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): December 19, 2014

ONCOGENEX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other Jurisdiction of Incorporation) 033-80623 (Commission File Number) 95-4343413 (IRS Employer Identification No.)

1522 217th Place S.E. Bothell, Washington (Address of Principal Executive Offices)

98021 (Zip Code)

Registrant's telephone number, including area code: (425) 487-9500

N/A (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))

D Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On December 19, 2014, OncoGenex Pharmaceuticals, Inc. (the "Company") announced results from the randomized, controlled Phase 2 Borealis-1 trial evaluating low and high dose (600mg and 1000mg) apatorsen in combination with gemcitabine/cisplatin chemotherapy compared to chemotherapy alone in the treatment of metastatic bladder cancer.

Overall trial results indicated that the addition of 600mg apatorsen to standard of care chemotherapy showed a 14% reduction in risk of death (overall survival hazard ratio (HR) = 0.86) and a 17% reduction in progressive disease and death (progression-free survival HR = 0.83) when compared to chemotherapy alone. Over one-third of the patients in the trial had lower performance status, as defined by a Karnofsky score of 80% or less. These patients derived the greatest benefit from 600mg apatorsen in combination with chemotherapy, resulting in a 50% reduction in risk of death (overall survival HR = 0.50) compared to chemotherapy alone. Less benefit was observed in the 1000mg apatorsen arm due to increased adverse events leading to a higher rate of discontinuation of both apatorsen and chemotherapy. Apatorsen 600mg was well tolerated in combination with chemotherapy. OncoGenex will be working closely with investigators and regulatory agencies to determine next steps.

A copy of the Company's press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: December 19, 2014

ONCOGENEX PHARMACEUTICALS, INC.

/s/ Scott Cormack

Scott Cormack President and Chief Executive Officer

Exhibit Number

- umber Exhibit Title or Description
- 99.1 Press Release issued by OncoGenex Pharmaceuticals, Inc. dated December 19, 2014

4



OncoGenex Announces Results from the Phase 2 Borealis-1™ Trial of Apatorsen in the Treatment of Metastatic Bladder Cancer

Exploratory Analysis Shows Addition of 600mg Apatorsen to Standard of Care Chemotherapy Resulted in 50 Percent Reduction in Risk of Death in Patients with Lower Performance Status

Phase 2 Trial Informs Appropriate Apatorsen Dosing and Patient Population for Future Trials in Metastatic Bladder Cancer

Bothell WA and Vancouver BC, Dec. 19, 2014– OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) today announced results from the randomized, controlled Phase 2 Borealis-1TM trial evaluating low and high dose (600mg and 1000mg) apatorsen in combination with geneitabine/cisplatin chemotherapy compared to chemotherapy alone in the treatment of metastatic bladder cancer.

Overall trial results indicated that the addition of 600mg apatorsen to standard of care chemotherapy showed a 14 percent reduction in risk of death (overall survival hazard ratio (HR) = 0.86) and a 17 percent reduction in progressive disease and death (progression-free survival HR = 0.83) when compared to chemotherapy alone. Over one-third of the patients in the trial had lower performance status, as defined by a Karnofsky score of 80 percent or less. These patients derived the greatest benefit from 600mg apatorsen in combination with chemotherapy, resulting in a 50 percent reduction in risk of death (overall survival HR = 0.50) compared to chemotherapy alone. Less benefit was observed in the 1000mg apatorsen arm due to increased adverse events leading to a higher rate of discontinuation of both apatorsen and chemotherapy. Apatorsen 600mg was well tolerated in combination with chemotherapy.

"These data provide greater insight into the most appropriate dose and patient type for further evaluation of apatorsen in first-line metastatic bladder cancer," said Scott Cormack, President and Chief Executive Officer of OncoGenex. "Based on these results, as well as those seen in our superficial bladder cancer trial of patients who received single-agent apatorsen intravesically, we are encouraged by the potential of this compound across the paradigm of bladder cancer treatment."

Limited options currently exist for patients with advanced bladder cancer. Given these results and the urgent need for new treatments, OncoGenex will be working closely with investigators and regulatory agencies to determine next steps.

"While the advent of chemotherapy helped to increase survival in metastatic bladder cancer, in the last three decades there have been limited treatment advances to improve outcomes," said Joaquim Bellmunt, MD, PhD Director, Bladder Cancer Center at the Dana-Farber Cancer Institute, Associate Professor of Medicine at Harvard Medical School, and one of the Primary Investigators of the trial. "These data support this unique approach to cancer treatment, which aims to improve standard of care therapy by targeting Hsp27, an important mechanism through which cancer develops resistance to treatment."

Apatorsen is designed to inhibit production of heat shock protein 27 (Hsp27), which increases with cancer treatment as well as with tumor stage and grade. High levels of Hsp27 contribute to cancer cell survival, proliferation and migration and also play a role in dampening a cancer patient's immune function.

Borealis-1 enrolled approximately 180 patients with documented metastatic or locally inoperable transitional cell carcinoma (TCC) of the urinary tract who had not previously received chemotherapy for metastatic disease and were not candidates for potentially curative surgery or radiotherapy. Patients were randomized to receive standard chemotherapy (gemcitabine/cisplatin) in combination with apatorsen at two dose levels (600 mg and 1000 mg) or gemcitabine/cisplatin plus placebo. Patients received up to six cycles of weekly intravenous therapy. Following the discontinuation of a minimum of four cycles of chemotherapy, all patients received weekly apatorsen or placebo maintenance therapy until disease progression or other reason for withdrawal from protocol treatment. The primary endpoint of the trial was overall survival. Secondary endpoints measured disease response as well as safety of each of the two doses of apatorsen.

"We are extremely grateful to the Borealis-1 investigators for their efforts, and most importantly, to the patients who participated in the trial and the family and friends who supported them," said Cormack.

Borealis-1 is part of the The ORCATM (Ongoing Studies Evaluating Treatment Resistance in CAncer) program and one of two ongoing clinical trials of apatorsen in metastatic bladder cancer. The Borealis- 2^{TM} trial is an investigator-sponsored, randomized Phase 2 trial evaluating apatorsen in combination with docetaxel in patients with advanced or metastatic bladder cancer who have disease progression following first-line platinum-based chemotherapy. This trial is sponsored by the Hoosier Oncology Group and currently enrolling patients. Please visit <u>http://clinicaltrials.gov/show/NCT01780545</u> for more information.

About Bladder Cancer

Worldwide, more than 429,000 cases of bladder cancer are diagnosed each year, and nearly 75,000 cases of bladder cancer will be diagnosed in the U.S. in 2014. Approximately 70 percent of patients present with superficial or non-muscle-invasive bladder cancer, with about 30 percent of patients having locally invasive or metastatic disease at the time of diagnosis. Of patients with locally invasive disease, 50 percent will relapse with metastases within two years. Limited options exist for both the first- and second-line treatment of advanced bladder cancer and there continues to be a high unmet need for additional therapeutic options for this patient population.

About Apatorsen and ORCA

Apatorsen (OGX-427) is a once-weekly intravenous (IV) experimental drug that is designed to inhibit production of heat shock protein 27 (Hsp27) to disable cancer cells' defenses and overcome treatment resistance. Hsp27 is an intracellular protein that protects cancer cells by

helping them survive, leading to resistance and more aggressive cancer phenotypes. Both the potential single-agent activity and synergistic activity of apatorsen with cancer treatments may increase the overall benefit of existing therapies and augment the durability of treatment outcomes, which could lead to increased patient survival.

The ORCA program encompasses clinical trials of apatorsen. Phase 2 clinical trials are underway in bladder, lung, pancreatic and prostate cancers. For more information on apatorsen and ORCA, please visit <u>www.OncoGenex.com</u> or <u>www.orcatrials.com</u>.

About OncoGenex

OncoGenex is a biopharmaceutical company committed to the development and commercialization of new therapies that address treatment resistance in cancer patients. OncoGenex has a diverse oncology pipeline, with each product candidate having a distinct mechanism of action and representing a unique opportunity for cancer drug development. OncoGenex and Teva Pharmaceutical Industries Ltd. have entered a global collaboration and licensing agreement to develop and commercialize OncoGenex' lead drug candidate, custirsen. Custirsen is currently in Phase 3 clinical development as a treatment in men with metastatic castrate-resistant prostate cancer and in patients with advanced, unresectable non-small cell lung cancer. Apatorsen is in Phase 2 clinical development and OGX-225 is currently in pre-clinical development. More information is available at www.OncoGenex.com and at the company's Twitter account <u>https://twitter.com/OncoGenex_IR</u>.

OncoGenex' Forward Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the potential benefits and potential development of our product candidates. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements. Such forward-looking statements are subject to risks and uncertainties, including, among others, the risk that our product candidates will not demonstrate the hypothesized or expected benefits, the risk of delays in our expected clinical trials, the risk that new developments in the rapidly evolving cancer therapy landscape require changes in our clinical trial plans or limit the potential benefits of our product and the other factors described in our risk factors set forth in our filings with the Securities and Exchange Commission from time to time, including the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. The Company undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof, other than as may be required by applicable law.

Borealis-1TM, Borealis-2TM and ORCATM are registered trademarks of OncoGenex Pharmaceuticals, Inc.

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