



Talon Therapeutics' New Drug Application for Marqibo(R) Accepted for Filing by the United States Food and Drug Administration

- Accelerated approval review path confirmed by the FDA
- Prescription Drug User Fee Act (PDUFA) date set for May 13, 2012

SAN MATEO, Calif., Sept. 27, 2011 (GLOBE NEWSWIRE) -- Talon Therapeutics, Inc. (OTCBB:TALON) announced its new drug application (NDA) seeking accelerated approval of Marqibo® (vincristine sulfate liposomes injection) has been accepted for filing by the FDA. Marqibo will be reviewed by the FDA under Subpart H — *Accelerated Approval of New Drugs for Serious or Life Threatening Illnesses*, for the treatment of adult Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or that has progressed following two or more lines of anti-leukemia therapy.

"Two important hurdles have been crossed with the acceptance for filing of the Marqibo NDA and affirmation of the accelerated approval review path. We remain 100% focused on our goal of an FDA approval of Marqibo," stated Steven R. Deitcher, President, Chief Executive Officer and Board Member of Talon Therapeutics. "The patients we are seeking to treat represent a rare hematologic malignancy and have a grave prognosis. The accelerated approval path has the potential to provide access to a new, well-tolerated, and effective treatment more quickly for these patients. We aim to initiate and commence enrollment in the Phase 3 confirmatory trial, that recently received an SPA, prior to the May PDUFA date," Dr. Deitcher added.

In August 2011, Talon received Special Protocol Assessment (SPA) agreement from the FDA for its proposed Phase 3 confirmatory study, named HALLMARQ, for the treatment of adults ≥ 60 years old with newly diagnosed ALL. In addition to the Phase 3 adult, front-line ALL study, Talon is developing Marqibo for pediatric cancers (solid tumors and hematologic malignancies) in a Phase 1-2 clinical study conducted by the National Cancer Institute and for newly diagnosed aggressive Non-Hodgkin's Lymphoma to be conducted by the German High Grade Non-Hodgkin's Lymphoma Study Group.

About Marqibo

Marqibo is a novel, targeted Optisome™ encapsulated formulation product candidate of the FDA-approved anticancer drug vincristine. Talon has been primarily developing Marqibo for the treatment of adult, Ph- ALL. Vincristine, a microtubule inhibitor, is FDA-approved for ALL and is widely used as a single agent and in combination regimens for treatment for hematologic malignancies such as lymphomas and leukemias. Talon's encapsulation formulation is designed to provide prolonged circulation of the drug in the blood and accumulation at the tumor site. These characteristics are intended to increase the dose of vincristine delivered in a safe and effective manner.

About Talon Therapeutics

Talon Therapeutics, Inc. is a biopharmaceutical company dedicated to seizing upon medical opportunities, efficiently and expertly leading product candidates through clinical development, and transferring value to patients, patient care providers, shareholders, corporate partners, and employees.

In addition to Marqibo, the Company has additional pipeline opportunities some of which, like Marqibo, have the potential to improve delivery and enhance the therapeutic benefits of well characterized, proven chemotherapies and enable high potency dosing without increased toxicity.

Additional information on Talon Therapeutics can be found at www.talontx.com.

The Talon Therapeutics, Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=3290>

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are often, but not always, made through the use of words or phrases such as "anticipates," "expects," "plans," "believes," "intends," and similar words or phrases. These forward-looking statements include without limitation, statements regarding potential FDA approval of Talon's NDA for Marqibo, the potential of Marqibo to be a safe and effective alternative for existing therapies, the timing of initiating Talon's proposed Phase 3 clinical trial of Marqibo, and the timing, progress and anticipated results of the clinical development of Marqibo and Talon's other product candidates. Such statements

involve risks and uncertainties that could cause Talon's actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements. Such risks and uncertainties include: that there can be no assurances that any of Talon's clinical and regulatory development efforts relating to Marqibo will be successful; that Talon's NDA for Marqibo will be approved; that the data of the clinical trials of Marqibo will be sufficient to support approval by the FDA of the NDA for Marqibo; that the results of the clinical trials of Marqibo will support Talon's claims or beliefs concerning Marqibo's safety and effectiveness; that Talon will be able to secure the additional capital necessary to fund its product development programs, including Marqibo, to completion; Talon's reliance on third-party researchers to develop its product candidates, and its lack of experience in developing and commercializing pharmaceutical products. Additional risks are described in the company's Annual Report on Form 10-K for the year ended December 31, 2010 and its Quarterly Report on Form 10-Q for the quarter ended June 30, 2011. Talon assumes no obligation to update these statements, except as required by law.

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