
**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): November 04, 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 November 4, 2024, Corbus Pharmaceuticals Holdings, Inc. (the “Company”) issued a press release announcing pre-clinical data for CRB-913 that is being presented at Obesity Week 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.

The Company is presenting new pre-clinical data for CRB-913 at Obesity Week 2024. CRB-913 is a second-generation highly peripherally restricted CB1 receptor inverse agonist designed to treat obesity. The Company is currently conducting IND-enabling studies and expects to treat the first patient in a Phase 1 study in the first quarter of 2025.

Key findings:

- CRB-913 brain levels (both C_{max} and AUC) were 15-fold lower than monlunabant at the same dose in mice.
- Plasma-to-brain ratio for CRB-913 was 10 times higher than monlunabant and 50 times higher than rimonabant at the same dose.
- CRB-913 demonstrated a wide dose response weight loss curve in diet-induced obesity (“DIO”) mice ranging from 5 mg/kg/day to 80 mg/kg/day with no plateauing effect and reaching a weight loss of 31% by day 19. Extending the dosing at 80 mg/kg/day to 28 days resulted in an additional weight loss reaching 38%.
- Allometrically, this dose range corresponds to human-equivalent doses of 30 mg/day to 450 mg/day.
- A first-of-its-kind experimental protocol in DIO mice demonstrated that weight loss induced by an incretin analog (semaglutide) can be maintained post withdrawal by replacing it with a CB1 inverse agonist (CRB-913) whereas replacement of semaglutide with vehicle led to a rapid and complete regain of weight.
- DEXA-scanning data revealed that switching from semaglutide to CRB-913 in DIO mice led to additional weight loss that was driven by a doubling in fat percentage reduction compared to the corresponding semaglutide maintenance cohort. This indicates a peripheral effect on fat metabolism not present with semaglutide.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Corbus Pharmaceuticals Holdings, Inc. dated November 4, 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 thereunto duly authorized.

Corbus Pharmaceuticals Holdings, Inc.

Date: November 4, 2024

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

Corbus Pharmaceuticals Presents New CRB-913 Pre-Clinical Data At Obesity Week 2024

- CRB-913 brain levels are 15-fold lower than monlunabant in lean mice
- Dose-response demonstrated for a range of 5 to 80 mg/kg/day achieving up to 38% weight loss in DIO mice
- Semaglutide treatment followed by its replacement with CRB-913 demonstrated continued weight loss in DIO mice
- Switching from semaglutide to CRB-913 led to a doubling of fat loss in DIO mice

Norwood, MA, November 4, 2024 (GLOBE NEWSWIRE) -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), an oncology and obesity company with a diversified portfolio, presents new pre-clinical data at Obesity Week 2024 further characterizing CRB-913, its highly peripherally restricted CB1 inverse agonist. The data are being presented as a Poster Presentation titled: "Induction and Maintenance Regimens with CB1 Inverse Agonist CRB-913 and Semaglutide in DIO Mice".

Key findings:

- CRB-913 brain levels (both C_{max} and AUC) were 15-fold lower than monlunabant at the same dose in mice.
- Plasma-to-brain ratio for CRB-913 was 10 times higher than monlunabant and 50 times higher than rimonabant at the same dose.
- CRB-913 demonstrated a wide dose response weight loss curve in DIO mice ranging from 5 mg/kg/day to 80 mg/kg/day with no plateauing effect and reaching a weight loss of 31% by day 19. Extending the dosing at 80 mg/kg/day to 28 days resulted in an additional weight loss reaching 38%.
- Allometrically, this dose range corresponds to human-equivalent doses of 30 mg/day to 450 mg/day.
- A first-of-its-kind experimental protocol in DIO mice demonstrated that weight loss induced by an incretin analog (semaglutide) can be maintained post withdrawal by replacing it with a CB1 inverse agonist (CRB-913) whereas replacement of semaglutide with vehicle led to a rapid and complete regain of weight.
- DEXA-scanning data revealed that switching from semaglutide to CRB-913 in DIO mice led to additional weight loss that was driven by a doubling in fat percentage reduction compared to the corresponding semaglutide maintenance cohort. This indicates a peripheral effect on fat metabolism not present with semaglutide.

"This work adds noteworthy new data to the pre-clinical characterization of CRB-913 and provides important context in comparison to monlunabant" said Yuval Cohen, PhD, CEO of Corbus. "It provides further evidence in support of CRB-913 as a markedly more peripherally restricted CB1 inverse agonist than monlunabant and suggests potential clinical use both as a monotherapy as well as a maintenance therapy post incretin analog induction treatment. This is in addition to our previously published work Morningstar et al, Obesity Aug 2023 showing that CRB-913 provides additive weight loss when combined with incretin analogs in DIO mice. The totality of this body of work provides insight into potentially three separate clinical usages: monotherapy, combination therapy and an induction/maintenance therapy."

CRB-913 is on schedule to begin a Phase 1 clinical study in Q1 of 2025.

About Corbus

Corbus Pharmaceuticals Holdings, Inc. is an oncology and obesity 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 receptor 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 X, 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 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

LifeSci Advisors, LLC

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Exhibit 99.2

CORBUS[™]
PHARMACEUTICALS



Corporate Presentation

November 4, 2024

Connecting Innovation to Purpose

NASDAQ: CRBP

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 trial results, product development, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities, including timing or completion of trials and presentation of data 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, 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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Investment Summary

CRB-701

Nectin-4 targeting ADC for treatment of solid tumors

CRB-913

Oral CB1R inverse agonist to treat obesity

CRB-601

TGF β blocker Anti- α v β 8 integrin mAb for treatment of solid tumors

\$147M

Cash, cash equivalents and investments as of June 30, 2024. Approximately 11.5M Common Shares Outstanding (~12.5M Fully-Diluted Shares)

A Diversified Pipeline with Differentiated Clinical Risk Profiles

Therapy	Disease Indication	Sponsor	Pre-Clinical	Phase 1	Phase 2	Phase 3	Milestones
Next-Generation Nectin-4 targeting ADC							
CRB-701 Next-generation Nectin-4 targeting ADC	Nectin-4 positive solid tumors	CSPC (China)	[Progress bar: ~75%]				Multiple Cohorts Expanding
		Corbus (US + Europe)	[Progress bar: ~50%]				Enrollment for Dose Escalation Stage Completed
Anti-Integrin mAb							
CRB-601 Anti- α v β 8 mAb (TGF β -targeting)	α v β 8 enriched solid tumors	Corbus	[Progress bar: ~25%]				FPI Expected in Q4-2024
Highly peripherally-restricted CB1R inverse agonist							
CRB-913 CB1 inverse agonist	Obesity and related conditions	Corbus	[Progress bar: ~15%]				FPI Expected in Q1-2025



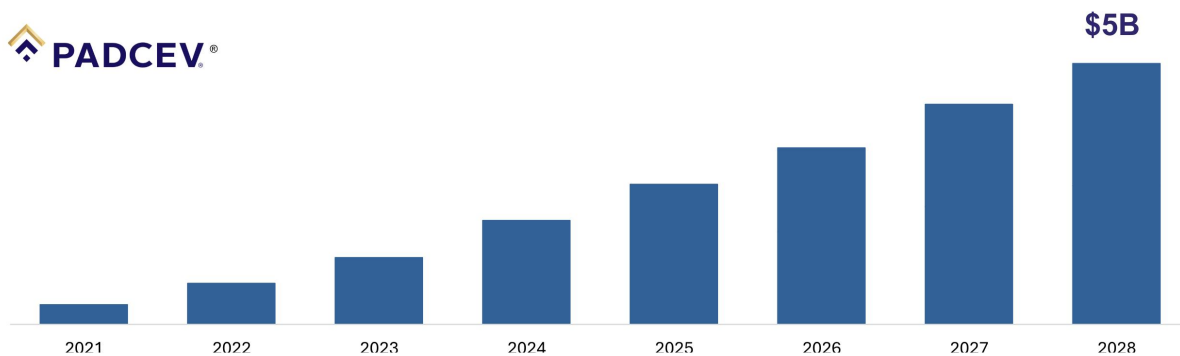
CRB-701

Next Generation
Nectin-4 Targeting ADC



PADCEV® Projected to Reach Up to ~\$5B in Global Sales by 2028

PADCEV® Global Projected Revenues in UC/Bladder²



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

22nd October 2023¹

Does Tolerability for PADCEV® Impact Clinical Adoption?

PADCEV® Prescribing Information



Duration of Response ~5 months

47%

Rate of Serious Adverse Events (SAEs)



61%
Dose
Interruptions



34%
Dose
Reductions



17%
Dose
Discontinuations

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 (enfortumab vedotin) for injection, for intravenous use Initial U.S. Approval: 2019

WARNING: SERIOUS SKIN REACTIONS

PADCEV can cause severe and fatal cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN).

- 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. (4.1a) (4.1d)

RECENT MAJOR CHANGES

Indications and Usage (1) 4/2023
Dosage and Administration (2.2) 10/2022
Warnings and Precautions (4.1) (4.2) (4.3) (4.4) (4.5) 4/2023

INDICATIONS AND USAGE

PADCEV is a human-derived antibody that selectively inhibits coxsackie integrin.

- as a single agent for the treatment of adult patients with locally advanced or metastatic urothelial cancer who
 - have previously received programmed death receptor 1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy, or
 - are eligible for cytotoxic-containing chemotherapy and have previously received one or more prior lines of therapy. (1)
- in combination with pembrolizumab for the treatment of adult patients with locally advanced or metastatic urothelial cancer who are not eligible for cytotoxic-containing chemotherapy. (2)

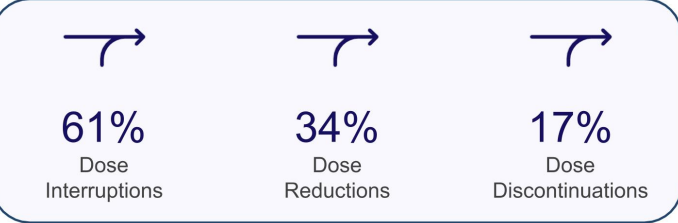
DOSE AND ADMINISTRATION

- For intravenous use. Do not mix with, or administer in the same infusion with, other medicinal products. (2.2)
- The recommended dose of PADCEV as a single agent is 1.25 mg/kg up to a maximum dose of 125 mg given as an intravenous infusion over 30 minutes on Days 1, 8 and 15 of a 21-day cycle until disease progression or unacceptable toxicity. (2.2)
- The recommended dose of PADCEV in combination with pembrolizumab is 1.25 mg/kg up to a maximum dose of 125 mg given as an intravenous infusion over 30 minutes on Days 1 and 8 of a 21-day cycle until disease progression or unacceptable toxicity. (2.2)
- Avoid use in patients with moderate or severe hepatic impairment. (4.4)

ADVERSE REACTIONS

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 4/2023



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

Source(s): PADCEV® Prescribing Information as of Apr 2023.



PADCEV® is Associated with Skin Toxicities and Peripheral Neuropathy

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)].

Adverse Events (% of Patients)

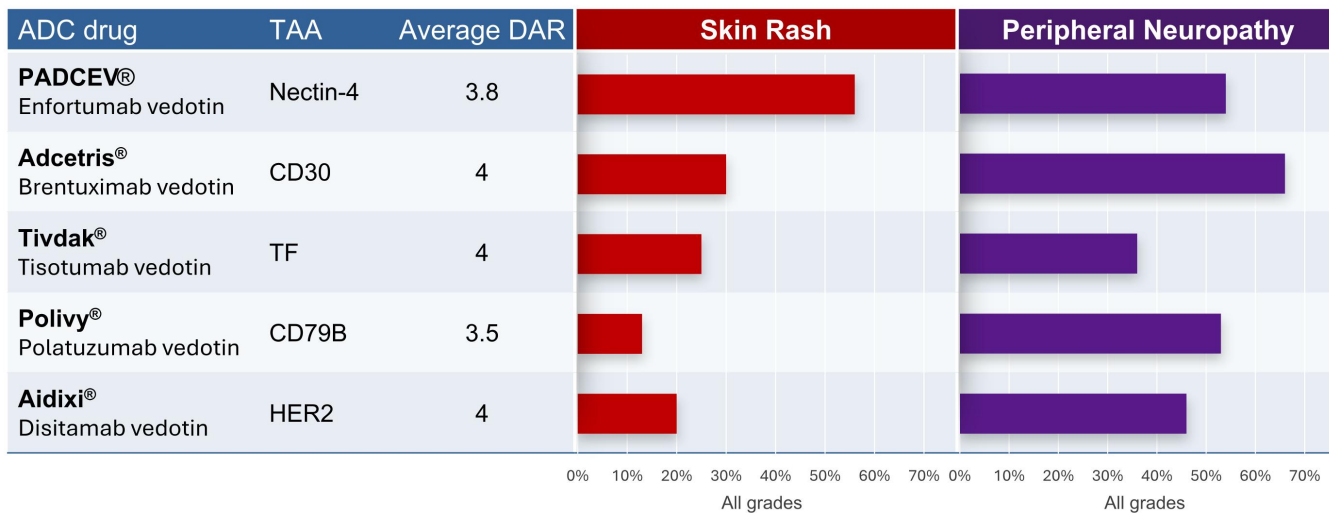
	PADCEV® monotherapy ¹		PADCEV® + Keytruda® ¹	
	All Grades	≥ Gr 3	All Grades	≥ Gr 3
Skin Reactions	58%	14%	70%	17%
Peripheral Neuropathy	53%	5%	67%	7%

- 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

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

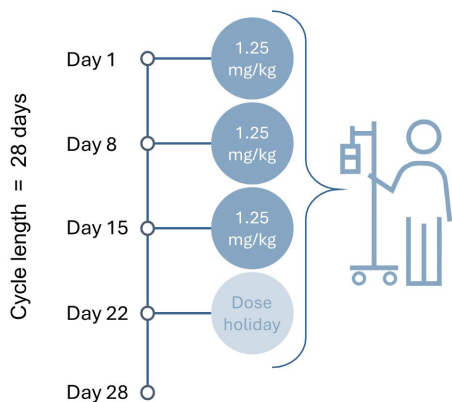


Padcev[®] Val-Cit linker + payload = mc-VC-PABC = Maleimidocaproyl-L-valine-L-citrulline-p-aminobenzyl alcohol p-nitrophenyl carbonate
 Source(s): 1. Fu et al., Science. 2023 doi: 10.1016/j.isci.2023.107778, Padcev[®] Prescribing information, Adcetris[®] Prescribing Information, Tivdak[®] Prescribing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



PADCEV® Requires Frequent Dosing and Real-world Usage Differs from Label

Monotherapy PADCEV®



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

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

Metric	Results (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] %

Designing a Nectin-4 ADC Intended to Address PADCEV[®] Unmet Needs

Toxicity

Nectin-4 targeting ADC for treatment of solid tumors

Compliance

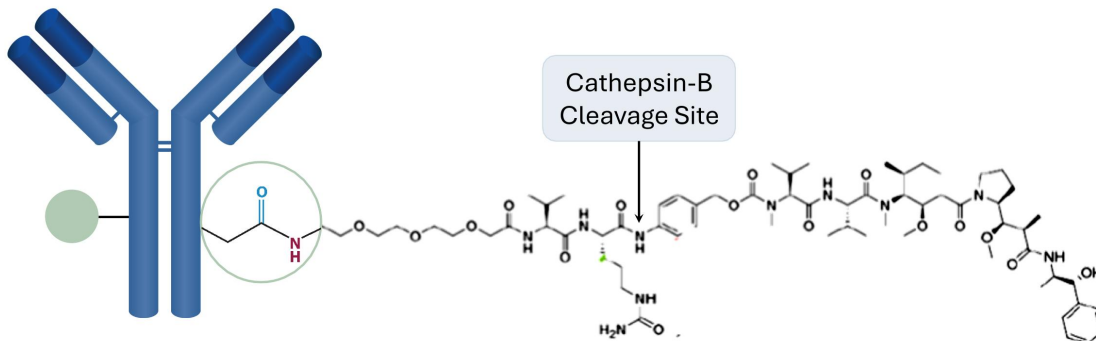
Extend ADC half-life → Reduce dosing frequency

Efficacy

Lower DAR + longer half-life → Dose higher than PADCEV[®]

CRB-701: Next Generation Site-specific Nectin-4 Targeting ADC

Novel Nectin-4 Antibody
ADCC + CDC functionality



Glutamine Focused
Side chain
conjugation

Payload: MMAE
Microtubule disruption

MMAE = Monomethyl auristatin E. ADCC = antibody-dependent cellular cytotoxicity. CDC = complement dependent cytotoxicity
Source(s): Modified image from Corbus data on file; Corbus data on file



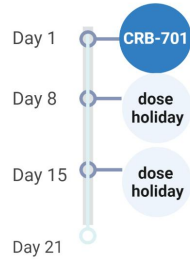
CRB-701: One Dose Every 21 Days Offers Advantages Over More Frequent Dosing

Clinical Cycle Comparison

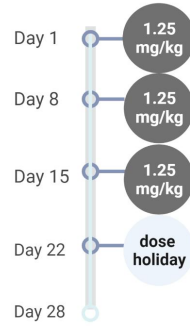
**Patient / Physician
Convenience**

**Combination
Flexibility**

CRB-701



PADCEV®



ASCO 2024 Update: Phase 1 Dose Escalation Study (China)

KEY ELIGIBILITY

Age \geq 18 years
Advanced urothelial carcinoma or Nectin-4 positive
Advanced solid tumors ECOG 0-1
Adequate organ function
No uncontrolled diabetes
No active CNS metastasis

ESCALATION DESIGN

Bayesian Optimal Interval (BOIN) design with accelerated titration at DL-1
IV Q3W over a 21-day cycle

0.2 mg/Kg
0.6 mg/Kg
1.2 mg/Kg
1.8 mg/Kg
2.7 mg/Kg (expanding)
3.6 mg/Kg (expanding)
4.5 mg/Kg (escalating)

KEY ENDPOINTS

Safety/tolerability
Pharmacokinetics
Anti-tumor activity

NEXT STEPS

Continue escalation
PK expansion at 3.6 mg/kg
MTD or RP2D
Specific expansion

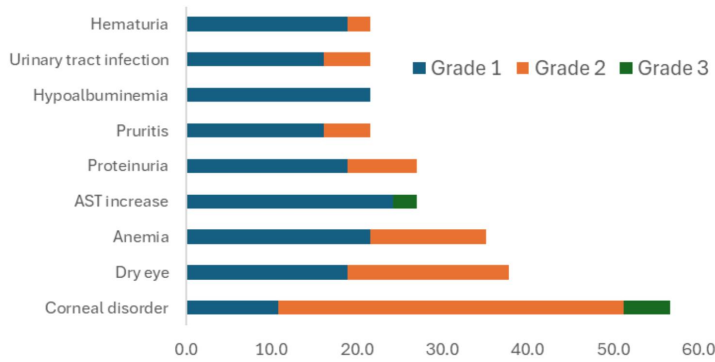
ASCO 2024 Update: Demographics & Key Characteristics

Characteristic	Value
Median age (range)	55 (35, 76)
Sex (M/F)	29.7%, 70.3%
ECOG PS 0,1, missing	8.1%, 89.2%, 2.7%
Weight in Kg mean (range)	59.01 (36.0, 84.9)
Prior therapies median (range)	4.0 (0,10)
Creatinine clearance <60μ mol/L	29.7%
Visceral metastasis (Y/N/missing)	73%, 8.1%, 18.9%
HbA1c <6.5%	97.3%
Primary tumor type	n=37
Urothelial	13
Cervical	15
TNBC/Breast	5
CRC	1
Esophageal	2
Not assigned	1
Corneal and conjunctival disease	16 out of 30 reviewed

An additional 19 patients have been enrolled since January 2024

25 patients evaluable for efficacy assessment at time of ASCO data cut

ASCO 2024 Update: Safety and Dose Modifications



Dose Modifications	n
Discontinuations	0
Reductions	0
Interruptions	1

- CRB-701 continues to be well tolerated with mainly grade 1 or 2 AEs
- Still no DLTs or Grade 4 or 5 AEs observed to date including in the 4.5 mg/Kg cohort
- No additional grade 3 treatment related SAEs since ASCO-GU data (January 2024)

ASCO 2024 Update: TEAEs of Special Interest (<20% incidence)

AE of special interest	Grade	Dose (n out of 37)	Notes
Skin rash	3	2.7 mg/Kg (n=1)	Resolved after 8 days (no dose change)
Skin rash	2	3.6mg/kg (n=1)	Resolved after 5 weeks (no dose change)
Skin rash	1	3.6 mg/kg (n=1)	Resolved after 19 days (no dose change)
Peripheral neuropathy	1	3.6 mg/Kg (n=1)	Associated with underlying hypokalemia Resolved after 10 days with K ⁺ therapy No dose reduction or discontinuation
Cornea	3	2.7 mg/Kg (n=1) 3.6 mg/Kg (n=1)	Ocular prophylaxis recently introduced starting at 4.5 mg/Kg 53% of sampled patients at baseline had corneal or conjunctival pathology and were recruited on trial (acceptable per Chinese protocol)

ASCO 2024 Update: Pharmacokinetics

21 Day PK	Comparison	%ADC		%Free MMAE	
		C _{max}	AUC _{0-21d}	C _{max}	AUC _{0-21d}
Enfortumab vedotin (EV) 1.25 mg/Kg Q1Wx3	EV Benchmark	100%	100%	100%	100%

CRB-701

1.2 mg/Kg Q3W	Matched ADC dose	78%	103%	33%	29%
2.7 mg/Kg Q3W	Matched for MMAE dose (DAR)	190%	217%	67%	72%
3.6 mg/Kg Q3W	2.9-fold EV ADC dose	245%	324%	69%	79%
4.5 mg/Kg Q3W	3.6-fold EV ADC dose	287%	428%	62%	64%

- Continuing to indicate differentiation from PADCEV®
- Delivering higher amounts of ADC at the higher doses explored
- Consistently less free MMAE levels across all doses tested to date

Favorable Emerging Safety Profile vs. Nectin-4 ADC Competitors



Bicycle

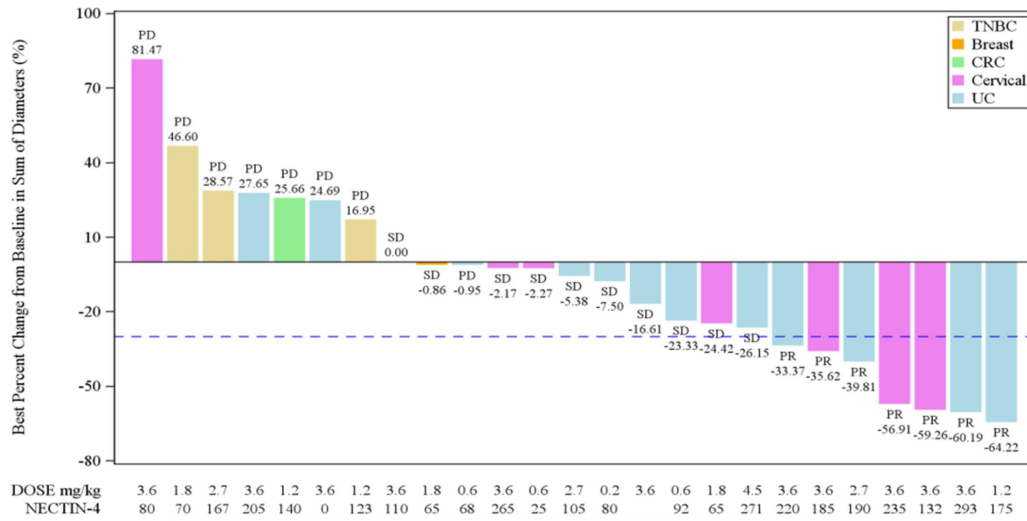


Limitation	Padcev®	BT8009	9MW-2821	CRB-701
Upper dose limit	1.25 mg/Kg ¹	5 mg/m ³	1.25 mg/Kg ⁴	No DLTs up to 4.5mg/Kg ⁵
Schedule	D1, D8, D15 /28 days	Q1W	D1, D8, D15 /28 days	Q3W
≥ Grade 3 AE rate	58% (n=179 of 310) ²	53% (n=24/45) ³	70% ⁶	16% (n=6/37) ⁵
Peripheral neuropathy	49% (n=76/155) ¹	36% (n=16/45) ³	22.5% (n=54/240) ⁴	3% (n=1/37) ⁵
Skin reactions	45% (n=70/155) ¹	18% (n=8/45) ³	30% (n=72/240) ⁴	8% (n=3/37) ⁵
Neutropenia (Gr 3)	6.8% (21/379) ²	4% (n=2/45) ³	27.9% (n=67/240) ⁴	0% ⁵
Dose reduction	30.3% (n=94/310) ²	27% (n=12/45) ³	Not released	0% ⁵
Dose interruptions	46.8% (n=145/310) ²	53% (n=24/45) ³	Not released	2% (n=1/37) ⁵

1. Rosenberg, et al., JCO, 2020 Apr 1; 38(10): 1041–1049. 2. NDA/BLA Multidisciplinary Review and Evaluation BLA 761137 PADCEV™ (enfortumab vedotin-ievx). 3. Torras, O. Reig, et al. "652P BT8009 monotherapy in enfortumab vedotin (EV)-naïve patients (pts) with metastatic urothelial carcinoma (mUC): Updated results of Duravelo-1." Annals of Oncology 35 (2024): S515-S516. 4. Mabwell Announces 9MW2821 Clinical Data and Latest Progress to be presented at 2024 ASCO Annual Meeting. 5. Clinical Update ASCO 2024 Jian Zhang et al Abst 3151. 6. Efficacy and safety of 9MW2821, an antibody-drug conjugate targeting Nectin-4, monotherapy in patients with recurrent or metastatic cervical cancer: A multicenter, open-label, phase I/II study. Yang et al SGO plenary Mar 2024.

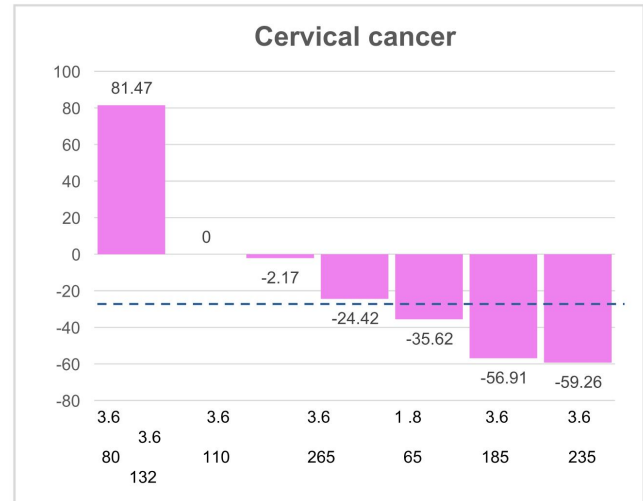
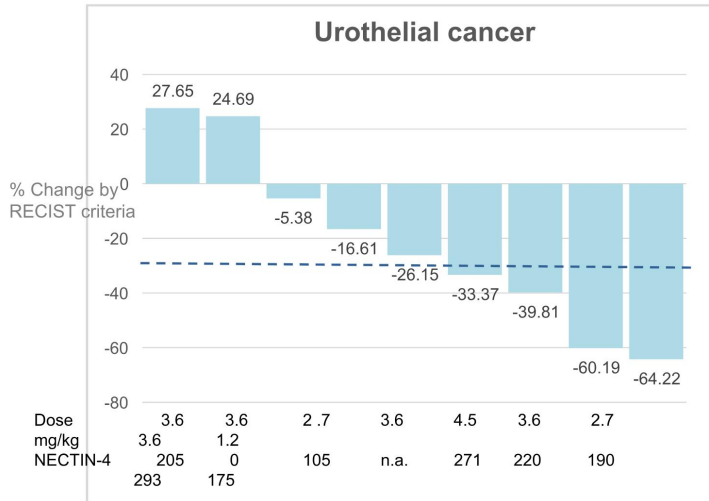


ASCO 2024 Update: Phase 1 Dose Escalation Disease Responses



- Two of seven PRs are ongoing and unconfirmed.
- All of the previous (January ASCO GU data) PRs were confirmed.

ASCO 2024 Update: Disease Response-mUC & Cervical ≥ 1.2 mg/Kg



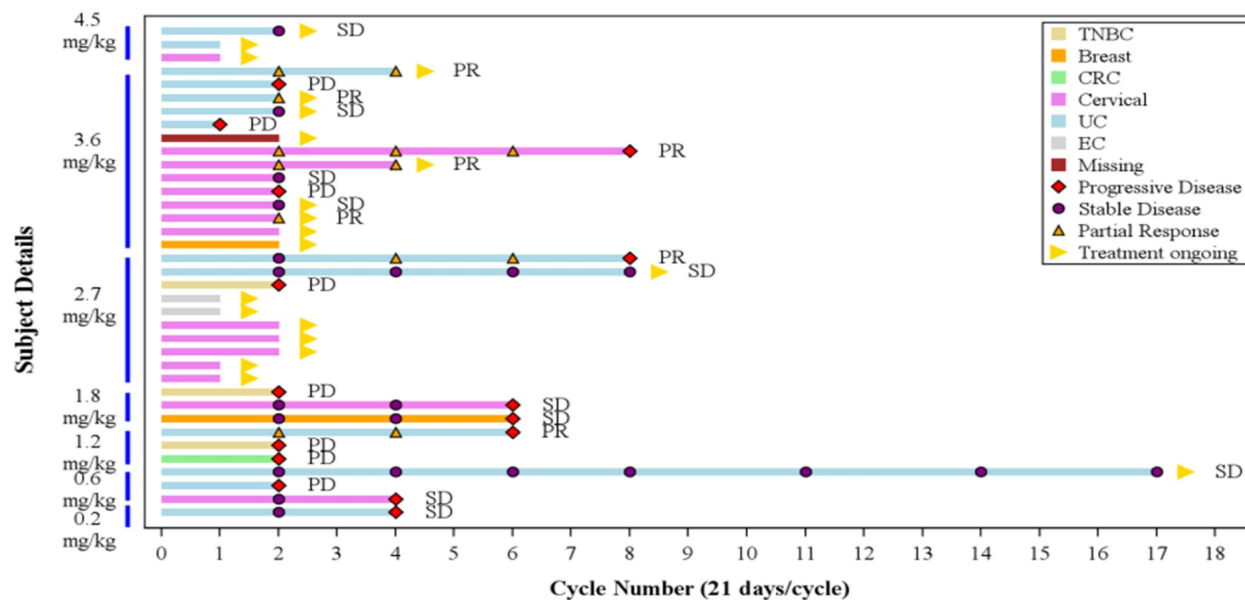
ORR: 44% (4 of 9 at 3.6mg/Kg)

DCR: 78%

ORR: 43% (3 of 7 at 2.6mg and 3.6mg/Kg)

DCR: 86%

ASCO 2024 Update: Swimmer Plots



ASCO 2024 Update: Phase 1 Summary Data

Objective Response Rate in mUC at doses \geq 1.2 mg/KG	44%: 4 out of 9 patients with PR's (1 unconfirmed, DCR-78%)
Objective Response Rate in Cervical at doses \geq 1.2mg/KG	43%: 3 out of 9 patients with PR's (1 unconfirmed, DCR-86%)
Dose for first observed SD	0.2 mg/Kg
Dose for first observed PR	1.2 mg/Kg
Longest observed response duration to date	24 weeks for longest Partial Response =8 cycles 51 weeks for longest Stable Disease =17 cycles
Participants still on CRB-701	21/37 (57%)
First two expansion doses chosen	2.7 and 3.6 mg/Kg (cohorts 5 and 6)

CRB-701: A Differentiated Clinical Development Approach to Competitors

Proprietary insights are driving indication selection for CRB-701

Non-UC Nectin-4 solid tumors

Emerging clinical data from current dose escalation is informative

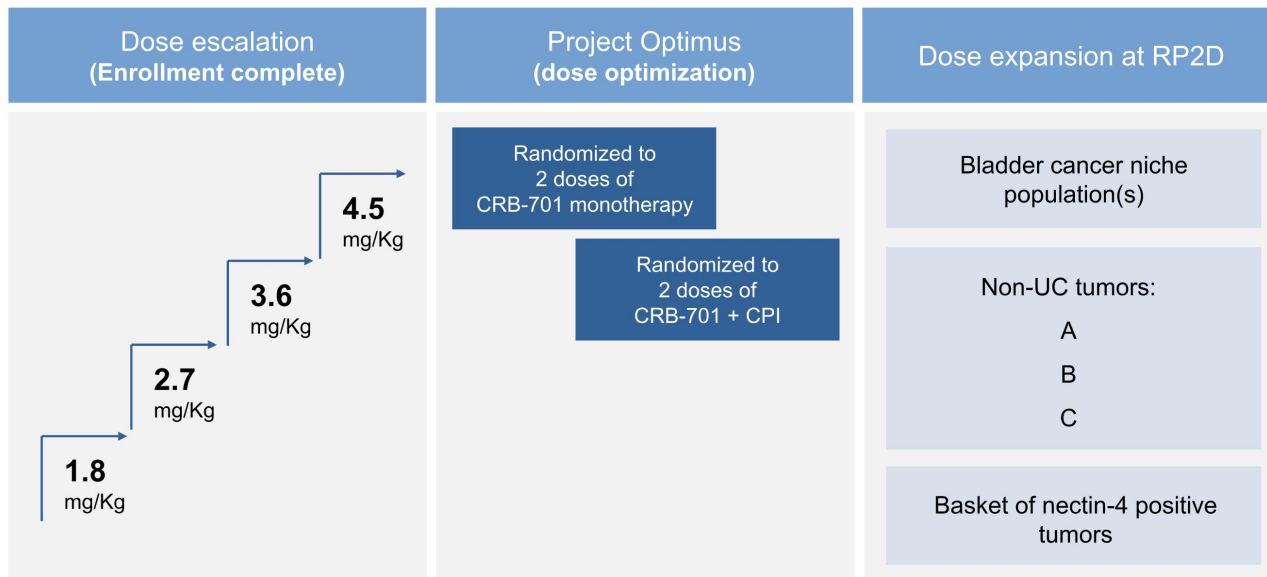
Focus on unexplored Nectin-4 solid tumors starting with **cervical cancer**

mUC

New reality of PADCEV® + Keytruda® 1L therapy

Under-served niche mUC populations remain and are attractive targets

CRB-701-01 Study Design (Corbus)



Validation of Nectin-4 as a Tumor Associated Antigen beyond mUC



H&NSCC (1)



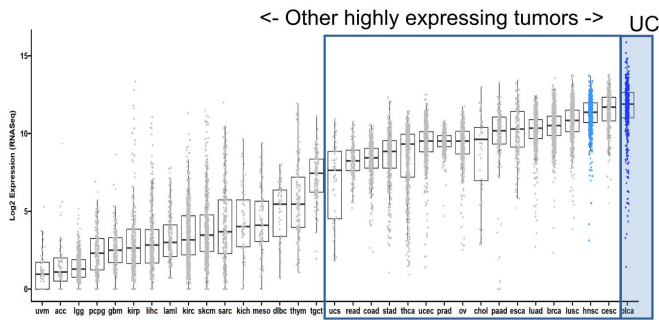
Cervical (2)



June 2023



March 2024



Parameter	Patients (N=46)	Patients (N=37)
Confirmed ORR	11 (23.9%)	15 (40.5%)
CR	1 (2.2%)	1 (2.7%)
PR	10 (21.7%)	14 (37.9%)
DCR	26 (55%)	33 (89.2%)
PFS	3.94 months	Too early
Neutropenia (Grade 3+4)	4.3%	40%
Skin Rash	All grades: 45.7%	Grade 3+4: 17.5%
All grade 3+4 AEs	Not disclosed	70%




PADCEV [®] monotherapy 2019 FDA review (3)	Patients (N=310) 1.25mg/Kg
Skin rash (grade 3+4)	10%
Any Grade 3-4 TEAE	58%

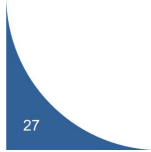
References: 1. https://ascopubs.org/doi/abs/10.1200/JCO.2023.41.16_suppl.6017 2. Efficacy and safety of 9MW2821, an antibody-drug conjugate targeting Nectin-4, monotherapy in patients with recurrent or metastatic cervical cancer: A multicenter, open-label, phase I/II study. SGO 2024 –source www.mabwell.com 3. NDA/BLA Multi-disciplinary review and Evaluation – BLA 761137



Expected Milestones



Q1-2024 	ASCO-2024 	Q4-2024 	Expected Q1-2025
First patient dosed in U.S. dose escalation study	Clinical data update on China dose escalation study	Enrollment complete U.S. dose escalation study	Present U.S. dose escalation data



Competitive Landscape in Cervical Cancer

	Tivdak innovaTV-301(2) N=502 Median prior Tx=2	Tivdak initial approval(1) N=101 Median prior Tx=1	Mabwell (3) N=53 Cervical N=240 safety	CRB-701 N=37
ORR	17.8% (TV) vs 5.2% (Chemo) (TV: CR 2.4%, PR 15.4%)	23.8% CR 7% PR17%	35.8% (cORR30.2%)	Around 40-45%
Ocular adverse events	50.4% (34% Asian population)	54.5% (Asian 2% White 95%)	Not reported	67% (100% Asian population).
Discontinuations	5.6% Ocular and neuropathy	13% Ocular and neuropathy	2.9%	0% ASCO 2024
Dose reductions	n.a.	23% overall of which 17% were Ocular (9% 'conjunctival'+ 8% 'corneal') + 6% were neuropathy and/or 'other'	7.9% (54.2% interruption rate)	0% (5.4% ocular grade 3 events would have had dose reductions under western protocol)
All AEs (grade ≥3)	TRAE 87.6% (29.2%)	(Any ≥grade 3 =60%)	Est. 70% (SAE-related 25%)	83.8% TEAE (16.2%)

Cervical Cancer: Commercial Opportunity for CRB-701

- **14,000** new cervical cases in U.S. annually with **4,000** deaths¹
- Incidence in U.S. is still growing despite effective HPV vaccination due to:
 - Low HPV screening rates in Asian and Hispanic women, lower vaccination in rural areas and lack of access to insurance in certain patient groups²
 - **39%** of women ages 13-15 remain unvaccinated for HPV (2022 NIH data³)
 - Incidence rate for women ages 30-44 increased by **1.7%** from 2017-2019¹
- Cervical cancer market in U.S. projected to grow to **\$1.8 billion** by 2028⁴
 - Approvals of Keytruda® +chemo with or without Avastin® as first line therapy and Tivdak ® as 2nd line driving growth
- Market opportunity for CRB-701
 - Potential for CRB-701 as a first line therapy in combination with PD-1
 - Favorable safety and efficacy profile emerging versus Tivdak ®-potential to compete as 2nd line monotherapy

1. <https://www.cancer.org/cancer/types/cervical-cancer/about/key-statistics.html>

2. [Study reveals why cervical cancer screening rates are declining, which populations are most affected - UTHealth Houston School of Public Health](#)

3. [HPV Vaccination | Cancer Trends Progress Report](#)

4. [GlobalData Report-Cervical Cancer Global Drug and Market Analysis to 2030](#)

CRB-701: Summary



Emerging clinical safety appears differentiated to PADCEV®



Clinical activity seen in mUC and cervical cancer patients



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



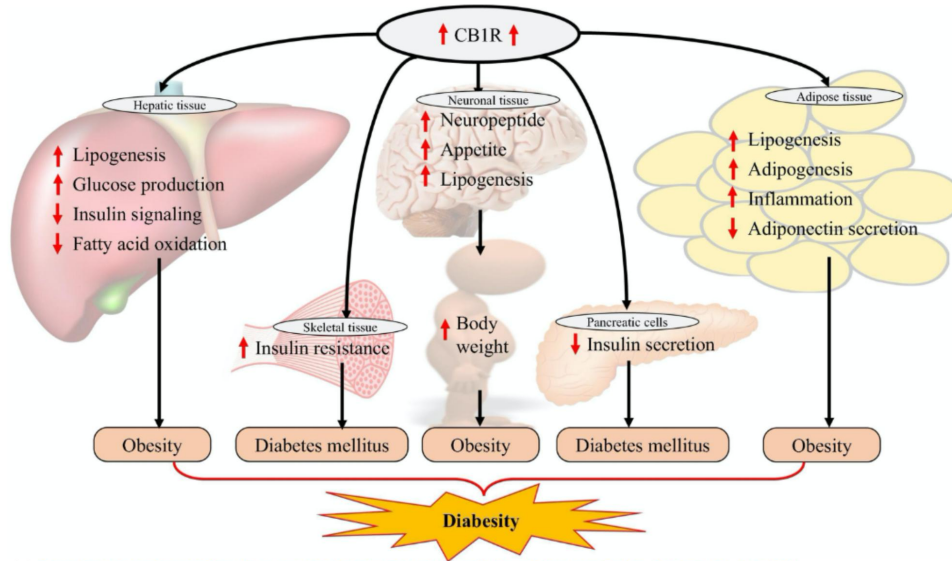
CRB-913

Oral cannabinoid Type-1 inverse agonist for superior incretin therapy in obesity



CB1 is a Well-Understood Receptor in Metabolism

>9K papers in PubMed on CB1 and metabolism







Source(s): [Targeting the endocannabinoid system in diabesity: Fact or fiction?](#), Drug Discovery Today, Deeba et al. Mar 2021.

Next-Generation CB1 Inverse Agonists are Peripherally Restricted

First-generation (2000-2007)

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

	Rimonabant
	Otenabant
	Ibipinabant
	Taranabant

Next-generation (2020 onwards)

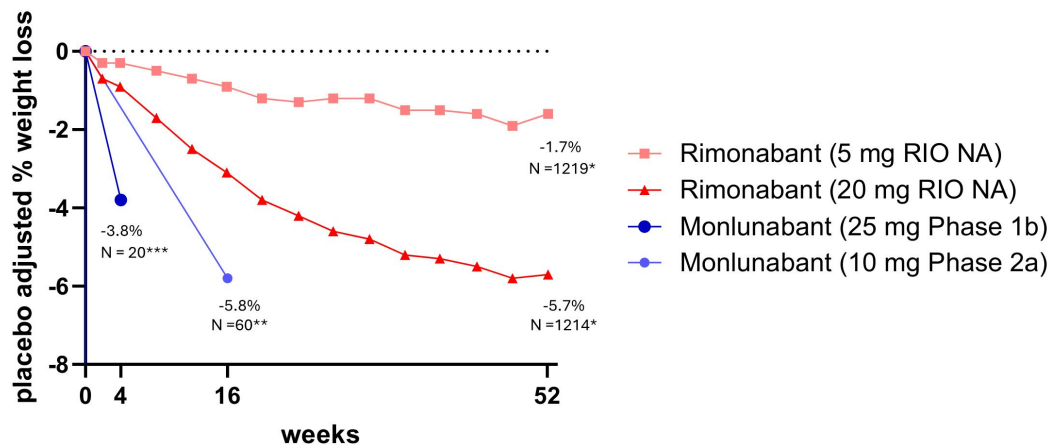
Designed to be peripherally restricted with minimal BBB penetration → avoid safety issues

	→		Monlunabant
			CRB-913



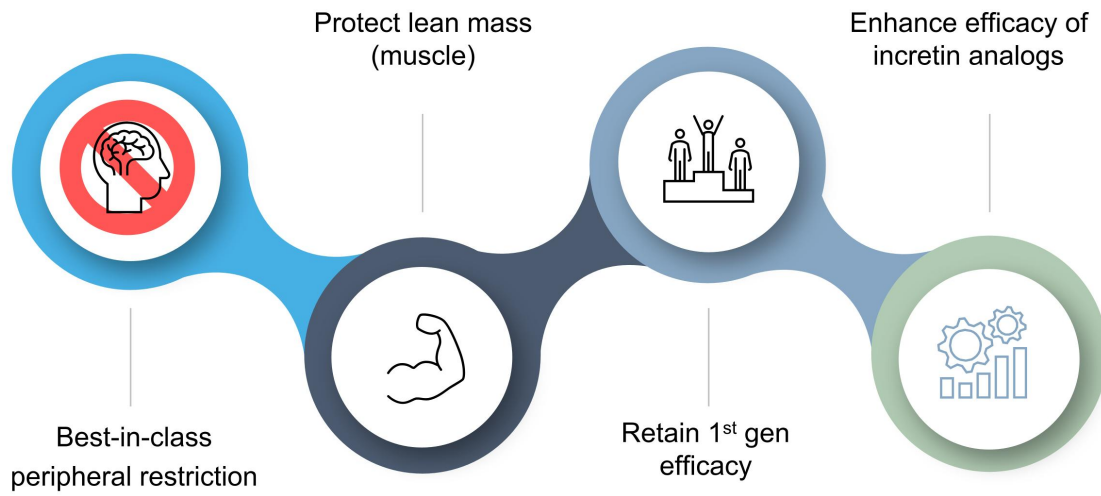
Clinical efficacy of monlunabant vs rimonabant: what do we know?

Placebo-adjusted weight loss cross-trial comparison

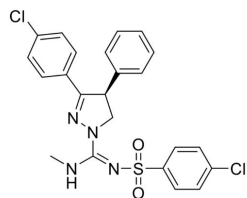


CRB-913: Designed to be a Best-in-class Next Generation CB1 Inverse Agonist

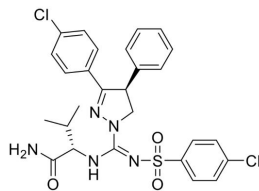
Design Goals



CRB-913 is the Outcome of a Multi-year Medicinal Chemistry Campaign



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

Same backbone as Inversago
compounds (MRI/INV family)

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

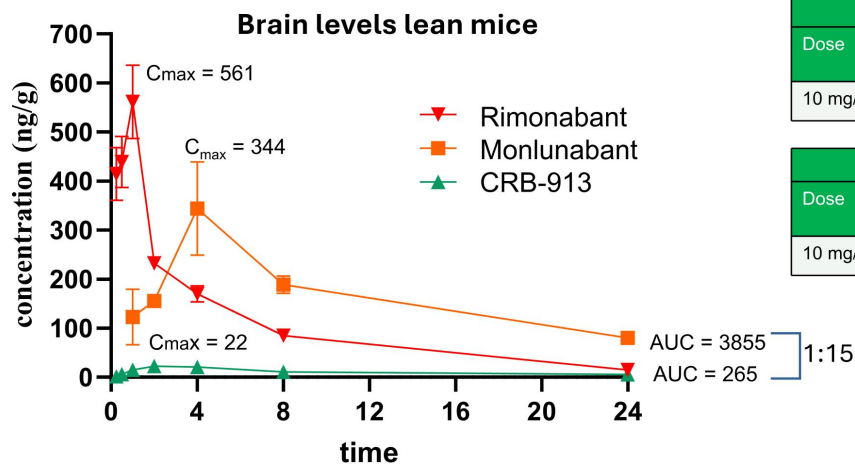
PK profile optimized for TPP

Favorable multi-species bioavailability (>50%)

Lower mfg. cost vs. incretins

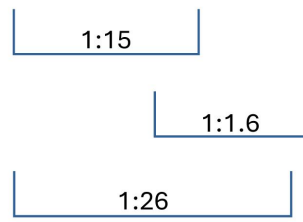
Oral

CRB-913: Higher Degree of Peripheral Restriction Than Monlunabant or Rimonabant



AUC Plasma:Brain ratio			
Dose	CRB-913	Monlunabant	Rimonabant
10 mg/kg	1:50	1:5	1:1

C _{max} Brain concentration (ng/g)			
Dose	CRB-913	Monlunabant	Rimonabant
10 mg/kg	22	344	561



CRB-913: Potential Clinical Usage and supportive pre-clinical data

1. Incretin analog therapy for insensitive/intolerant/high-risk patients

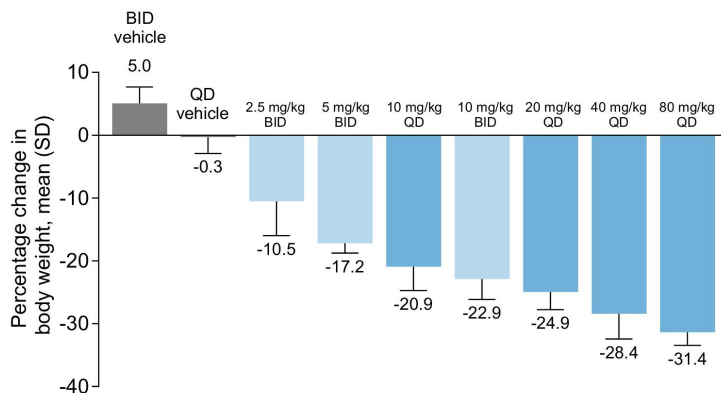
2. Combination with oral incretin agonists → potentially enhances efficacy OR improve tolerability

3. “Induction/maintenance” model: goal to potentially maintain weight loss post incretin analog therapy

CRB-913: Dose response weight loss across wide range in DIO mice



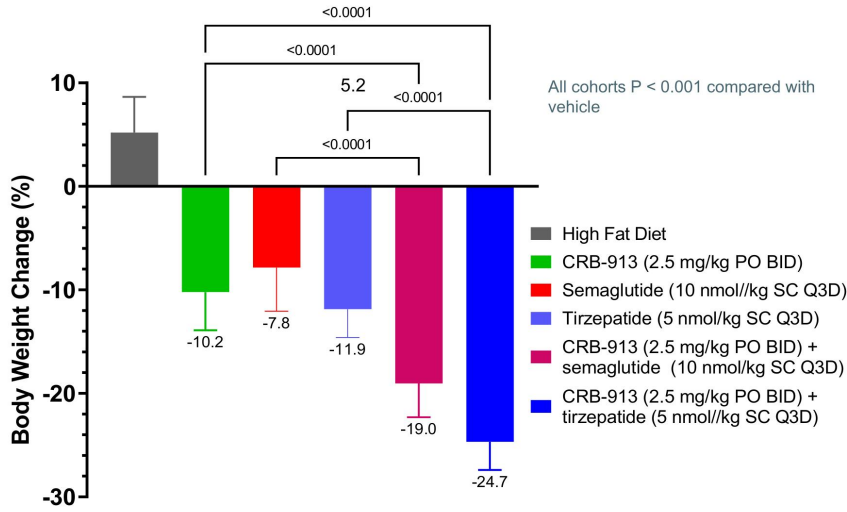
Weight loss (%) by day 19 in DIO mice



- Allometric scaling to humans: 30 mg/day to >450 mg/day
- Top weight loss observed: 38% for 80 mg/kg/day QD on day 28

CRB-913: Enhanced Combo Effect with Semaglutide or Tirzepatide

Body weight change (%) at day 18



OBESITY SYMPOSIUM
Obesity Biology and Integrated Physiology

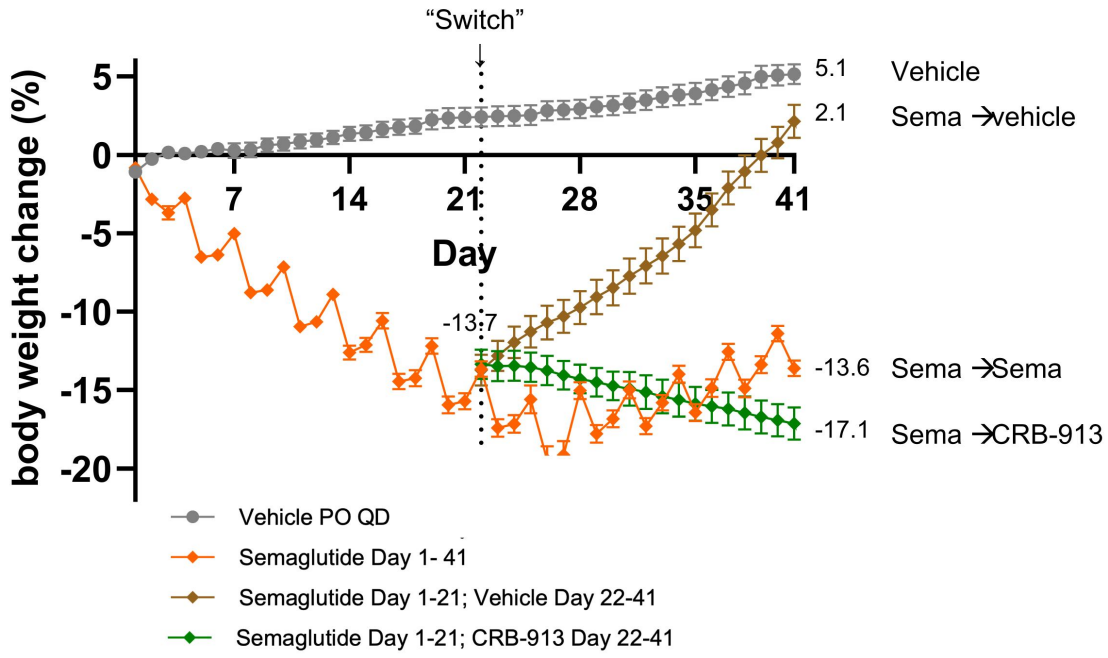
Obesity WILEY

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

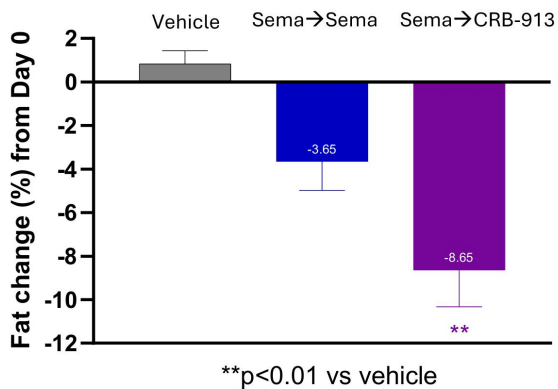
Marshall Morningstar | Andrew Kolodziej | Suzie Ferreira | Tracy Blumen | Rachael Brake | Yuval Cohen

Source(s): Company data on file. 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)

CRB-913: Induction/Maintenance with Semaglutide

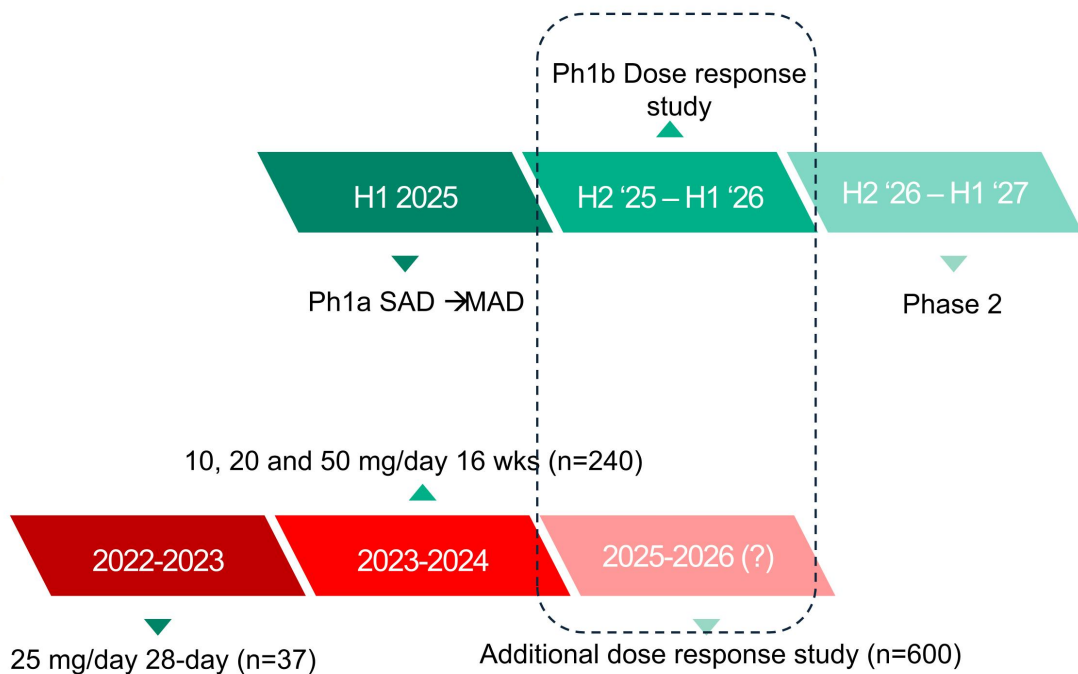


Weight Loss From CRB-913 Driven By More Fat Loss Than Semaglutide



At day 41 (end of study period)			
	Sema → Sema	Sema → CRB-913	Difference
Weight loss (%)	-13.6	-17.1	↑25%
Fat change from baseline	-3.65%	-8.65%	↑x2.3

Clinical Development Pathway To Determination Of Dose Response Curve



Expected Milestones

Produce drug for toxicology and clinical studies	Q2-2024 ✓
Complete toxicology and IND enabling studies	Q4-2024
FPI SAD/MAD	Q1-2025



Leadership
Upcoming Catalysts
Financials



Management Team



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.



Dominic Smethurst, PhD
Chief Medical Officer, MA MRCP

Dr. Smethurst, MA MRCP, joined Corbus as our Chief Medical Officer in February 2024. He most recently served as CMO of Bicycle Therapeutics.



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.

Board of Directors



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 TigeTx.



Winston Kung, MBA Director

More than 20 years of senior financial, business development and investment banking experience; currently CFO of ArriVent. (NASDAQ:AVBP)



Yuval Cohen, PhD Chief Executive Officer, Director

Corbus co-founder and Chief Executive Officer since 2014. Previous 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; Former 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. CMO of BridgeBio Oncology Therapeutics and former CMO of BeiGene.

Expected Corporate Milestones



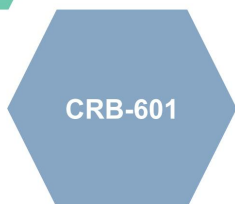
Complete Enrollment in U.S. dose escalation study: Q4-2024



Present U.S. dose escalation data: Q1-2025



First patient dosed: Q1-2025



First patient dosed: Q4-2024

Investment Summary

CRB-701

Nectin-4 targeting ADC for treatment of solid tumors

CRB-913

Oral CB1R inverse agonist to treat obesity

CRB-601

TGF β blocker Anti- α v β 8 integrin mAb for treatment of solid tumors

\$147M

Cash, cash equivalents and investments as of June 30, 2024. Approximately 11.5M Common Shares Outstanding (12.5M Fully-Diluted Shares)



Corporate Presentation

October 2024

Connecting Innovation to Purpose

NASDAQ: CRBP



Appendix

CRB-601

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



CRB-601 has the Potential to Enhance Checkpoint Inhibition



Novel mechanism to target TGF β in the tumor microenvironment



Focus on adopting a precision-targeted approach



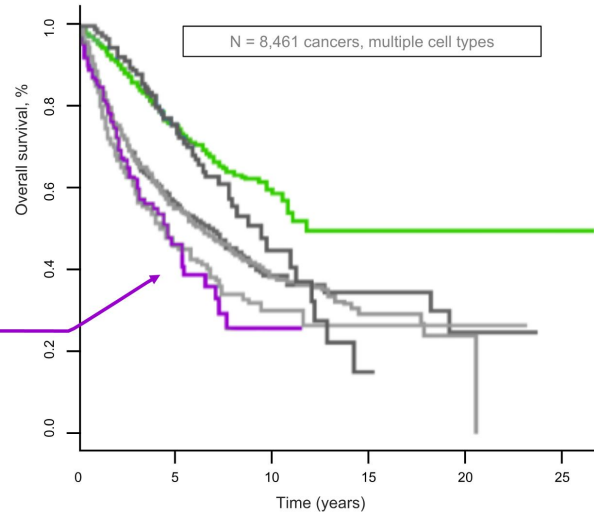
Large opportunity potential if POC is validated

TGFβ predicts poor clinical outcomes in a subset of cancer patients

Immunogenomic subtypes in cancer

- C1 WOUND HEALING
- C2 INF-γ DOMINANT
- C3 INFLAMMATORY
- C4 LYMPHOCYTE DEPLETED
- C5 IMMUNOLOGICALLY QUIET
- C6 TGFβ DOMINANT

TGFβ predominance gene signature



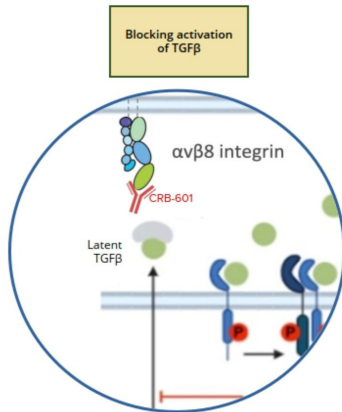
Gene expression, immune cell quantification & network mapping

- 33 different cancer types / 8,000+ tumors

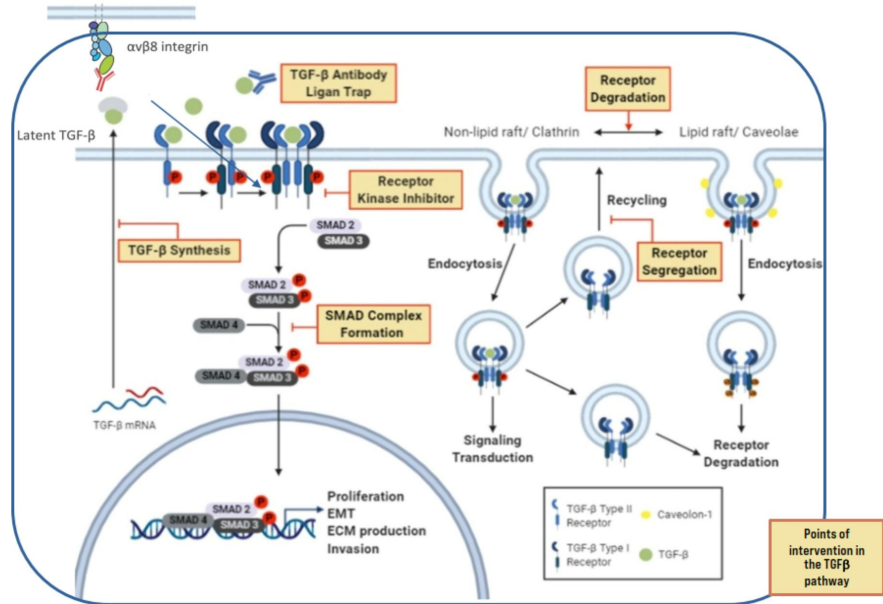
Targeting the Integrin $\alpha\beta 8$ Represents a Novel Approach to Regulating TGF β

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 $\alpha\beta 8$

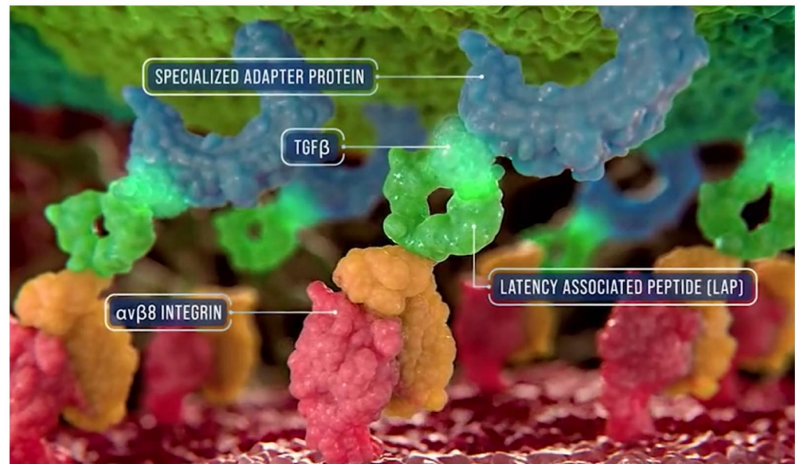


CRB-601 is Targeting Latent -TGF β by Blocking the Integrin $\alpha\text{v}\beta\text{8}$

The integrin $\alpha\text{v}\beta\text{8}$ 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

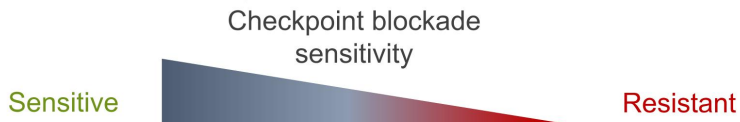
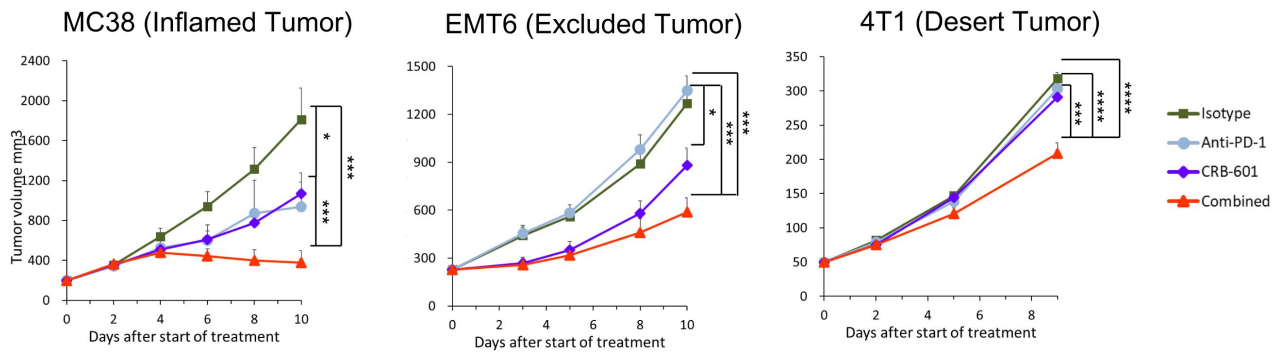


mAbs targeting TGFβ activation in the clinic



	CRB-601	PF-06940434	SRK-181	ABBV-151	RG6440
MOA	αvβ8	αvβ8	L-TGFβ	GARP (TGFβ1)	L-TGFβ
Clinical Stage	IND Cleared FPI Q4-2024	Phase 1/2	Phase 1	Phase 2	Phase 1
Indications	Solid Tumors	Solid Tumors	Solid Tumors	HCC	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

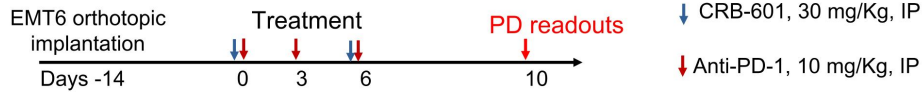


% TGI	MC38	EMT6	4T1
Anti-PD-1	54	-8	6
CRB-601	46	37	10
Combo	89	65	41

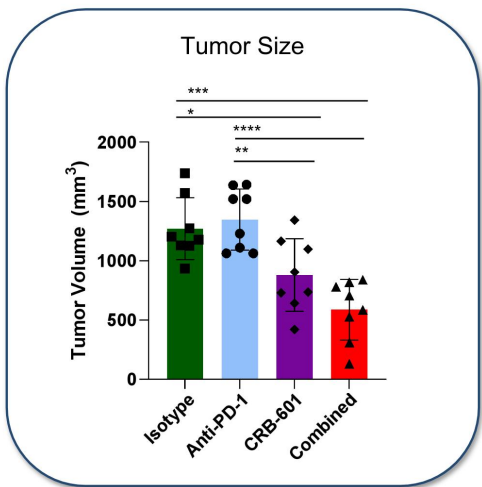
CRB-601: 10 mg/kg BIW
 Anti-PD-1: 10 mg/kg BIW
 10 animals / group
 Animals randomized at 50-80 mm³
 Comparisons across arms
 *p<0.05, ***p<0.001, ****p<0.0001



Blockade of $\alpha\beta 8$ in Combination with anti-PD-1 Increased TIL Populations in Immune Excluded EMT6 Tumors

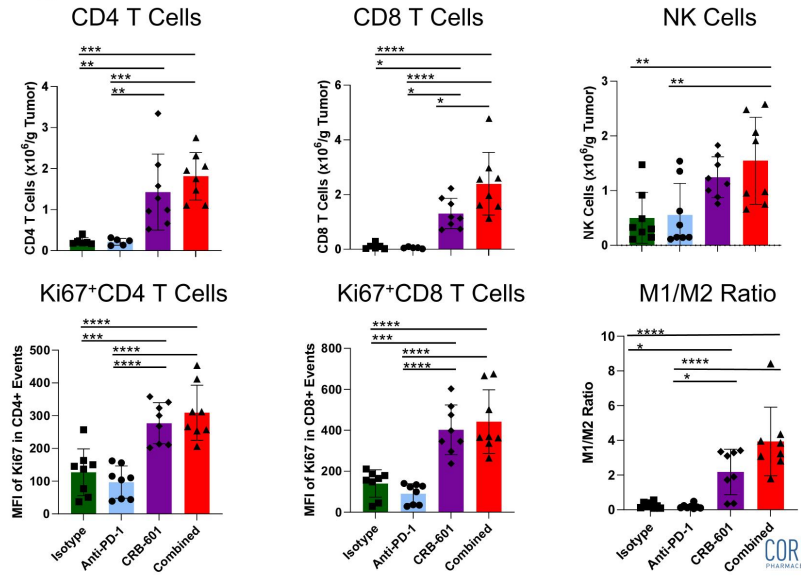


Tumor volume = 200 mm³ (when treatment initiated)

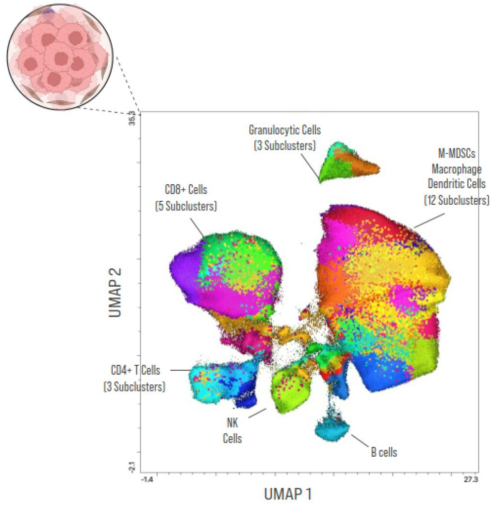


*p<0.05; **p<0.01; ***p<0.001; ****p<0.0001

Source(s): Corbus data on file

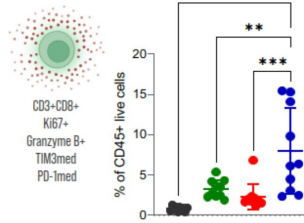


CRB-601 Reshapes The Landscape Of Effector T and NK Cells in MC38 Tumors

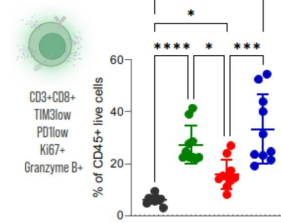


- 22 antibody flow cytometry panel
- 1.25 million live CD45+ cells analyzed
- 31 immune clusters from high dimensional flow analysis
- Sample processing (1) Downsample (2) UMAP (3) X-Sift (4) Euclid (5) Cluster Explorer
- Animals have undergone 10 days of treatment.

Cytotoxic Effector CD8 T Cells

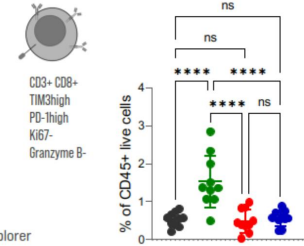


Intermediate Exhausted CD8 T cells

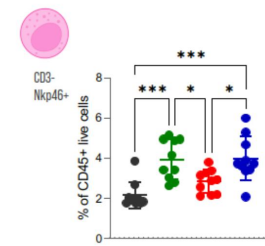


- Isotype
- PD-1
- CRB-601
- Combination

Terminally Exhausted CD8 T cells



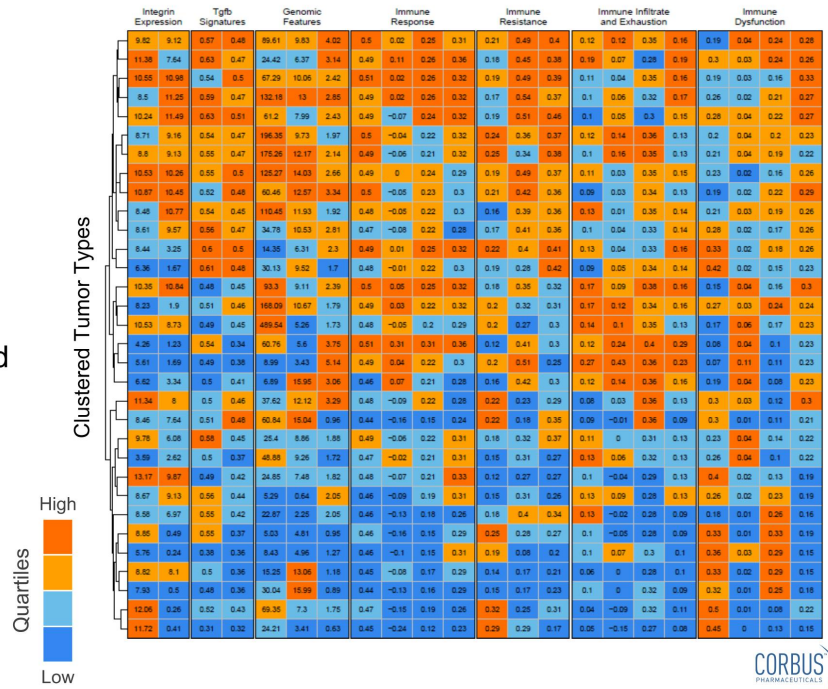
Natural Killer Cells



Applying a Proprietary Algorithm To Define The Clinical Focus for CRB-601

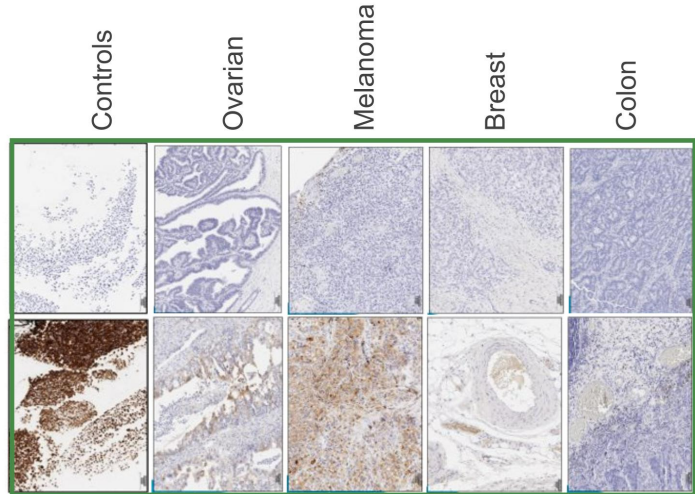
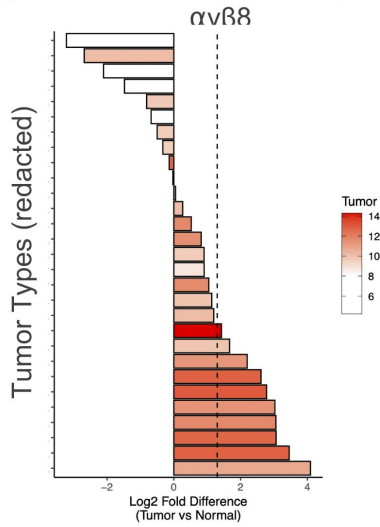
A multi-parametric, immune-focused algorithm has refined indications for CRB-601

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



Patient Selection Strategies Will Enhance the Probability of Success

Prioritization of indications with differential gene expression vs. normal tissues will emphasize focus on the tumor potential of



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

Expected Milestones

IND cleared	January 2024	✓
First patient dosed	Q4-2024	
Dose escalation and confirmation	1st Half of 2025	