Moleculin's New Drug for the Treatment of Glioblastoma Nears Clinical Trials at MD Anderson Cancer Center

HOUSTON, TX -- (Marketwired) -- 07/25/17 -- 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 it has agreed to provide support to help accelerate the start of a physician-sponsored Investigational New Drug (IND) application to study the Company's drug candidate WP1066 for the treatment of adult glioblastoma (brain tumors).

Dr. Robert Shepard, Moleculin's Chief Medical Officer added: "We have never seen a drug like WP1066 that appears capable in vitro of both stimulating a natural immune response and directly killing tumor cells to block tumor progression. There continues to be a serious unmet need for the treatment of glioblastomas, the most aggressive and lethal form of brain cancer, which is why we are working so hard and are excited to get WP1066 into the clinic."

A recent Facebook post by MD Anderson Brain and Spine expanded: "The drug, known as WP1066, is modeled after a natural compound that has certain tumor-fighting properties. WP1066 amplifies these properties to potent levels, and it can cross the blood-brain barrier. WP1066 belongs to a class of drugs known as STAT3 inhibitors; they prevent tumors from using the STAT3 pathway to evade the immune system. WP1066 can also induce tumor cell death. It's effective against human glioblastoma in preclinical models. The next step is to see if this unique drug is effective when given to glioblastoma patients." (link to post: www.facebook.com/MDAndersonBrainandSpine/photos/a.293040624101698.69475.221408934598201/1603466399725774/)

An IND application sponsored by an MD Anderson physician is currently on clinical hold because FDA has requested additional chemistry, manufacturing and control (CMC) data, among other things. The Company also announced on June 26, 2017 its agreement to support research at the Mayo Clinic on the potential for WP1066 to treat pediatric brain tumors.

"By providing additional guidance and data, we think we can help accelerate the ability of the physician investigator to respond to FDA's requests in a way that will allow the study to begin," commented Walter Klemp, CEO of Moleculin, "which we believe could position WP1066 for a brain tumor trial this year."

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a preclinical 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, 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 visit http://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 to successfully generate the CMC data requested by the FDA, the physician-sponsored WP1066 IND being filed and permitted, a clinical trial studying WP1066 in adult brain tumors beginning this year and that ability of WP1066 to show activity in adult 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.
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