April 29, 2019

US Biopharma Company Undertakes Anti-Cancer Clinical Trials in Poland, First Patient Showing Positive Initial Treatment

Moleculin quickly recruited qualified patients and started trials for two of its portfolio drugs to supplement US efforts.

HOUSTON, April 29, 2019 /PRNewswire/ -- A small public company with 6 highly promising anti-cancer drugs in the pipeline is augmenting US clinical trials with trials in Poland, speeding the process of patient recruitment and data collection. The company, Moleculin (NASDAQ: MBRX), recently recruited 3 patients in 6 weeks in Poland, whereas in the U.S. it took a full year to build a similar, complete cohort. The company now has 2 clinical trials with patients enrolled in Poland.

The phase 1/2 clinical trial now underway in Poland for the company's Annamycin compound has already shown promising results with one trial patient's acute myeloid leukemia (AML) now in remission, making the patient eligible for a bone marrow transplant. While significant additional study is necessary to definitively demonstrate causality, Moleculin has already begun to identify more patients in Poland for the next cohort of the same trial and 2 more patients for its WP1220 topical treatment of cutaneous T-cell lymphoma (CTCL).

"The clock is ticking for many patients suffering from hard-to-combat cancers," said Walter Klemp, CEO, Moleculin Inc. "For a smaller pharmaceutical company with a promising roster of drug candidates for targeting these highly resistant tumors, speed in launching trials is critical. We feel lucky to have found a well-established medical community where access to patients is easier and faster. If the promising results continue, we look forward to getting our drugs into the hands of such patients much sooner."

"While the response of a single patient doesn't necessarily predict the outcome of the trial, this is a great way to begin and it's consistent with our expectations for Annamycin," Mr. Klemp continued. "We have seen no evidence of cardiotoxicity in any of the patients treated thus far and intend to advance the clinical study of Annamycin with the goal of ultimately demonstrating the drug's safety and effectiveness to support regulatory approval in the US and European Union."

The additional patient safety data gained from the Polish trials may also assist in the FDA's review of cardiac safety which can be a key factor in regulatory approval.

US Market Recruitment Challenges

Without data from clinical trials, drug development companies have no way forward. However, recruiting for anti-cancer clinical trials in the US can be slow. With large pharma companies targeting the US market with both ground-breaking and "me-too" drugs, there is significant competition for patients in the United States.

Also, oncology clinical trials are typically conducted in one of 61 major cancer centers in urban areas, making it difficult for qualified rural patients to participate. Elderly American patients often decline because they or their families have caregiving and scheduling demands that make such trials difficult.

Other issues that make trials difficult include insurance and financial concerns, as insurers often require that clinical trials be conducted in-network.

To build a larger base of clinical trial patients more quickly, Moleculin began working with the medical community in Poland, where the company's Founding Scientist Dr. Waldemar Priebe was born. Currently a researcher at M.D. Anderson Cancer Center in Houston, Priebe is extremely familiar with the Polish medical establishment. As a location for clinical trials, Poland has a medical infrastructure and community acceptable to the FDA and offers many benefits to the small biopharma. These include:

- Highly rated medical infrastructure and medical community (Poland is ranked seventh in Europe for clinical trial participation, with an annual average of about 40,000 patients in clinical trials. The clinical trial market there was estimated to be about 200M euros as of 2014.
- With fewer drug developers, there is less competition for clinical trial patients in Poland.
- A greater number of patients who are "treatment-naïve," meaning they are less likely to have resistant cells from other medical treatments.
- The European Medicines Agency is receptive to starting clinical trials at higher, more therapeutic drug doses.

For the current Moleculin Polish trial, the allowable starting dose was 120 mg/m^2, offering the opportunity to provide patients with what the Company considers a potentially more therapeutic dose than the 100 mg/m^2 required in the US. Once 3 patients have completed the safety evaluation period of the first cohort in Poland, the second cohort will begin there at a dose level of 150 mg/m^2.

About Moleculin Biotech, Inc.
Moleculin Biotech, Inc. is a clinical stage pharmaceutical company focused on the development of oncology drug candidates, all of which are based on discoveries made at M.D. Anderson Cancer Center. The Company's clinical stage drugs are Annamycin, an 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, and WP1066, an immuno-stimulating STAT3 inhibitor targeting brain tumors, pancreatic cancer and AML. Moleculin Biotech is also engaged in preclinical development of additional drug candidates, including additional

STAT3 inhibitors and compounds targeting the metabolism of tumors.

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 WP1066 to show safety and efficacy in patients. 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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