BAUSCH Health

PROVENGE® (sipuleucel-T) Demonstrates Sustained Immune Response Two Years after Treatment in Biochemically-Recurrent Prostate Cancer

February 25, 2015

- New, long-term preliminary data from Phase II STAND trial to be presented at 2015 Genitourinary Cancers Symposium (ASCO GU)
- Successful efforts to nearly double African American enrollment in PROCEED prostate cancer registry also highlighted

LAVAL, Quebec, Feb. 25, 2015 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) today announced the presentation of new long-term, preliminary results from the Phase II STAND trial demonstrating a robust immune response with PROVENGE® (sipuleucel-T) that continues two years after completing treatment in men with biochemically-recurrent prostate cancer (BRPC). The findings, along with valuable data from the ongoing Phase IV registry, PROCEED, related to increasing enrollment of African Americans in prostate cancer trials, are being presented at the 2015 Genitourinary Cancers Symposium (ASCO GU) February 26-28 in Orlando, Florida.

The STAND study is a randomized, Phase II trial that consisted of two patient study groups. One group completed PROVENGE two weeks before initiation of androgen deprivation therapy (ADT) and the second received PROVENGE three months after the start of ADT. PROVENGE is not indicated for use in patients with BRPC. Preliminary results from STAND indicate that immune responses were observed in both study arms and suggest there may be a greater cellular immune response in patients who received PROVENGE prior to ADT compared with those who received PROVENGE following three months of ADT. Humoral immune responses were observed and similar between both treatment arms.

"It is very encouraging to observe that PROVENGE provides an immune response in men with biochemical-recurrent prostate cancer long after the course of androgen deprivation therapy has ended," said Neal Shore , M.D., medical director at the Carolina Urologic Research Center. "This study may also provide guidance on the optimal sequencing of immunotherapy and ADT in biochemical-recurrent prostate cancer."

PROVENGE, the first personalized immunotherapy, stimulates a patient's own immune system to fight cancer. It is approved in the U.S. and the European Union as a treatment for asymptomatic or minimally symptomatic metastatic castrate-resistant prostate cancer.

"These are very encouraging preliminary data and the longest duration of immune responses observed following PROVENGE completion in men with this particular type of prostate cancer," said Andrew S. Sandler , M.D., chief medical officer at Dendreon. "Dendreon and Valeant remains committed to exploring the use of PROVENGE in different prostate cancer treatment settings to provide important clinical information to practicing oncologists."

In 2012, an exploratory analysis of African American patients from the PROVENGE Phase III trials suggested a positive treatment effect in this population. Building on this observation, another abstract being presented at ASCO GU highlights successful efforts that nearly doubled enrollment

of African American men in the ongoing PROCEED registry. Through tactics such as utilizing research sites in racially and ethnically diverse communities, conducting focus groups with African Americans for insight on recruitment materials and study plans, and educating research staff on enrollment goals, enrollment in this population was 11.7 percent, a rate comparable to the U.S. African American population, versus 5.8 percent in the PROVENGE Phase III registration trials. Overall, African American men are underrepresented in randomized clinical trials for prostate cancer, yet they have the highest incidence rate for
prostate
cancer in the United States and are more than twice as likely as white men to die of the disease.[i]

Important Safety Information for PROVENGE

PROVENGE® (sipuleucel-T) is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer.

Before getting PROVENGE, tell your doctor if you:

- Have heart problems
- Have lung problems
- Have a history of stroke
- Take any other medicines including prescription and nonprescription drugs, vitamins, and dietary supplements.

What are the possible side effects of PROVENGE?

PROVENGE infusion can cause serious reactions.

Tell your doctor right away if you:

- Have breathing problems, chest pains, racing heart or irregular heartbeats, high or low blood pressure, dizziness, fainting, nausea, or vomiting after getting PROVENGE. Any of these may be signs of heart or lung problems.
- Develop numbness or weakness on one side of the body, decreased vision in one eye or difficulty speaking. Any of these may be signs of a stroke.
- Develop symptoms of thrombosis which may include pain and/or swelling of an arm or leg with warmth over the affected area, discoloration of an arm or leg, unexplained shortness of breath or chest pain that worsens on deep breathing.
- Get a fever over 100°F, or redness or pain at the infusion or collection sites. Any of these may be signs of infection.

The most common side effects of PROVENGE include chills, fatigue, fever, back pain, nausea, joint ache, and headache.

These are not all the possible side effects of PROVENGE treatment. For more information, talk with your doctor.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For more information on PROVENGE, please see the Full Prescribing Information or call 1-877-336-3736.

About Valeant

Valeant Pharmaceuticals International, Inc. (NYSE/TSX:VRX) is a multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of

pharmaceutical products primarily in the areas of dermatology, eye health, neurology and branded generics. More information about Valeant can be found at **www.valeant.com**. On February 23, 2015, Valeant acquired the worldwide rights to PROVENGE, as well as certain other assets, from Dendreon Corporation.

About Dendreon

Dendreon's first product, PROVENGE® (sipuleucel-T), was approved by the U.S. Food and Drug Administration (FDA) in April 2010. Dendreon is exploring the application of additional ACI product candidates and small molecules for the potential treatment of a variety of cancers. For more information about the Company and its programs, visit http://www.dendreon.com/.

Forward-looking Statements

This press release may contain forward-looking statements, including, but not limited to, the results of and the observations from the STAND study and the impact thereof, the guidance provided from such study, and the plans for PROVENGE in different treatment settings. Forward-looking statements may generally be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, risks and uncertainties discussed in the Company's most recent annual or quarterly report and detailed from time to time in Valeant's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. Readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. Valeant undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this press release or to reflect actual outcomes, except as required by law.

Contact Information:

Laurie W. Little
949-461-6002
laurie.little@valeant.com

References

1. Ferlay, EJC 49 (2013). 1374-1403

[i] National Cancer Institute. Cancer health disparities. Available at: http://www.cancer.gov/cancertopics/factsheet/disparities/cancer-health-disparities. Accessed February 11, 2015.

To view the original version on PR Newswire, visit: http://www.prnewswire.com/news-releases/provenge-sipuleucel-t-demonstrates-sustained-immune-response-two-years-after-treatment-in-biochemically-recurrent-prostate-cancer-300041051.html

SOURCE Valeant Pharmaceuticals International, Inc.

Investor Inquiries
ir@bauschhealth.com
877-281-6642
514-856-3855 (Canada)

Media inquiries
Corporate.communications@bauschhealth.com
908-569-3692

LEGAL NOTICE PRIVACY POLICY

EMAIL ALERTS EMAIL PAGE RSS FEED

Use of this site signifies your agreement to the Legal Notice and Privacy Policy.
©2026 Bausch Health Companies Inc. All rights reserved. MTB.0230.USA.18 V2.0

CALIFORNIA RESIDENTS: DO NOT SELL MY PERSONAL INFORMATION

Powered by SITECORE