SEATTLE GENETICS INC /WA
Form 8-K
August 17, 2015

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): August 17, 2015

Seattle Genetics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**0-32405**	**91-1874389**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

21823 30th Drive SE

Bothell, Washington 98021

(Address of principal executive offices, including zip code)

(425) 527-4000

(Registrant s telephone number, including area code)

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 (see General Instruction A.2. below):

¨ 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))

Item 8.01. Other Events.

On August 17, 2015, Seattle Genetics, Inc. announced that the U.S. Food and Drug Administration (FDA) has approved ADCETRIS (brentuximab vedotin) for the treatment of patients with classical Hodgkin lymphoma at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation. The approval is based on a phase 3 clinical trial called AETHERA that was designed to compare up to 16 cycles (approximately one year) of ADCETRIS therapy administered every three weeks following auto-HSCT to placebo. In addition, data from the AETHERA trial converted the U.S. accelerated approval of the relapsed classical Hodgkin lymphoma indication to regular approval. This is the third indication for ADCETRIS, which was granted accelerated FDA approval in August 2011 for two other indications: (1) treatment of classical Hodgkin lymphoma patients who fail autologous transplant or who fail at least two prior multi-agent chemotherapy regimens and are not autologous transplant candidates, and (2) treatment of systemic ALCL (sALCL) patients who fail at least one prior multi-agent chemotherapy regimen. The sALCL 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.

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.

SEATTLE GENETICS, INC.

Date: August 17, 2015

By: /s/ Clay B. Siegall
Clay B. Siegall

President and Chief Executive Officer