November 12, 2019

Moleculin Biotech, Inc. Reports Financial Results for the Third Quarter Ended September 30, 2019

HOUSTON, Nov. 12, 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, today announced its financial results for the third quarter ended September 30, 2019. Additionally, the Company announced potential upcoming milestones and recent corporate developments.

Management Discussion

Walter Klemp, chairman and chief executive officer of Moleculin, said, "We are extremely pleased with the progress we have achieved year-to-date with our research programs and ongoing clinical trials setting the stage for the Company to report clinical results in the near future. During the third quarter we continued to make great progress, particularly on the Annamycin front. The recent discovery that Annamycin accumulates at elevated levels in the lungs, liver, spleen and pancreas represents what we believe could be a significant opportunity to treat certain difficult cancers. We've known for some time that Annamycin is effective in the treatment of AML (acute myeloid leukemia) in animal models. In that regard, our expectation for positive activity from our current AML clinical trials may very well correlate with this. What's new here is the observation that Annamycin may also be more effective than currently approved anthracyclines due to its high uptake and effectiveness in eliminating cancer cells localized in different organs. Annamycin may be well suited to treat metastasized tumors because of its ability in murine research models to accumulate in certain organs at nearly six times the level of the current standard of care anthracycline. This is an important development as we progress through our research and clinical trials."

Mr. Klemp continued, "In Poland, our Annamycin clinical trial continues to indicate positive results from patients dosed at the 180mg level. We expect to report treatment results for this latest cohort in the fourth quarter of this year. This is our third cohort of patients in the Polish trial that have been successfully treated with increased dosages from 120 mg/m^2 to 150 mg/ m^2 to 180 mg/ m^2 with minimal to no adverse events and has continued to exhibit no cardiotoxicity. We believe this sets the stage for yet another increased dose in the next cohort at 210 mg/kg. Given the potential for the first ever non-cardiotoxic anthracycline and

Annamycin's apparent ability to avoid multi-drug resistance, we are excited with the opportunities ahead."

"Due to the positive results we are achieving with Annamycin in our research and ongoing clinical trials, we recently announced the expansion of Annamycin production commitments. To this point, our clinical supply of Annamycin has been produced in a smaller pilot-level facility. Our supplier is now shifting Annamycin production to a larger-scale production facility. We believe this is a positive indication as we continue the development of Annamycin."

"Given the positive results reported in recent quarters from (1) the physician sponsored research and clinical trial in the treatment of glioblastoma with our lead STAT3 inhibitor - WP1066 – in combination with radiation therapy, (2) the elevated accumulation of Annamycin in the lungs, liver, pancreas and spleen, and the possibilities for triple negative breast cancer metastasized to the lungs, and (3) the expectation of reporting results soon from our proof of concept clinical trial to evaluate our p-STAT3 inhibitor, WP1220, for the topical treatment of Cutaneous T-Cell Lymphoma ("CTCL"), we remain highly focused on developing 'multiple shots on goal' for the treatment of rare and difficult cancers. We are pleased with the progress being achieved on a number of different clinical fronts in developing treatments for highly resistant cancers," concluded Mr. Klemp.

Jonathan Foster, executive vice president and chief financial officer of Moleculin, stated, "We finished the third quarter with a solid balance sheet with cash of approximately $15.4 million and no debt. We believe our existing cash and cash equivalents will be sufficient to fund our planned operations well into the second quarter of 2020 without the issuance of additional equity for cash. During the third quarter our R&D expense increased to $2.8 million due to increased clinical activity with three drugs in four clinical trials. For the nine-month period, cash used in operations was $12.5 million and net cash provided by financing activities was $20.9 million. We are highly focused on our ongoing research programs, clinical trials and remaining capital efficient through our important developmental process. We also continue to be pleased with our team's progress on the Company's stated milestones."

Anticipated Milestones

Anticipated Milestones	Potential Time Frame
Next Generation Anthracycline - Annamycin	
Clinical Trials - Complete cohort of 150 mg/m^2 - prior trial recommended Phase II dose (RP2D)	**Accomplished** and ongoing 2019
Announcement of initial clinical data for Annamycin trial	**Accomplished** and ongoing 2019
Announcement of RP2D for Poland Trial	2020
Poland clinical trial (MB-105) begins Phase II	2020
Approach FDA on U.S. trial (MB-104) on dose expansion using Poland trial data	2020 **(Fast Track Approved)**
Announce clinical research in distant metastases	2020
Immune/Transcription Modulators - WP1066 Family	
Clinical Trials WP 1066 - Announcement of initial clinical data from WP1066 clinician sponsored trial	2019
Phase 1 surgical cohort begins	2020
Transfer clinician sponsored trial WP1066 IND to Moleculin	2020
Emory Physician Led Pediatric Medulloblastoma Trial begins	Second Half of 2019
Announcement of further benefits of our sponsored research agreement with MD Anderson	**Accomplished** and ongoing 2019
Clinical Trial WP1220 - Announce filing and approval of CTA for WP1220 for the treatment of cutaneous T-cell lymphoma (CTCL)	**Accomplished**
Assess WP1220 initial patient data	**Q4-2019**
IND for IV formulated STAT3 inhibitor submitted	2021
Dose first patient in Phase I trial for IV formulated STAT3 inhibitor	2021
Announce further preclinical research results on WP1066 family	**Accomplished** and ongoing 2019
Metabolism/Glycosylation Inhibitors	
Begin preclinical work on WP1122	**Accomplished**
Complete formulation and begin manufacture of drug for trial	2020
File IND or CTA for WP1122	2021

Third Quarter Highlights and Recent Corporate Developments

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 -*** October 29, 2019, the Company announced the presentation of a poster at the AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Conference 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 that Annamycin may 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. 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.

From the abstract: Based on bioluminescence imaging, the liposomal formulation of the Annamycin 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

Moleculin Increases Annamycin Production Due to Positive Clinical Trial Activity and Expanded Potential Indications - ***Expansion of potential indications includes lung-localized tumors*** - October 22, 2019, the Company announced the expansion of Annamycin production commitments in response to management's assessment of positive AML clinical trial activity and the potential expansion of indications for use to include lung-localized tumors. The purchase commitment arranged through Davos Pharmaceuticals includes moving final production of Annamycin to a larger-scale suite within BSP Pharmaceuticals S.p.A. ("BSP") in Latina, Italy.

The Company's clinical trials of Annamycin in relapsed and refractory AML are going better than expected and it appears it will be able to reach a higher maximum tolerable dose than what was established in previous clinical trials. The Company believes this will increase its chances for improved patient outcomes. Coupled with the recent discovery in animal models that Annamycin may be well suited to treat lung-localized tumors because of its ability in such models to accumulate in the lungs at nearly 6 times the level of the current standard of care anthracycline.

Management's view of success in clinic and the expectation of wider demand resulting from additional clinical trials in lung-localized tumors, it's time for Moleculin to start preparing for an eventual drug approval process. That requires the development and validation of commercial scale methods and this move with BSP marks the beginning of that process. In addition to increasing the scale of clinical supply production, the Company will be working with BSP and with our manufacturer of API to develop the commercial scale synthesis and drug production methods we will need to ultimately prepare for New Drug Approval.

Moleculin Announces its Sponsored Research at MD Anderson Cancer Center Has Resulted in the Filing of Patent Protection for New Discovery - September 16, 2019, the Company announced its sponsored research at MD Anderson Cancer Center has resulted in the filing of a new patent on behalf of MD Anderson Cancer Center covering the combination of its immune stimulating/transcriptional-modulator, WP1066, with well-known immune checkpoint inhibitors.

The Company previously announced preliminary preclinical data showing beneficial therapeutic effect from WP1066 when used in combination with PDL-1 and CTLA-4 immune checkpoint inhibitors in pancreatic cancer models. This new discovery opens new potentially effective approaches to utilize check point inhibitors for treatment of pancreatic cancer and other types cancers that are unresponsive to current immunotherapies.

Moleculin Announces CTRC Approval of WP1066 Pediatric Brain Tumor Trial -August 20, 2019, the Company announced approval by the Emory University Clinical Trial Review Committee (CTRC) to move forward with an Investigator Initiated clinical trial of Moleculin's immune-stimulating/transcriptional-modulator, WP1066, for the treatment of pediatric brain tumors. The trial will take place at the Aflac Cancer and Blood Disorders Center at Children's Healthcare of Atlanta.

Continued progress with the MD Anderson clinical trial of WP1066 in brain tumors has cleared the way for a pediatric brain tumor trial with investigators from Emory University School of Medicine. With CTRC approval, the investigators can now submit a request for an IND from the FDA for this indication referencing the MD Anderson IND already in place.

Dr. Tobey MacDonald, Professor of the Department of Pediatrics at Emory University School of Medicine, Director of Pediatric Neuro-Oncology at Aflac Cancer and Blood Disorders Center and Principle Investigator for this clinical trial commented: "We've done a lot of preclinical research suggesting that WP1066 may be beneficial in treating pediatric brain tumors, including medulloblastoma, where there continues to be a critical unmet need for more effective therapies. We are excited to finally get this trial moving."

Moleculin Announces Completion of Lymphoma Trial Enrollment -August 13, 2019, the Company announced its proof of concept clinical trial to evaluate its p-STAT3 inhibitor, WP1220, for the topical treatment of Cutaneous T-Cell Lymphoma ("CTCL") has reached full enrollment.

The Company believes there continues to be an unmet need for an improved topical therapy for Stage I-III CTCL skin lesions, especially one that may avoid significant unwanted side effects. CTCL is known to frequently involve the upregulation of the activated form of STAT3 (p-STAT3), which has been linked to a range of tumor-related transcriptional activity. This proof of concept, if successful, could be an important first demonstration of a therapeutic effect in humans from such a p-STAT3 inhibitor. This trial represents one of four clinical trials currently underway. The Company believes showing activity with one of its STAT3 inhibitors, within its WP1066 family of molecules, could be an indicator of both the value of p-STAT3 as a target and the potential for its drugs in the treatment of other cancers where STAT3 is highly activated.

Moleculin Announces Breakthrough Discovery: WP1066 Potentially Capable of Immune Reprogramming in Glioblastoma Animal Models - ***Data to be presented at the Inaugural Conference on Brain Metastases, August 16-17, 2019*** - August 6, 2019, the Company announced that a paper entitled "Immunological Reprogramming in the CNS Tumor Microenvironment and Therapeutic Efficacy of Radiotherapy with STAT3 Blockade" was presented at the Inaugural Conference on Brain Metastases, in New York City, August 16-17, 2019. Dr. Martina Ott, of MD Anderson Cancer Center, presented the findings of the research she conducted in collaboration with Dr. Amy Heimberger (the Principle Investigator of the current investigator-initiated clinical of WP1066 for brain tumors) in combining WP1066 with radiation therapy in glioblastoma animal models.

One of the findings of her research that is especially encouraging is that immune-competent mice treated with both radiation and WP1066 developed an immunological memory that enabled them to prevent regrowth of the tumor after these tumor cells were reintroduced. The result was the development of long-term survivors, leading to an increase in overall

survival in these models.

This study was also particularly interesting because it showed the most robust immunological responses were located in the CNS (Central Nervous System) tumor microenvironment rather than peripheral non-tumor tissue. Importantly, the study indicated that the combination of STAT3 inhibition with whole brain radiotherapy had the capacity to enhance the therapeutic effect against established tumors based on immunological competence.

Moleculin Announces Annamycin in Acute Myeloid Leukemia in Poland Advances to 3rd Cohort - July 18, 2019, the Company announced additional positive interim safety and efficacy data from its ongoing open label, single arm Phase 1/2 study of Annamycin in Poland. Three patients were treated at a dose level of 150 mg/m^2 with no drug-related adverse events, including no signs of cardiotoxicity. The results for all 3 patients were reviewed by the Drug Safety Review Committee, which determined that the trial could progress to the next higher dose level of 180 mg/m^2. To date in Poland, one patient experienced grade 2 mucositis (which resolved to grade 1 within 2 days) and no other adverse events related to Annamycin have been reported. One patient has completed treatment in the 120 mg/m^2 (second) cohort in the Company's parallel US clinical trial (the US trial started at a lower initial dose of 100 mg/m^2). The Company continues to see no evidence of cardiotoxicity in any of the patients treated thus far in its clinical trials.

Moleculin Files for New Patents for Annamycin After Receiving FDA Approval of Fast Track Designation - July 10, 2019, the Company announced it has filed new patents covering the production and reconstitution of Annamycin, which is currently in two clinical trials for the treatment of relapsed or refractory acute myeloid leukemia (AML). Annamycin has Orphan Drug Designation in the US for the treatment of AML and the Company recently announced promising preclinical data showing the potential for Annamycin to become an important treatment for lung metastases. If these patent applications are approved, this will potentially give the Company 20 years of patent protection for Annamycin.

Moleculin Announces Additional Positive Interim Results in First Cohort of Phase 1/2 Clinical Studies of Annamycin in Acute Myeloid Leukemia in Europe - ***2 of 3 patients qualify to proceed to a potentially curative bone marrow transplant; trial advances to next higher dose level*** - May 7, 2019, the Company announced additional positive interim safety and efficacy data from its ongoing open label, single arm Phase 1/2 study of Annamycin in Poland. After receiving a single starting dose of 120 mg/m^2 in the first cohort of the dose escalation phase of the trial, 2 of 3 patients treated responded sufficiently to qualify for a potentially curative bone marrow transplant. The results for all 3 patients were reviewed by the Safety Review Committee, which determined that no drug-related adverse events were observed that would prevent advancing the trial to the next higher dose level of 150 mg/m^2. To date in the European trial, one patient experienced grade 2 mucositis (which resolved to grade 1 within 2 days) and no other adverse events related to Annamycin have been reported. No additional patient data have been developed in the Company's parallel US clinical trial, which is currently recruiting its second cohort to be given a dose level of 120 mg/m^2 (the U.S. trial started at a lower initial dose of 100 mg/m^2).

Financial Results for the Third Quarter ended September 30, 2019

For detailed financial results, please find the link to the Company's quarterly and other filings with the SEC at https://ir.moleculin.com/sec-filings.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a clinical-stage pharmaceutical company focused on the treatment of highly resistant cancers. Moleculin has three core technologies, all of which are based on discoveries made at M.D. Anderson Cancer Center by Dr. Waldemar Priebe and his team. The Company's clinical-stage drugs are Annamycin, a Next Generation Anthracycline being studied for the treatment of relapsed or refractory acute myeloid leukemia, or AML, and WP1066, an Immune/Transcription Modulator targeting brain tumors, pancreatic cancer and AML. The Company is also engaged in preclinical development of additional drug candidates, including additional Immune/Transcription Modulators, as well as Metabolism/Glycosylation Inhibitors. Moleculin's Next Generation Anthracycline, Annamycin, we believe, is unlike any currently approved anthracyclines, as it is designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity. Annamycin has preliminary clinical data suggesting its potential to become the first successful therapy suitable for the majority of relapsed or refractory AML patients and is currently in two Phase I/II clinical trials. WP1066 is one of several Immune/Transcription Modulators capable of stimulating immune response to tumors by inhibiting the errant activity of Regulatory T-Cells (TRegs) while also inhibiting key oncogenic transcription factors, including p-STAT3, c-Myc and HIF-1α . These transcription factors are widely sought targets that may also play a role in the inability of immune checkpoint inhibitors to affect more resistant tumors. Moleculin is also developing new prodrugs to exploit the potential uses of inhibitors of glycolysis. The Company's lead Metabolism/Glycosylation Inhibitor compound, WP1122, provides an opportunity to cut off the fuel supply of tumors by taking advantage of their overdependence on glucose as compared with healthy cells. New research also points to the potential for the glucose decoy (2-DG) within WP1122 to be capable of enhancing the usefulness of checkpoint inhibitors.

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 Moleculin to successfully recruit sufficient patients to complete its current clinical trials; the ability of Moleculin to file an IND for WP1732; the ability of Moleculin's drug candidates to show safety and efficacy in patients; and the ability of Moleculin to receive patent protection for Annamycin. 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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