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): **July 24, 2020**

Blueprint Medicines Corporation

(Exact name of registrant as specified in its charter)

Delaware	**001-37359**	**26-3632015**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

45 Sidney Street **Cambridge, Massachusetts**	**02139**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(617) 374-7580**

(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))

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. ☐

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	BPMC	Nasdaq Global Select Market

Item 8.01 Other Events.

On July 24, 2020, Blueprint Medicines Corporation issued a press release announcing that the European Medicines Agency's Committee for Medicinal Products for Human Use has adopted a positive opinion, recommending conditional marketing authorization for avapritinib as a monotherapy for the treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumors harboring the PDGFRA D842V mutation. A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Blueprint Medicines Corporation on July 24, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and incorporated as Exhibit 101)

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.

BLUEPRINT MEDICINES CORPORATION

Date: July 24, 2020

By: /s/ Jeffrey W. Albers
Jeffrey W. Albers
Chief Executive Officer

Blueprint Medicines Receives Positive CHMP Opinion for Avapritinib for the Treatment of Adults with Unresectable or Metastatic PDGFRA D842V Mutant Gastrointestinal Stromal Tumors

-- European Commission decision anticipated by the end of September 2020 --

CAMBRIDGE, Mass., July 24, 2020 – Blueprint Medicines Corporation (NASDAQ: BPMC), a precision therapy company focused on genomically defined cancers, rare diseases and cancer immunotherapy, today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending conditional marketing authorization for avapritinib as a monotherapy for the treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumors (GIST) harboring the PDGFRA D842V mutation.

The CHMP opinion will now be reviewed by the European Commission, which has the authority to grant marketing authorization for medicinal products in the European Union (EU). A final decision on the marketing authorization application for avapritinib is anticipated by the end of September 2020. If approved by the European Commission, avapritinib would be the first treatment in the EU indicated for patients with PDGFRA D842V mutant GIST and would be commercialized under the brand name AYVAKYT®.

"Avapritinib has shown unprecedented clinical activity in patients with PDGFRA D842V mutant GIST, who have traditionally had poor prognoses," said Andy Boral, M.D., Ph.D., Chief Medical Officer at Blueprint Medicines. "Today's positive CHMP opinion reflects important progress toward our goal of making this highly effective treatment option available in the EU. For patients with PDGFRA D842V mutant GIST, avapritinib is designed to fundamentally change the treatment paradigm by selectively inhibiting an oncogenic driver shown to be resistant to existing GIST therapies."

The CHMP based its opinion on efficacy results from the Phase 1 NAVIGATOR trial as well as combined safety results from the NAVIGATOR and Phase 3 VOYAGER trials. Treatment with avapritinib showed deep and durable clinical responses and was well-tolerated in patients with PDGFRA D842V mutant GIST. Data in this patient population were published in *The Lancet Oncology* on June 29, 2020.

About Avapritinib

Avapritinib is a kinase inhibitor approved by the U.S. Food and Drug Administration (FDA) under the brand name AYVAKIT™ for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. The FDA granted breakthrough therapy designation to avapritinib for the treatment of unresectable or metastatic GIST harboring the PDGFRA D842V mutation.

Avapritinib is not approved for the treatment of any other indication in the U.S. by the FDA or for any indication in any other jurisdiction by any other health authority.

The European Commission granted orphan medicinal product designation for avapritinib for the treatment of GIST and mastocytosis. Blueprint Medicines is developing avapritinib globally for patients with advanced and indolent systemic mastocytosis (SM). The FDA granted breakthrough therapy designation to avapritinib for the treatment of advanced SM, including the subtypes of aggressive SM, SM with an associated hematologic neoplasm and mast cell leukemia.

Blueprint Medicines has an exclusive collaboration and license agreement with CStone Pharmaceuticals for the development and commercialization of avapritinib and certain other drug candidates in Mainland China, Hong Kong, Macau and Taiwan. Blueprint Medicines retains development and commercial rights for avapritinib in the rest of the world.

About GIST

GIST is a sarcoma, or tumor of bone or connective tissue, of the GI tract. Tumors arise from cells in the wall of the GI tract and occur most often in the stomach or small intestine. Most patients are diagnosed between the ages of 50 to 80, and diagnosis is typically triggered by GI bleeding, incidental findings during surgery or imaging and, in rare cases, tumor rupture or GI obstruction.

About 5 to 6 percent of primary GIST cases are caused by a PDGFRA D842V mutation, the most common PDGFRA exon 18 mutation. Prior to the FDA approval of AYVAKIT, there were no highly effective treatments for PDGFRA D842V mutant GIST in the U.S. Published data have shown poor outcomes in patients with PDGFRA D842V mutant GIST treated with imatinib and other approved therapies, including a median overall survival of 15 months, a median progression-free survival of 3 months and an overall response rate of 0 percent.[1]

About Blueprint Medicines

Blueprint Medicines is a precision therapy company striving to improve human health. With a focus on genomically defined cancers, rare diseases and cancer immunotherapy, we are developing transformational medicines rooted in our leading expertise in protein kinases, which are proven drivers of disease. Our uniquely targeted, scalable approach empowers the rapid design and development of new treatments and increases the likelihood of clinical success. We have one FDA-approved precision therapy and are currently advancing multiple investigational medicines in clinical development, along with a number of research programs. For more information, visit www.BlueprintMedicines.com and follow us on Twitter (@BlueprintMeds) and LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the expectations and timing for a decision from the European Commission on the marketing authorization application for avapritinib for the treatment of adults with PDGFRA D842V mutant GIST; the potential benefits of avapritinib in treating patients; timing and plans for commercialization of avapritinib in the U.S. and, if approved, in additional geographies; and Blueprint Medicines' strategy, goals and anticipated milestones, business plans and focus. The words "aim," "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks and uncertainties related to the impact of the COVID-19 pandemic to Blueprint Medicines' business, operations, strategy, goals and anticipated milestones, including Blueprint Medicines' ongoing and planned research and discovery activities, ability to conduct ongoing and planned clinical trials, clinical supply of current or future drug candidates, commercial supply of current or future approved products, and launching, marketing and selling current or future approved products; Blueprint Medicines' ability and plan in establishing a commercial infrastructure, and successfully launching, marketing and selling current or future approved products; the delay of any current or planned clinical trials or the development of Blueprint Medicines' drug candidates or licensed product candidate; Blueprint Medicines' advancement of multiple early-stage efforts; Blueprint Medicines' ability to successfully demonstrate the safety and efficacy of its drug candidates and gain approval of its drug candidates on a timely basis, if at all; the preclinical and clinical results for Blueprint Medicines' drug candidates, which may not support further development of such drug candidates; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; Blueprint Medicines' ability to develop and commercialize companion diagnostic tests for its current and future drug candidates; and the success of Blueprint Medicines' current and future collaborations or licensing arrangements. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Blueprint Medicines' filings with the Securities and Exchange Commission (SEC), including Blueprint Medicines' most recent Annual Report on Form 10-K, as supplemented by its most recent Quarterly

Report on Form 10-Q and any other filings that Blueprint Medicines has made or may make with the SEC in the future. Any forward-looking statements contained in this press release represent Blueprint Medicines' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Except as required by law, Blueprint Medicines explicitly disclaims any obligation to update any forward-looking statements.

Reference

[1] Cassier PA, Fumagalli E, Rutkowski P., et al. Outcome of patients with platelet-derived growth factor receptor alpha-mutated gastrointestinal stromal tumors in the tyrosine kinase inhibitor era. *Clin Cancer Res.* 2012;18(16):4458-4464.

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