NORTHWEST BIO REAFFIRMS ITS FREEDOM TO OPERATE;
REFUTES OTHER PARTIES’ MISLEADING PATENT ASSERTIONS

Confirmed by Legal Opinions from Nationally Recognized Law Firms

Bethesda, Maryland, December 19, 2011 -- After obtaining confirmatory opinions from multiple experts in patent law, Northwest Biotherapeutics (OTC.BB: NWBO) (NW Bio) today reaffirms that its lead program, applying DCVax®-L for treatment of brain cancer, continues to have clear freedom to operate with respect to US Patent 7,939,090 (the ‘090 patent), recently issued to Cedars Sinai, and licensed to Immunocellular Therapeutics (IMUC) (collectively, Cedars Sinai/IMUC). Contrary to numerous misleading claims by certain parties, the ‘090 patent is extremely narrow and limited, and neither DCVax-L nor NW Bio’s treatment regimen infringes upon the ‘090 patent. All of the information about the ‘090 patent is publicly available online from the US Patent and Trademark Office (USPTO).

Cedars Sinai/IMUC applied for a broad scope of patent and tried repeatedly, through an unusually protracted process lasting nearly eight years, to get it allowed by the USPTO. However, the broad scope was repeatedly rejected by the USPTO and was never granted. One of the many bases for the rejections explicitly cited by the USPTO was the work by Dr. Linda Liau and NW Bio with DCVax, stretching back years prior to the 2003 patent application by Cedars Sinai/IMUC, which was the same DCVax product and program that NW Bio now has in late stage clinical development.

In order to get even a narrow scope of patent claim granted, Cedars Sinai/IMUC had to explicitly argue to the USPTO that the subject matter of their patent application was different than the prior work of NW Bio and Dr. Liau with DCVax. In addition, Cedars Sinai/IMUC had to drop all but one of the operative (i.e., “independent”) claims in their application in order for their patent to finally be granted.
The sole independent claim that was finally granted in the ‘090 patent has two parts -- part "(a)" and part ")(b)" -- and they must both be satisfied in order to find any infringement. The claim provides as follows:

1. A method for treating a glioma in a mammal, the method comprising:

   (a) administering at least one vaccination of dendritic cells ("DC") to said mammal suffering from a glioma, wherein the [sic] at least one vaccination of DC comprises autologous DC that present autologous glioma antigens;

   and

   (b) after glioma recurrence following (a), administering a regimen of chemotherapy to said mammal, wherein said regimen of chemotherapy includes the administration of at least one chemotherapeutic agent selected from the group consisting of temozolomide, procarbazine, vincristine, BCNU, CCNU, thalidomide, irinotecan, isotretinoin, imatinib, etoposide, and combinations thereof.

Thus, this patent claim only covers situations where the method of treatment used includes BOTH steps (a) AND (b).

The 090 patent does not cover the combination of a dendritic cell based vaccine treatment combined either before or concurrently with chemotherapy at the recurrence of cancers of the central nervous system.

Furthermore, to be within the scope of the ‘090 patent, it is not even enough to do both steps (a) and (b)…… the steps must be performed in a precise sequence, and they must straddle the timing of the recurrence of the glioma tumor. Step (a), the dendritic cell vaccination, must occur first and specifically be before the tumor recurrence, and step (b) must follow step (a) and specifically be after the tumor recurrence. The ‘090 patent is limited to this precise sequence and timing.

Cedars Sinai/IMUC tried repeatedly over nearly eight years to obtain a broader scope, but the USPTO rejected all of those attempts because multiple other researchers (including Dr. Liau and NW Bio) had already used dendritic cell treatments in a wide variety of sequences and timings with chemotherapies years before the Cedars Sinai/IMUC patent application was filed.

Simply stated, NW Bio’s DCVax product and treatment regimen do not fall within the narrow sequence and timing covered by the ‘090 patent. The purpose and focus of NW Bio’s clinical trials is to prove that DCVax is an effective treatment on its own. Moreover, when NW Bio’s DCVax reaches commercialization, the treating physician, not NW Bio, will be the party who administers DCVax, and who determines what further treatment to use in the event of recurrence. NW Bio does not advise on post-recurrence therapies other than the use of its vaccine. It is the physician who will determine whether to administer chemotherapy and, if so, which type of chemotherapy and in what manner.
Additionally, all of these treatment activities can be undertaken by the physician free of the ‘090 patent in a variety of ways. For example, step (b) of the patent was narrowed following USPTO rejections so as to include only the specific drugs listed. This list does not include the chemotherapy that doctors usually prescribe today after glioma recurrence (Avastin).

► The ‘090 patent is not applicable to treatment for most types of cancer.

Cedars Sinai/IMUC application sought a patent for “treating a disease condition in a mammal” but this was rejected by the USPTO. Indeed, the USPTO would not even allow coverage of all cancers, or even all cancers of the central nervous system. The patent claim was narrowed to just “treating a glioma in a mammal.” Glioma is only one of multiple sub-types of one cancer: primary brain cancer. It does not include any of the myriad other types of cancers.

Linda Powers, CEO of Northwest Bio, commented that "We want to correct the misleading statements about patents that have been made by certain parties with a vested interest in slowing us down. We have confirmed our analysis with patent experts at leading national law firms, and received supporting opinions from them. We plan to continue correcting misleading statements by other parties, and we urge anyone who is interested in confirming the true facts to review the entire 8-year record of the Cedars Sinai/IMUC ‘090 patent application process, and the USPTO rejections. The entire record is publicly available to all online from the USPTO."

Powers concluded by stating that “We are justifiably confident that we do not infringe the ‘090 patent, and are prepared to assert all of our rights and remedies. The ‘090 patent is neither a barrier nor even a speed bump in the way of our development and future commercialization of DCVax.”

About Northwest Biotherapeutics

NW Bio is a biotechnology company focused on developing immunotherapy products to treat cancers more effectively than current treatments, without toxicities of the kind associated with chemotherapies, and on a cost-effective basis in both the US and Europe. The Company has a broad platform technology for dendritic cell-based vaccines. The Company’s lead clinical trial is a 240-patient Phase II trial in newly diagnosed Glioblastoma multiforme (“GBM”), the most aggressive and lethal of brain cancer. The Company also previously received clearance from the FDA for a 612-patient Phase III trial in prostate cancer, and clearance from the FDA for Phase I trials in multiple other cancers. The Company has also conducted a Phase I/II trial with DCVax® for recurrent metastatic ovarian cancer. For further information about clinical sites and about the Company, please visit the Company’s web site at www.nwbio.com.
Disclaimer

Statements made in this news release that are not historical facts, including statements concerning future treatment of patients with GBM using DCVax®-Brain and future clinical trials, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “expects,” “believes,” “intends,” and similar expressions are intended to identify 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 the Company’s ability to raise additional capital, risks related to the Company’s ability to enroll patients in its clinical trials and complete the trials on a timely basis, the uncertainty of the clinical trials process, uncertainties about the timely performance of third parties, and whether the Company’s products will demonstrate safety and efficacy. Additional information on these and other factors, including Risk Factors, which could affect the Company’s results, is included in its Securities and Exchange Commission (“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. You should not place undue reliance on any forward-looking statements. 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.