For immediate release on August 29, 2023

# Northwest Biotherapeutics Announces Completion of Prerequisites, and

### Plans for Submission of Marketing Authorization Application

BETHESDA, MD, August 29, 2023 – Northwest Biotherapeutics (OTCQB: NWBO) ("NW Bio"), a biotechnology company developing DCVax® personalized immune therapies for solid tumor cancers, announces that it plans to submit a Marketing Authorization Application (MAA) in the U.K., to the Medicines and Healthcare Products Regulatory Agency (MHRA)(the equivalent of the U.S. FDA), for commercial approval of the Company's DCVax®-L treatment for glioblastoma.

The Company believes that it has now completed all of the remaining prerequisites for such an application, including certain steps related to implementation of the approved Pediatric Investigation Plan and submission of the required formal notification to the MHRA of the upcoming MAA. As the Company reported in its recent 10-Q filing, the Company is in the final stages of completing the application package itself.

The Company anticipates submitting the MAA in approximately the next 30-45 days. The Company plans to request that the MHRA review the MAA under the 150-business day process that the MHRA has established to accelerate the availability of new medicines for patients in the U.K.

### **About Northwest Biotherapeutics**

Northwest Biotherapeutics is a biotechnology company focused on developing personalized immunotherapy products designed to treat cancers more effectively than current treatments, without toxicities of the kind associated with chemotherapies, and on a cost-effective basis, in both North America and Europe. The Company has a broad platform technology for DCVax® dendritic cell-based vaccines. The Company's lead program is a 331-patient Phase III trial of DCVax®-L for newly diagnosed Glioblastoma multiforme (GBM). GBM is the most aggressive and lethal form of brain cancer, and is an "orphan disease." This Phase III trial has been completed, and the results have been presented in scientific meetings and published in JAMA Oncology. The Company has also developed DCVax®-Direct for inoperable solid tumor cancers. It has completed a 40-patient Phase I trial and, as resources permit, plans to pursue Phase II trials. The Company previously conducted a Phase I/II trial with DCVax-L for advanced ovarian cancer together with the University of Pennsylvania.

### Disclaimer

Statements made in this news release that are not historical facts, including statements concerning plans for DCVax are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "expect," "believe," "intend," "design," "plan," "continue," "may," "will," "anticipate," and similar expressions are intended to identify forwardlooking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those projected in any forward-looking statement. Readers should not rely upon forward-looking statements. There are a number of important factors that could cause actual results to differ materially from those anticipated, including, without limitation, risks related to delays or uncertainties in regulatory processes, risks related to the Company's ability to achieve timely performance of third parties, risks related to whether the Company's products will be viewed as demonstrating safety and efficacy, risks related to the Company's ongoing ability to raise additional capital, and other risks included in the Company's Securities and Exchange Commission ("SEC") filings. Additional information on the foregoing risk factors and other factors, including Risk Factors, which could affect the Company's results, is included in its SEC filings. Finally, there may be other factors not mentioned above or included in the Company's SEC filings that may cause actual plans, results or timelines to differ materially from those projected in any forward-looking statement. The Company assumes no obligation to update any forwardlooking statements as a result of new information, future events or developments, except as required by securities laws.

#### **CONTACTS**

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