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Moleculin Announces MD Anderson has Filed an IND with the FDA on its Drug WP1066 for the Treatment of Brain Tumors

HOUSTON, TX -- (Marketwired) -- 11/01/17 -- 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 M.D. Anderson Cancer Center, today announced that responses to U.S. Food and Drug Administration ("FDA") requests for additional information relating to the physician-sponsored Investigational New Drug ("IND") application to study WP1066 as a potential treatment for brain tumors have been submitted.

"We have been working closely with MD Anderson to help them respond to questions from the FDA," commented Walter Klemp, Chairman and CEO of Moleculin. "A favorable response from the FDA on this request for IND would mean we will have two distinctly different potential cancer drugs in clinic, both Annamycin and WP1066."

As the Company has disclosed previously, the physician-sponsored IND had been placed on clinical hold pending satisfactory responses to questions provided by the FDA. An MD Anderson physician is planning to conduct a Phase 1 clinical trial to study WP1066 in patients with glioblastoma or melanoma that has metastasized to the brain. Standard FDA procedure is to respond to such IND submissions within 30 days.

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 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 willingness of the FDA to allow the physician-sponsored IND request as amended and the willingness and ability of MD Anderson to begin a Phase 1 clinical trial with WP1066 and the ability of WP1066 to show safety and efficacy in patients with glioblastoma or melanoma that has metastasized to the brain. 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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