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Valeant Pharmaceuticals Announces that Alexza Pharmaceuticals Has Received A Complete Response Letter For AZ-004 (Staccato® Loxapine) Inhalation Aerosol NDA

October 11, 2010

Mississauga, Ontario, October 11, 2010 /PRNewswire via COMTEX/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) announced today that Alexza Pharmaceuticals, Inc. (Nasdaq: ALXA) has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding Alexza's New Drug Application (NDA) for AZ-004 (Staccato® loxapine) submitted as Adusuve™ Staccato® (loxapine) inhalation aerosol, 5 mg and 10 mg. Valeant's subsidiary, Biovail Laboratories International SRL (BLS), entered into a collaboration and license agreement with Alexza Pharmaceuticals, Inc. in February 2010 for the U.S. and Canadian rights to commercialize AZ-004. AZ- 004 is being developed for the rapid treatment of agitation in patients with schizophrenia or bipolar disorder.

A CRL is issued by the FDA's Center of Drug Evaluation and Research indicating that the NDA review cycle is complete and that the application is not ready for approval. In the CRL received by Alexza, the FDA stated that their primary clinical safety concern was related to data from three Phase I pulmonary safety studies with AZ-004. This concern was based on observed, dose-related post-dose decreases in forced expiratory volume in one second, or FEV1, a standard measure of lung function, in healthy subjects, and in subjects with chronic obstructive pulmonary disease (COPD) and asthma. Alexza intends to meet with the FDA in the near future to discuss steps necessary to address this FDA concern. Alexza has previously reported that there were no serious or severe respiratory adverse events in these trials or reported in the two Phase III clinical trials of AZ-004. All respiratory symptoms that developed after treatment in Phase I subjects with COPD and asthma were either self-limiting or readily managed with an inhaled bronchodilator.

The CRL also raised issues relating to the suitability of the stability studies undertaken by Alexza and certain other items relating to the FDA's recently completed pre-approval manufacturing inspection. Because AZ-004 incorporates a novel delivery system, the CRL also included input from FDA's Center for Devices and Radiological Health (CDRH). CDRH requested a human factors study and related analysis to validate that the product can be used effectively in the proposed clinical setting. CDRH also requested further bench testing of the product under an additional "worst-case" manufacturing scenario.

About Valeant Pharmaceuticals International, Inc.

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 neurology, dermatology and branded generics. More information about Valeant Pharmaceuticals International, Inc. can be found at www.valeant.com

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Caution Regarding Forward-Looking Information

To the extent any statements made in this document contain information that is not historical, these statements are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and may be forward-looking information as defined under applicable Canadian securities legislation (collectively, "forward-looking statements").

These forward-looking statements relate to, among other things, future interactions with FDA with respect to AZ-004. Forward-looking statements can generally be identified by the use of words such as "believe", "anticipate", "expect", "estimate", "intend", "continue", "plan", "project", "will", "may", "should", "could", "would", "target", "potential" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Actual results may differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from these expectations include, among other things, future actions by Alexza or BLS with respect to AZ-004, the FDA's review of the approvability of or other action with respect to AZ-004, and the risk factors as detailed from time to time in Valeant's reports filed with the Securities and Exchange Commission ("SEC") and the Canadian Securities Administrators ("CSA").

Valeant does not undertake any obligation to update or revise any forward-looking statement, except as may be required by law.

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