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Moleculin Announces FDA Approval of Annamycin IND

HOUSTON, TX -- (Marketwired) -- 09/26/17 -- 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 the Food and Drug Administration (FDA) has advised Moleculin it may begin clinical trials of Annamycin in the treatment of relapsed or refractory Acute Myeloid Leukemia (AML). The FDA's determination came after the agency completed its safety review of information and a proposed protocol submitted by Moleculin in an Investigational New Drug application (IND).

"This represents a tremendous milestone for Moleculin," commented Walter Klemp, Chairman and CEO of Moleculin. "Our primary focus has been to get Annamycin back into the clinic so we can begin optimizing the dosing of the drug as the next step in evaluating its potential to become the first 2nd line therapy suitable for the majority of relapsed or refractory AML patients. It is a thrill to now refer to Moleculin as a 'clinical stage' company."

Dr. Don Picker, Chief Science Officer for Moleculin, added, "We are grateful for the FDA's thorough and comprehensive review of our IND, and for the manner in which they worked with us to address some key technical issues in the area of Chemistry, Manufacturing and Control."

Moleculin's Chief Medical Officer, Dr. Robert Shepard, added: "Responding to comments from the FDA, we have adopted additional patient safeguards that will be implemented while we seek to establish the 'Recommended Phase 2 Dose.' This will include reporting interim safety data to FDA before allowing US patients to progress beyond initial agreed-upon dosing limits. After seeing indications of what Annamycin may be capable of from earlier clinical trials, I made it a career goal to get the drug back into the proper clinical trials to determine its potential."

The US IND going into effect also allows Moleculin to make a submission to Polish authorities necessary for the planned Annamycin clinical trial to also be conducted in Poland.

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 potential for Annamycin to demonstrate safety and efficacy in AML patients and the ability of the Company to obtain Polish regulatory approvals to commence clinical trials for Annamycin there. 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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