash, cash equivalents and investments as of September 30, 2023
4.4M Common Shares Outstanding
(5.2M Fully-Diluted Shares)



Appendix

A decorative graphic on the right side of the slide, consisting of a network of interconnected nodes and lines, resembling a molecular structure or a network diagram. The nodes are represented by circles of varying sizes, and the lines are thin and light green.

CRB-601

Potential “best-in-class”
 $\alpha v \beta 8$ mAb



Novel mechanism to target TGF β in the tumor microenvironment



Focus on adopting a precision-targeted approach



Large opportunity potential if POC is validated

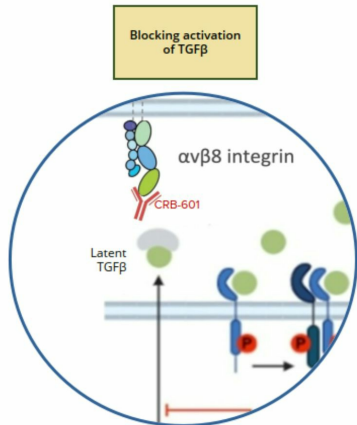


Targeting the integrin $\alpha\beta 8$ represents a novel approach to regulating TGF β

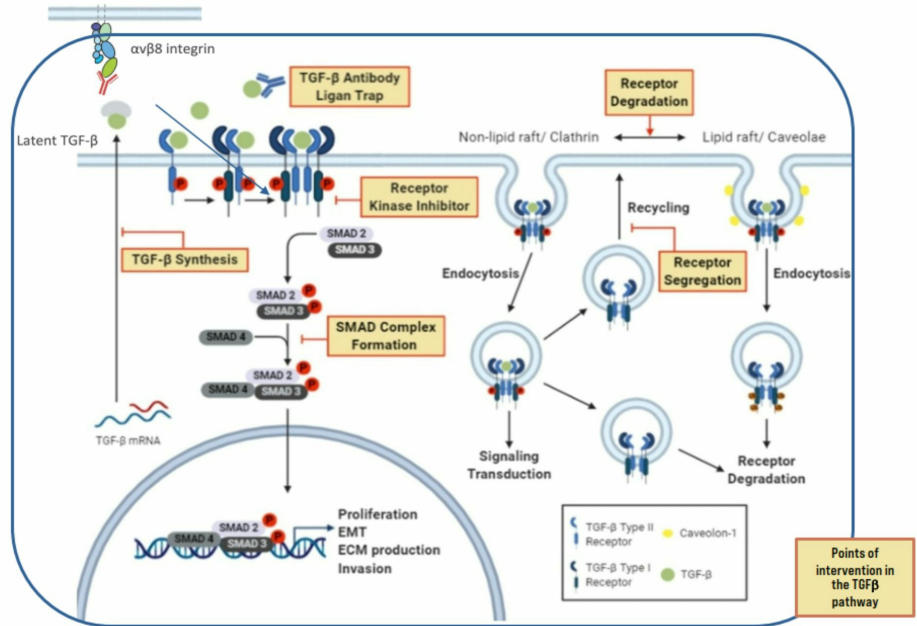


Novel point of therapeutic intervention

Blocking the $\alpha\beta 8$ activation of TGF β in the local tumor microenvironment



CRB-601 binds at the interface between latent TGF β and $\alpha\beta 8$

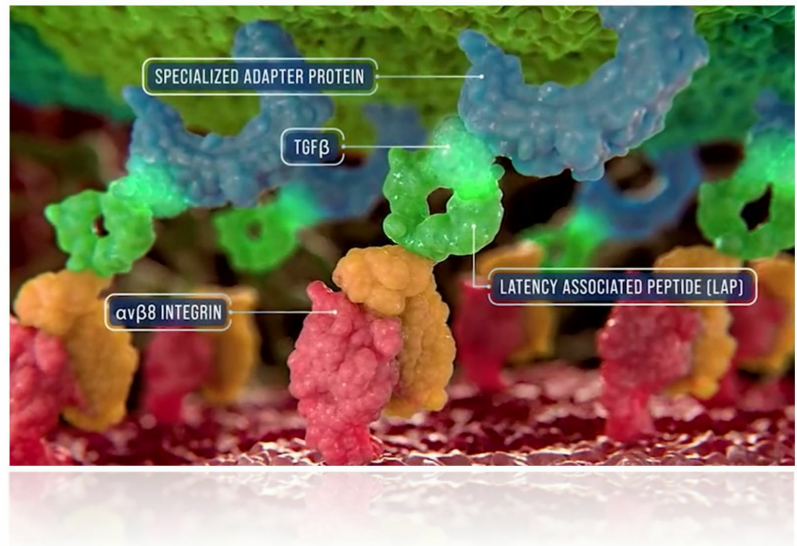




The integrin $\alpha v \beta 8$ is expressed in the tumor microenvironment (TME)

Latent-TGF β is also expressed in the TME

CRB-601 is a blocking antibody preventing the interaction of these two proteins

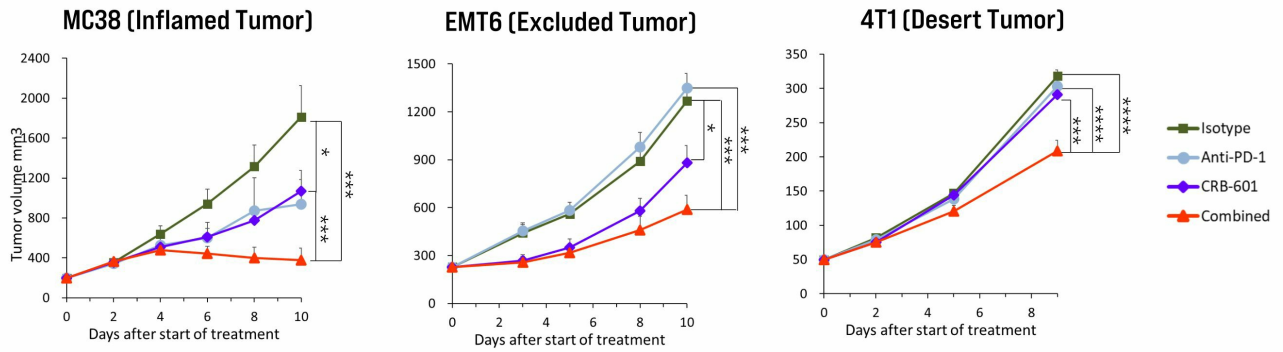


mAbs targeting TGFβ activation are advancing clinically



	CRB-601	PF-06940434	SRK-181	ABBV-151	R66440
MOA	αvβ8	αvβ8	L-TGFβ	GARP (TGFβ1)	L-TGFβ
Clinical Stage	IND in Q4 2023	Phase 1/2 <i>updated July 2023</i>	Phase 1	Phase 2 <i>updated July 2023</i>	Phase 1
Indications	Solid Tumors	Solid Tumors	Solid Tumors	Solid Tumors	Solid Tumors
Type	Monoclonal Antibody	Monoclonal Antibody	Monoclonal Antibody	Monoclonal Antibody	Monoclonal Antibody
ROA	IV	IV	IV	IV	IV

CRB-601 enhances anti-PD-1 therapy in checkpoint inhibition sensitive and resistant murine tumor models



Checkpoint blockade sensitivity



% TGI	MC38	EMT6	4T1
Anti-PD-1	54	-8	6
CRB-601	46	37	10
Combo	89	65	41

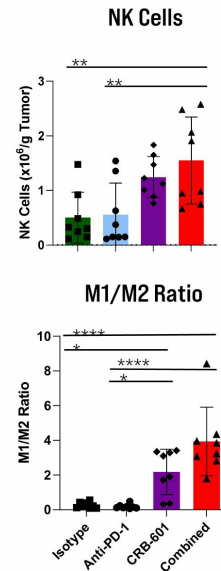
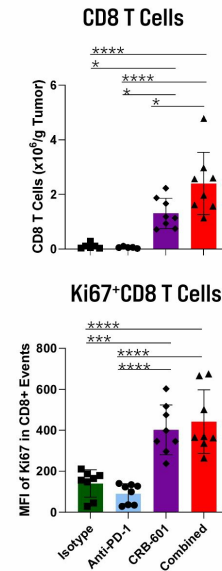
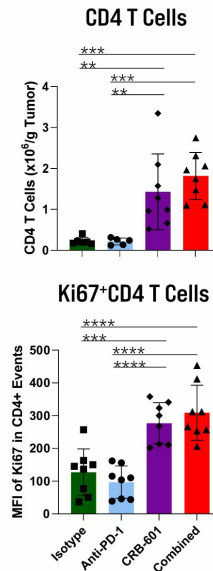
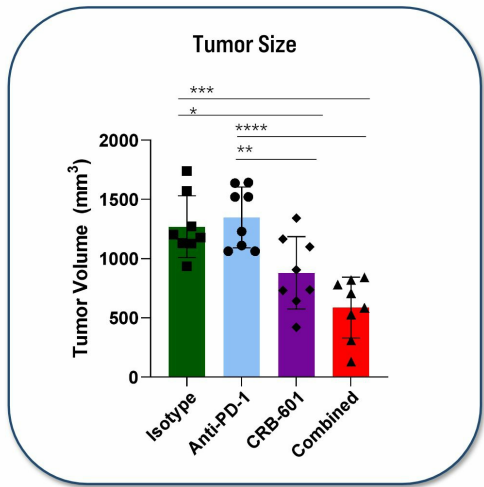
CRB-601: 10 mg/kg BIW
Anti-PD-1: 10 mg/kg BIW
10 animals / group
Animals randomized at 50-80 mm³
Comparisons across arms
 * $p < 0.05$, *** $p < 0.001$, **** $p < 0.0001$

Blockade of $\alpha\beta 8$ in combination with anti-PD-1 increased TIL populations in immune excluded EMT6 tumors

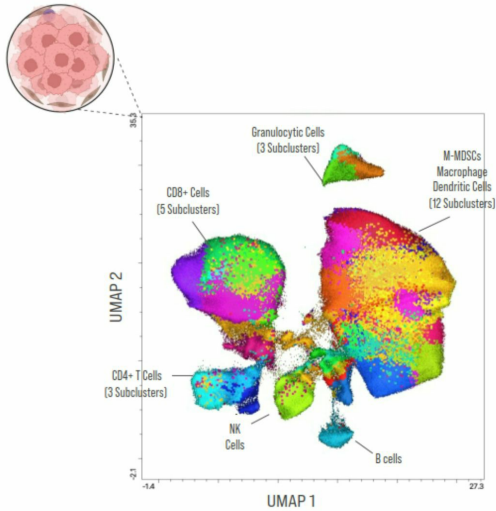


↓ CRB-601, 30 mg/kg, IP
↓ Anti-PD-1, 10 mg/kg, IP

Tumor volume = 200 mm³
(when treatment initiated)

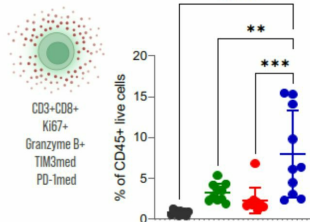


62 * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$; **** $p < 0.0001$
Source(s): Corbus data on file

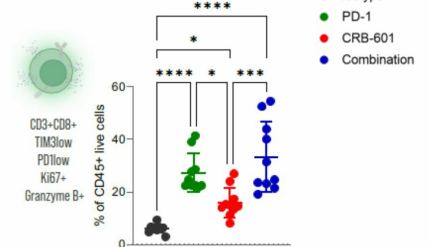


- 22 antibody flow cytometry panel
- 1.25 million live CD45+ cells analyzed
- 31 immune clusters from high dimensional flow analysis
- Sample processing (1) Downsample (2) UMAP (3) X-Sift (4) Euclid (5) Cluster Explorer
- Animals have undergone 10 days of treatment.

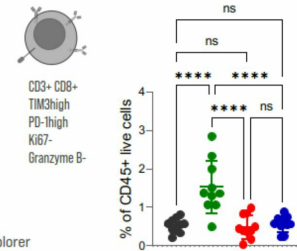
Cytotoxic Effector CD8 T Cells



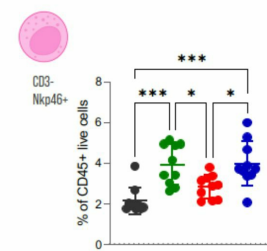
Intermediate Exhausted CD8 T cells



Terminally Exhausted CD8 T cells



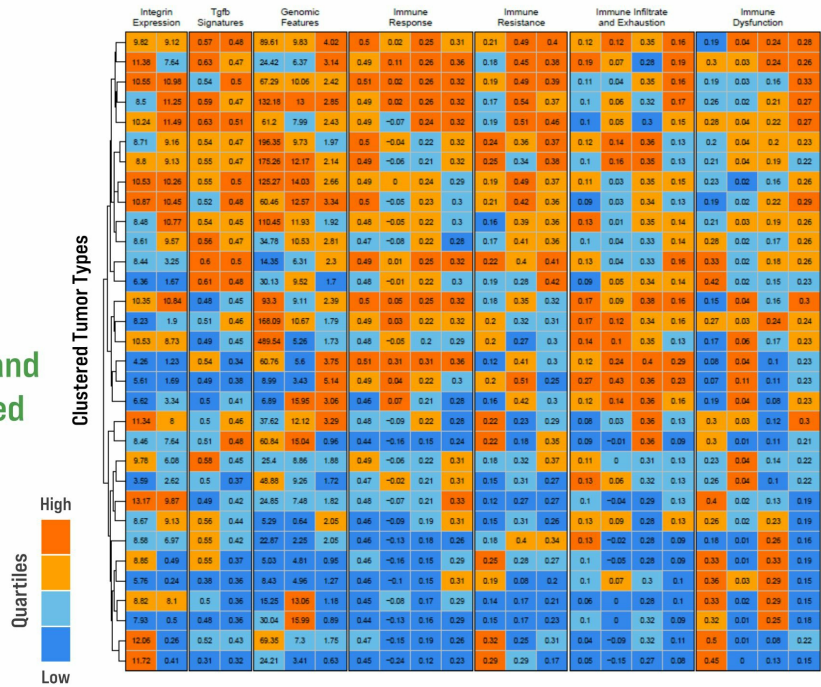
Natural Killer Cells





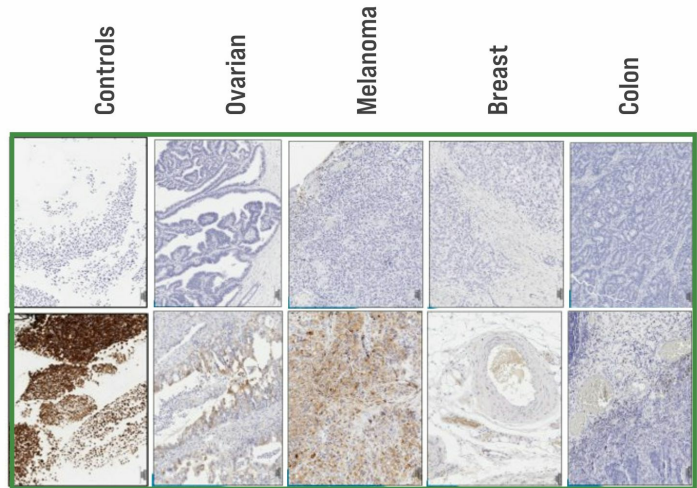
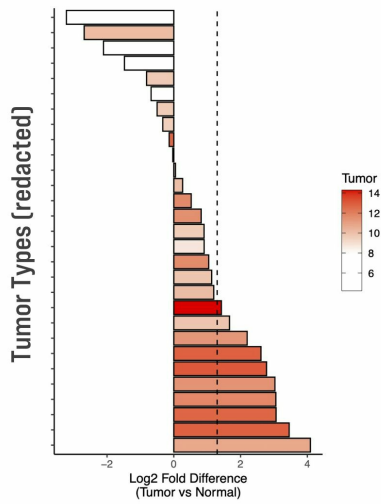
A multi-parametric, immune-focused algorithm has refined indications for CRB-601

The combination of immune features and gene expression profiles have identified 9 indications for clinical priority





Prioritization of indications with differential gene expression vs. normal tissues will emphasize focus on the tumor potential of $\alpha v\beta 8$



Development of a NEW patient enrichment biomarker will assist in enriching for responses and addressing the right immune resistant patient population with CRB-601



- IND cleared in January-2024
- FPI expected H1-2024
- Non-clinical validation of a potential patient selection biomarker in 2023
- Dose escalation and confirmation will be the focus through 2024