

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): January 15, 2020

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

Delaware
(State or other jurisdiction
of incorporation)

001-36783
(Commission
File Number)

20-1450200
(IRS Employer
Identification No.)

2130 W. Holcombe Blvd., Ste. 800
Houston, TX
(Address of principal executive offices)

77030
(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 Global 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 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

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

Item 7.01 Regulation FD Disclosure.

We are furnishing this Current Report on Form 8-K in connection with the disclosure of information, in the form of a slide presentation, to be given at meetings with institutional investors or analysts. The slide presentation is attached hereto as Exhibit 99.1.

The information contained in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished pursuant to Item 7.01 and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this item of this report.

By filing this Current Report on Form 8-K, including Exhibit 99.1, and furnishing this information, we make no admission as to the materiality of any information in this report. The information contained in this report is intended to be considered in the context of our filings with the SEC and other public announcements that we make, by press release or otherwise, from time to time. We undertake no duty or obligation to publicly update or revise the information contained in this report, although we may do so from time to time as our management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Slide presentation.

Investor Presentation

Building a powerful new future in cellular IO

January 2020



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™ (incorporating “iMC”), GoCAR-T® CaspaCIDE® (“iC9”), and related technologies; our product candidates including BPX-601, BPX-603, OTS GoCAR-NK, 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; our plans regarding interactions with the FDA related to the IND submitted for BPX-603; 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 the success of our collaborations with academic and commercial partners, including with respect to our manufacturing facility. Our estimates, projections and other forward-looking statements are based on our 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, 2018 and our quarterly report on Form 10-Q for the period ended September 30, 2019.



Bellicum

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 in pancreatic cancer
- Phase 1/2 enrolling
- Multiple data updates in 2020, starting with ASCO GI

BPX-603

- Autologous GoCAR-T targeting HER2 in solid tumors
- Supplementary IND-enabling studies underway

GoCAR-NK Program

- First off-the-shelf (OTS) GoCAR program targeting BCMA
- Formal preclinical development initiated

Cash runway extends into 2021

- \$106.9M cash as of Sep 30, 2019
- Seeking transaction for manufacturing facility to reduce operating expenses and maintain production capabilities



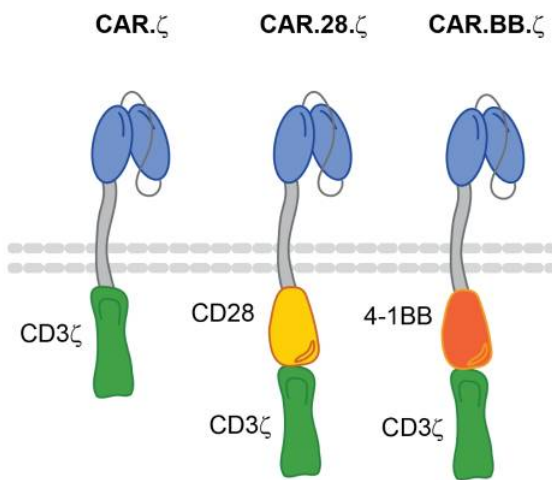


Technology Overview

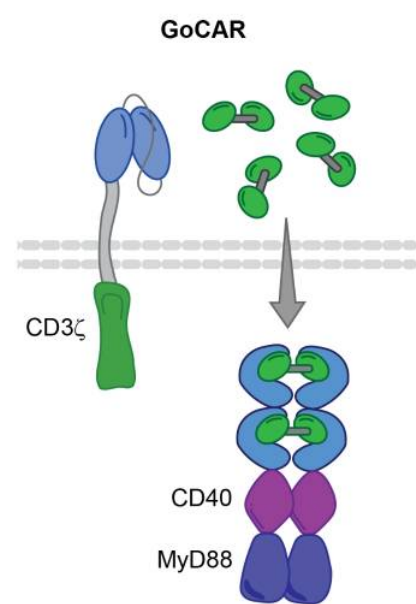


GoCAR: Differentiated Technology Platform

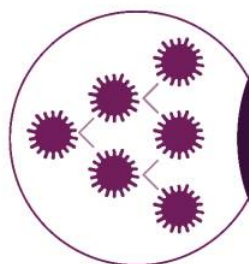
Current Generation CAR Technology



Next Generation GoCAR Technology



GoCAR: Driving the Future of Cellular IO



Proliferation

Boosts effector cell proliferation and extends survival of these activated cells, leading to more durable responses



Persistence

Enhances effector cell functional persistence by resisting exhaustion and inhibitory signals from the tumor environment



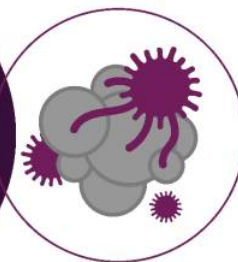
Power

Re-ignites the cohost immune response, unleashing the power to combat tumor intolerance and intensify tumor killing



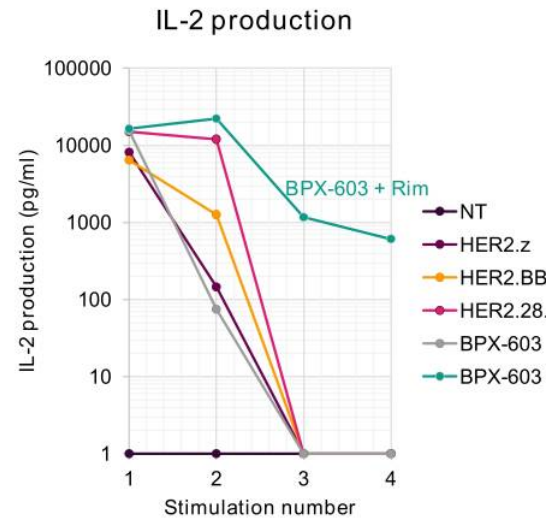
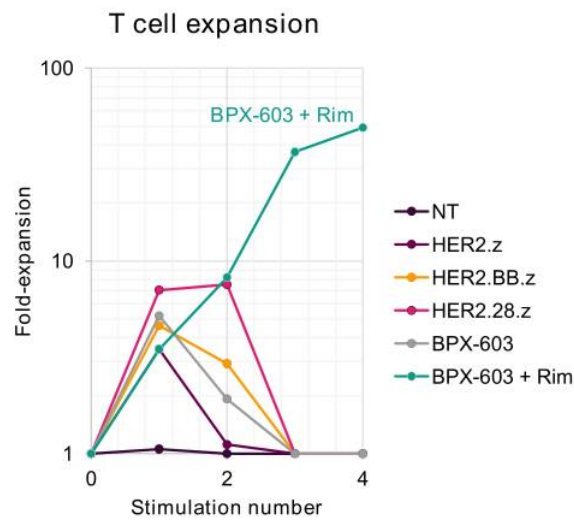
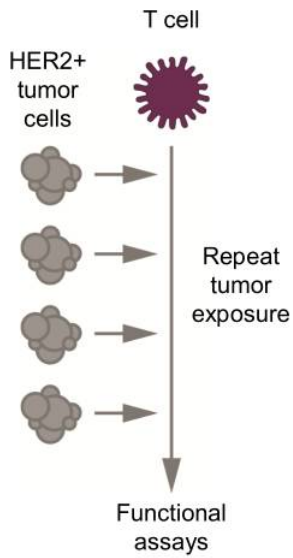
Performance

Allows for superior control of our GoCAR cells, transforming the way cancer is targeted and treated



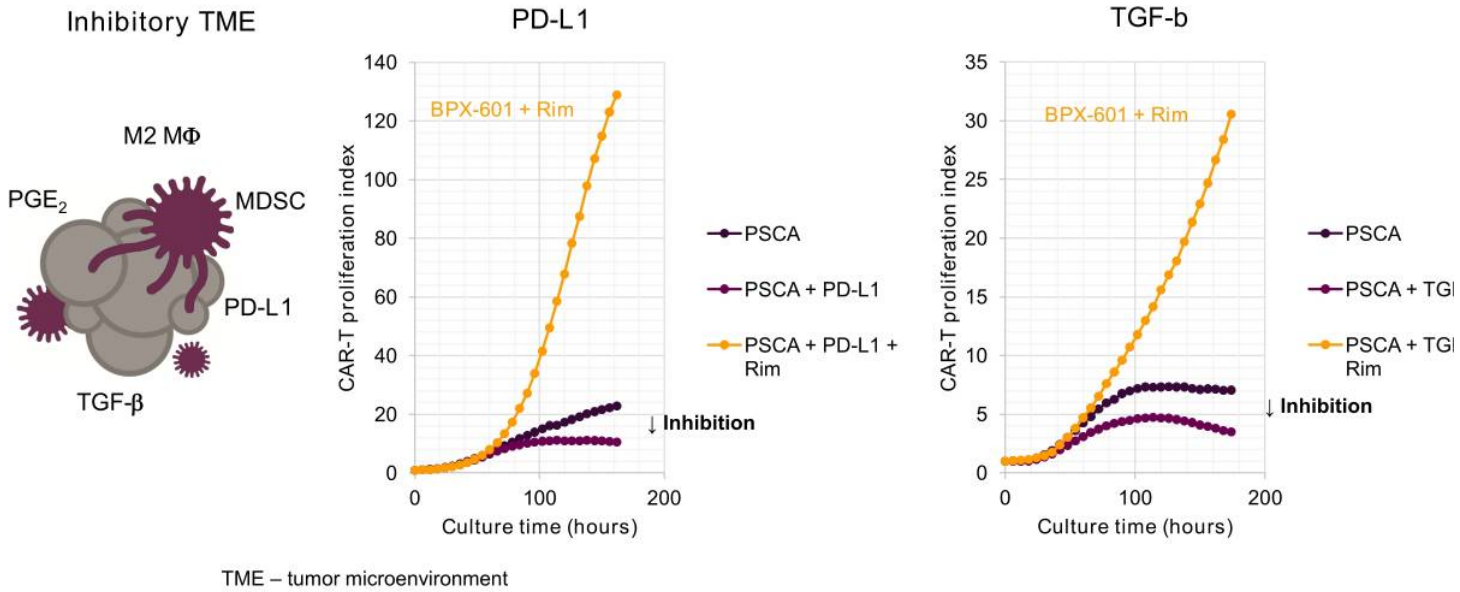
GoCAR Proliferation: Superior Expansion and Resistance to Cell Exhaustion

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



Expanding Proprietary Development Pipeline

PRODUCT CANDIDATE	DISCOVERY	IND ENABLING	CLINICAL PROOF OF CONCEPT	STATUS
<i>Wholly owned proprietary development programs:</i>				
BPX-601 GoCAR-T PSCA 	Pancreatic Cancer, Phase 1/2			<ul style="list-style-type: none"> Cohort 5B new translational at ASCO GI in Jan 2020 Cohort 5C repeat Rim clinic data update in 2H'20
BPX-603 GoCAR-T HER-2  	Solid Tumors			<ul style="list-style-type: none"> Additional studies to support IND underway
Off-the-Shelf Program GoCAR-NK BCMA	Multiple Myeloma			<ul style="list-style-type: none"> Preclinical program underway



BPX-601 PSCA Autologous 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
- Updated Phase 1 results presented in June 2019 demonstrate safety, iMC-driven T cell activation, and biologic activity
- Phase 1 enrollment ongoing; multiple data updates in 2020
 - Additional translational data – ASCO GI (January)
 - Updated clinical results – 2H'2020

Unmet Need

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

	Annual Incidence (U.S.)	Annual Deaths (U.S.)	% Expressing PSCA
Pancreatic	55k	44k	~50%
Prostate	165k	29k	75-90%
Gastric	26k	11k	76-89%

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 Enrolling Cohort 5C

BP-012 trial 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 <i>x10⁶ cells/kg @ Day 0</i>	1.25	1.25, 2.5, 5.0	5.0	5.0
Conditioning	Cytosan 1g/m ² @ Day -3	Cytosan 1g/m ² @ Day -3	Cytosan 0.5g/m ² Fludarabine 30mg/m ² @ Days -5, -4, -3	Cytosan 0.5g/m ² Fludarabine 30mg/m ² @ Days -5, -4, -3
Rimiducid Dose	None	Single dose Day 7	Single dose Day 7	Repeat dosing starting at Day 7
Enrollment Status	Completed			Enrolling

Lead-In & Dose Escalation

Conservatively designed to evaluate

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

Standard Conditioning Cohort

- Evaluated safety of standard Fludarabine regimen with GoCAR-T
- Single dose of rimiducid to activate

Repeat Rimiducid Cohort (5C)

- First POC using iMC repeatedly designed
- Clinical data expected 2H 2020

ClinicalTrials.gov Identifier: NCT01



BPX-601: No Dose Limiting Toxicities Observed

Data presented at ASCO 2019

Patients, n (%)	Cohort 0 n = 3	Cohort 3 n = 3	Cohort 4 n = 3	Cohort 5A n = 4	Cohort 5B n = 5	All Patients N = 18
Any AE	3 (100)	3 (100)	3 (100)	4 (100)	5 (100)	18 (100)
Any SAE	2 (67)	1 (33)	0	3 (75)	4 (80)	10 (56)
Grade 3 & 4 TRAEs	0	0	0	0	1 (20)	1 (<1)
AEs in >15% of all patients, n (%)						
Febrile neutropenia	0	0	0	2 (50)	4 (80)	6 (33)
Fatigue	2 (67)	1 (33)	0	2 (50)	0	5 (28)
Neutropenia	0	0	0	1 (25)	4 (80)	5 (28)
Pyrexia	0	0	1 (33)	2 (50)	2 (40)	5 (28)
Dysuria	0	0	0	0	4 (80)	4 (22)
Hematuria	0	0	0	0	4 (80)	4 (22)
Nausea	2 (67)	0	0	0	2 (40)	4 (22)
Abdominal pain	1 (33)	1 (33)	0	0	1 (20)	3 (17)
Abdominal pain upper	0	1 (33)	1 (33)	1 (25)	0	3 (17)
Anemia	0	0	0	1 (25)	2 (40)	3 (17)
Back pain	1 (33)	1 (33)	0	1 (25)	0	3 (17)
Blood bilirubin increased	0	0	0	1 (25)	2 (40)	3 (17)
Hypotension	0	0	2 (67)	1 (25)	0	3 (17)

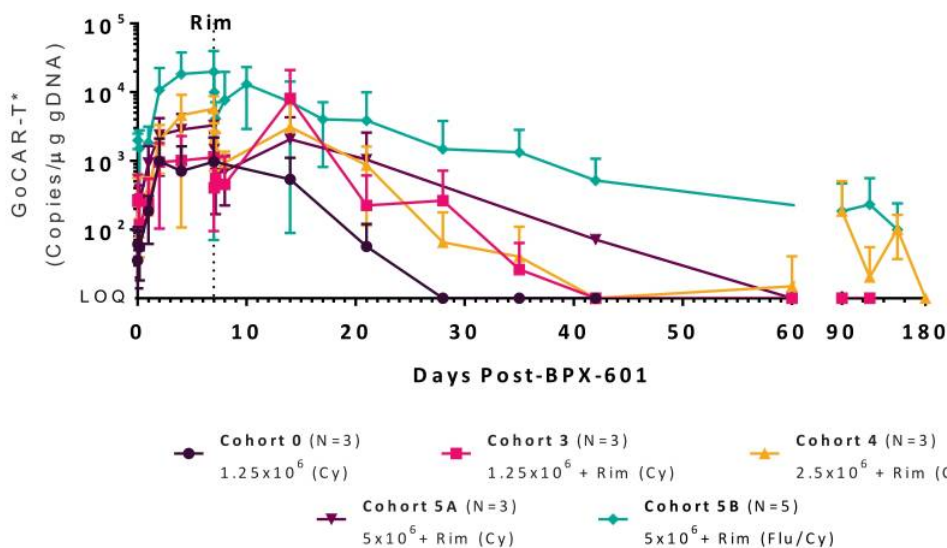
Becerra et al, ASCO 2019

- No dose limiting toxicities observed
- 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 cytokine release syndrome (CRS)
 - One case of Grade 2 encephalopathy
 - Four cases of Grade 1-3 urinary toxicity (dysuria, hematuria, cystitis)



BPX-601: iMC-Driven T Cell Expansion & Persistence

Flu/Cy Lymphodepletion results in Increased BPX-601 cell expansion and persistence



- Peak expansion 4.9-fold in Flu/Cy cohort vs Cy cohorts
- Persistence improves v
- Administration of rimiducid to activ
- Higher cell dose
- Lymphodepletion Flu/Cy

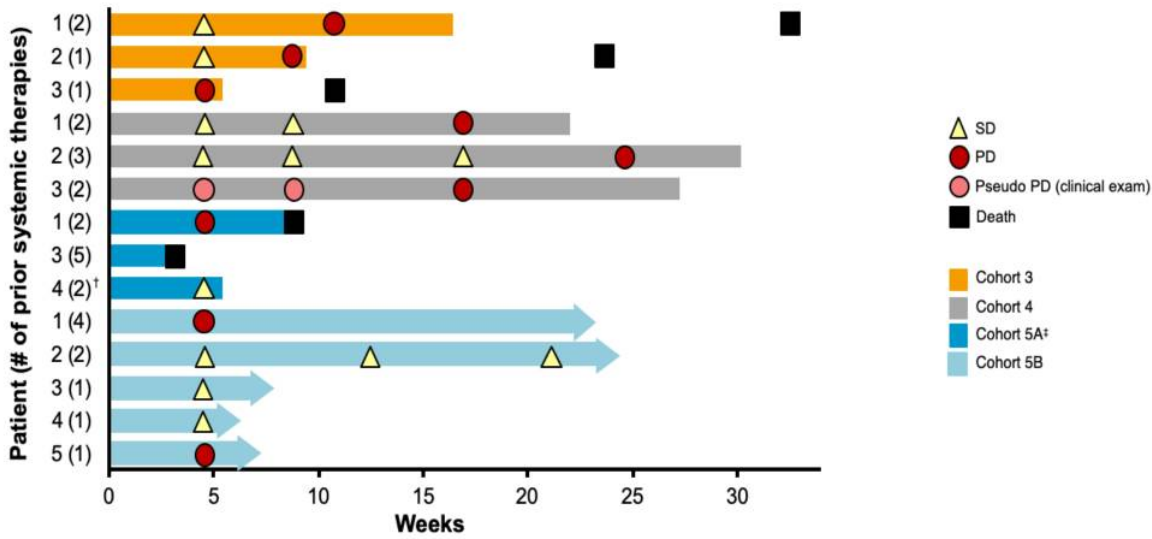
Becerra et al, ASCO 2019

* Data points represent the mean log VCN for each cohort and the dotted black line represents rimiducid administration at Day 7; † Patient 3 in cohort 5A did not have data for time points beyond Day 4 and thus is not included in summary of cell persistence.

Cy, cyclophosphamide; Flu, fludarabine; LOQ, limit of quantitation; pts, patients; Rim, rimiducid.



BPX-601: Evidence of Anti-tumor Activity



- 8 (62%) of 13 evaluable patients treated with BPX-601 and single-dose pembrolizumab achieved stable disease or had tumor shrinkage (24%)
- With 9.1 weeks median follow-up (range: 2.9-30.3), median time to next treatment in patients that received subsequent treatment was 16.6 weeks (range 5.6-30.3)
- In Flu/Cy cohort, 2 patients with >median follow-up time to next treatment (ongoing)

* Right arrow cap indicates ongoing treatment-free interval; [†] Patient withdrew consent for further follow-up; [‡] Patient 2 was not efficacy evaluable due to non-measurable disease at baseline.
 PD, progressive disease; pseudo, pseudoprogression; SD, stable disease.

Becerra et al, ASCO 2019





BPX-603
HER-2 Autologous 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
- Historical HER2 CAR-T studies have shown modest overall activity and off-tumor / on-target toxicity
- BPX-603 designed to potentially address limitations of previous efforts:
 - 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 to time and manage CAR-T activation and enable mitigation of acute toxicities

Unmet Need

Indication	Incidence ¹	HER2 ⁺	5-year OS (Stage IV)
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%



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

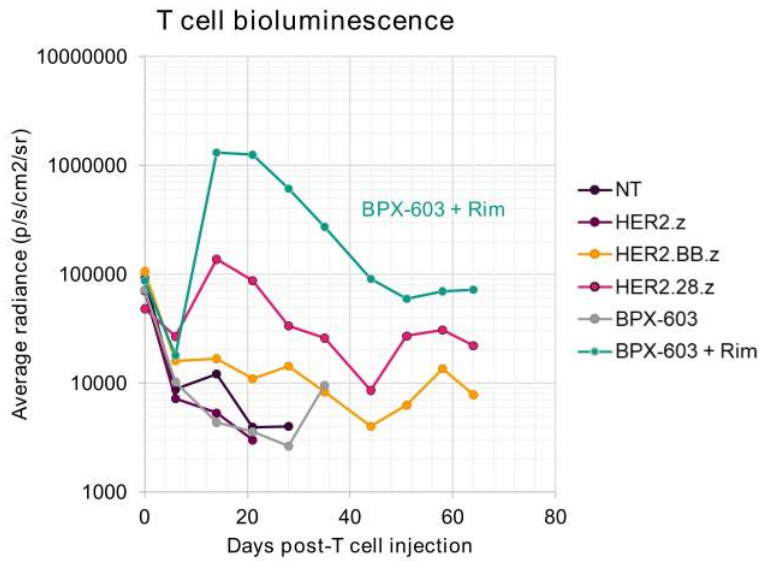
Historical HER2 Studies: Modest Clinical Outcomes

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

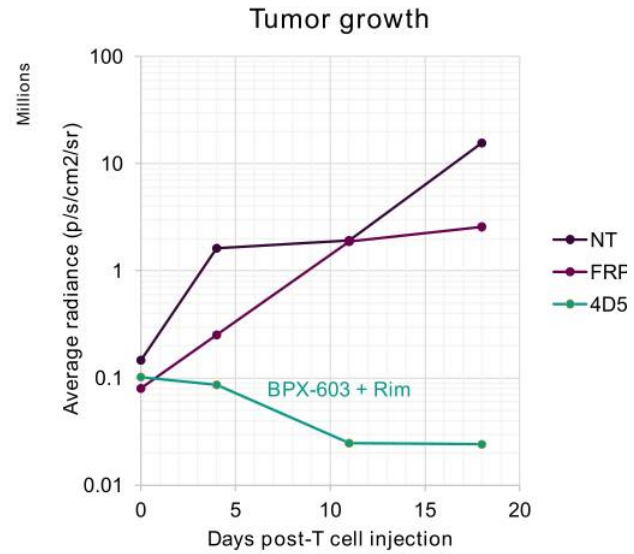
Increased CAR-T expansion

iMC activation enhances CAR-T cell proliferation compared to conventional costimulatory domains



Increased Efficacy with Higher Affinity Binder

Comparison to lower affinity binder



BPX-603 Regulatory Status

- IND application on hold pending additional non-clinical data to characterize the potential risk of off-tumor / on-target toxicity
- Based on dialogue with FDA, Bellicum believes additional *in vitro* studies may be sufficient to address FDA's questions and has initiated these experiments
- IND clearance timeline dependent on results of non-clinical studies, which are expected to become available for submission in 2H 2020
- Upon IND clearance, preparing for initiation of a Phase 1 clinical trial of BPX-603 in HER2+ solid tumors



BCMA OTS GoCAR-NK



GoCAR-NK Powers Potential of NK Cell Therapies

NK Cells Have Therapeutic Advantages

- Innate ability to kill tumor cells through multiple mechanisms
- Good safety profile following adoptive transfer
- Potential off-the-shelf cell therapy given low propensity to cause GvHD

Other NK Cell Features Limit Therapeutic Utility

- Unmodified NK cells show limited in vivo expansion and persistence (7-14 days)
- Tumors can develop defense mechanisms to limit NK cell cytotoxicity and cytokine production

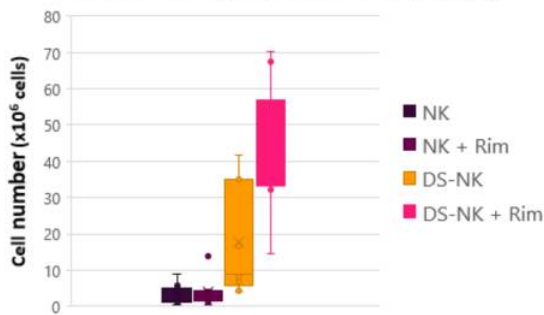
Preclinical Data Support GoCAR-NK Advantages

- MC improves proliferation and survival of NK cells
- MC signaling enhances innate cytotoxicity of NK cells
- MC synergizes with IL-15 to further increase anti-tumor potency
- iMC, IL-15 and tumor-specific CAR transgene expression result in superior anti-tumor effects in multiple tumor models

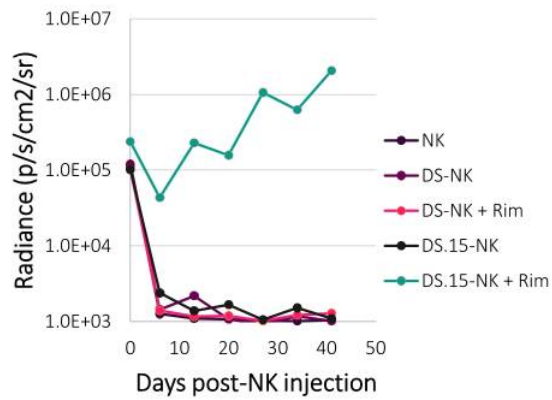
iMC Drives NK Cell Proliferation

iMC and IL-15 synergize to promote NK cell survival and persistence

Proliferation against K562 cells (9 days)



NK persistence (tumor-free mice)

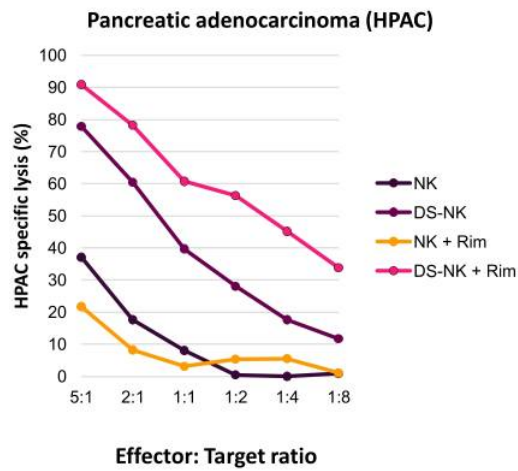
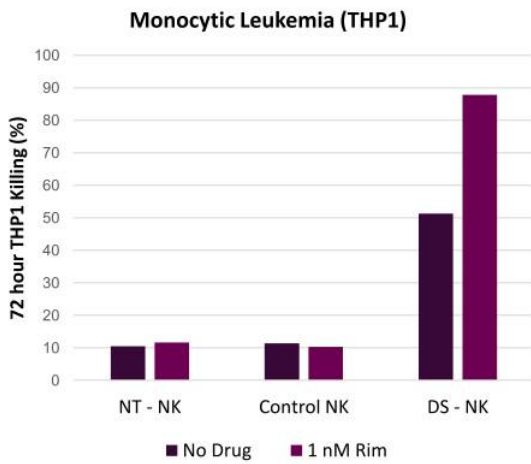


- NK cell infusions frequently die from poor growth and survival
- iMC activation enhances NK cell expansion
- IL-15 is a potent growth and survival factor for T and NK cells but not T_{reg}
- iMC activation synergizes with autocrine expression of IL-15 to promote NK cell persistence

*DS: Dual switch that includes iMC and CaspaCIDE switches;
DS-15: Dual switch and express IL-15



iMC Increases Innate Cytotoxicity of NK Cells

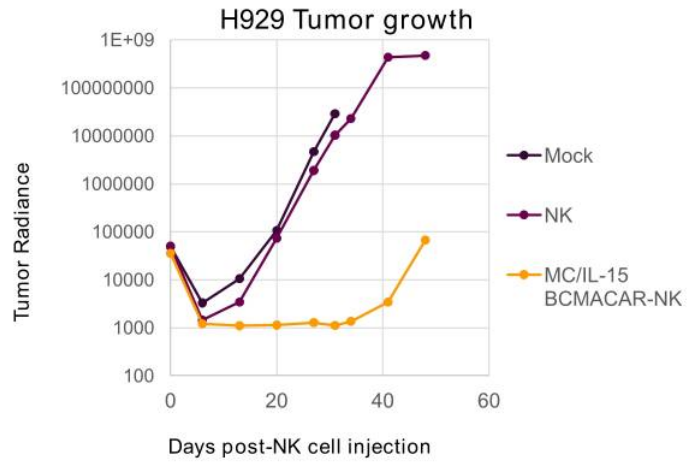
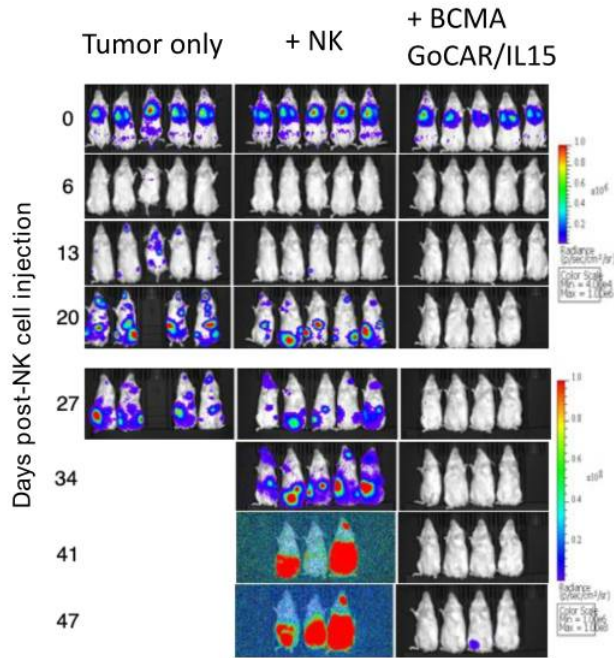


- CAR-based cell therapies frequently suffer from tumor relapse due to loss of the target antigen's expression
- NK cells possess mechanisms for direct innate anti-tumor cytotoxicity
- iMC expression and activation enhances innate NK cell cytotoxicity against tumors with high and low MHC-I expression
- iMC enhanced CAR-NK therapy may reduce the risk of tumor antigen escape

*DS: Dual switch that includes iMC and CaspaCIDE switches

MC/IL-15 BCMA CAR-NK Cells - Anti-tumor Efficacy

CAR-NK persistence with rimiducid stimulation extends past eight weeks



*Tumor cell bioluminescence



BCMA - Attractive Target for OTS GoCAR-NK

- BCMA is a well validated target for autologous CAR-T therapy
 - High response rates observed in pivotal trial (73.4%¹) with emerging questions about durability (mDoR 10.6mo¹)
- GoCAR-NK has the opportunity to improve durability
 - GoCAR enhances NK cell persistence and cytotoxicity
 - GoCAR enhances innate NK cell anti-tumor activity against myeloma cells that may compensate for antigen loss
 - Potential to improve durability using healthy patient donor cells^{2,3}
- OTS GoCAR-NK cells expected to have added advantages of shorter time to treatment and lower cost of good.

¹BMS and Bluebird joint ASH2019 press release, NCT03361748 KarMMa topline data

²Graham et al. Cells 2018;

³June et al. NEJM 2018





Summary

Anticipated Key Program Goals & Milestones

	Goals & Milestones	Timing
BPX-601	Presentation of new translational results, cohort 5B	Jan 2020
	Presentation of interim repeat Rim data, cohort 5C	2H 2020
BPX-603	IND clearance, dependent on resolution of FDA request for additional non-clinical data	Update 2H 2020
OTS GoCAR-NK	Presentation of preclinical data	2H 2020

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