

Northwest Biotherapeutics, Inc. t (240) 497-9024 f (240) 627-4121 www.nwbio.com NASDAQ: NWBO

4800 Montgomery Lane Suite 800 Bethesda, MD 20814

### Deferred for Release Until Thursday, March 7, 2013, 8:15 AM EDT

Media Contacts:

Les Goldman 202-841-7909 lgoldman@nwbio.com Beverly Jedynak 312-943-1123 bjedynak@janispr.com

## **NW BIO PROVIDES GUIDANCE ON PHASE III TRIAL ENROLLMENT TIMING:**

## **COMPLETION EXPECTED TO BE FASTER OR MORE EFFICIENT**

# THAN RELEVANT COMPARISON TRIALS

BETHESDA, MD, March 7, 2013 -- Northwest Biotherapeutics (NASDAQ: NWBO) (NW Bio), a biotechnology company developing DCVax<sup>®</sup> personalized immune therapies for solid tumor cancers, announced today that it expects to complete enrollment in its 312-patient Phase III clinical trial for Glioblastoma multiforme (GBM) brain cancer within a period that is faster or more efficient than relevant comparison trials with immune therapies for the same brain cancer. The Company anticipates completing enrollment of its Phase III trial by Q1 or early Q2 of next year, and expects to reach its first interim analysis for efficacy by approximately Q3 of this year.

Relevant comparisons include the following (according to information publicly reported on <u>www.clinicaltrials.gov</u> and in company announcements and filings):

- Celldex Therapeutics (NASDAQ: CLDX) is conducting a Phase III trial with 440 patients, at 164 clinical trial sites worldwide, which began enrolling in November 2011, and appears likely to continue enrolling over at least a 4-year period through the end of 2015, with topline results expected at the end of 2016.
- Immunocellular Therapeutics (NYSE MKT: IMUC) is conducting a Phase II trial with 124 patients, which were enrolled over the course of 7 calendar quarters from Q1 2011 through Q3 2012. (IMUC apparently screened 278 patients, but actually enrolled and treated less than half of them: only 124 patients were enrolled, in aggregate, and treated in either the treatment arm or the placebo arm of the trial.)
- Agenus, Inc. (NASDAQ: AGEN) is conducting a Phase II trial with 55 patients, which began recruiting in Q2, 2009 and stopped recruiting in Q2, 2012.

NW Bio has primarily been enrolling its Phase III trial since Q2 of 2011. The Company undertook a limited period of enrollment in 2008, and then kept the trial going with the patients already enrolled, but suspended new enrollment due to resource constraints during the worst of the economic downturn, through the end of 2010. The Company began the process of reactivating clinical trial sites for new enrollment in Q1 2011, and resumed screening in Q2 of 2011.

NW Bio expects to complete enrollment in its phase III trial by Q1 or early Q2 of next year – an overall enrollment period of 14 or 15 calendar quarters, including both the 2008 period and the period since Q2 2011.

	Total Trial Enrollment	Enrollment Period	Pace of Enrollment to Completion, Based On Enrollment Period
NW Bio Ph. III	312 patients	14 quarters or 15 quarters	<ul><li>22.3 patients per quarter or</li><li>20.8 patients per quarter</li></ul>
IMUC Ph. II	124 patients	7 quarters	17.7 patients per quarter
Celldex Ph. III	440 patients	≥16 quarters [est.]	27.5 patients per quarter* *[164 clinical trial sites worldwide]
Agenus Ph. II	55 patients	12 quarters	4.6 patients per quarter

This represents a rate of enrollment that compares as follows with Celldex, IMUC and Agenus:

Notably, even if the completion of NW Bio's Phase III trial enrollment were to take substantially longer than the Company's projection of Q1 or early Q2 2014, the Company's enrollment would still compare favorably with these relevant comparison trials.

"There has been widespread confusion in the investment community about the size and pace of clinical trials being conducted with various immune therapies for brain cancer," commented Linda F. Powers, CEO of NW Bio. "It is basic to clinical trials that the sponsor must *screen* more patients than they *enroll*. Normally, there is no confusion about the fundamental difference between these: 'enrollment' means only the patients actually being treated (with drug or placebo) in the trial. This is a key metric for investors: it is the measure of the size and the pace of a trial. By providing detailed information here, our intention is to help correct the misunderstandings about the actual enrollment (both size and pace) of certain immune therapy trials in brain cancer."

The Company plans to provide periodic updates of this enrollment guidance through various communication channels.

### **About Northwest Biotherapeutics**

Northwest Biotherapeutics 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 United States and Europe. The Company has a broad platform technology for DCVax dendritic cell-based vaccines. The Company's lead program is a 312-patient Phase III trial in newly diagnosed Glioblastoma multiforme (GBM). GBM is the most aggressive and lethal 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/II trials in multiple other cancers. The Company has also conducted a Phase I/II trial with DCVax for metastatic 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," "plan," "continue," "may," "will," "anticipate," 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.