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): November 5, 2018

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

Delaware	**000-31141**	**33-0655706**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

784 Memorial Drive, Cambridge, MA	**02139**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 453-1000

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. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 5, 2018, Infinity Pharmaceuticals, Inc. (the "Company") issued a press release announcing our results for the quarter ended September 30, 2018 and will conduct a previously announced, publicly available conference call to discuss those results. The full text of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The information contained on the websites referenced in the press release is not incorporated herein.

This information and Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On November 5, 2018, the Company issued a press release announcing plans to initiate MARIO-275, a global, randomized Phase 2 study to evaluate the effect of adding IPI-549 to nivolumab in checkpoint-naïve advanced urothelial cancer patients who have progressed or recurred following treatment with platinum-based chemotherapy. In connection with the Phase 2 study, the Company and Bristol Myers Squibb ("BMS") have entered into a clinical trial supply agreement under which BMS has agreed to supply nivolumab for the study. The full text of this press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. The information contained on the websites referenced in the press release is not incorporated herein.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibit is included in this report:

Exhibit No.	Description
99.1	Press release dated November 5, 2018
99.2	Press release dated November 5, 2018

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.

INFINITY PHARMACEUTICALS, INC.

Date: November 5, 2018

By: /s/Seth A. Tasker
Seth A. Tasker
Vice President, General Counsel

Exhibit 99.1

www.infi.com

Infinity Pharmaceuticals Provides Company Update and Third Quarter 2018 Financial Results

– Plans to Initiate IPI-549 MARIO-275, a Randomized, Global Phase 2 Study in Urothelial Cancer in Clinical Collaboration with Bristol-Myers Squibb –

– Late-Breaking Presentation at the Society for Immunotherapy of Cancer (SITC) Annual Meeting of Data from Combination Expansion Cohorts of the IPI-549 MARIO-1 Phase 1b Study –

– Company to Host Investor Event at SITC –

Cambridge, Mass. – November 5, 2018 – Infinity Pharmaceuticals, Inc. (NASDAQ: INFI) today announced its third quarter 2018 financial results and provided an update on the company and its progress with IPI-549, a first-in-class oral immuno-oncology product candidate that selectively inhibits phosphoinositide-3-kinase-gamma (PI3K-gamma) and targets immuno-suppressive tumor macrophages/myeloid-derived suppressor cells (MDSCs).

"We approach the end of 2018 with tremendous momentum in developing IPI-549 as an effective therapy for patients whose cancers are not adequately treated by existing immuno-therapies," said Adelene Perkins, Chief Executive Officer and Chair of Infinity Pharmaceuticals. "Our clinical and translational data have laid the foundation for the broader, later-stage development of IPI-549, including Infinity's clinical development of IPI-549 in a Phase 2 trial in urothelial cancer in collaboration with Bristol-Myers Squibb. We look forward to providing an update at the SITC annual meeting on November 10."

Infinity is evaluating IPI-549 as a monotherapy and in combination with Opdivo® (nivolumab), a PD-1 immune checkpoint inhibitor, in collaboration with Bristol-Myers Squibb, in the MARIO-1 Phase 1b study in approximately 200 patients with advanced solid tumors. Infinity is also planning to initiate the MARIO-275 global, randomized Phase 2 study to evaluate the effect of adding IPI-549 to Opdivo in checkpoint inhibitor-naïve advanced urothelial cancer patients who have progressed or recurred following treatment with platinum-based chemotherapy. Approximately 150 patients will be randomized between combination therapy and Opdivo monotherapy. In addition, Arcus Biosciences will initiate two triple combinations investigating IPI-549 with their dual adenosine receptor antagonist, AB928, anti-PD-1 antibody, AB122, and chemotherapy in triple negative breast cancer and ovarian cancer. One triple combination therapy will evaluate IPI-549 in combination with AB928 and AB122 and the second will

evaluate IPI-549 in combination with AB928 and chemotherapy, with topline data expected in 2019.

Recent developments include the following:

IPI-549

- **Infinity to Host Investor Reception and Webcast at the SITC Annual Meeting to Discuss Combination Expansion Data from the IPI-549 MARIO-1 Phase 1b Study:** Saturday, November 10, 2018 from 6:30 a.m. ET – 7:30 a.m. ET.
- **Announcement of clinical collaboration with BMS to evaluate IPI-549 in MARIO-275 Controlled Phase 2 Study of IPI-549 in Combination with Opdivo in Urothelial Cancer:** This study leverages the exploratory analyses of data from Bristol-Myers Squibb's CheckMate-275 study, in which high levels of MDSCs were associated with shorter overall survival in patients treated with Opdivo.[1] In Infinity's MARIO-1 trial, MDSCs were reduced in the majority of patients treated with IPI-549 monotherapy.[2] IPI-549 in combination with nivolumab has been well tolerated and demonstrated early evidence of clinical activity with translational studies demonstrating evidence of on-mechanism IPI-549-mediated effects.[3]

Third Quarter 2018 Financial Results

- At September 30, 2018, Infinity had total cash, cash equivalents and available-for-sale securities of $42.2 million, compared to $49.2 million at June 30, 2018.
- Revenue for the third quarter of 2018 was $22.0 million, all of which related to the amount due from Verastem for the approval by the U.S. Food and Drug Administration on September 24, 2018 of duvelisib for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma after at least two prior therapies, as well as adult patients with relapsed or refractory follicular lymphoma after at least two prior systemic therapies. Infinity received the $22.0 million in cash on November 2nd, which is not reflected in the $42.2 million cash balance as of September 30, 2018. Revenue for the third quarter of 2017 was $6.0 million, all of which related to the amount due from Verastem for the DUO study meeting the pre-specified criteria at completion.
- R&D expense for the third quarter of 2018 was $5.4 million, compared to $9.3 million for the same period in 2017. The decrease in R&D expense was primarily due to the convertible note issued to Takeda in July 2017.
- General and administrative expense was $3.4 million for the third quarter of 2018, compared to $4.5 million for the same period in 2017. The decrease in G&A expense was primarily due to a reduction in stock compensation.
- Net income for the third quarter of 2018 was $13.4 million, or a basic and diluted earnings per common share of $0.23, compared to a net loss of $7.1 million, or a basic and diluted loss per common share of $0.14 for the same period in 2017.

Financial Outlook

Infinity's 2018 financial guidance is:

- **Net Loss:** Infinity expects net loss for 2018 to range from $10 million to $20 million.
- **Cash and Investments:** Infinity expects to end 2018 with a year-end cash, cash equivalents and available-for-sale securities balance ranging from $50 million to $60 million.
- **Cash Runway:** Based on its current operational plans, Infinity expects that its existing cash, cash equivalents and available-for-sale securities will be adequate to satisfy the company's capital needs into 2020. Infinity's financial guidance excludes additional funding or business development activities and does not include a potential $2 million payment from PellePharm, a private company, upon initiation of a Phase 3 study for the hedgehog inhibitor program, which Infinity licensed to PellePharm in 2013.

Conference Call Information

Infinity will host a conference call today, November 5, 2018, at 4:30 p.m. ET to discuss these financial results and company updates. A live webcast of the conference call can be accessed in the "Investors/Media" section of Infinity's website at www.infi.com. To participate in the conference call, please dial 1-877-316-5293 (domestic) or 1-631-291-4526 (international) five minutes prior to start time. The conference ID number is 8617458. An archived version of the webcast will be available on Infinity's website for 30 days.

About IPI-549 and the Ongoing MARIO-1 Phase 1/1b Study

IPI-549 is an investigational first-in-class, oral, immuno-oncology product candidate targeting tumor-associated myeloid cells through selective phosphoinositide-3-kinase-gamma (PI3K-gamma) inhibition, thereby reducing pro-tumor macrophage function and increasing anti-tumor macrophage function. In preclinical studies, IPI-549 demonstrated the ability to reprogram macrophages from a pro-tumor (M2), immune suppressive function, to an anti-tumor (M1) immune activating function and enhance the activity of, and overcome resistance to, checkpoint inhibitors.[4, 5] As such, IPI-549 may have the potential to treat a broad range of solid tumors and represents a potentially additive or synergistic approach to restoring anti-tumor immunity in combination with other immunotherapies such as checkpoint inhibitors.

The ongoing MARIO-1 Phase 1/1b study being conducted by Infinity is designed to evaluate the safety, tolerability, activity, pharmacokinetics and pharmacodynamics of IPI-549 as a monotherapy and in combination with Opdivo in approximately 200 patients with advanced solid tumors.[6] The study includes monotherapy and combination dose-escalation components, in addition to monotherapy expansion and combination expansion components. The monotherapy dose-escalation and expansion components are complete. The combination dose-escalation component is also complete, and combination expansion cohorts are enrolling.

The combination expansion component of the study includes multiple cohorts designed to evaluate IPI-549 in patients with specific types of cancer, including patients with non-small cell lung cancer (NSCLC), melanoma and head and neck cancer whose tumors show initial resistance or initially respond to but subsequently develop resistance to immune checkpoint blockade therapy. The combination expansion component also includes a cohort of patients with triple

negative breast cancer (TNBC) who have not been previously treated with immune checkpoint blockade therapy, a cohort of patients with mesothelioma, a cohort of patients with adrenocortical carcinoma and a cohort of patients with high baseline blood levels of MDSCs.

IPI-549 is an investigational compound and its safety and efficacy has not been evaluated by the U.S. Food and Drug Administration or any other health authority.

About Infinity

Infinity is an innovative biopharmaceutical company dedicated to advancing novel cancer treatments. Infinity is advancing IPI-549, a potentially transformative immuno-oncology approach that aims to reprogram tumor-associated macrophages by selectively inhibiting PI3K-gamma. A Phase 1/1b study in approximately 200 patients with advanced solid tumors is ongoing. Infinity will also initiate a Phase 2 study to evaluate the effect of adding IPI-549 to Opdivo in checkpoint-naïve advanced urothelial cancer patients who have progressed or recurred following treatment with platinum-based chemotherapy. Approximately 150 patients will be randomized between combination therapy and Opdivo monotherapy. For more information on Infinity, please refer to Infinity's website at www.infi.com.

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. Such forward-looking statements include those regarding: the therapeutic potential of PI3K-gamma selective inhibition and IPI-549, alone and in combination with checkpoint inhibitors, including Opdivo; clinical trial plans regarding IPI-549; plans to report clinical and translational data of IPI-549; 2018 financial guidance; and the company's ability to execute on its strategic plans. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the company's current expectations. For example, there can be no guarantee that IPI-549 will successfully complete necessary preclinical and clinical development phases. Further, there can be no guarantee that any positive developments in Infinity's product portfolio will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other factors, including the following: Infinity's results of clinical trials and preclinical studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities; Infinity's ability to obtain and maintain requisite regulatory approvals and to enroll patients in its clinical trials; unplanned cash requirements and expenditures; development of agents by Infinity's competitors for diseases in which Infinity is currently developing or intends to develop IPI-549; and Infinity's ability to obtain, maintain and enforce patent and other intellectual property protection for IPI-549. These and other risks which may impact management's expectations are described in greater detail under the caption "Risk Factors" included in Infinity's quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 5, 2018, and other filings filed by Infinity with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and Infinity expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets
(unaudited)
(in thousands)

	September 30, 2018	December 31, 2017
Cash, cash equivalents and available-for-sale securities	$ 42,169	$ 57,609
Receivable	22,000	—
Other current assets	961	777
Property and equipment, net	58	219
Other long-term assets	725	748
Total assets	$ 65,913	$ 59,353
Accounts payable and accrued expenses	$ 6,105	$ 5,595
Note payable	—	6,000
Long-term liabilities	36	28
Total stockholders' equity	59,772	47,730
Total liabilities and stockholders' equity	$ 65,913	$ 59,353

INFINITY PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Collaboration revenue	$ 22,000	$ 6,000	$ 22,000	$ 6,000
Operating expenses:				
Research and development	5,379	9,338	15,039	17,278
General and administrative	3,442	4,505	10,435	17,147
Total operating expenses	8,821	13,843	25,474	34,425
Income (loss) from operations	13,179	(7,843)	(3,474)	(28,425)
Other income (expense):				
Investment and other income	202	1,026	534	1,663
Interest expense	—	(287)	(93)	(890)
Other expense	—	—	—	(6,882)
Total other income (expense)	202	739	441	(6,109)
Net income (loss)	$ 13,381	$ (7,104)	$ (3,033)	$ (34,534)
Earnings (loss) per common share:				
Basic	$ 0.23	$ (0.14)	$ (0.06)	$ (0.68)
Diluted	$ 0.23	$ (0.14)	$ (0.06)	$ (0.68)
Weighted average number of common shares outstanding:				
Basic	56,851,811	50,635,828	54,918,963	50,505,783
Diluted	57,638,660	50,635,828	54,918,963	50,505,783

Contact

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1 Sharma et al. AACR Annual Meeting 2018
2 Sullivan et al., ASCO 2018
3 Sullivan et al., ASCO 2018
4 Kaneda, M., Messer, K., Ralainirina, N., Li, H., et al. PI3K-gamma is a molecular switch that controls immune suppression. Nature, 2016 Nov;539:437–442.
5 De Henau, O., Rausch, M., Winkler, D., Campesato, L., et al. Overcoming resistance to checkpoint blockade therapy by targeting PI3K-gamma in myeloid cells. Nature, 2016 Nov;539:443-447.
6 www.clinicaltrials.gov, NCT02637531.

Exhibit 99.2

Bristol-Myers Squibb and Infinity Pharmaceuticals Announce a New Clinical Collaboration to Evaluate *Opdivo* (Nivolumab) in Combination with IPI-549 in Urothelial Cancer

– Plans to Initiate MARIO-275, a Randomized, Global Phase 2 Study in 1H'19 –

NEW YORK and Cambridge, MA – November 5, 2018 – Bristol-Myers Squibb Company (NYSE: BMY) and Infinity Pharmaceuticals, Inc. (NASDAQ: INFI) today announced a clinical trial collaboration to evaluate Bristol-Myers Squibb's *Opdivo* (nivolumab) in combination with Infinity's IPI-549 in patients with advanced urothelial cancer. IPI-549 is an oral immuno-oncology development candidate that is designed to selectively inhibit phosphoinositide-3-kinase (PI3K)-gamma and is the only investigational PI3K-gamma inhibitor in clinical development.

Infinity will operationalize MARIO-275: MAcrophage Reprogramming in Immuno-Oncology, a global, randomized Phase 2 study to evaluate the effect of adding IPI-549 to Opdivo in checkpoint-naïve advanced urothelial cancer patients who have progressed or recurred following treatment with platinum-based chemotherapy. Approximately 150 patients will be randomized between combination therapy and Opdivo monotherapy. The primary endpoint of the trial will be overall response rate, which will be assessed in the overall population as well as in subsets of patients with different baseline levels of myeloid derived suppressor cells (MDSCs). Opdivo is approved for use by the FDA as a single agent in patients with locally advanced or metastatic urothelial cancer who have progressed or recurred following treatment with platinum-based chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. In exploratory analyses of the CheckMate-275 data, high levels of MDSCs were associated with shorter overall survival in patients treated with Opdivo[2]. In Infinity's MARIO-1 trial, MDSCs were reduced in the majority of patients treated with IPI-549 monotherapy.[3] IPI-549 in combination with Opdivo has been administered to over 80 patients and demonstrated early evidence of clinical activity with translational studies demonstrating evidence of on-mechanism IPI-549-mediated effects.[4]

“The expansion of our relationship with Infinity underscores our efforts to follow the science and support potential novel combination therapies in immuno-oncology for cancer patients with limited treatment options,” said Fouad Namouni, M.D., Head of Oncology Development, Bristol-Myers Squibb. “Our goal is to determine whether targeting the tumor microenvironment with IPI-549 will enhance the activity of Opdivo for people with urothelial cancer and potentially in other tumor types where MDSCs suppress the immune response.”

“We are excited to advance the development of IPI-549 further into the checkpoint inhibitor treatment-naïve setting with this randomized study in collaboration with the team at Bristol-Myers Squibb.,” said Dr. Sam Agresta, Chief Medical Officer of Infinity. “There continues to be a significant unmet need for additional treatment options for people living with urothelial cancer, and we are excited to evaluate the potential of this combination.”

Infinity is continuing to evaluate IPI-549 in combination with Opdivo in MARIO-1, a Phase 1/1b study in patients with advanced solid tumors.

Opdivo was the first PD-1 immune checkpoint inhibitor to receive regulatory approval anywhere in the world in July 2014, and currently has regulatory approval in 54 countries including the United States, Japan, and in the European Union.

About *Opdivo*

Opdivo is a programmed death-1 (PD-1) immune checkpoint inhibitor that is designed to uniquely harness the body’s own immune system to help restore anti-tumor immune response. By harnessing the body’s own immune system to fight cancer, *Opdivo* has become an important treatment option across multiple cancers.

Opdivo’s leading global development program is based on Bristol-Myers Squibb’s scientific expertise in the field of Immuno-Oncology and includes a broad range of clinical trials across all phases, including Phase 3, in a variety of tumor types. To date, the *Opdivo* clinical development program has enrolled more than 25,000 patients. The *Opdivo* trials have contributed to gaining a deeper understanding of the potential role of biomarkers in patient care, particularly regarding how patients may benefit from *Opdivo* across the continuum of PD-L1 expression.

In July 2014, *Opdivo* was the first PD-1 immune checkpoint inhibitor to receive regulatory approval anywhere in the world. *Opdivo* is currently approved in more than 60 countries,

including the United States, the European Union, and Japan. In October 2015, the company's *Opdivo* and *Yervoy* combination regimen was the first Immuno-Oncology combination to receive regulatory approval for the treatment of metastatic melanoma and is currently approved in more than 50 countries, including the United States and the European Union.

U.S. FDA-APPROVED INDICATIONS FOR OPDIVO

OPDIVO® (nivolumab) as a single agent is indicated for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

OPDIVO® (nivolumab) as a single agent is indicated for the treatment of patients with BRAF V600 wild-type unresectable or metastatic melanoma.

OPDIVO® (nivolumab), in combination with YERVOY® (ipilimumab), is indicated for the treatment of patients with unresectable or metastatic melanoma. This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

OPDIVO® (nivolumab) is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving OPDIVO.

OPDIVO® (nivolumab) is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.

OPDIVO® (nivolumab), in combination with YERVOY® (ipilimumab), is indicated for the treatment of patients with intermediate or poor-risk, previously untreated advanced renal cell carcinoma (RCC).

OPDIVO® (nivolumab) is indicated for the treatment of adult patients with classical Hodgkin lymphoma (cHL) that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin or after 3 or more lines of systemic therapy that includes autologous HSCT. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

OPDIVO® (nivolumab) is indicated for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) with disease progression on or after platinum-based therapy.

OPDIVO® (nivolumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

OPDIVO® (nivolumab) is indicated for the treatment of adult and pediatric (12 years and older) patients with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

OPDIVO® (nivolumab) is indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

OPDIVO® (nivolumab) is indicated for the adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.

IMPORTANT SAFETY INFORMATION

Immune-Mediated Pneumonitis

OPDIVO can cause immune-mediated pneumonitis. Fatal cases have been reported. Monitor patients for signs with radiographic imaging and for symptoms of pneumonitis. Administer corticosteroids for Grade 2 or more severe pneumonitis. Permanently discontinue for Grade 3 or 4 and withhold until resolution for Grade 2. In patients receiving OPDIVO monotherapy, fatal cases of immune-mediated pneumonitis have occurred. Immune-mediated pneumonitis occurred in 3.1% (61/1994) of patients.

In Checkmate 205 and 039, pneumonitis, including interstitial lung disease, occurred in 6.0% (16/266) of patients receiving OPDIVO. Immune-mediated pneumonitis occurred in 4.9% (13/266) of patients receiving OPDIVO: Grade 3 (n=1) and Grade 2 (n=12).

Immune-Mediated Colitis

OPDIVO can cause immune-mediated colitis. Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 (of more than 5 days duration), 3, or 4 colitis. Withhold OPDIVO monotherapy for Grade 2 or 3 and permanently discontinue for Grade 4 or recurrent colitis upon re-initiation of OPDIVO. In patients receiving OPDIVO monotherapy, immune-mediated colitis occurred in 2.9% (58/1994) of patients.

Immune-Mediated Hepatitis

OPDIVO can cause immune-mediated hepatitis. Monitor patients for abnormal liver tests prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater transaminase elevations. For patients without HCC, withhold OPDIVO for Grade 2 and permanently discontinue OPDIVO for Grade 3 or 4. For patients with HCC, withhold OPDIVO and administer corticosteroids if AST/ALT is within normal limits at baseline and increases to >3 and up to 5 times the upper limit of normal (ULN), if AST/ALT is >1 and up to 3 times ULN at baseline and increases to >5 and up to 10 times the ULN, and if AST/ALT is >3 and up to 5 times ULN at baseline and increases to >8 and up to 10 times the ULN. Permanently discontinue OPDIVO and administer corticosteroids if AST or ALT increases to >10 times the ULN or total bilirubin increases >3 times the ULN. In patients receiving OPDIVO monotherapy, immune-mediated hepatitis occurred in 1.8% (35/1994) of patients.

In Checkmate 040, immune-mediated hepatitis requiring systemic corticosteroids occurred in 5% (8/154) of patients receiving OPDIVO.

Immune-Mediated Endocrinopathies

OPDIVO can cause immune-mediated hypophysitis, immune-mediated adrenal insufficiency, autoimmune thyroid disorders, and Type 1 diabetes mellitus. Monitor patients for signs and symptoms of hypophysitis, signs and symptoms of adrenal insufficiency, thyroid function prior to and periodically during treatment, and hyperglycemia. Administer hormone replacement as clinically indicated and corticosteroids for Grade 2 or greater hypophysitis. Withhold for Grade 2 or 3 and permanently discontinue for Grade 4 hypophysitis. Administer corticosteroids for Grade 3 or 4 adrenal insufficiency. Withhold for Grade 2 and permanently discontinue for Grade 3 or 4 adrenal insufficiency. Administer hormone-replacement therapy for hypothyroidism. Initiate medical management for control of hyperthyroidism. Withhold OPDIVO for Grade 3 and permanently discontinue for Grade 4 hyperglycemia.

In patients receiving OPDIVO monotherapy, hypophysitis occurred in 0.6% (12/1994) of patients. In patients receiving OPDIVO monotherapy, adrenal insufficiency occurred in 1% (20/1994) of patients. In patients receiving OPDIVO monotherapy, hypothyroidism or thyroiditis resulting in hypothyroidism occurred in 9% (171/1994) of patients. Hyperthyroidism occurred in 2.7% (54/1994) of patients receiving OPDIVO monotherapy. In patients receiving OPDIVO monotherapy, diabetes occurred in 0.9% (17/1994) of patients.

Immune-Mediated Nephritis and Renal Dysfunction

OPDIVO can cause immune-mediated nephritis. Monitor patients for elevated serum creatinine prior to and periodically during treatment. Administer corticosteroids for Grades 2-4 increased serum creatinine. Withhold OPDIVO for Grade 2 or 3 and permanently discontinue for Grade 4 increased serum creatinine. In patients receiving OPDIVO monotherapy, immune-mediated nephritis and renal dysfunction occurred in 1.2% (23/1994) of patients.

Immune-Mediated Skin Adverse Reactions

OPDIVO can cause immune-mediated rash, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), some cases with fatal outcome. Administer corticosteroids for Grade 3 or 4 rash. Withhold for Grade 3 and permanently discontinue for Grade 4 rash. For symptoms or signs of SJS or TEN, withhold OPDIVO and refer the patient for specialized care for assessment and treatment; if confirmed, permanently discontinue. In patients receiving OPDIVO monotherapy, immune-mediated rash occurred in 9% (171/1994) of patients.

Immune-Mediated Encephalitis

OPDIVO can cause immune-mediated encephalitis. Evaluation of patients with neurologic symptoms may include, but not be limited to, consultation with a neurologist, brain MRI, and lumbar puncture. Withhold OPDIVO in patients with new-onset moderate to severe neurologic signs or symptoms and evaluate to rule out other causes. If other etiologies are ruled out, administer corticosteroids and permanently discontinue OPDIVO for immune-mediated encephalitis. In patients receiving OPDIVO monotherapy, encephalitis occurred in 0.2% (3/1994) of patients. Fatal limbic encephalitis occurred in one patient after 7.2 months of exposure despite discontinuation of OPDIVO and administration of corticosteroids.

Other Immune-Mediated Adverse Reactions

Based on the severity of the adverse reaction, permanently discontinue or withhold OPDIVO, administer high-dose corticosteroids, and, if appropriate, initiate hormone-replacement therapy. Across clinical trials of OPDIVO, the following clinically significant immune-mediated adverse reactions, some with fatal outcome, occurred in <1.0% of patients receiving OPDIVO: myocarditis, rhabdomyolysis, myositis, uveitis, iritis, pancreatitis, facial and abducens nerve paresis, demyelination, polymyalgia rheumatica, autoimmune neuropathy, GuillainBarré syndrome, hypopituitarism, systemic inflammatory response syndrome, gastritis, duodenitis, sarcoidosis, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), motor dysfunction, vasculitis, aplastic anemia, pericarditis, and myasthenic syndrome.

If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, which has been observed in patients receiving OPDIVO and may require treatment with systemic steroids to reduce the risk of permanent vision loss.

Infusion Reactions

OPDIVO can cause severe infusion reactions, which have been reported in <1.0% of patients in clinical trials. Discontinue OPDIVO in patients with Grade 3 or 4 infusion reactions. Interrupt or slow the rate of infusion in patients with Grade 1 or 2. In patients receiving OPDIVO monotherapy as a 60-minute infusion, infusion-related reactions occurred in 6.4% (127/1994) of patients. In a separate study in which patients received OPDIVO monotherapy as a 60-minute infusion or a 30-minute infusion, infusion-related reactions occurred in 2.2% (8/368) and 2.7% (10/369) of patients, respectively. Additionally, 0.5% (2/368) and 1.4% (5/369) of patients, respectively, experienced adverse reactions within 48 hours of infusion that led to dose delay, permanent discontinuation or withholding of OPDIVO.

Complications of Allogeneic HSCT after OPDIVO

Complications, including fatal events, occurred in patients who received allogeneic HSCT after OPDIVO. Outcomes were evaluated in 17 patients from Checkmate 205 and 039, who underwent allogeneic HSCT after discontinuing OPDIVO (15 with reduced-intensity conditioning, 2 with myeloablative conditioning). Thirty-five percent (6/17) of patients died from complications of allogeneic HSCT after OPDIVO. Five deaths occurred in the setting of severe or refractory GVHD. Grade 3 or higher acute GVHD was reported in 29% (5/17) of patients. Hyperacute GVHD was reported in 20% (n=2) of patients. A steroid-requiring febrile syndrome, without an identified infectious cause, was reported in 35% (n=6) of patients. Two cases of encephalitis were reported: Grade 3 (n=1) lymphocytic encephalitis without an identified infectious cause, and Grade 3 (n=1) suspected viral encephalitis. Hepatic veno-occlusive disease (VOD) occurred in one patient, who received reduced-intensity conditioned allogeneic HSCT and died of GVHD and multi-organ failure. Other cases of hepatic VOD after reduced-intensity conditioned allogeneic HSCT have also been reported in patients with lymphoma who received a PD-1 receptor blocking antibody before transplantation. Cases of fatal hyperacute GVHD have also been reported. These complications may occur despite intervening therapy between PD-1 blockade and allogeneic HSCT.

Follow patients closely for early evidence of transplant-related complications such as hyperacute GVHD, severe (Grade 3 to 4) acute GVHD, steroid-requiring febrile syndrome, hepatic VOD, and other immune-mediated adverse reactions, and intervene promptly.

Embryo-Fetal Toxicity

Based on its mechanism of action, OPDIVO can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with an OPDIVO-containing regimen and for at least 5 months after the last dose of OPDIVO.

Lactation

It is not known whether OPDIVO is present in human milk. Because many drugs, including antibodies, are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from an OPDIVO-containing regimen, advise women to discontinue breastfeeding during treatment.

Serious Adverse Reactions

In Checkmate 037, serious adverse reactions occurred in 41% of patients receiving OPDIVO (n=268). Grade 3 and 4 adverse reactions occurred in 42% of patients receiving OPDIVO. The most frequent Grade 3 and 4 adverse drug reactions reported in 2% to <5% of patients receiving OPDIVO were abdominal pain, hyponatremia, increased aspartate aminotransferase, and

increased lipase. In Checkmate 066, serious adverse reactions occurred in 36% of patients receiving OPDIVO (n=206). Grade 3 and 4 adverse reactions occurred in 41% of patients receiving OPDIVO. The most frequent Grade 3 and 4 adverse reactions reported in ≥2% of patients receiving OPDIVO were gamma-glutamyltransferase increase (3.9%) and diarrhea (3.4%). In Checkmate 017 and 057, serious adverse reactions occurred in 46% of patients receiving OPDIVO (n=418). The most frequent serious adverse reactions reported in ≥2% of patients receiving OPDIVO were pneumonia, pulmonary embolism, dyspnea, pyrexia, pleural effusion, pneumonitis, and respiratory failure. In Checkmate 032, serious adverse reactions occurred in 45% of patients receiving OPDIVO (n=245). The most frequent serious adverse reactions reported in at least 2% of patients receiving OPDIVO were pneumonia, dyspnea, pneumonitis, pleural effusion, and dehydration. In Checkmate 025, serious adverse reactions occurred in 47% of patients receiving OPDIVO (n=406). The most frequent serious adverse reactions reported in ≥2% of patients were acute kidney injury, pleural effusion, pneumonia, diarrhea, and hypercalcemia. In Checkmate 205 and 039, adverse reactions leading to discontinuation occurred in 7% and dose delays due to adverse reactions occurred in 34% of patients (n=266). Serious adverse reactions occurred in 26% of patients. The most frequent serious adverse reactions reported in ≥1% of patients were pneumonia, infusion-related reaction, pyrexia, colitis or diarrhea, pleural effusion, pneumonitis, and rash. Eleven patients died from causes other than disease progression: 3 from adverse reactions within 30 days of the last OPDIVO dose, 2 from infection 8 to 9 months after completing OPDIVO, and 6 from complications of allogeneic HSCT. In Checkmate 141, serious adverse reactions occurred in 49% of patients receiving OPDIVO (n=236). The most frequent serious adverse reactions reported in ≥2% of patients receiving OPDIVO were pneumonia, dyspnea, respiratory failure, respiratory tract infection, and sepsis. In Checkmate 275, serious adverse reactions occurred in 54% of patients receiving OPDIVO (n=270). The most frequent serious adverse reactions reported in ≥2% of patients receiving OPDIVO were urinary tract infection, sepsis, diarrhea, small intestine obstruction, and general physical health deterioration. In Checkmate 040, serious adverse reactions occurred in 49% of patients (n=154). The most frequent serious adverse reactions reported in ≥2% of patients were pyrexia, ascites, back pain, general physical health deterioration, abdominal pain, and pneumonia. In Checkmate 238, Grade 3 or 4 adverse reactions occurred in 25% of OPDIVO-treated patients (n=452). The most frequent Grade 3 and 4 adverse reactions reported in ≥2% of OPDIVO-treated patients were diarrhea and increased lipase and amylase. Serious adverse reactions occurred in 18% of OPDIVO-treated patients.

Common Adverse Reactions

In Checkmate 037, the most common adverse reaction (≥20%) reported with OPDIVO (n=268) was rash (21%). In Checkmate 066, the most common adverse reactions (≥20%) reported with OPDIVO (n=206) vs dacarbazine (n=205) were fatigue (49% vs 39%), musculoskeletal pain (32% vs 25%), rash (28% vs 12%), and pruritus (23% vs 12%). In Checkmate 017 and 057, the most common adverse reactions (≥20%) in patients receiving OPDIVO (n=418) were fatigue, musculoskeletal pain, cough, dyspnea, and decreased appetite. In Checkmate 032, the most common adverse reactions (≥20%) in patients receiving OPDIVO (n=245) were fatigue (45%), decreased appetite (27%), musculoskeletal pain (25%), dyspnea (22%), nausea (22%), diarrhea (21%), constipation (20%), and cough (20%). In Checkmate 025, the most common adverse reactions (≥20%) reported in patients receiving OPDIVO (n=406) vs everolimus (n=397) were

fatigue (56% vs 57%), cough (34% vs 38%), nausea (28% vs 29%), rash (28% vs 36%), dyspnea (27% vs 31%), diarrhea (25% vs 32%), constipation (23% vs 18%), decreased appetite (23% vs 30%), back pain (21% vs 16%), and arthralgia (20% vs 14%). In Checkmate 205 and 039, the most common adverse reactions (≥20%) reported in patients receiving OPDIVO (n=266) were upper respiratory tract infection (44%), fatigue (39%), cough (36%), diarrhea (33%), pyrexia (29%), musculoskeletal pain (26%), rash (24%), nausea (20%), and pruritus (20%). In Checkmate 141, the most common adverse reactions (≥10%) in patients receiving OPDIVO (n=236) were cough and dyspnea at a higher incidence than investigator's choice. In Checkmate 275, the most common adverse reactions (≥20%) reported in patients receiving OPDIVO (n=270) were fatigue (46%), musculoskeletal pain (30%), nausea (22%), and decreased appetite (22%). In Checkmate 142 in MSI-H/dMMR mCRC patients receiving OPDIVO as a single agent, the most common adverse reactions (≥20%) were fatigue (54%), diarrhea (43%), abdominal pain (34%), nausea (34%), vomiting (28%), musculoskeletal pain (28%), cough (26%), pyrexia (24%), rash (23%), constipation (20%), and upper respiratory tract infection (20%). In Checkmate 040, the most common adverse reactions (≥20%) in patients receiving OPDIVO (n=154) were fatigue (38%), musculoskeletal pain (36%), abdominal pain (34%), pruritus (27%), diarrhea (27%), rash (26%), cough (23%), and decreased appetite (22%). In Checkmate 238, the most common adverse reactions (≥20%) reported in OPDIVO-treated patients (n=452) vs ipilimumab-treated patients (n=453) were fatigue (57% vs 55%), diarrhea (37% vs 55%), rash (35% vs 47%), musculoskeletal pain (32% vs 27%), pruritus (28% vs 37%), headache (23% vs 31%), nausea (23% vs 28%), upper respiratory infection (22% vs 15%), and abdominal pain (21% vs 23%). The most common immune-mediated adverse reactions were rash (16%), diarrhea/colitis (6%), and hepatitis (3%).

Please see U.S. Full Prescribing Information for OPDIVO.

About IPI-549 and the Ongoing Phase 1/1b Study

IPI-549 is an investigational first-in-class, oral, immuno-oncology product candidate targeting tumor-associated myeloid cells through selective phosphoinositide-3-kinase-gamma (PI3K-gamma) inhibition, thereby reducing pro-tumor macrophage function and increasing anti-tumor macrophage function. In preclinical studies, IPI-549 demonstrated the ability to reprogram macrophages from a pro-tumor (M2), immune suppressive function, to an anti-tumor (M1) immune activating function and enhance the activity of, and overcome resistance to, checkpoint inhibitors.[i] [ii] As such, IPI-549 may have the potential to treat a broad range of solid tumors and represents a potentially additive or synergistic approach to restoring anti-tumor immunity in combination with other immunotherapies such as checkpoint inhibitors.

The ongoing Phase 1/1b study being conducted by Infinity is designed to evaluate the safety, tolerability, activity, pharmacokinetics and pharmacodynamics of IPI-549 as a monotherapy and in combination with nivolumab (Opdivo®) in approximately 200 patients with advanced solid tumors.[iii] The study includes monotherapy and combination dose-escalation components, in addition to monotherapy expansion and combination expansion components. The monotherapy dose-escalation and expansion components are complete. The combination dose-escalation component is also complete, and the combination expansion component is enrolling.

The combination expansion component of the study includes multiple cohorts designed to evaluate IPI-549 in patients with specific types of cancer, including patients with non-small cell lung cancer (NSCLC), melanoma and head and neck cancer whose tumors show initial resistance

or initially respond to but subsequently develop resistance to immune checkpoint blockade therapy. The combination expansion component also includes a cohort of patients with triple negative breast cancer (TNBC) who have not been previously treated with immune checkpoint blockade therapy, a cohort of patients with mesothelioma, a cohort of patients with adrenocortical carcinoma and a cohort of patients with high baseline blood levels of MDSCs.

IPI-549 is an investigational compound and its safety and efficacy has not been evaluated by the U.S. Food and Drug Administration or any other health authority.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit us at BMS.com or follow us on LinkedIn, Twitter, YouTube and Facebook.

About Infinity

Infinity is an innovative biopharmaceutical company dedicated to advancing novel medicines for people with cancer. Infinity is advancing IPI-549, an oral immuno-oncology development candidate that selectively inhibits PI3K-gamma. A Phase 1/1b study in approximately 200 patients with advanced solid tumors is ongoing. For more information on Infinity, please refer to Infinity's website at www.infi.com.

Bristol-Myers Squibb Forward-Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding the research, development and commercialization of pharmaceutical products. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that the Opdivo *plus* IPI-549 *combination will receive regulatory approval in the US for any of the indications described in this release. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2017 in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.*

Infinity's Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding: the therapeutic potential of PI3K-gamma selective inhibition and IPI-549, alone and in combination with Opdivo; clinical trial plans regarding IPI-549; and the company's ability to execute on its strategic plans. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the company's

current expectations. For example, there can be no guarantee that IPI-549 will successfully complete necessary preclinical and clinical development phases or that the combination of IPI-549 and Opdivo will receive regulatory approval for any of the indications described in this release. Further, there can be no guarantee that any positive developments in Infinity's product portfolio will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other factors, including the following: Infinity's results of clinical trials and preclinical studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities; Infinity's ability to obtain and maintain requisite regulatory approvals and to enroll patients in its clinical trials; unplanned cash requirements and expenditures; development of agents by Infinity's competitors for diseases in which Infinity is currently developing or intends to develop IPI-549; and Infinity's ability to obtain, maintain and enforce patent and other intellectual property protection for IPI-549. These and other risks which may impact management's expectations are described in greater detail under the caption "Risk Factors" included in Infinity's quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 7, 2018, and other filings filed by Infinity with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and Infinity expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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[i] Kaneda, M., Messer, K., Ralainirina, N., Li, H., et al. PI3Kγ is a molecular switch that controls immune suppression. Nature, 2016 Nov;539:437–442.
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[iii] www.clinicaltrials.gov, NCT02637531.

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