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Northwest Biotherapeutics Announces Completion of Phase 3 Trial Sites' Databases

BETHESDA, Md., July 24, 2020 - Northwest Biotherapeutics (OTCQB: NWBO) (“NW Bio”), a biotechnology company developing DCVax® personalized immune therapies for solid tumor cancers, today announced that the data collection from all of the clinical trial sites for the Company’s Phase 3 trial of DCVax®-L for Glioblastoma brain cancer (the “Trial”) has been completed and all of the sites have signed off on the locking of their data.

As noted in the Company’s prior reports, in order to reach overall data lock for the Trial, each site’s data must go through final collection, review, checking for queries, resolution of queries preparatory steps for locking the site and finally personal sign-off by the lead investigator at each site for that site’s data. For that purpose, the lead investigator must undergo training on the system, review the site data, personally complete the confirmation and deliver it to the independent contract research organization (CRO) managing the Trial.

Reaching these personal sign-offs by each lead investigator at each of the Trial sites has been a key focus of activity towards data lock for the last couple of months, especially during June and July. At the time of the Company’s last report near the end of June, about 30 Trial sites were in varying stages of progress towards sign-off, and about half a dozen Trial sites had not yet completed the preparatory steps necessary to begin the process towards such sign-off.

All of the Trial sites are now finished. The independent CRO has obtained all of the investigator sign-offs for their site’s data lock. The sites’ data includes all of the clinical data gathered in the Case Report Forms throughout the Trial, and now sit in a signed off, locked position with the CRO.

These datasets from each of the Trial sites (hospitals) are the largest component of the overall dataset for the Trial and contain most of the data. The remaining information for the overall Trial dataset includes some analyses from specialized service providers who are separate from the Trial site hospitals. Such analyses include, for example, genetic profiles such as IDH mutations. For some of these analyses, it has been necessary to go back and obtain additional material due to the age of the samples. For other analyses, it has been necessary to have the analyses done by two separate experts as a cross-check.

This process continues to be impacted by the effects of COVID-19, especially with the resurgence of COVID cases in many areas. For example, key experts at certain specialized service providers have been unavailable for periods of time due to illness in their family. Other experts have gone on extended leave due to restrictions on operations. However, the CRO and the Company are working intensively with these vendors on a continuous basis to move as quickly as possible.

The Company currently anticipates that the remaining analyses by these specialty service providers will be completed within the next couple weeks. When this external data joins the now locked data from the Trial sites, the overall Trial dataset will be locked.

Following completion of the Trial data lock, the independent statisticians will be given access to the raw data in the Trial database, and will undertake the calculations and the preparations of the Tables and Listings which provide the Trial results. The Company anticipates that the statisticians' work will take several weeks.

The Company will remain blinded throughout this period and will not become unblinded until the independent statisticians deliver the initial results to the Company.

When the Company receives the initial results, it will review the data and results with its Scientific Advisory Board, the Trial Steering Committee, and other key advisors. During this process, any questions or comments from the experts will be addressed as part of the preparation of the results for public reporting. The Company anticipates that these very important discussions with experts could take several weeks, especially with the significant logistical challenges due to COVID-related restrictions (which may be further increasing as the COVID resurgence grows).

In light of the significant progress reported here, together with the next steps in the process and the operational and logistical challenges, the Company currently anticipates that Trial results will be ready for reporting approximately sometime after Labor Day in the month of September. The Company will be consulting with its Principal Investigator and experts on the appropriate venue and manner of presenting the Trial results.

The Company will also continue to provide progress reports as key milestones are reached.

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." The Company is also pursuing development of DCVax®-Direct for inoperable solid tumor cancers. It has completed a 40-patient Phase I trial, and is preparing for 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 future treatment of patients using DCVax and future clinical trials, 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 forward-looking statements,

although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results may differ materially from those projected in any forward-looking statement. Specifically, there are a number of important factors that could cause actual results to differ materially from those anticipated, such as risks related to the Company's ability to enroll patients in its clinical trials and complete the trials on a timely basis, uncertainties about the clinical trials process, uncertainties about the timely performance of third parties, risks related to whether the Company's products will demonstrate 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 results to differ materially from those projected in any forward-looking statement. The Company assumes no obligation to update any forward-looking statements as a result of new information, future events or developments, except as required by securities laws.

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