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): June 2, 2019

CORVUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37719**	**46-4670809**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

863 Mitten Road, Suite 102
Burlingame, CA 94010
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 900-4520

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company [X]

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. [X]

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, Par Value $0.0001 per share	CRVS	Nasdaq Global Market

Item 8.01 Other Events.

On June 2, 2019, Corvus Pharmaceuticals, Inc. ("Corvus" or the "Company") announced initial results from its Phase 1/1b trial of CPI-006, the Company's anti-CD73 antibody. The initial clinical data from the dose escalation study showed a trend toward longer disease control with higher doses of CPI-006, and enhanced disease control with CPI-006 in combination with ciforadenant (CPI-444) compared with monotherapy, in patients with advanced, refractory cancer.

The CPI-006 Phase 1/1b study is currently enrolling patients with a variety of cancers who have failed standard therapies. It is designed to select the dose and evaluate the safety, pharmacokinetics, immune biomarkers and efficacy of CPI-006 as a single agent; in combination with ciforadenant (CPI-444), a selective and potent inhibitor of the adenosine A2A receptor; and in combination with pembrolizumab, an anti-PD-1 antibody. The efficacy endpoints are complete response (CR), partial response (PR), disease control rate, duration of response, progression-free survival and overall survival.

The initial results are from the first two arms of the CPI-006 Phase 1/1b study, which are evaluating CPI-006 as a single agent and in combination with ciforadenant, and include data from 12 patients who received CPI-006 given intravenously as monotherapy (at doses of 1, 3, 6 or 12 mg/kg every 21 days) and eight patients who received the combination treatment of CPI-006 (1, 3 or 6 mg/kg every 21 days plus a fixed dose of ciforadenant 100 mg twice daily). These patients had advanced, refractory disease (four had colorectal cancer, four had pancreatic cancer, four had prostate cancer, three had head and neck cancer, three had renal cell cancer, one had bladder cancer and one had sarcoma), and had failed a median of four prior therapies. The key highlights from the initial CPI-006 clinical results include:

- Pharmacokinetic studies showed a dose-dependent increase in CPI-006 plasma exposure, with doses of 12 mg/kg achieving complete and sustained occupancy of CD73 on peripheral blood lymphocytes.

- Biopsies revealed penetration of CPI-006 and occupancy of CD73 in tumors at doses of 12 mg/kg.

- Infusions of CPI-006 resulted in rapid activation and migration of B lymphocytes with concomitant changes in peripheral blood CD4 to CD8 ratios. These changes are believed to be consistent with trafficking and activation of antigen presenting cells to peripheral lymph nodes. In vitro and in vivo studies revealed increased expression of the activation markers CD69, CD83 and CD25, as well as increases in CD86 and class II MHC (major histocompatibility complex) indicating activation of antigen presenting cells, such as B cells, macrophages and dendritic cells.

- A patient with metastatic prostate cancer that had previously failed multiple anti-androgen therapies and chemotherapy received over 11 cycles (a cycle equals 21 days) of CPI-006 monotherapy at a dose of 6 mg/kg and showed reduction in tumor volume and a reduction in bone pain.

- A trend toward longer disease control was seen in patients treated with doses of 6 mg/kg and higher, doses which achieved sustained target occupancy; combination therapy appeared to enhance disease control.

- For all dose cohorts of monotherapy, four patients had stable disease (two pancreatic, one prostate and one colorectal cancer). No patients receiving 1mg/kg of monotherapy achieved stable disease; all of these patients had disease progression at first evaluation. For the ciforadenant combination cohorts, the follow up period was short; two patients (one pancreatic and one prostate) have stable disease at the lowest dose of 1 mg/kg. Five patients (two monotherapy and three combination) continue on therapy with follow-up of 2-11 treatment cycles.

- CPI-006 was well tolerated at all dose levels, with no dose-limiting toxicities. Grade 1 infusion reactions were detected (N=3 patients) and mitigated with premedication with acetaminophen and antihistamine. Grade 3 or 4 toxicities included a grade 3 anemia (N=1).

Item 7.01 Regulation FD Disclosure.

On June 2, 2019, the initial results discussed above were presented in an oral session at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago by Jason J. Luke, M.D., principal investigator of the trial and Director of the Cancer Immunotherapeutics Center at UPMC Hillman Cancer Center and Associate Professor of Medicine at the University of Pittsburgh School of Medicine. A copy of the presentation is furnished as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Forward-Looking Statements

To the extent that statements contained herein or in the presentation attached hereto as Exhibit 99.1 are not descriptions of historical facts regarding Corvus, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements related to the potential safety and efficacy of CPI-006 and ciforadenant (CPI-444) and the Company's ability to develop and advance product candidates into and successfully complete preclinical studies and clinical trials, including the Company's Phase 1/1b clinical trial of CPI-006. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's clinical development programs, future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. For a description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see Corvus' reports filed with the Securities and Exchange Commission ("SEC"), including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, filed with the SEC on May 9, 2019, as well as other documents that may be filed by the Company from time to time with the SEC.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Presentation by Jason J. Luke, M.D., principal investigator of the trial and Director of the Cancer Immunotherapeutics Center at UPMC Hillman Cancer Center and Associate Professor of Medicine at the University of Pittsburg School of Medicine, dated June 2, 2019.

SIGNATURES

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

CORVUS PHARMACEUTICALS, INC.

Date: June 3, 2019

By: /s/ Leiv Lea
Leiv Lea
Chief Financial Officer

Immunobiology, Preliminary Safety and Efficacy of CPI-006, an Anti-CD73 Antibody with Immune Modulating Activity, in a Phase 1 Trial in Advanced Cancers

Jason J. Luke*, John D. Powderly II, Jaime R. Merchan, Minal A. Barve, Andrew N. Hotson, Mehrdad Mobasher, Long Kwei, Gabriel Luciano, Joseph J. Buggy, Emily Piccione, Richard A. Miller

University of Chicago Comprehensive Cancer Center, Chicago, IL; Carolina BioOncology Institute, Huntersville, NC; University of Miami, Miami, FL; Mary Crowley Cancer Research Center, Dallas, TX; Corvus Pharmaceuticals Inc, Burlingame, CA

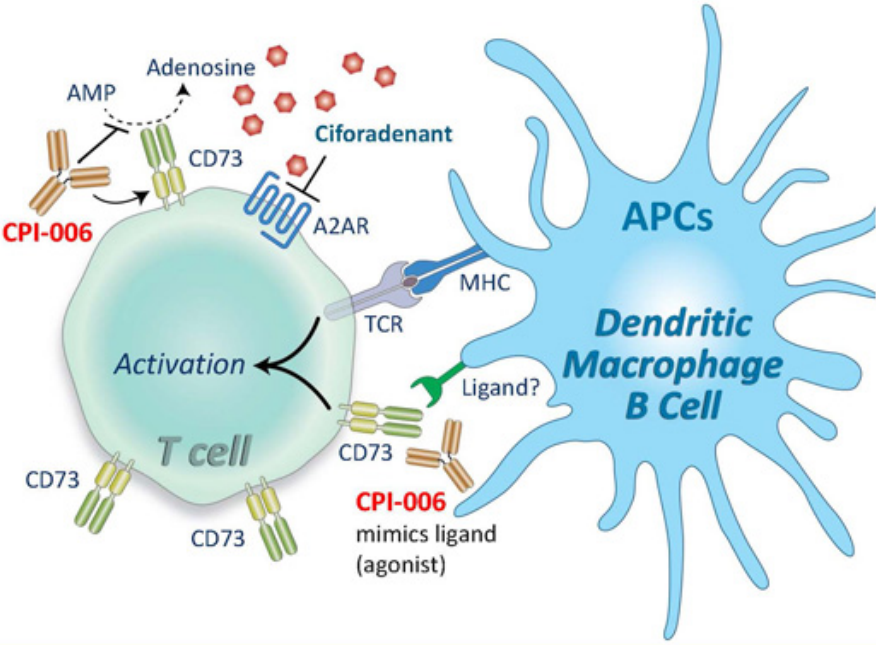
*Currently at University of Pittsburgh Medical Center

PRESENTED AT: 2019 ASCO ANNUAL MEETING #ASCO19

PRESENTED BY: Jason J. Luke, MD

Background

- Adenosine in the tumor microenvironment is immunosuppressive
- CD73 is an ectoenzyme present on many tissues including subsets of T and B cells
  - Converts AMP to adenosine
  - Functions in lymphocyte adhesion, migration and activation*
- CPI-006 is a humanized IgG1 Fcγ receptor deficient anti-CD73 with unique properties
  - Blocks catalytic activity
  - Has agonistic immunomodulatory activity on CD73 positive cells
- Ciforadenant (CPI-444) is an adenosine 2A receptor (A2AR) antagonist with anti-tumor activity in animals and in human clinical trials
  - Adenosine gene signature in tumor correlates with response

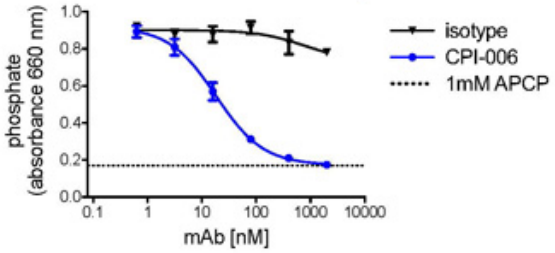


*Resta & Thompson, Cell Signaling, 1997

CPI-006 Blocks CD73 Enzymatic Activity

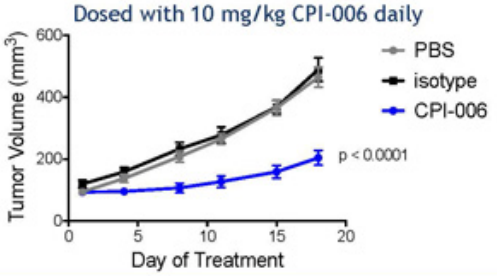
CD73 Catalytic Activity

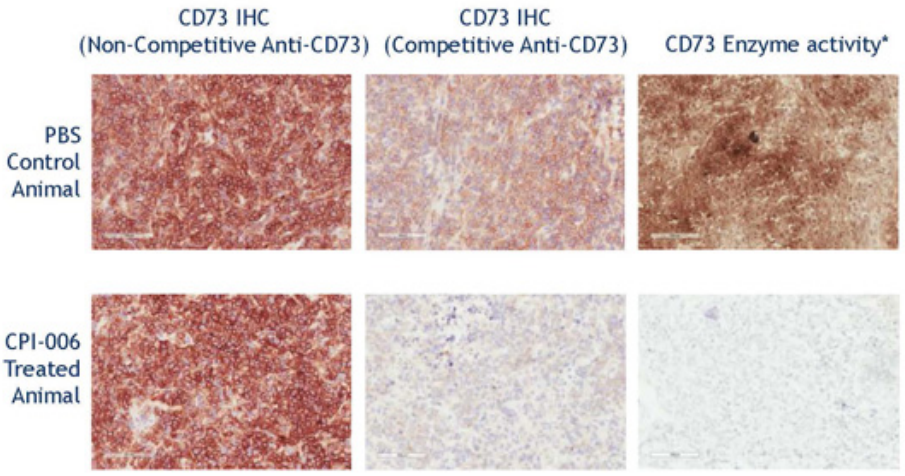
AMP → Adenosine + Phosphate



MDA-MB-231 Xenograft

Dosed with 10 mg/kg CPI-006 daily

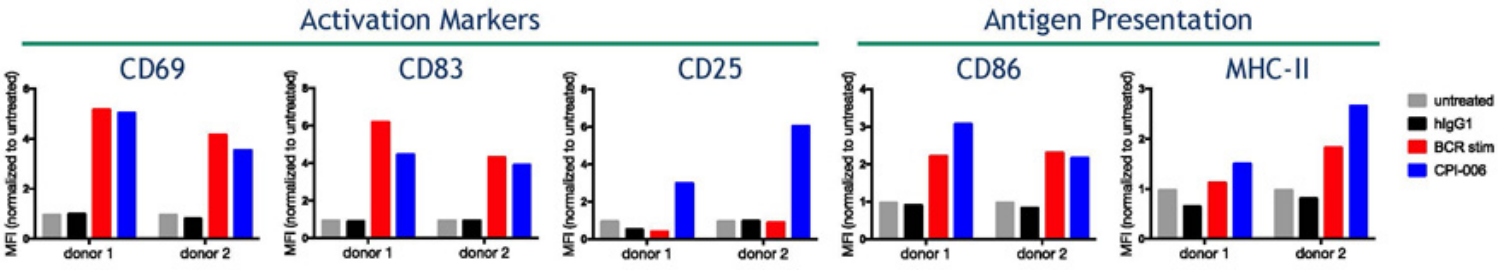


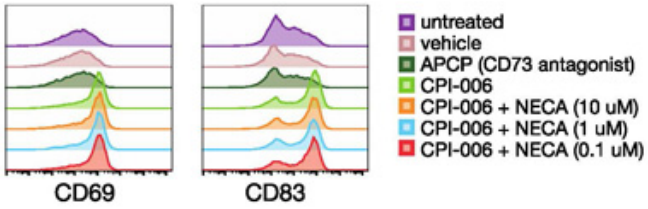


MDA-MB-231: Human TNBC Xenograft Model

*Method: Silber et al. J Clin Invest, 1975, 56(5): 1324-7.

Immunomodulatory Activities of CPI-006 are Adenosine Independent

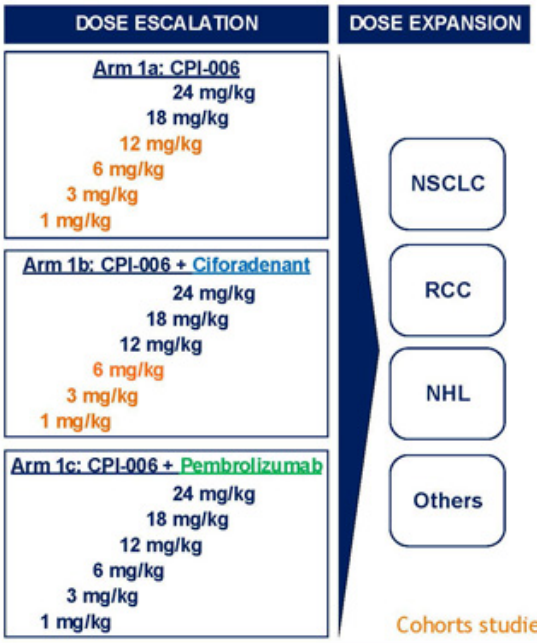




- Healthy donor PBMC treated overnight
- Flow cytometry analysis of surface markers on B cells ($CD19^{POS}CD3^{NEG}$)

- Lymphocyte markers are consistent with activation of B cells as well as other antigen presenting cell populations, e.g., APCs

Clinical Trial Design



Cohorts studied to date

Design
- Phase 1/1b open label, 3 + 3 dose escalation/dose expansion
- CPI-006 given as 1 hour IV infusion every 3 weeks; fixed dose of ciforadenant (100 mg po BID) for combo

Eligibility
- Advanced cancers progressed on 1-5 prior therapies
- ECOG status 0 or 1
- CD73 expression: required in expansion, not in dose escalation
- Adenosine gene signature not used to select patients

Objectives
- Primary: Safety and tolerability
- Secondary: PK/PD, efficacy, biomarkers

Biomarker Assessments
- Effects on CD73 expression in tumors
- Peripheral blood lymphocyte subsets
- Antibody occupancy of target
- Serum cytokines

Patient Characteristics

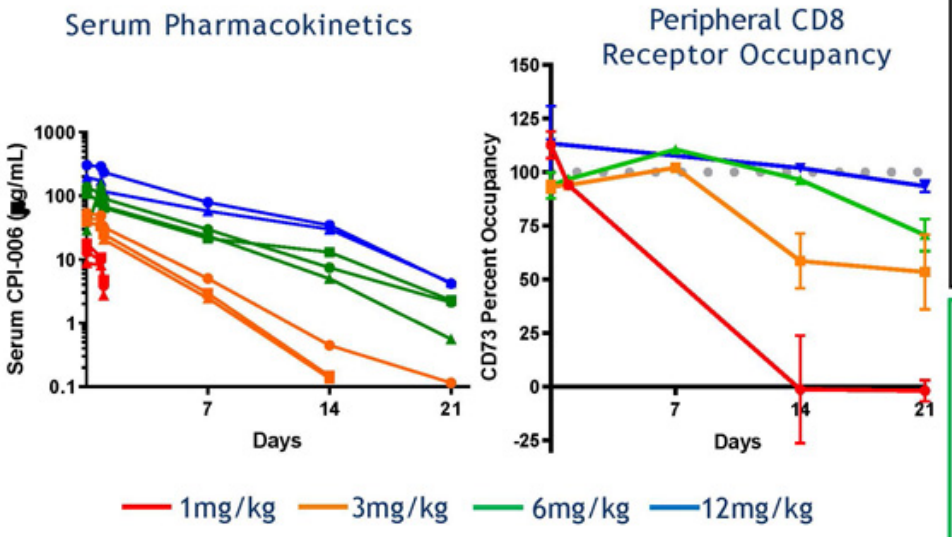
Baseline Demographics		
Description	CPI-006 (N=12)	CPI-006 + ciforadenant (N=8)
Age (yrs), median (range)	62 (46, 78)	64 (36, 86)
Gender, male n (%)	10 (83)	8 (100)
No. of prior therapies, median (range)	4 (1, 5)	4 (3, 7)
Histologies	**N**	**N**
Bladder Cancer	1	0
Colorectal Cancer	2	2
Head and Neck Cancer	2	1
Pancreatic Cancer	2	2
Prostate Cancer	3	1
Renal Cell Cancer	1	2
Sarcoma	1	0

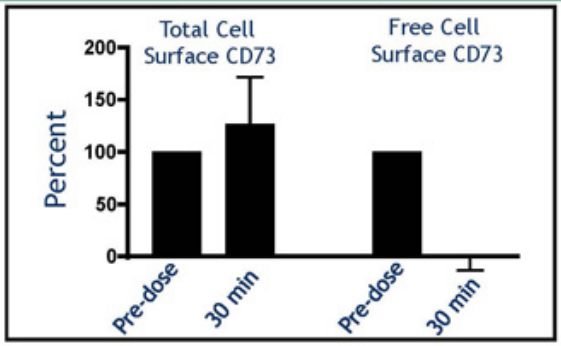
Adverse Events

Adverse Events N(%)	CPI-006 Monotherapy (N=12)		CPI-006 + Ciforadenant (N=8)	
	All Grades	Grade 3 or 4	All Grades	Grade 3 or 4
Subjects with any TEAE	8 (66.7)	1 (8.3)	5 (62.5)	0 (0.0)
Anemia	1 (8.3)	1 (8.3)	1 (12.5)	0 (0.0)
Diarrhea	1 (8.3)	0 (0.0)	1 (12.5)	0 (0.0)
Nausea	3 (25.0)	0 (0.0)	2 (25.0)	0 (0.0)
Chills	4 (33.3)	0 (0.0)	1 (12.5)	0 (0.0)
Fatigue	2 (16.7)	0 (0.0)	2 (25.0)	0 (0.0)
Infusion related reaction	2 (16.7)	0 (0.0)	1 (12.5)	0 (0.0)
Headache	2 (16.7)	0 (0.0)	1 (12.5)	0 (0.0)
Pruritus	2 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)

- Treatment related adverse events: Any grade 3 or 4 events, or 2 or more all grades

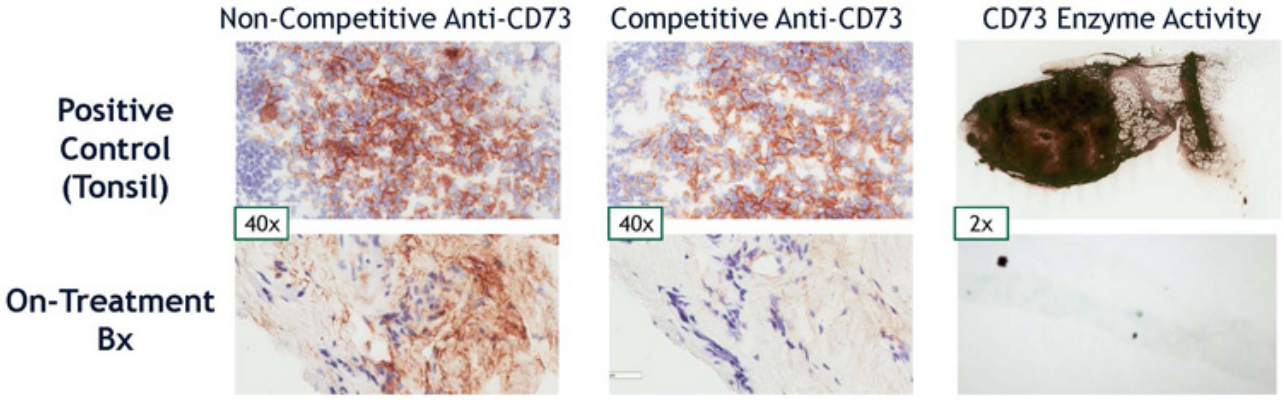
Pharmacokinetics and Receptor Occupancy





- Exposure increases and clearance decreases with increasing dose
- CPI-006 detectable for 21 days after a single dose of 6 mg/kg or higher
- Total cell surface CD73 unchanged; CPI-006 epitope blocked

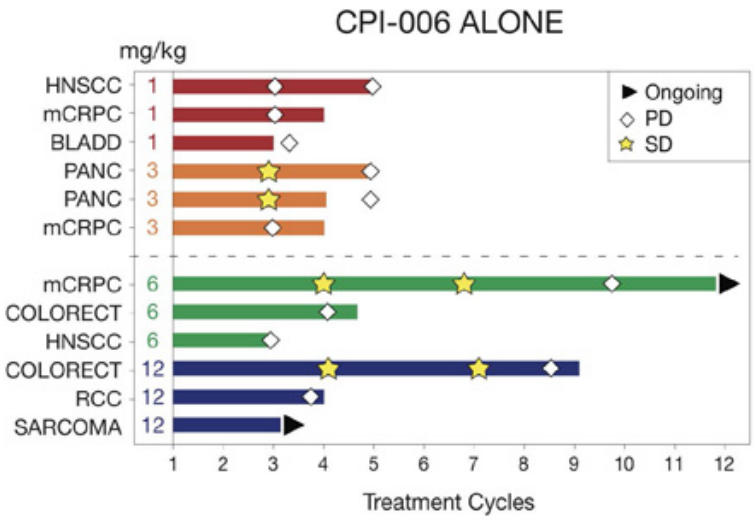
Occupancy and Inhibition of CD73 in the Tumor



- Colorectal patient treated with 12 mg/kg CPI-006
- Tumor biopsy of retroperitoneal lesion obtained at trough pre-dose 3

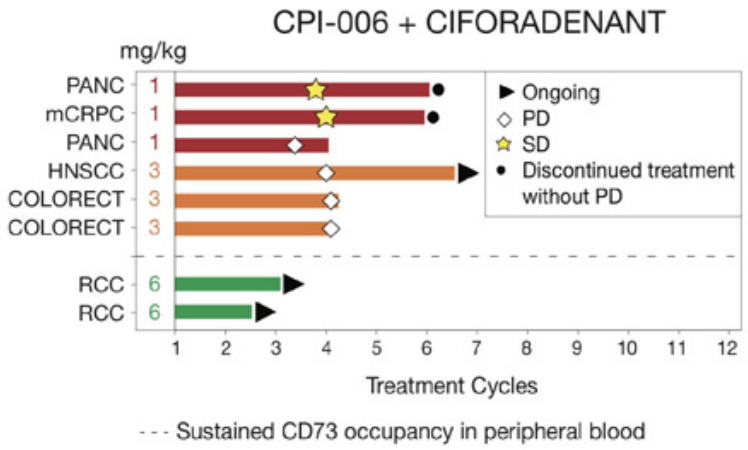
- Tumor biopsy demonstrates presence of CD73 which is occupied by CPI-006
- CPI-006 saturates CD73 and inhibits enzymatic activity

Disease Assessment



Cycle = 21 days

Disease assessment every 3-4 cycles

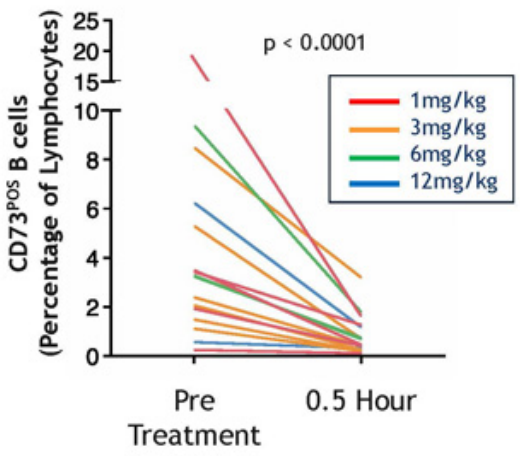


--- Sustained CD73 occupancy in peripheral blood

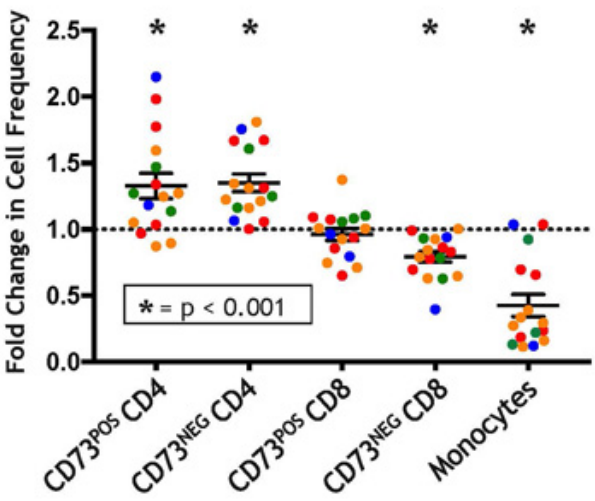
- Higher doses appear to be providing longer term disease control with monotherapy
- Combination appears to improve disease control

Treatment Induces Rapid Changes in PBMCs

CD73^{POS} B cells



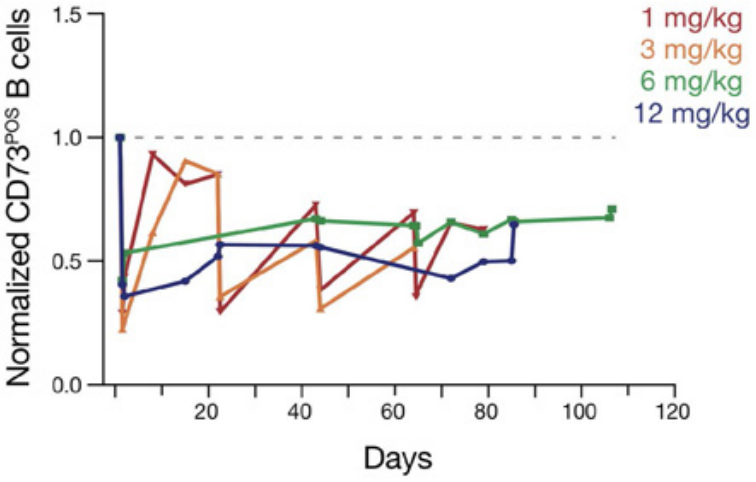
Changes in PBMCs at 0.5 Hour



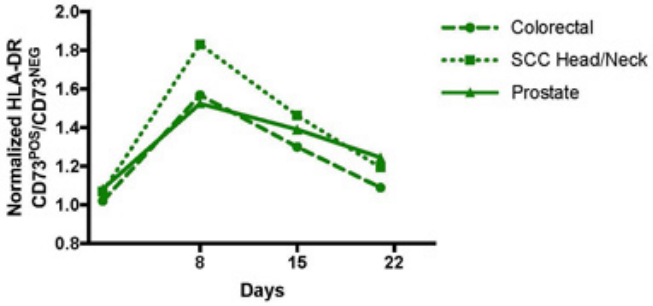
- Consistent with
  - Trafficking of CD73^{POS} B cells out of the blood
  - Redistribution of T cells & monocytes (CD73^{NEG})
- Increase in CD4/CD8 ratios – including CD73^{NEG} subsets

Changes in Blood B Cells Over Time

Changes in $CD73^{POS}$ B cells

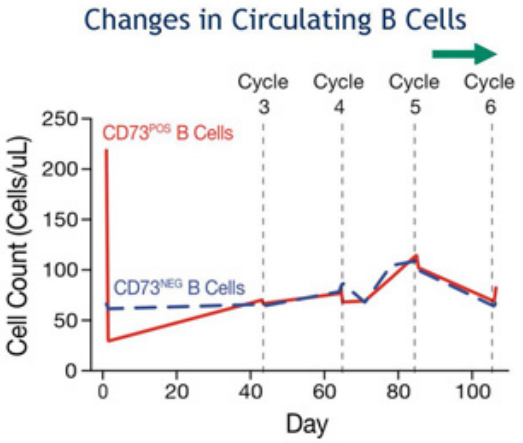


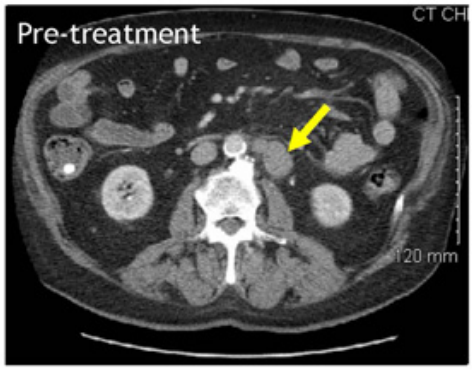
Changes in HLA-DR Expression
6 mg/kg Monotherapy cohort

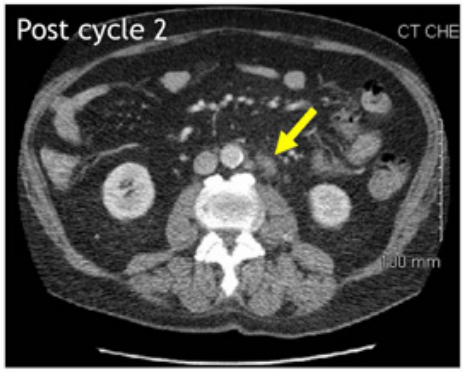


- $CD73^{POS}$ B cells drop with each infusion and partially return reaching new steady state
- Consistent with redistribution of B cells to lymphoid tissue
- Increased expression of HLA-DR

Changes in CD73^{POS} B Cells & Tumor Reduction in a Prostate Cancer Patient





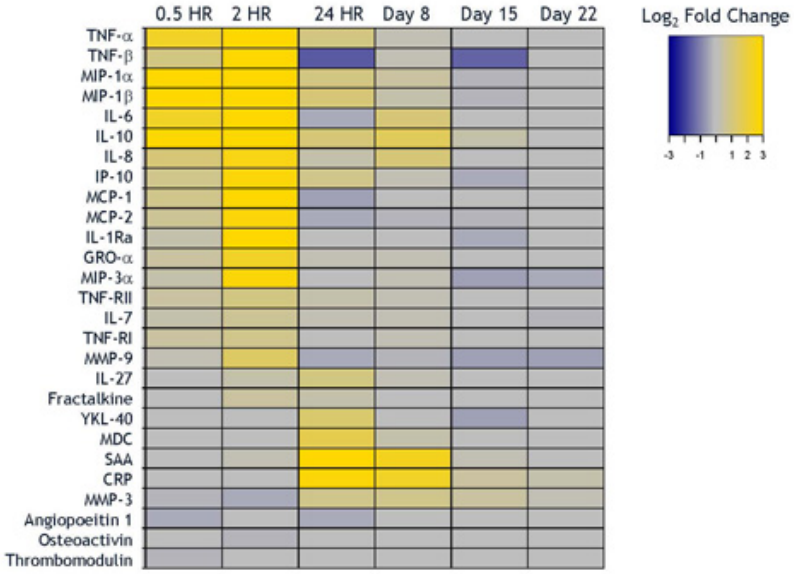


- 72 year old man with widely metastatic prostate cancer; previous therapies include leuprolide/bicalutamide, abiraterone, enzalutamide and docetaxel

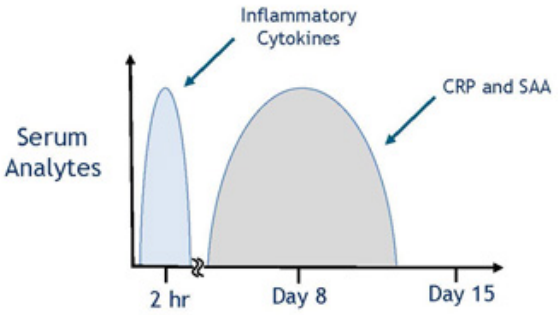
- Decrease in target lesion in patient receiving 6 mg/kg monotherapy, treatment ongoing through 11 cycles

Treatment Induces Cytokines Consistent with Immune Activation

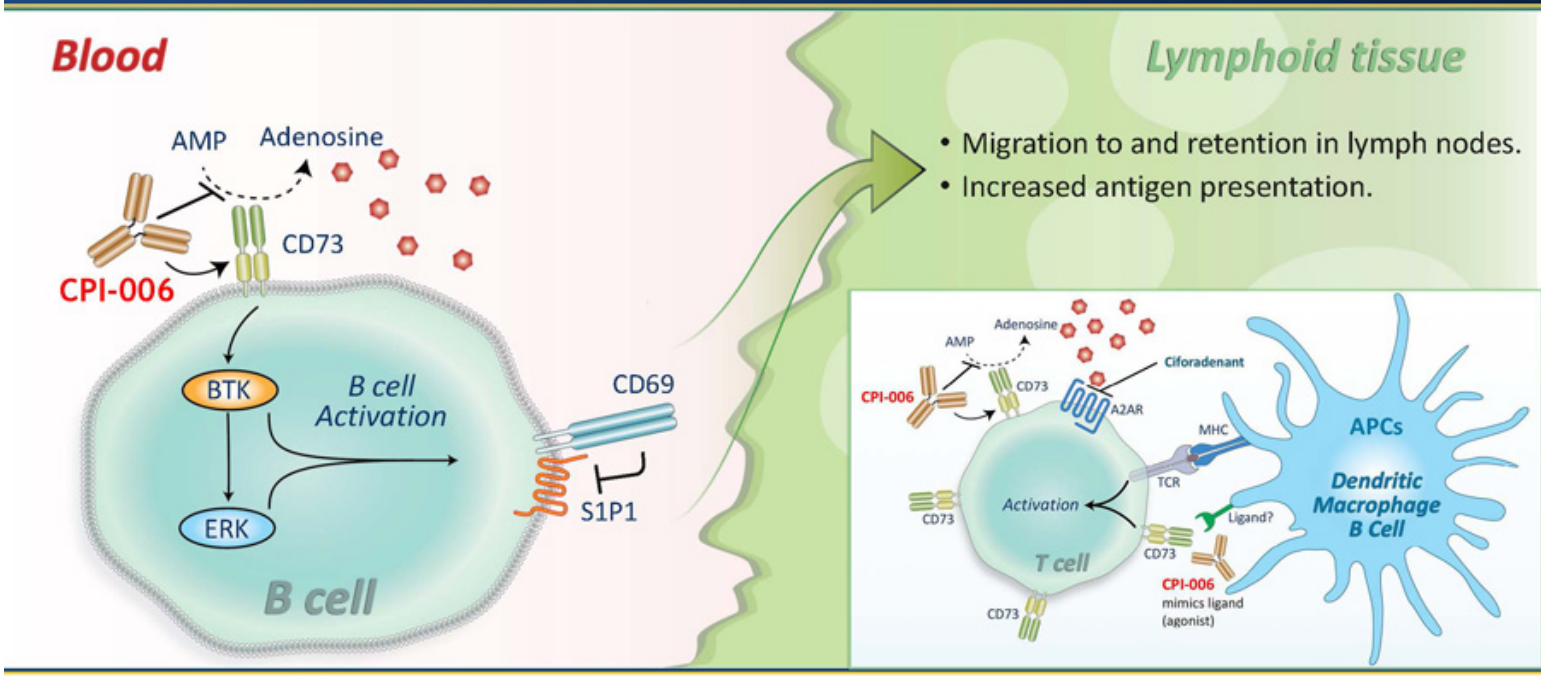
Fold change in Serum Analytes N=3, 6mg/kg Cohort



- Rapid induction of inflammatory cytokines
- Subsequent induction of C-reactive protein and serum amyloid A
- These findings are consistent with early inflammatory response



Proposed Model for CPI-006 Immunomodulatory Activity



Conclusions

- CPI-006 has novel immunomodulatory activity with dual mechanisms of action:
  - Affects B cell trafficking and increases expression of CD69 and other markers consistent with increased antigen presentation by APCs
  - Complete inhibition of CD73 enzyme activity without internalization
- CPI-006 is safe as monotherapy at least to doses of 12 mg/kg and in combination with ciforadenant to 6 mg/kg. No DLTs reported and MTD not reached.
- Doses of 12 mg/kg achieve:
  - Sustained occupancy of PBL
  - Target saturation and complete inhibition of enzyme activity in tumor biopsies
- Treatment with CPI-006 induces serum cytokines that mediate inflammatory response
- Preliminary data suggest increasing disease control with higher doses and enhancement with combination therapy
- Enrollment in this study continues with both monotherapy and combination in dose escalation

Acknowledgements

- **The patients and their families**
- **Participating Centers**: *Carolina BioOncology Institute, University of Chicago, Medical College of Wisconsin, Roswell Park Cancer Institute, Yale University, Mount Sinai, Icahn School of Medicine, Dana Farber Cancer Institute, Mary Crowley Cancer Center, University of Miami, City of Hope, Sarah Cannon Research Institute, University of Oklahoma, Monash Health*
- **Colleagues at Corvus**