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): February 9, 2021

Bellicum Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36783**	**20-1450200**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3730 Kirby Drive, Ste. 1200, Houston, TX 77098
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: 832-384-1100

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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 $0.01 per share	**BLCM**	**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. ☐

In this report, “we,” “us” and “our” refer to Bellicum Pharmaceuticals, Inc.

Item 8.01 Other Events.

On February 9, 2021 we made available on our corporate website an updated corporate presentation, in connection with our previous announcement that, on January 28, 2021, the U.S. Food and Drug Administration lifted the clinical hold on patient enrollment and dosing in our ongoing Phase 1/2 dose-escalation clinical trial evaluating BPX-601 and rimiducid in patients with previously treated metastatic pancreatic or prostate cancer. A copy of the corporate presentation is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate 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.

Bellicum Pharmaceuticals, Inc.

Dated: February 9, 2021

By: /s/ Richard A. Fair
Richard A. Fair
President and Chief Executive Officer

Exhibit 99.1

Investor Presentation

Building a powerful new future in cellular IO

February 2021

Bellicum

Bellicum

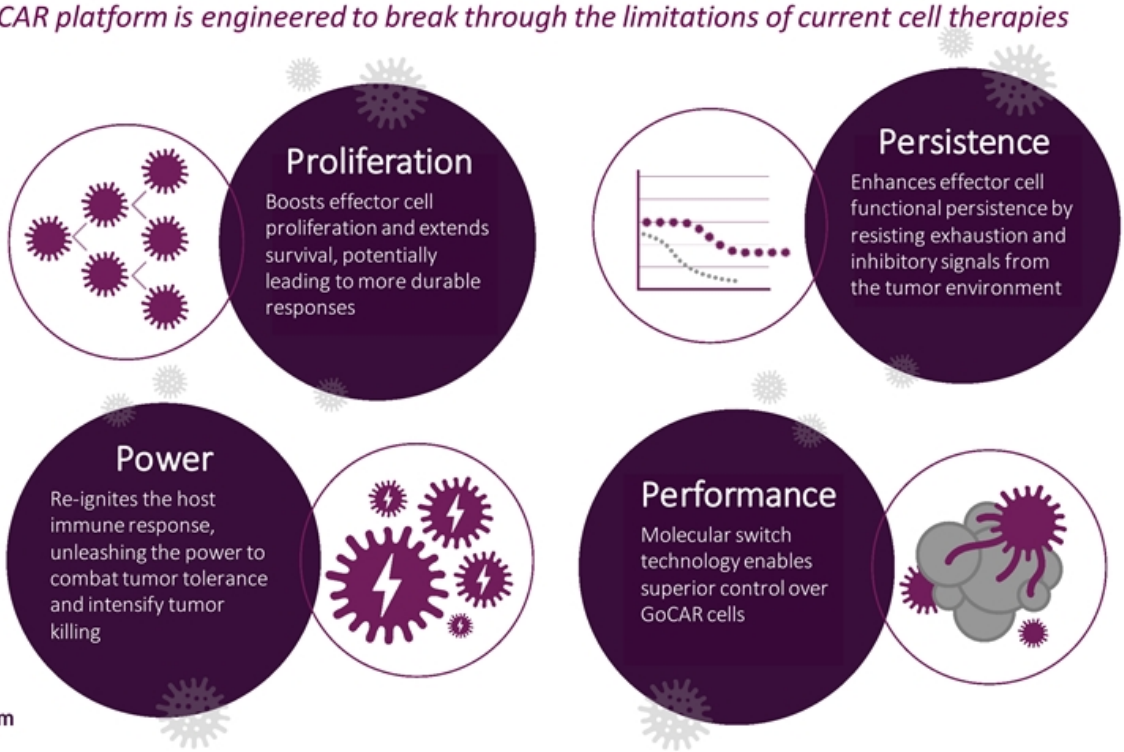
Forward Looking Statement

This presentation contains estimates, projections and other forward-looking statements, concerning, among other things: our research and development activities relating to our GoCAR™ platform, and related technologies; our product candidates including BPX-601, BPX-603, and rimiducid; the timing and success of our current and planned clinical trials, including the timing of receipt of data from such clinical trials and the timing of our reports of such data; the possible range of applications of our cell therapy programs and potential curative effects and safety in the treatment of diseases, including as compared to other treatment options and competitive therapies; and our near-term restructuring plan, including focus of our clinical and research and development activities, reduction in employee headcount and reduction in cash utilization. Our estimates, projections and other forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect our business, strategy, operations or financial performance. Although we believe that these estimates, projections and other forward-looking statements are based upon reasonable assumptions, they are subject to numerous known and unknown risks and uncertainties and are made in light of information currently available to us. Many important factors, in addition to the factors described in this presentation, may adversely and materially affect our results as indicated in forward-looking statements. All statements other than statements of historical fact are forward-looking statements.

Estimates, projections and other forward-looking statements speak only as of the date they were made, and, except to the extent required by law, we undertake no obligation to update any forward-looking statement. These statements are also subject to a number of material risks and uncertainties that are described more fully in Bellicum's filings with the Securities and Exchange Commission, including without limitation our annual report on Form 10-K for the year ended December 31, 2019 and our quarterly report on Form 10-Q for the period ended September 30, 2020.

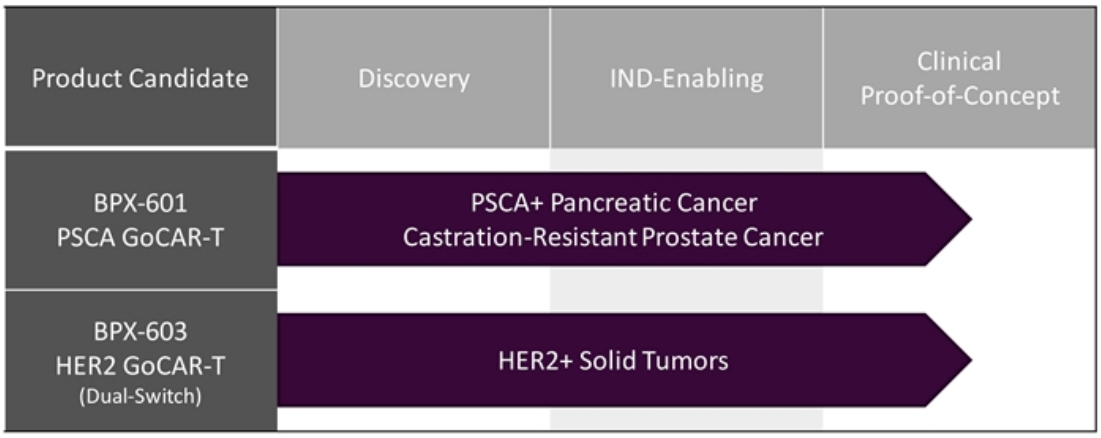
Building a Powerful New Future in Cellular IO

Our GoCAR platform is engineered to break through the limitations of current cell therapies



Product Pipeline

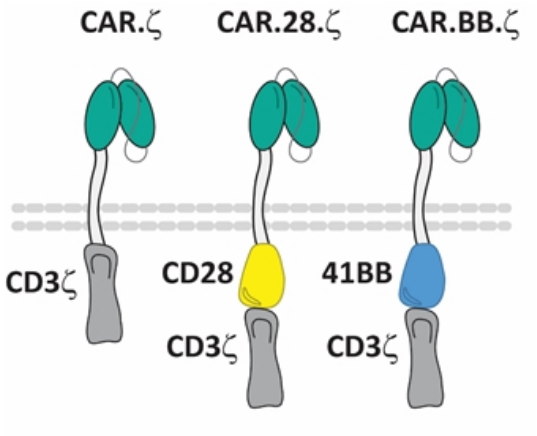
Establishing the clinical value of GoCAR-T in solid tumors to propel cellular IO forward



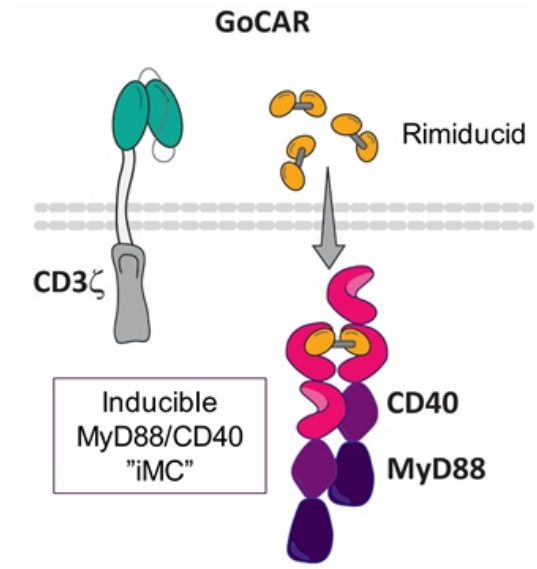

Technology Overview

GoCAR: Differentiated Technology Platform

Current Generation CAR Technology

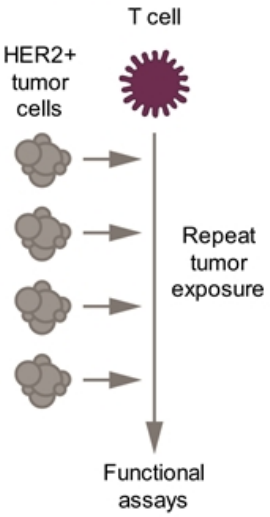


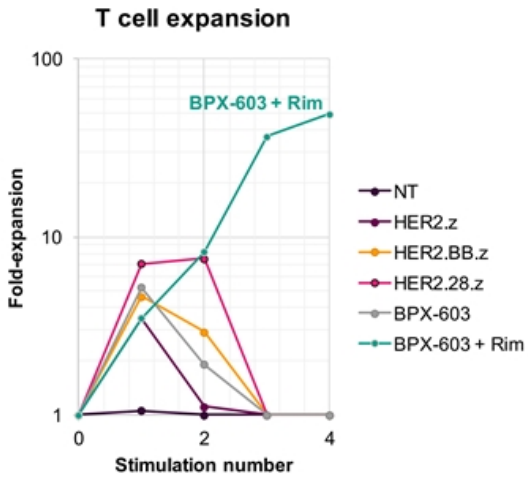
Next Generation GoCAR Technology

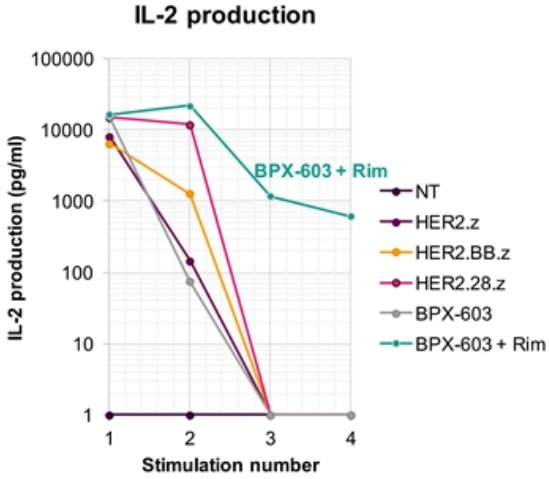


GoCAR Proliferation: Superior Expansion and Resistance to T Cell Exhaustion

iMC activation limits T cell dysfunction in repeat tumor stimulation exhaustion assay

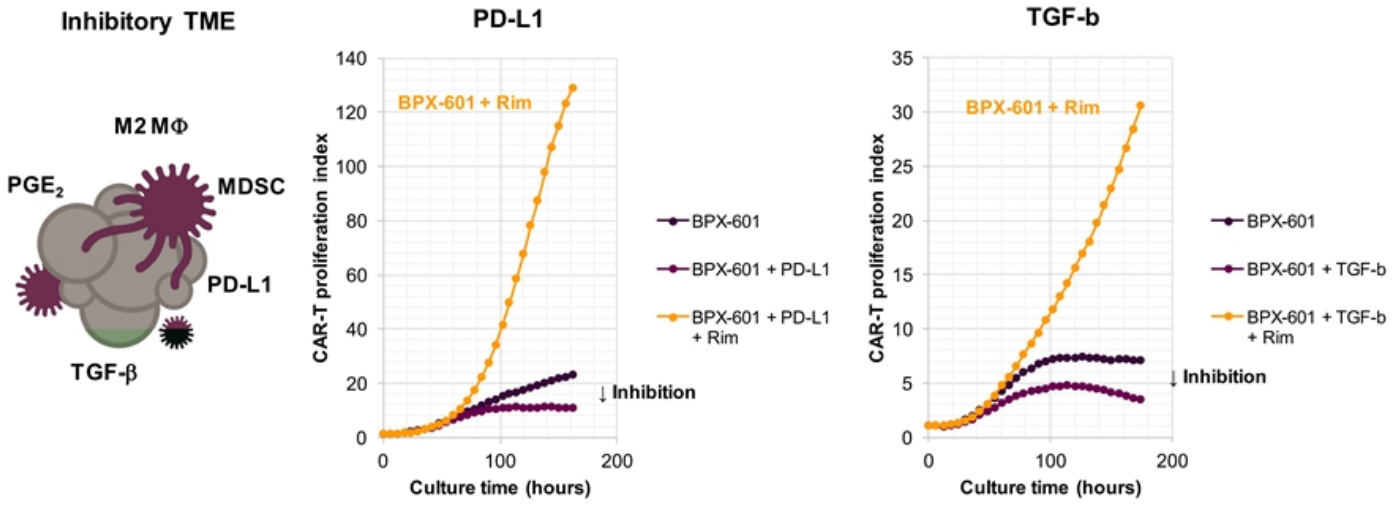






GoCAR Persistence: Resistance to Immune Suppressive TME

iMC overrides common inhibitory molecules in the tumor microenvironment



TME – tumor microenvironment


BPX-601
PSCA GoCAR-T

BPX-601 GoCAR-T Targets Solid Tumors Expressing PSCA

Product Profile Summary

- Attractive first-in-class solid tumor CAR-T opportunity
- First-in-human experience with iMC

Status Update

- FDA Clinical Hold removed January 28, 2021
- Dose escalation in previously treated mCRPC being initiated at 5m cells/kg followed by single-dose rimiducid

Unmet Need

High unmet need in solid tumors expressing prostate stem cell antigen (PSCA)

	Annual Incidence (U.S.)	Annual Deaths (U.S.)	% Expressing PSCA
Prostate	165k	29k	75-90%
Pancreatic	55k	44k	~50%

Incidence and annual deaths: Noone AM, Howlader N, Krapcho M, Miller D, Brest A, Yu M, Ruhl J, Tatalovich Z, Mariotto A, Lewis DR, Chen HS, Feuer EJ, Cronin KA (eds). SEER Cancer Statistics Review, 1975-2015, National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/csr/1975_2015/, based on November 2017 SEER data submission, posted to the SEER web site, April 2018.
PSCA expression: Argani et al, Cancer Res 2001; Reiter et al., PNAS 1998; Abate-Daga et al, HGT 2014; Data on file

BPX-601: Phase 1 Trial

Dose escalation in relapsed/refractory pancreatic cancer

	Lead-in (Cohort 0)	Dose Escalation (Cohorts 3, 4, 5A)	Standard Conditioning (Cohort 5B)	Repeat Rimiducid (Cohort 5C)
Pancreatic Patient Population	2L to 6L	2L to 6L	2L	2L
BPX-601 Dose *$x10^6$ cells/kg @ Day 0*	1.25	**1.25, 2.5, 5.0**	5.0	5.0
Conditioning	Cytoxan 1g/m^2 @ Day -3	Cytoxan 1g/m^2 @ Day -3	**Cytoxan 0.5g/m^2 Fludarabine 30mg/m^2 @ Days -5, -4, -3**	Cytoxan 0.5g/m^2 Fludarabine 30mg/m^2 @ Days -5, -4, -3
Rimiducid Dose	None	Single dose Day 7	Single dose Day 7	**Weekly dosing starting at Day 7**

Lead-In & Dose Escalation

Conservatively designed to evaluate safety

- Lead-in cohort with cells only
- Partial conditioning with Cytoxan monotherapy
- Single dose of rimiducid to activate iMC

Standard Conditioning Cohort (5B)

- Evaluated safety of standard Flu/Cy regimen with GoCAR-T
- Single dose of rimiducid to activate iMC

Repeat Rimiducid Cohort (5C)

- First data using iMC repeatedly as designed

ClinicalTrials.gov Identifier: NCT02744287

BPX-601: Safety Reported Through Cohort 5C

*Updated based on data cut December 1, 2020**

Patients, n (%)	Cohort 0 n = 3	Cohort 3 n = 3	Cohort 4 n = 3	Cohort 5A n = 4	Cohort 5B n = 5	Cohort 5C n = 5	All Patients n = 23
Any AE	3 (100)	3 (100)	3 (100)	4 (100)	5 (100)	5 (100)	23 (100)
Any SAE	1 (33)	1 (33)	0	3 (75)	4 (80)	4 (80)	13 (57)
AEs in >15% of all patients, n (%)							
Neutropenia	0	1 (33)	0	3 (75)	4 (80)	3 (60)	11 (48)
Febrile neutropenia	0	0	0	2 (50)	4 (80)	2 (40)	8 (35)
Leukopenia	0	0	0	1 (25)	3 (60)	3 (60)	7 (30)
Pyrexia	0	0	1 (33)	2 (50)	2 (40)	2 (40)	7 (30)
Fatigue	2 (67)	1 (33)	0	2 (50)	0	0	5 (22)
Anemia	0	0	0	1 (25)	2 (40)	2 (40)	5 (22)
Nausea	2 (67)	0	0	0	3 (60)	0	5 (22)
Hypotension	0	0	2 (67)	1 (25)	0	2 (40)	5 (22)
Blood bilirubin increased	0	0	0	1 (25)	2 (40)	2 (40)	5 (22)
Dysuria	0	0	0	0	4 (80)	0	4 (17)
Hematuria	0	0	0	0	3 (60)	1 (20)	4 (17)
Abdominal pain upper	0	1 (33)	0	1 (25)	1 (20)	1 (20)	4 (17)
Constipation	0	0	0	2 (50)	1 (20)	1 (20)	4 (17)
Vomiting	1 (33)	0	0	0	1 (20)	2 (40)	4 (17)
Back pain	1 (33)	1 (33)	0	2 (50)	0	0	4 (17)

- Adverse events (AEs) were generally consistent with cytotoxic chemotherapy or other cancer immunotherapies
- AEs related to BPX-601/rimiducid included:
  - One case of Grade 2 and one case of Grade 4 cytokine release syndrome (CRS)**
  - One case of Grade 2 encephalopathy
  - Five cases of Grade 1-3 urologic toxicity, mitigated by prophylactic measures introduced in Cohort 5C

Bellicum

*BPX-601 Investigator's Brochure v4, December 2020; **Grade 4 CRS reported in one patient (SAE report CIOMS US-BLCM-2020000S8)

BPX-601: Updated Efficacy Through Cohort 5C

*Updated based on data cut December 1, 2020**

Anti-tumor Activity in ITT Population

Patients, n (%)	Cohort 0 n = 3	Cohort 3 n = 3	Cohort 4 n = 3	Cohort 5A n = 4	Cohort 5B n = 5	Cohort 5C n = 5	Overall n = 23
Progressive Disease (PD), n	2	1	1	1	2	1	8
Stable Disease (SD), n	1	2	2	1	3	3	12
Partial Response (PR), n	0	0	0	0	0	0	0
Complete Response (CR), n	0	0	0	0	0	0	0
Disease Control Rate (CR+PR+SD), n(%)	1 (33)	2 (67)	2 (67)	1 (25)	3 (60)	3 (60)	12 (55)

ITT population defined as all patients who received BPX-601 and rimiducid and had at least one post-baseline disease evaluation.

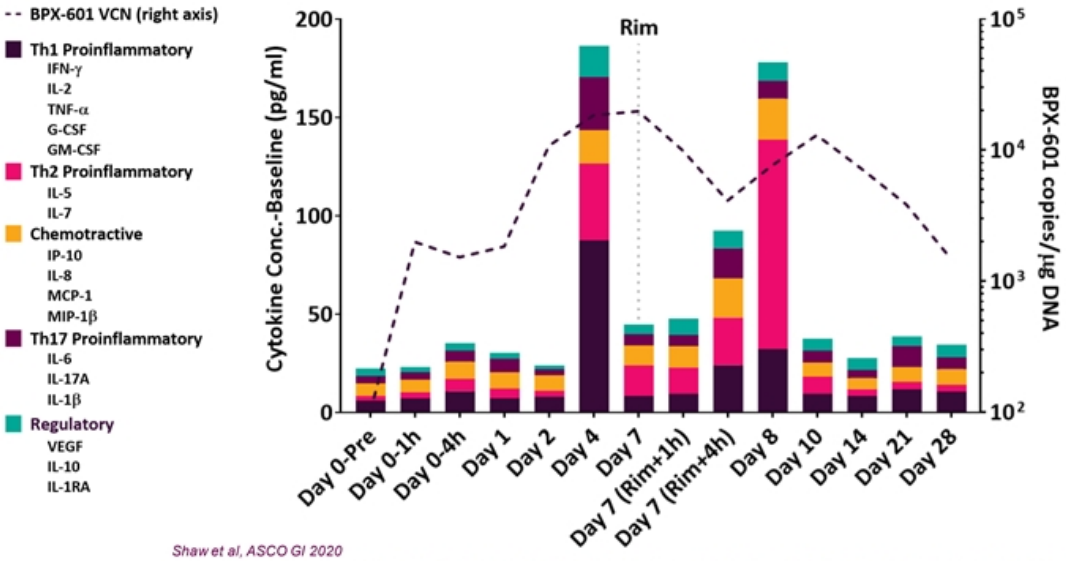
Interim Biomarker Update: BPX-601 Cohort 5C

Evidence of repeat rimiducid-mediated CAR-T cell activation was observed

- Rimiducid administration was associated with increased serum cytokine levels, including IL-5, TNF-α, and IFN-γ
- Rimiducid treatment was also associated with increased expression of activation markers (e.g. CD25) on peripheral CD4+ and CD8+ T cells, indicative of systemic immune modulation via BPX-601 iMC activation
- In two evaluable subjects receiving >2 doses of rimiducid, repeat dosing was not shown to increase peak or AUC circulating BPX-601 cells relative to single-dose rimiducid
- Consistent with previous cohorts, rimiducid administration was associated with a transient decline followed by partial recovery in circulating BPX-601 cells

BPX-601: GoCAR-T Increased Immunomodulatory Cytokines

Infusion of BPX-601 and activation with rimiducid increased immunomodulatory cytokines



- Increases in Th1 and Th2 cytokines were observed with:
  - Administration of BPX-601 GoCAR-T cells
  - GoCAR-T activation with rimiducid

Shaw et al, ASCO GI 2020

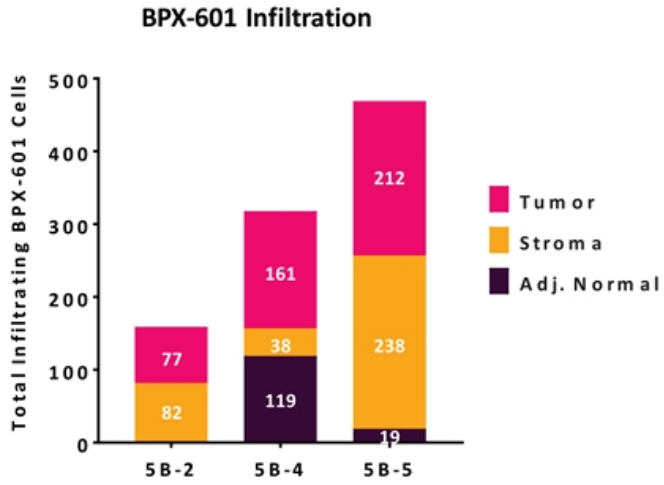
Stacked bars represent the summed mean fold-change in concentration of cytokines in each category in patients from Cohort 5B (n=5). Black dotted line represents the mean VCN for Cohort 5B. Gray dotted line represented rimiducid administration on Day 7.

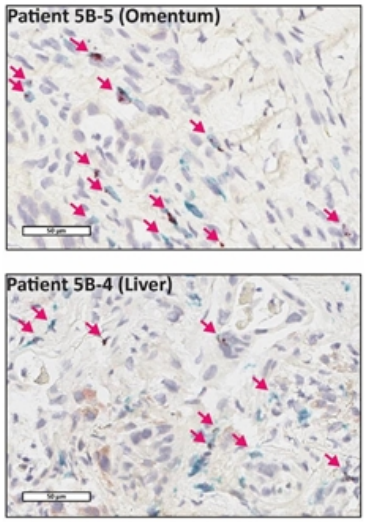
Conc., concentration; Rim, rimiducid.

Bellicum

BPX-601: GoCAR-T Infiltrated Metastatic Pancreatic Tumors

On-treatment biopsies taken from metastatic lesions show BPX-601 tumor infiltration





CD3 = Blue; BPX-601 = Red, arrows

- Analysis of tumor metastases from patients showed:
  - Infiltration of BPX-601 GoCAR-T cells
  - BPX-601 effectively localized to tumor

Shaw et al, ASCO GI 2020

(Left) Stacked bars represent the total number of BPX-601 cells quantified in ISH stained tissue sections of available (n=3) biopsies from metastatic lesions of Cohort 5B patients. White numbers in bars indicate the number of BPX-601 cells measured within each ROI.
(Right) Representative images of CD3 (IHC) and BPX-601 (ISH) stained tissue sections of available (n=3) biopsies from metastatic lesions of Cohort 5B patients. Red arrows indicate BPX-601 GoCAR-T cells
Adj. normal, adjacent normal; ROI, region of interest.

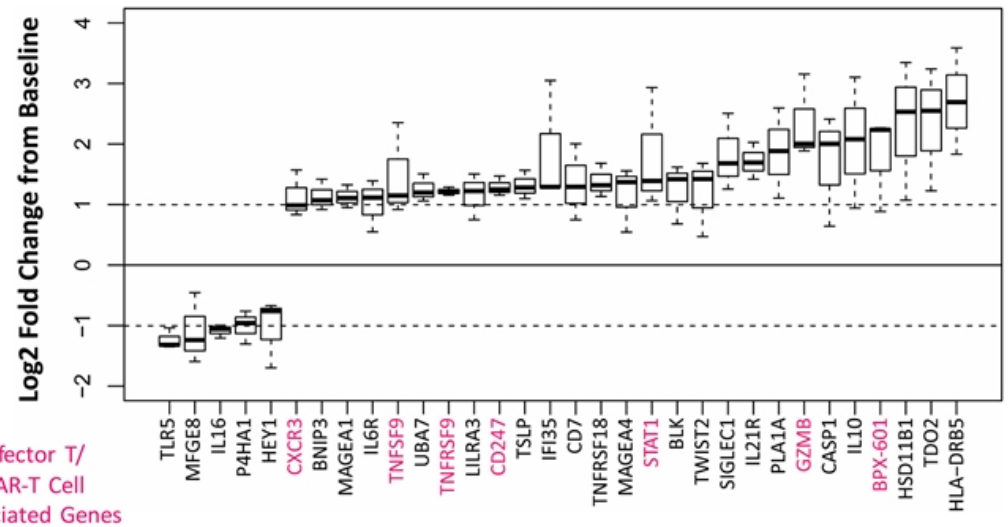
Bellicum

BPX-601: Modulation of Tumor Microenvironment

Changes in gene expression consistent with productive T cell immune responses

Differentially Expressed Genes in Tumor Metastases After BPX-601 + Rim

(Cohort 5B, n=3)



Effector T/ CAR-T Cell Associated Genes

- Upregulation of T/CAR-T cell associated genes including:
  - GZMB – Target cell killing by cytotoxic T cells
  - CXCR3 – Activated T cell trafficking
  - 41BB(TNFSF9) / 41BBL(TNFRSF9) – T cell costimulation
  - CD3Z (CD247) – TCR Signaling
  - STAT1 – Interferon signaling
  - BPX-601 – Infiltrating GoCAR-T cells

Shaw et al, ASCO GI 2020

Box and whisker plots indicate log2 fold change of genes with altered expression (upregulation or downregulation) while on-treatment (Day 14-21) from paired baseline sample (p-value < 10%). nCounter data using NanoString PanCan IO360 panel.

Bellicum


BPX-603
HER-2 GoCAR-T

BPX-603 Dual Switch GoCAR-T Targeting HER2

Product Profile Summary

- HER2 is a validated tumor antigen expressed on numerous solid tumors with high unmet need
- BPX-603 designed to potentially address limitations of previous CAR-T efforts targeting HER2
  - Moderate affinity scFv to enhance target engagement and activity
  - MC signaling to increase cell proliferation & persistence, modulate the TME, and enhance host immunity
  - Bellicum switch technology designed to time and manage CAR-T activation and enable mitigation of acute toxicities

Status Update

- Initial study sites activated; first patient enrolled

Unmet Need

Indication	Incidence[1]	HER2+	5-year OS (Stage IV)[1]
Gastric	28,000	10-30%[3]	<20%
Colorectal	145,000	10%[4]	<15%
Ovarian	22,000	20-30%[5]	<30%
Uterine/ Endometrial	61,000	50-80%[6]	14-69%
Glioblastoma	12,000	20-30%[2]	<20%
Breast	271,000	16%[7]	90%

[1]National Cancer Database, American Cancer Society, https://www.cancer.org, accessed 21 December 2018; [2]Liu et al, Cancer Res 2004; [3]Gravalos et al, Annals Oncol 2008; [4]Tu et al, Exp Ther Med 2018; [5]Berchuck et al, Cancer Res 1990, Bartlett et al, Brit J Cancer 1996; [6]Grushko et al, Gynecologic Oncol 2008, (7) Cronin et al, Cancer Invest. 2010

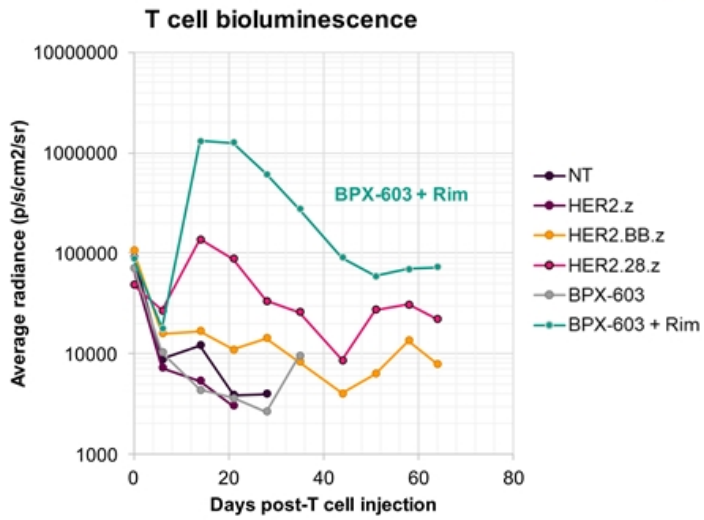
Bellicum

Historical HER2 Studies: Modest Clinical Outcomes

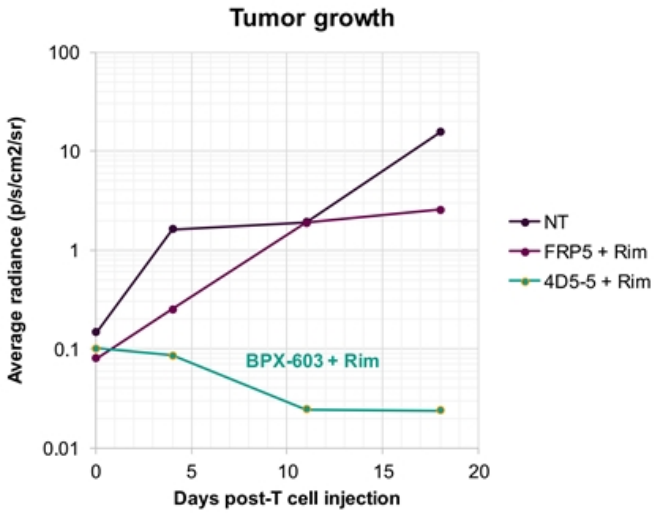
Study Properties	Morgan, 2010	Ahmed, 2015	Feng, 2017	Ahmed, 2017	Hegde, 2019
Construct	4D5-28-BB-z	FRP5-28-z	Her2-BB-z	FRP5-28-z	FRP5-28-z
Indication(s)	Metastatic colon	Sarcomas	CCA and PCa	GBM	Sarcomas
Patient number	1	19	11	17	10
HER2 expression	≥2+ (IHC)	≥1+ (IHC)	>50% positive	≥1+ (IHC)	≥1+ (IHC)
CAR-T dose	10^{10}	10^{4} - 10^{8}	10^{6}	10^{6} - 10^{8}	10^{8}
CAR-T expansion	NE	Negligible	>1,000 copies	Negligible	>10,000 copies
Toxicity	Lung reactivity	No DLTs	Mild AEs	Mild AEs	Mild AEs
Outcome	Grade 5 toxicity	1 PR	1 PR	1 PR	2 CR
Total Responses	2 CR, 3 PR, 5/58 (8.6% ORR)				

BPX-603: Compelling Preclinical Evidence

iMC co-activation enhances cell proliferation relative to current CAR-T standards



Moderate affinity scFv enhances anti-tumor effect relative to low affinity FRP5

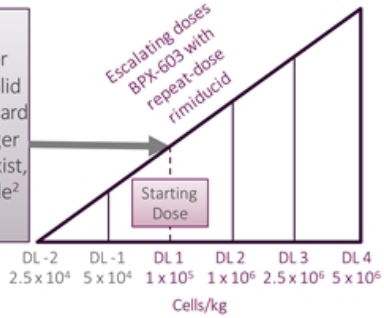


BPX-603 Phase 1/2 Trial Design

Two-Part Safety/Activity Study of HER2-Targeted Dual Switch GoCAR-T Cells in Previously Treated HER2+ Solid Tumors

Phase 1: 3+3 Dose Escalation

Locally advanced or metastatic HER2+ solid tumors[1] where standard treatment is no longer effective, does not exist, or subject is ineligible[2]



- Sequential patient enrollment
  - ≥28 days for cohort 1
  - ≥14 days for subsequent cohorts
- First subject in each dose level receives cells only without rimiducid

Phase 2: Multi-Arm Dose Expansion in Select Tumor Types

Cohort 1: Gastric

Cohort 2: Breast

- Expansion cohorts 10 patients each
- Ability to expand each cohort based on clinical response

If ≥1 response

- Cohort 3: Ovarian
- Cohort 4: Colorectal
- Cohort 5: GBM[3]
- Cohort 6: Uterine/Endometrial

[1] GBM excluded from Phase 1

[2] Must include approved HER2-targeted therapy for breast/gastric cancers

[3] Subjects with GBM will be dosed at recommended dose for expansion (RDE) -1

Bellicum


Summary

Anticipated Key Program Goals & Milestones

	Goals & Milestones	Planned Timing
BPX-601	Phase 1 data update in mCRPC	1Q'22
BPX-603	Initial Phase 1 data	2H'21

Investment Summary

Building a next generation cell therapy pipeline around the GoCAR platform

GoCAR Platform

Differentiated co-activation domain (MyD88/CD40) and switch technology drive greater proliferation, persistence, power, and performance

BPX-601

- Autologous GoCAR-T targeting PSCA
- Screening for enrollment of a cohort in mCRPC underway
- Data update planned 1Q'22

BPX-603

- Autologous Dual-Switch GoCAR-T targeting HER2 in HER2+ solid tumors
- Phase 1/2 trial initiated
- First data update planned 2H'2021

Cash runway extends into 2Q'22

- Pro forma estimated cash balance of $49.9M as of September 30, 2020; adjusted for net proceeds of +$22.7M from November 2020 financing and -$27.4M from Oxford Debt Payoff