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# Moleculin Announces Filing with FDA of IND for its Leukemia Drug Annamycin

HOUSTON, TX -- (Marketwired) -- 08/29/17 -- 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 filed with the Food and Drug Administration (FDA) an Investigational New Drug (IND) application to study Annamycin in the treatment of relapsed or refractory acute myeloid leukemia (AML).

Submitting this revised IND marks a significant milestone for Moleculin. FDA allowing the IND to go into effect -- which is the anticipated next step and normally would occur within 30 days -- will allow the Company to begin additional clinical trials as part of demonstrating the safety and effectiveness of Annamycin. The current plan is to seek approval for treating relapsed or refractory acute myeloid leukemia. If the IND goes into effect as planned, the Company expects to begin clinical trials during the fourth quarter of this year. There can be no assurance, however, that the IND will go into effect within in expected time frame, or at all.

"It took considerable time to produce the additional CMC data requested by the FDA," commented Walter Klemp, Chairman and CEO of Moleculin, "but now that we have all of what the FDA requested, we are pleased to submit a revised IND. We have seen considerable interest from Principle Investigators who are eager to enroll AML patients in an Annamycin clinical trial, so this is a critical step for us."

The Company previously filed an IND, in response to which the FDA requested certain revisions to the protocol, additional information, and additional data related to Chemistry, Manufacturing and Controls (CMC). The Company withdrew its original application in order to develop the additional information and CMC data and revise the protocol, with the goal of resubmitting the application when that was accomplished. The current IND submission represents the completion of that process.

***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 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 potential for the FDA to allow the IND for Annamycin to go into effect. 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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