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Moleculin's WP1066 Drug gets FDA Brain Tumor IND Clearance

HOUSTON, TX -- (Marketwired) -- 12/05/17 -- Moleculin Biotech, Inc.,(NASDAQ: MBRX) ("Moleculin" or the "Company"), a clinical stage 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 MD Anderson Cancer Center ("MD Anderson"), announced the physician-sponsored Investigational New Drug ("IND") application for a Phase I trial of Moleculin's drug WP1066 in patients with recurrent malignant glioma and brain metastasis from melanoma has been allowed by the US Food and Drug Administration ("FDA").

"We are so pleased to now have a second drug enter the clinical stage," commented Walter Klemp, Chairman and CEO of Moleculin. "We believe WP1066 represents a new class of anticancer drugs able to fight tumors on two fronts by directly inhibiting cell signaling supporting tumor activity, and independently stimulating a natural immune response. This constitutes a new approach to treating brain tumors and tumor metastasis to the brain.

Mr. Klemp concluded, "Since the discovery of WP1066 at MD Anderson by Prof. Waldemar Priebe, it has now been studied by many independent groups and is widely recognized as a potent inhibitor of the activated form of a protein called STAT3, which has been implicated in many difficult to treat tumors, including brain tumors. Animal studies have shown that inhibition of STAT3 directly blocks tumor proliferation and its survival, while most importantly boosting the immune system's ability to fight cancer. We finally have our first opportunity for a clinical proof of concept and confirmation of promising preclinical activity."

This IND was sponsored by Dr. Amy Heimberger, who will serve as the principal investigator for the Phase I trial at MD Anderson Cancer Center to evaluate safety and efficacy. Details about the trial can be viewed on www.clinicaltrials.gov.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a clinical stage 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 being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML. We also have two preclinical small molecule portfolios in development, 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 the Company, 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. Forward-looking statements in this press release include, without limitation, the ability of the WP1066 to demonstrate safety and efficacy in brain tumor patients. 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 Item 1A. "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission ("SEC") and updated from time to time in our Form 10-Q filings and in our other public filings with the SEC. 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.

Contacts
Joe Dorame, Robert Blum or Joe Diaz
Lytham Partners, LLC
602-889-9700
mbrx@lythampartners.com

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