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Moleculin Receives Orphan Drug Designation for Annamycin for the Treatment of Acute Myeloid Leukemia

HOUSTON, TX -- (Marketwired) -- 03/22/17 -- Moleculin Biotech, Inc., (NASDAQ: MBRX) ("Moleculin" or the "Company"), a preclinical pharmaceutical company focused on the development of anti-cancer drug candidates, some of which are based on license agreements with The University of Texas System on behalf of the M.D. Anderson Cancer Center, today announced its lead candidate, Annamycin (also known as "Liposomal Annamycin"), an anthracycline, has received Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of acute myeloid leukemia (AML).

Moleculin's Chairman and CEO, Walter Klemp, commented, "We are pleased to report this key milestone and the FDA's decision to grant Annamycin orphan drug designation. We look forward to announcing additional milestones in regard to our clinical pathway as we make further progress."

The FDA grants orphan drug designation to drugs and biologics that are intended for the treatment of rare diseases that affect fewer than 200,000 people in the U.S. Orphan drug status is intended to facilitate drug development for rare diseases and may provide several benefits to drug developers, including tax credits for qualified clinical trials costs, exemptions from certain FDA application fees, and seven years of market exclusivity upon regulatory product approval.

About AML

Leukemia is a cancer of the white blood cells and the acute forms of leukemia can manifest quickly and leave patients with limited treatment options. AML is the most common type of acute leukemia in adults. It occurs when a clone of leukemic progenitor white blood cells proliferates in the bone marrow suppressing the production of normal blood cells. In order to qualify for a curative bone marrow transplant, patients must first undergo induction therapy. The current standard of care is the combining of 2 chemotherapeutic drugs, always including an anthracycline intended to induce a CR or complete response, which has not improved since it was first used in the 1970's. We estimate that it has the same cure rate of about 20% as then. Currently, the only viable long term option for acute leukemia patients is a bone marrow transplant for those 20%, which is successful in a significant number of patients. For more information on AML click: http://www.moleculin.com/technology/about-acute-myeloid-leukemia/.

About Annamycin

Annamycin is an anthracycline intended for the treatment of relapsed or refractory AML.

Annamycin is a unique liposome formulated anthracycline (also referred to in literature as "L-Annamycin") that has been designed to produce little to no cardiotoxicity and avoid the multidrug resistance mechanisms that often defeat current anthracyclines. It has been tested in 114 patients in 6 clinical trials, 3 of which focused on leukemia, with little to no cardiotoxicity and 3 of those clinical trials focused on leukemia. The Company is working with the FDA on an investigative new drug application for a Phase I/II trial for second line treatment of relapsed or refractory AML, for which no approved therapy currently exists.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a preclinical pharmaceutical company focused on the development of anti-cancer drug candidates, some of which are based on discoveries made at M.D. Anderson Cancer Center. Our lead product candidate is Annamycin, an anthracycline for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML. We also have two pre-clinical small molecule portfolios, one of which is focused on the modulation of hard-to-target tumor cell signaling mechanisms and the recruitment of the patient's own immune system. The other portfolio targets the metabolism of tumors.

For more information about Moleculin, please visithttp://www.moleculin.com

Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. These statements relate to future events, future expectations, plans and prospects. Although Moleculin Biotech believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Moleculin Biotech has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed under the heading "Risk Factors" in our Registration Statement on Form S-1 originally filed with the Securities and Exchange Commission on February 7, 2017, as amended (Registration No. 333-214898). Any forward-looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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