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Moleculin Receives Approval to Extend Dose Escalation in Phase 1/2 European Clinical Trial Evaluating Annamycin for the Treatment of Acute Myeloid Leukemia

- Protocol amendment allows for change in dose limiting toxicity (DLT) criteria for future enrolled subjects

- Demonstrated efficacy in 240 mg/m² cohort with Annamycin

- Annamycin has demonstrated little to no cardiotoxicity, avoids multidrug resistance, has been shown to be more potent in AML cell lines and has shown activity in patients for whom standard of care has failed

- Company expects to report topline results from the ongoing Phase 1/2 study for treatment of AML in the second half of 2022

HOUSTON, July 13, 2021 /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 and viruses, today announced that it has received approval from the Bioethics Committee of the Medical University of Karol Marcinkiewicz in Poznań (Ethics Committee) as well as an allowance from the Polish Department of Registration of Medicinal Products (URPL) for a protocol amendment for its Phase 1/2 evaluating Annamycin for the treatment of subjects with acute myeloid leukemia (AML) that is refractory to or relapsed after induction therapy.

Annamycin is the Company's next-generation anthracycline that has demonstrated a lack of cardiotoxicity in recently conducted human clinical trials for the treatment of AML. Additionally, Annamycin has been shown in animal models to accumulate in the lungs at up to 30-fold the level of doxorubicin. The Company believes that the use of Annamycin may not face the same usage limitations imposed on doxorubicin. Annamycin is currently in development for the treatment of AML and STS lung metastases.

"Based on the preliminary data seen demonstrating clinical benefit for patients receiving a full course of treatment in the 240 mg/m^2 cohort and the recommendation from our medical advisors on the dose limiting toxicity criteria, we are pleased to have Ethics Committee approval and the allowance from the URPL to amend the protocol for future patients. This amendment will allow us to continue dose escalation in the Phase 1 portion of the trial and establish the maximum tolerated dose as we work toward the recommended dose for the Phase 2 portion of the study. Our team is committed to advancing this important clinical program forward and to potentially address the limitations with current treatment options for AML patients," commented Walter Klemp, Chairman and CEO of Moleculin.

The Phase 1/2 AML trial in Poland remains ongoing and is currently dosing patients at 240 mg/m^2. Under the previous protocol transient elevated liver enzymes (AST and ALT) observed in two patients were considered a dose limiting toxicity (DLT), which investigators believe would inappropriately limit the potential for continued dose escalation. The amendment to the Annamycin clinical trial protocol allows for a change in the DLT criteria as it relates to transient grade 3 elevations and allows dosing of three additional patients in the 240 mg/m^2 cohort. If no DLT (as defined by the new criteria) is experienced with these next three patients, the Company plans to escalate dosing in new cohorts by 30 mg/m^2 instead of the 60 mg/m^2 previously planned, and with a de-escalation of 15 mg/m^2 at the DLT dose if future patients experience a DLT.

The results from the Phase 1 portion of the Company's U.S. Phase 1/2 clinical trial of Annamycin for the treatment of AML met its primary endpoint and demonstrated a clean safety profile with no evidence of cardiotoxicity when delivered to patients at or below the lifetime maximum anthracycline dose established by the FDA. To date, an independent expert assessment of the absence of cardiotoxicity in the first 19 patients treated with Annamycin in both the Company's U.S. and European Phase 1 clinical trials in which an independent expert concluded that he "does not see evidence of cardiotoxicity."

Moleculin Biotech expects to continue reporting cohort topline results from the ongoing Phase 1/2 study for treatment of AML and to report the study's topline results in the second half of 2022. Annamycin has been granted Fast Track Status and Orphan Drug Designation from the U.S. Food and Drug Administration for the treatment of AML.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a clinical stage pharmaceutical company focused on the development of a broad portfolio of drug candidates for the treatment of highly resistant tumors and viruses. The Company's lead program, Annamycin is a next-generation anthracycline designed to be noncardiotoxic and to avoid multidrug resistance mechanisms. In addition, Annamycin has been shown in animal models to reach higher concentration levels than doxorubicin (a leading anthracycline) in certain key organs, such as the lungs, liver and pancreas considered to be difficult-to-reach "sanctuary sites" for tumors. Annamycin is currently in development for the treatment of relapsed or refractory acute myeloid leukemia (AML) and soft tissue sarcoma (STS) lung metastases.

Additionally, the Company is developing 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 and other

cancers, and WP1220, an analog to WP1066, for the topical treatment of cutaneous T-cell lymphoma. Moleculin is also engaged in the development of a portfolio of antimetabolites, including WP1122 for the potential treatment of COVID-19 and other viruses, as well as cancer indications including brain tumors, pancreatic and other cancers.

For more information about the Company, please visitwww.moleculin.com and connect on [Twitter](), [LinkedIn]() and [Facebook]().

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 patients, the ability of clinical trials to begin recruiting patients on a timely basis, the timing of the disclosure of interim data in the second half of 2022, and whether Annamycin will receive New Drug Approval. 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 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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