

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): October 14, 2020

CHECKMATE PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39425
(Commission
File Number)

36-4813934
(I.R.S. Employer
Identification No.)

Checkmate Pharmaceuticals, Inc.
245 Main Street, 2nd Floor
Cambridge, MA 02142
(Address of principal executive offices, including zip code)

(617) 682-3625
(Registrant's telephone number, including area code)

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	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	CMPI	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

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 October 15, 2020, Checkmate Pharmaceuticals, Inc. (the “Company”) issued a press release announcing new data presentations evaluating CMP-001, the Company’s Toll-like receptor 9 (TLR9) agonist, to be presented at the 35th Annual Meeting of the Society for Immunotherapy of Cancer (“SITC”). The Company also reported that on October 14, 2020, the abstracts for these presentations were inadvertently made publicly available on SITC’s website, in violation of SITC’s disclosure embargo, for a period of time prior to their intended release on November 9, 2020. During this time, investors and other interested parties may have accessed and downloaded such abstracts. The press release, which contains copies of such abstracts as submitted to SITC, is furnished hereto as Exhibit 99.1 and is incorporated herein by reference. The Company undertakes no obligation to update, supplement or amend the materials attached hereto.

The information herein and in the exhibit hereto is being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits**(d) Exhibit****No. Description**

99.1 [Press Release, dated October 15, 2020.](#)

SIGNATURE

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.

Checkmate Pharmaceuticals, Inc.

Date: October 20, 2020

By: /s/ Kleem Chaudhary
Kleem Chaudhary, Ph.D.
Chief Business Officer



Checkmate Pharmaceuticals Announces Data Presentations for CMP-001 at The Society for Immunotherapy of Cancer (SITC) 35th Anniversary Annual Meeting

October 15, 2020

CMP-001 in combination with pembrolizumab continues to demonstrate durable responses in anti-PD-1 refractory melanoma Encouraging new data on pathological responses and 1-year RFS with neoadjuvant CMP-001 and nivolumab in resectable Stage III melanoma

CAMBRIDGE, Mass., Oct. 15, 2020 (GLOBE NEWSWIRE) — Checkmate Pharmaceuticals, Inc. (NASDAQ: CMPI) (“Checkmate”), a clinical stage biotechnology company focused on developing proprietary technology to harness the power of the immune system to combat cancer, today announced new data presentations evaluating CMP-001, Checkmate’s Toll-like receptor 9 (TLR9) agonist, at The Society for Immunotherapy of Cancer (SITC) 35th Anniversary Annual Meeting to be held virtually November 9-14, 2020.

The abstracts for these presentations appeared briefly on the SITC website in error prior to their intended release on November 9, 2020, and as a result are provided in full below.

“These data continue to demonstrate the compelling clinical activity and manageable safety profile of CMP-001 in combination with anti-PD-1 antibodies in patients with melanoma,” said Dr. James Wooldridge, Chief Medical Officer at Checkmate Pharmaceuticals. “Of particular note, we are encouraged by the maturing results in the neoadjuvant study that will be presented by Dr. Davar, including a pathological response rate (pCR, pMR, pPR) of 70%, and a 1-year relapse-free survival of 82%, which trended higher in patients achieving a pathological response.”

Presentation Details (presented without modification below):

Title: Intratumoral injection of CMP-001, a Toll-like receptor 9 (TLR9) agonist, in combination with pembrolizumab reversed programmed death receptor 1 (PD-1) blockade resistance in advanced melanoma

Presenting Author: Mohammed Milhem

Abstract #: 579

Location: Virtual Poster Hall November 11-14, 9:00am – 5:00pm ET

Full abstract:

Background: Therapeutic options are limited for patients with advanced melanoma that is refractory to PD-1 blockade. This study was performed in this patient population to assess the safety and antitumor activity of CMP-001, a CpG-A TLR9 agonist packaged within a virus-like particle.

Methods: Patients were eligible for this 2-part, open-label, multicenter, phase 1b study if they had metastatic/unresectable melanoma and stable disease after ³12 weeks or progressive disease (PD) on/after anti-PD-1 therapy. Part 1 evaluated CMP-001 plus pembrolizumab dose-escalation and dose-expansion. Part 2 evaluated CMP-001 monotherapy. Accessible lesion(s) were injected intratumorally with CMP-001, at a polysorbate 20 (PS20) concentration of either 0.01% or 0.00167%. The Part 1 primary objective was to identify the recommended phase 2 dose (RP2D) and schedule of CMP-001 plus pembrolizumab, while the Part 2 primary objective was to assess the safety of CMP-001 monotherapy. Secondary objectives for both parts were a preliminary assessment of antitumor activity of CMP-001 plus pembrolizumab and CMP-001 monotherapy, and the overall safety profile and pharmacodynamics of the combination.

Results: In Part 1 (N=159) and Part 2 (N=40), 93.1% and 80.0% of patients had PD as their last response to prior anti-PD-1 therapy, respectively. The most common treatment-related adverse events (TRAEs; >25%) were flu-like symptoms (Parts 1 and 2) and injection-site reactions (Part 1). Grade 3/4 TRAEs were reported in 36.5% (Part 1) and 22.5% (Part 2) of patients, the most common being hypotension (Part 1: 6.9%; Part 2: 5.0%). No Grade 5 TRAEs were observed.

In Part 1, the best objective response rate (ORR; RECIST v1.1) in patients treated with pembrolizumab and CMP-001 (PS20 0.01%) was 23.5% (23/98), while CMP-001 PS20 (0.00167%) resulted in a lower ORR of 11.5% (7/61). Seven additional patients had a delayed response after initial PD (Table). The median duration of response was >1 year. In the 37 RECIST v1.1 and post-progression responders, the mean regression in injected and noninjected target lesions was 54.7% and 52.7%, respectively. In Part 2, the best ORR with CMP-001 monotherapy was 17.5% (7/40 patients); the response duration was shorter than in Part 1. Intratumoral CMP-001 PS20 0.01% 10 mg was selected as the RP2D.

Conclusion: Intratumoral CMP-001 was well-tolerated and provided both local and distant responses in patients with advanced melanoma with disease progression on prior PD-1 blockade. CMP-001 monotherapy induced systemic tumor regression in some patients, but duration of response was substantially increased by the addition of pembrolizumab.

Title: Phase II Trial of Neoadjuvant Nivolumab (Nivo) and Intra-Tumoral (IT) CMP-001 in High-Risk Resectable Melanoma (Neo-C-Nivo) Presenting Author: Diwakar Davar

Abstract #: 612

Location: Virtual Oral Presentation November 11, 5:30 – 6:30pm ET

Full Abstract:

Background: Neoadjuvant PD-1 blockade produces major pathological responses (MPR) in ~30% of patients (pts) with high-risk resectable melanoma

(MEL) with durable relapse-free benefit, and increased circulating activated CD8+ T cells [1,2]. CMP-001 is a type A CpG packaged within a virus-like particle that activates tumor-associated plasmacytoid dendritic cells (pDC) via TLR9 inducing type I interferons and anti-tumor CD8+ T cells. CMP-001/pembrolizumab produces durable anti-tumor responses in PD-1 refractory melanoma [3]. We previously reported preliminary evidence of efficacy of neoadjuvant IT CMP/Nivo in high-risk resectable MEL; and herein present final results on 30 evaluable patients.

Methods: 30 pts with stage III B/C/D MEL were enrolled. Pre-operatively, CMP-001 was dosed at 5mg subcutaneous (SC, 1st), then 10mg IT (2nd-7th) weekly; and Nivo was dosed 240mg q2weeks for 3 doses – both over a 7-week period. Post-operatively, Nivo was dosed 480mg q4weeks with CMP-001 5mg q4 weeks SC for 48 weeks. Primary endpoints included major pathologic response (MPR) rate, and incidence of dose-limiting toxicities (DLT). Secondary endpoints were radiographic response, relapse-free survival (RFS) and overall survival (OS). Pathological response was scored by blinded pathologist based on residual volume of tumor (RVT) using prior cutoffs [4-6]: 0% (complete response, pCR); 0%<RVT<10% (major response, pMR); 10%<RVT<50% (partial response, pPR) and RVT>50% (non-response, pNR). Radiographic response was assessed using RECIST v1.1. Sequential blood draws and tumor biopsies were collected and analyzed for CD8+ T cell infiltrate (TIL), multiparameter flow cytometry (MFC) and multiplex immunofluorescence (mIF).

Results: 30 pts with advanced MEL were enrolled, and staged as: IIIB (57%), IIIC (37%), IIID (7%). 29/30 (97%) of pts completed 7 weeks of neoadjuvant Nivo/CMP; while 1 pt had a delay in surgery related to a pre-operative infection unrelated to therapy. No DLTs were reported; although grade 3/4 irAE were reported in 3 pts (11%) leading to CMP-001 discontinuation in 2 pts (7%). Radiographic responses seen in 13 pts (43%), while 9 pts (30%) had stable disease and 8 pts (27%) had progressive disease. Pathological responses (RVT <50%) were seen in 70% of pts: pCR 15 (50%), pMR 3 (10%), 3 pPR (10%); while 9 (30%) had pNR. Pathological responders (pCR/pMR) had increased CD8+ TIL and CD303+ pDC intra-tumorally by mIF; and activated PD1+/Ki67+ CD8+ T cells by MFC peripherally.

Conclusions: Neoadjuvant CMP/Nivo has an acceptable toxicity profile and promising efficacy. MPR rate is 60% in 30 pts. 1-year RFS was 82% (all pts) and 89% (pCR/pMR); and median RFS is 9 months (pNR/pPR) and unreached (pCR/pMR). Response is associated with evidence of immune activation intra-tumorally and peripherally. IT CMP001 together increases clinical efficacy of PD-1 blockade alone with minimal additional toxicity in neoadjuvant MEL.

Title: Intravenous CMP-001, a CpG-A Toll-like receptor 9 (TLR9) agonist delivered via a virus-like particle, causes tumor regression in syngeneic Hepa1-6 mouse models of hepatocellular carcinoma

Presenting Author: Arthur M. Krieg

Abstract #: 418

Location: Virtual Poster Hall November 11-14, 9:00am – 5:00pm ET

Full Abstract:

Background: Therapeutic options are limited for patients with liver metastases and hepatocellular carcinoma (HCC). Intratumoral and subcutaneous injections of CMP-001, a CpG-A TLR9 agonist packaged within a virus-like particle, have shown evidence of antitumor activity in patients with melanoma refractory to PD-1 blockade. In mice, CMP-001 intravenously distributes primarily to the liver, while CMP-001 subcutaneous is found mostly in local tissues and draining lymph nodes. The antitumor activity of CMP-001 intravenous and subcutaneous were compared with PD-1 blockade or sorafenib in two Hepa1-6 orthotopic mouse models of HCC.

Methods: Groups of 10-15 C57BL/6J mice were orthotopically implanted with syngeneic murine hepatoma cells using two different models. Model 1 used 1.5 x 10⁶ Hepa1-6 cells injected into the spleen following a partial hepatectomy; Model 2 used 1 x 10⁶ Hepa1-6-Luc cells injected into the upper left lobe of intact liver. Treatment was initiated 3-7 days later with either CMP-001 intravenous or subcutaneous Q4-5Dx3-4 doses, PD-1 blocking antibody intraperitoneal Q3-4Dx2 (Bio X Cell clone RPM1-14), or sorafenib QD oral. Antitumor activity was assessed by tumor imaging, liver weight, and/or survival.

Results: CMP-001 was compared with PD-1 blocking antibody therapy in Model 1, the more aggressive model. All animals were sacrificed at day 15 due to institutional welfare requirements. Tumor growth inhibition (TGI) was assessed by comparison of liver weight to body weight ratios, which relative to untreated control mice showed that CMP-001 intravenous achieved 85% mean TGI compared with 63% mean TGI for CMP-001 subcutaneous and 15% mean TGI for PD-1 blocking antibody intraperitoneal (Table 1). CMP-001 intravenous was compared to sorafenib oral in Model 2, which utilized an engineered Hepa1-6 cell line that expresses luciferase to enable noninvasive monitoring of liver tumor growth. CMP-001 intravenous was active, with a 67% mean TGI, and survival that was comparable to sorafenib (Table 2; Figure 1).

Conclusion: In orthotopic mouse models of HCC, the antitumor activity of CMP-001 intravenous was greater than PD-1 blockade and comparable to sorafenib. CMP-001 intravenous was more active than CMP-001 subcutaneous in this model, which we hypothesize is due to increased liver exposure with intravenous infusion. Antitumor activity of CMP-001 monotherapy may be increased by combining it with standard of care or other therapies, as observed relative to historical benchmarks in ongoing CMP-001 clinical trials in patients with melanoma. CMP-001 intravenous may be a promising treatment option for patients with primary or metastatic liver cancers.

About CMP-001

CMP-001 comprises a virus-like particle utilizing a CpG-A oligonucleotide. It is designed to trigger the body's innate immune system via TLR9 and infiltrate the tumor microenvironment by the subsequent induction of both innate and adaptive anti-tumor immune responses. Checkmate believes CMP-001 is the only compound utilizing a CpG-A class TLR9 agonist in clinical development. For information on CMP-001 trials that are currently recruiting patients, please visit www.clinicaltrials.gov.

About Checkmate Pharmaceuticals

Checkmate Pharmaceuticals is a clinical stage biotechnology company focused on developing proprietary technology to harness the power of the immune system to combat cancer. Checkmate's product candidate, CMP-001, is a differentiated TLR9 agonist delivered as a biologic virus-like particle designed to trigger the body's innate immune system to attack tumors in combination with other therapies. Checkmate's goal is to leverage its proprietary technology to discover, develop and commercialize transformative treatments to fight cancer. Information regarding Checkmate is available at www.checkmatepharma.com.

Forward Looking Statements

Various statements in this release are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including. Words such as, but not limited to, “anticipate,” “believe,” “can,” “could,” “expect,” “estimate,” “design,” “goal,” “intend,” “may,” “might,” “objective,” “plan,” “predict,” “project,” “target,” “likely,” “should,” “will,” and “would,” or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. These statements include those regarding our product candidate, including its development and therapeutic potential and the advancement of our clinical and preclinical pipeline; expectations regarding the results and analysis of data. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. These forward-looking statements are subject to risks and uncertainties, including those related to the development of our product candidate, including any delays in our ongoing or planned preclinical or clinical trials, positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies, the impact of the ongoing COVID-19 pandemic on our business, operations, clinical supply and plans, the risks inherent in the drug development process, the risks regarding the accuracy of our estimates of expenses and timing of development, our capital requirements and the need for additional financing, and obtaining, maintaining and protecting its intellectual property. These and additional risks are discussed in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our prospectus dated August 6, 2020, as filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act 1933, as amended, which is available on the SEC’s website at www.sec.gov.

Investor Contact
Kleem Chaudhary
Chief Business Officer
kleem@checkmatepharma.com

Media Contact
Karen Sharma MacDougall
781-235-3060
ksharma@macbiocom.com