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Moleculin Approved to Accelerate European Clinical Trial

Regulatory authorization doubles dose escalation in Annamycin AML trial

HOUSTON, April 28, 2020 /PRNewswire/ -- Moleculin Biotech, Inc., (Nasdaq: MBRX) ("Moleculin" or the "Company"), a clinical stage pharmaceutical company with a broad portfolio of drug candidates, today announced that it is now authorized by the Polish Department of Registration of Medicinal Products known as URPL to accelerate the Phase 1 dose escalation portion of its clinical trial of Annamycin for the treatment of acute myeloid leukemia (AML).

The URPL has allowed an amendment to the Annamycin clinical trial protocol, which among other things, includes an increase in the dose escalation increment between cohorts from 30 mg/m^2 to 60 mg/m^2. The clinical trial is currently recruiting for the 240 mg/m^2 cohort, so this amendment allows the next cohort to increase to 300 mg/m^2, assuming all requirements for safety are met with the 240 mg/m^2 cohort.

"Now that we have begun to demonstrate the absence of any cardiotoxicity associated with Annamycin," commented Walter Klemp, Chairman and CEO of Moleculin. "We believe we can and should move more aggressively to establish the maximum tolerated dose, or MTD, for Annamycin. This authorization now sets the stage to accelerate the dose escalation process. Thus far, even though we've seen promising activity from Annamycin, our dosing levels are still sub-therapeutic. Based on prior clinical experience with Annamycin, the 300 mg/m^2 dosing level will be our first opportunity to test Annamycin at what we expect will be therapeutic levels."

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 and viruses. 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, under investigation for brain tumors, pancreatic cancer and hematologic malignancies; and WP1220, an analog to WP1066, being developed 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 WP1122, a compound capable of metabolism/glycosylation disruption.

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 ability of Annamycin to demonstrate safety and efficacy in humans and the dosing level required to achieve therapeutic levels. 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.

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