



## **WPD Pharmaceuticals' Annamycin Drug Candidate Meets Endpoint in Successful U.S. Phase 1 AML Trial With No Evidence of Cardiotoxicity**

**Preliminary assessment shows efficacy in 2 out of 6 patients**

**Vancouver, British Columbia – April 23, 2020 – WPD Pharmaceuticals Inc.** (CSE: WBIO)(FSE: 8SV1) (the “**Company**” or “**WPD**”) a clinical stage pharmaceutical company is pleased to provide an update on its Annamycin drug candidate. Through its license partner, Moleculin Biotech, Inc. (Nasdaq: MBRX)(“**Moleculin**”), an open label, single arm US Phase 1 trial has been completed on its Annamycin drug candidate. The phase 1 trial met its objective of demonstrating the safety of Annamycin. Annamycin is intended for use in treating relapsed or refractory acute myeloid leukemia (“**AML**”). WPD has licensed rights to a portfolio of drug candidates, including Annamycin, from Moleculin.

The US Phase 1 trial shows the safety of Annamycin in a phase I trial setting when delivered to patients at or below the lifetime maximum anthracycline dose established by the FDA. The primary safety signal was the absence of cardiotoxicity (potential damage to the heart), a serious and often treatment-limiting issue prevalent with currently approved anthracyclines. This was determined by echocardiograms, as well as cardiac health biomarkers, principally blood troponin levels, which are considered an indicator of potential long-term heart damage. The data showed no cardiotoxicity in any of the 6 patients evaluated in the US Phase 1 trial. Additionally, there were no unexpected serious adverse events and no dose limiting toxicities at any dose tested.

Although the primary objective of the Phase 1 trial was to evaluate safety, the study also gathered data to support a preliminary assessment of the product's potential efficacy. Among other things, the study recorded complete response (CR), partial response (PR), event-free survival, overall survival (Kaplan-Meier), and time to and duration of remission/response. Based on these criteria, possible efficacy was seen in 2 of the US patients, even though the drug was dosed at what was expected to be sub-therapeutic levels. The evidence of efficacy consisted of 1 patient who achieved a "morphologically leukemia-free state," which the protocol defined as a CR with incomplete recovery of platelets or neutrophils (CRi), and another patient who had a substantial remission of leukemia cutis (a somewhat rare leukemia symptom), from diffuse to 3 small lesions.

**Mariusz Olejniczak, CEO of WPD commented,** *"We are encouraged by this kind of early activity during the Phase 1 trials of Annamycin, especially since these trials are typically designed to demonstrate safety, not efficacy, and the dosing was at levels we expected to be sub-therapeutic. Annamycin is being studied as a single agent, not in combination with any other drugs, and we believe this could be significant, because clinical advisors believe the vast majority of relapsed or refractory AML patients do not respond to single agents. FDA has already granted Fast Track designation, which recognizes that Annamycin shows the potential to address unmet medical needs, which can include providing efficacy comparable to available therapies while avoiding toxicity associated with the existing treatment. We look forward to our continued work with Moleculin on the advances of our drug candidate, Annamycin and the potential validation of these results in further study."*

## **About WPD Pharmaceuticals**

WPD is a biotechnology research and development company with a focus on oncology, namely research and development of medicinal products involving biological compounds and small molecules. WPD has 10 novel drug candidates with 4 that are in clinical development stage. These drug candidates were researched at institutions including the Mayo Clinic and Emory University, and WPD currently has ongoing collaborations with Wake Forest University and leading hospitals and academic centers in Poland.

WPD has entered into license agreements with Wake Forest University Health Sciences and sublicense agreements with Moleculin Biotech, Inc. and CNS Pharmaceuticals, Inc., respectively, each of which grant WPD an exclusive, royalty-bearing sublicense to certain technologies of the licensor. Such agreements provide WPD with certain research, development, manufacturing and sales rights, among other things. The sublicense territory from CNS Pharmaceuticals and Moleculin Biotech includes 31 countries in Europe and Asia, including Russia.

## **On Behalf of the Board**

*'Mariusz Olejniczak'*

Mariusz Olejniczak  
CEO, WPD Pharmaceuticals

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