GENTA INC DE/
Form 8-K
May 24, 2012

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): May 24, 2012

GENTA INCORPORATED
(Exact Name of Registrant
as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

| 0-19635 | 33-0326866 |
|---|---|
| (Commission File Number) | (IRS Employer Identification No.) |
| 200 Connell Drive<br>Berkeley Heights, NJ<br>(Address of Principal Executive Offices) | 07922<br>(Zip Code) |

(908) 286-9800
(Registrant's Telephone Number, Including Area Code)

(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a -12)

o Pre -commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d -2(b))

o 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 May 24, 2012, Genta Incorporated announced results from results from the Company's Phase 2, confirmatory, clinical trial of tesetaxel as 2nd-line treatment of patients with advanced gastric cancer. The trial was conducted at M.D. Anderson Cancer Center, Houston, TX, in collaboration with Northwestern University, Chicago, IL, the University of Pennsylvania, Philadelphia, PA, and the Severance Hospital, Seoul, Korea. Detailed results will be presented next month at the annual meeting of the American Society of Clinical Oncology (ASCO). Tesetaxel is the leading oral taxane in clinical development.

This 2nd-line study enrolled 53 patients who had progressed on at least one prior chemotherapy regimen that included a platinum compound (cisplatin, oxaliplatin, or carboplatin) and a fluoropyrimidine (5-fluorouracil, capecitabine [Xeloda®; Hoffman-La Roche, Inc.], or TS-1 (Taiho Pharmaceutical Co., Ltd.). Two patient cohorts (13 patients each) were treated with fixed oral doses starting at 40-45 mg (Cohort 1) and 50-60 mg (Cohort 2). Cohort 3 (27 patients) employed the maximally tolerable starting dose of 27 mg/m2, which is the dose specified in Genta's randomized multinational trial. Doses were repeated every 3 weeks, and overall response rate (ORR) was the study's primary endpoint.

The ORR in Cohorts 1, 2 and 3 were 8%, 15% and 21%, respectively. Median survival in Cohorts 1 and 2 was 7.6 and 7.5 months, respectively, whereas median survival has not been reached in Cohort 3. Tesetaxel was generally well-tolerated. Neutropenia was the most common adverse event, followed by anemia and anorexia. There were no episodes of fever associated with neutropenia. No hypersensitivity reactions were observed.

Docetaxel (Taxotere®; Sanofi, Inc.), an intravenous taxane, is approved for 1st-line treatment of advanced gastric cancer. Five studies have evaluated the activity of docetaxel as 2nd-line therapy. In these studies, the ORR ranged from 5% to 19% with median OS ranging from 3.5 to 8.4 months.

Based on these favorable data, Genta recently initiated the TESEGAST study -- a multinational, randomized, placebo-controlled trial of tesetaxel as 2nd-line therapy for patients with advanced gastric cancer. In this "all-oral" chemotherapy program, all patients receive capecitabine, and they are randomly assigned to receive tesetaxel or placebo. The primary endpoint of the TESEGAST trial is overall survival.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release of the Company dated May 24, 2012 |

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.

GENTA INCORPORATED

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| Date: | May 24, 2012 | By: | /s/ GARY SIEGEL | |
| | | | Name: | Gary Siegel |
| | | | Title: | Vice President, Finance |

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