
**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): June 25, 2018

Infinity Pharmaceuticals, Inc.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction
of incorporation)

000-31141
(Commission
File Number)

33-0655706
(IRS Employer
Identification No.)

784 Memorial Drive, Cambridge, MA
(Address of principal executive offices)

02139
(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 8.01 Other Events.

On June 26, 2018, Infinity Pharmaceuticals, Inc. (the “Company”) issued a press release announcing that the Company and Arcus Biosciences, Inc. entered into a clinical collaboration agreement effective June 25, 2018.

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.

Item 9.01. Financial Statements and Exhibits.

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated June 26, 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: June 26, 2018

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

Arcus Biosciences and Infinity Pharmaceuticals Announce Clinical Collaboration to Evaluate Lead Programs in Triple-Combination Studies

- IPI-549 with AB928 and AB122 in Triple Negative Breast Cancer and Ovarian Cancer -

- IPI-549 with AB928 and Chemotherapy in Triple Negative Breast Cancer and Ovarian Cancer -



HAYWARD, Calif. and CAMBRIDGE, Mass., June 26, 2018 – Arcus Biosciences, Inc. (NYSE:RCUS), a clinical-stage biopharmaceutical company focused on creating innovative cancer immunotherapies, and Infinity Pharmaceuticals, Inc. (NASDAQ: INFI), a clinical-stage biopharmaceutical company developing IPI-549, a first-in-class immuno-oncology product candidate that selectively inhibits phosphoinositide-3-kinase gamma (PI3K-gamma), today announced that they have entered into a clinical collaboration to evaluate two triple combination therapies in selected tumor types which typically show minimal response to checkpoint inhibition monotherapy.

The collaboration will evaluate IPI-549 in combination with AB928, Arcus's dual adenosine receptor antagonist, and AB122, Arcus's anti-PD-1 antibody, as well as IPI-549 in combination with AB928 and chemotherapy in patients with triple negative breast cancer (TNBC) or ovarian cancer in four separate cohorts. These four cohorts will be incorporated into Arcus's recently initiated Phase 1/1b trial to evaluate AB928 combinations in TNBC and ovarian cancer. As both macrophages and high adenosine levels are believed to play critical roles in creating a highly immune-suppressive tumor microenvironment in TNBC and ovarian cancer, the triple combinations being evaluated could represent a promising approach to treating these tumor types. By intervening in multiple mechanisms that mediate immuno-suppression, the companies hope to address two tumor types that lack effective therapies, particularly in later lines of treatment.

"This partnership with Infinity is important as, for the first time, we will be investigating the potential for the triple combination of a selective PI3K-gamma inhibitor, a dual adenosine receptor antagonist, and either a PD-1 inhibitor or chemotherapy to effectively treat patients with triple negative breast cancer or ovarian cancer," said Terry Rosen, Ph.D., Chief Executive Officer of Arcus Biosciences. "This collaboration also allows us to expand the number of promising combinations with strong biological rationale that we plan to evaluate in our recently initiated Phase 1/1b trial for AB928. Arcus has carefully considered which immuno-oncology therapies can best target immune suppressive macrophages and has concluded that selective inhibition of PI3K-gamma is a fundamental mechanism for reprogramming macrophages from a pro-tumor to an anti-tumor function."

"This collaboration with Arcus Biosciences enables an important expansion of our clinical development of IPI-549, investigating IPI-549 in triple-combination therapy with other important immuno-oncology agents as well as with chemotherapy," said Adelene Perkins, Chief Executive

Officer and Chair of Infinity Pharmaceuticals. “Combining these agents may result in enhanced reduction of pro-tumor immune suppression and increased anti-tumor immune activation. We look forward to working with the terrific team at Arcus in investigating these triple-combination therapies as potentially new treatment options for patients with cancers that are not adequately addressed by existing therapies.”

Under the terms of the agreement, Infinity and Arcus will share equally expenses related to the four triple-combination cohorts to evaluate the safety and activity of IPI-549 + AB928 + AB122 and IPI-549 + AB928 + chemotherapy. Each of the four triple-combination cohorts will enroll approximately 15 patients. Topline data from these studies are expected in 2019.

About AB928

AB928 is an orally bioavailable, highly potent antagonist of the adenosine 2a and 2b receptors. The activation of these receptors by adenosine interferes with the activity of key populations of immune cells and inhibits an optimal anti-tumor immune response. By blocking these receptors, AB928 has the potential to reverse adenosine-induced immune suppression within the tumor microenvironment. AB928 was designed specifically for the oncology setting, with a profile that includes potent activity in the presence of high concentrations of adenosine and a minimal shift in potency due to non-specific protein binding, both essential properties to be efficacious in the tumor microenvironment. AB928 has other attractive features, including high penetration of tumor tissue and low penetration through the healthy blood-brain barrier. In a Phase 1 trial in healthy volunteers, AB928 has been shown to be safe and well tolerated and to have pharmacokinetic and pharmacodynamic profiles consistent with a once-daily dosing regimen.

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 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 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.

About Arcus Biosciences

Arcus Biosciences is a clinical-stage biopharmaceutical company focused on creating innovative cancer immunotherapies. Arcus has several programs targeting important immuno-oncology pathways, including a dual adenosine receptor antagonist AB928, which will be evaluated in combination with other agents in multiple tumor types in a Phase 1/1b program, and an anti-PD-1 antibody, which is being evaluated in a Phase 1 trial and will be tested in combination with Arcus's other product candidates. Arcus's other programs include a small molecule inhibitor of CD73 and an anti-TIGIT antibody, both of which are in IND-enabling studies. Arcus has extensive in-house expertise in medicinal chemistry, immunology, biochemistry, pharmacology and structural biology. For more information about Arcus Biosciences, please visit www.arcusbio.com.

About Infinity Pharmaceuticals

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. For more information on Infinity, please refer to Infinity's website at www.infi.com.

Arcus Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts contained herein, including, but not limited to, the potential of the triple combination therapies in TNBC and ovarian cancers and timeline for topline data, are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause Arcus's actual results, performance or achievements to differ significantly from those expressed or implied. Factors that could cause or contribute to such differences include, but are not limited to, the inherent uncertainty associated with pharmaceutical product development and clinical trials, delays in our clinical trials due to difficulties or delays in the regulatory process, enrolling subjects or manufacturing or supplying product for such clinical trials, and the ability to demonstrate safety and activity of these triple combinations in the four cohorts. Risks and uncertainties facing Arcus are described more fully in Arcus's quarterly report on Form 10-Q for the quarter ended March 31, 2018 filed on May 9, 2018 with the SEC. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this press release. Arcus disclaims any obligation or undertaking to update, supplement or revise any forward-looking statements contained in this press release.

Infinity 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 one or more of Opdivo, AB928, AB122, and chemotherapy, and plans to report topline data from the triple combination studies. Management's expectations and such forward-looking 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, including the risks described under the caption "Risk Factors" included in Infinity's quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 8, 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.

OPDIVO® is a registered trademark of Bristol-Myers Squibb.

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- i Kaneda, M., Messer, K., Ralainirina, N., Li, H., et al. PI3Ky is a molecular switch that controls immune suppression. *Nature*, 2016 Nov;539:437–442.
 - ii De Henau, O., Rausch, M., Winkler, D., Campesato, L., et al. Overcoming resistance to checkpoint blockade therapy by targeting PI3Ky in myeloid cells. *Nature*, 2016 Nov;539:443-447.
 - iii www.clinicaltrials.gov, NCT02637531.