February 1, 2021

Moleculin Signs Agreement with Catalyst Clinical Research to Begin Sarcoma Trial

Annamycin being used to target soft tissue sarcoma lung metastases

HOUSTON, Feb. 1, 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 signed an agreement with Catalyst Clinical Research (Catalyst), a contract research organization, to manage its US clinical trial to study the ability of Annamycin to treat soft tissue sarcoma (STS) that has metastasized to the lungs.

Soft tissue sarcomas are the most common form of sarcoma, accounting for an estimated 130,000 incident cases per year worldwide. While many sarcomas can be addressed through surgical removal, it is estimated that as many as 20% to 50% of STS will eventually metastasize to the lungs, where treatment can become more challenging.

Once metastasized to the lungs, if tumors cannot be surgically removed, the primary chemotherapy regimen is the anthracycline doxorubicin, also known as Adriamycin. While 10% to 30% of patients with sarcoma lung metastases may initially respond to doxorubicin, most will relapse, leaving the majority of these patients without an alternative chemotherapy. Treatment options are further limited because of the inherent cardiotoxicity of currently approved anthracyclines, including doxorubicin, which limits the amount of anthracycline that can be given to patients.

Annamycin is a "next generation" anthracycline that has recently been shown in animal models to accumulate in the lungs at up to 34 times the level of doxorubicin. Importantly, Annamycin has also demonstrated a complete lack of cardiotoxicity in recently conducted human clinical trials for the treatment of acute myeloid leukemia, so the use of Annamycin should not face the same dose limitations imposed on doxorubicin.

"As soon as we received IND (Investigational New Drug) status, we began reaching out to potential clinical sites, and the response has been very positive," commented Walter Klemp, Chairman and CEO of Moleculin. "We believe engaging a well-respected CRO such as Catalyst will enable us to move quickly to initiate sites and get this trial under way."

"It's clear there is a significant unmet need for an improved therapy for STS lung

metastases," added Catalyst CEO Nick Dyer. "Catalyst Oncology is thrilled to be the selected partner to collaborate with Moleculin on this potentially ground-breaking study."

About Catalyst

Catalyst is a clinical development organization providing highly customizable clinical research solutions to the global biopharmaceutical industry through two established solutions: Catalyst Flex and Catalyst Oncology. With over 500 staff and offices in the US and EU, the company provides multi-therapeutic global resourcing and functional services through Catalyst Flex and a full-service oncology CRO offering through Catalyst Oncology. The company's flexible service model is built from more than a decade of listening to customers, devising customer-centric solutions, and helping them drive breakthrough clinical development studies leveraging Catalyst's expert teams and innovative technologies.

Catalyst is a portfolio company of NovaQuest Capital Management, LLC, a leading healthcare and life sciences investment firm.

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, 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 other Immune/Transcription Modulators, as well as WP1122 and related compounds capable of Metabolism/Glycosylation Inhibition.

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 patients and the ability of Moleculin to commence clinical trials to study the ability of Annamycin to treat soft tissue sarcoma (STS) that has metastasized to the lungs on a timely basis. 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.

Contacts

James Salierno / Carol Ruth
The Ruth Group
973-255-8361 / 917-859-0214
jsalierno@theruthgroup.com
cruth@theruthgroup.com

View original content to download multimedia: http://www.prnewswire.com/news-releases/moleculin-signs-agreement-with-catalyst-clinical-research-to-begin-sarcoma-trial-301218801.html

SOURCE Moleculin Biotech, Inc.