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Moleculin Announces New Data Confirms Anti-tumor Efficacy of Annamycin in Both Human and Murine AML Models

Data Presented at the AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Conference

HOUSTON, Oct. 29, 2019 /PRNewswire/ -- Moleculin Biotech, Inc., (Nasdaq: MBRX) ("Moleculin" or the "Company"), a clinical stage pharmaceutical company with a broad portfolio of drug candidates targeting highly resistant tumors, announced the presentation of a poster at the AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Conference today in Boston, MA. The poster, entitled "Dose and Schedule-Dependent Efficacy of Liposomal Annamycin in Pre-clinical Models of Acute Myeloid Leukemia," presents data documenting the high activity of Annamycin against AML, including in vitro studies in a panel of human AML cell lines, as well as in vivo studies in both human and murine AML models developed under the Company's sponsored research agreement with MD Anderson Cancer Center.



"This study highlights an important new finding," commented Walter Klemp, Moleculin's Chairman and CEO. "We've known for some time that Annamycin is effective in AML animal models and the activity that we believe is coming from our current AML clinical trials seems to correlate with this. But, what's new here is the observation that Annamycin may also be more effective than other drugs due to its high uptake and effectiveness in eliminating AML cells localized in different organs. Additional important observations made with these studies indicates that the long-term exposure of healthy mice (at least 12 doses so far) to a highly efficacious dose of 4 mg/kg administered weekly is not toxic and that even two weekly doses of 4 mg/kg are producing a significant increase in survival. And, because Annamycin is designed to be non-cardiotoxic, this extended dosing regimen may prove to be feasible and beneficial in humans. This potentially opens the door for expanded and improved dosing regimens in future clinical trials."

Quoting from the accepted abstract: "In vivo studies confirmed anti-tumor efficacy of Annamycin in both human and murine AML models. Based on bioluminescence imaging, the liposomal formulation of the drug significantly delayed AML progression in the human OCL-AML3/NSG model at 4 mg/kg with once weekly dosing. Similarly, significant dose-dependent

reduction of peripheral blood AML blasts was observed in the murine AML-Turq2 model, and this reduction was strongly correlated with prolongation of animal survival. The median survival of mice receiving four doses of L-Ann once a week at 4 mg/ml was 37 days while mice receiving vehicle lived only 14 days (p=0.0002). Different doses and administration schedules of [Annamycin] were tested in an effort to maximize survival benefits. In summary [Annamycin] is effective in AML, demonstrating significant activity in both in vitro and in vivo mouse models with a distinct pattern of intracellular uptake and organ distribution using a once a week schedule. This suggests that [Annamycin] with this profile, including a lack of cardiotoxicity and activity against [doxorubicin] resistant tumors, may be an advantageous approach in the treatment of AML."

To see the entire poster, please go to: www.moleculin.com

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a clinical stage pharmaceutical company focused on the development of a broad portfolio of oncology drug candidates for the treatment of highly resistant tumors. The Company's clinical stage drugs are: Annamycin, a Next Generation Anthracycline, designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML, WP1066, an Immune/Transcription Modulator capable of inhibiting p-STAT3 and other oncogenic transcription factors while also stimulating a natural immune response, targeting brain tumors, pancreatic cancer and hematologic malignancies, and WP1220, an analog to WP1066, for the topical treatment of cutaneous T-cell lymphoma. Moleculin is also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as compounds capable of Metabolism/Glycosylation Inhibition.

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 of Annamycin, with either the current or modified dosing regimens, to show safety and efficacy in patients. Although Moleculin 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. The Company cautions investors not to place undue reliance on the interim results announced today.

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