Neumedicines’ Anti-Radiation Therapy (HemaMax™) Demonstrates Unprecedented Survivability After Lethal Dose of Radiation in Mice and Non-human Primates

*Phase I human safety study to be completed by the end of March 2012.*

Pasadena, CA (PRWEB) March 05, 2012 -- Neumedicines Inc., a privately-held, development-stage company focused on therapies for the treatment of hematopoietic deficiencies and cancer, announced that its therapy for acute radiation syndrome, HemaMax™, administered 24 hours after a lethal dose of radiation, led to the survival of greater than 50% of mice and 50% non-human primates in the study. These results were achieved in the absence of any supportive care, including antibiotics. Given this level of survivability in the event of a mass radiation disaster with 100,000 casualties, HemaMax could potentially save 50,000 lives. The data was published in the scientific journal, PLoS ONE, in a paper entitled, “HemaMax™, a Recombinant Human Interleukin-12, Is a Potent Mitigator of Acute Radiation Injury in Mice and Non-Human Primates.” Investors and others can access the paper at PLoS ONE's website (http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0030434)

The results demonstrate that HemaMax™ (recombinant human interleukin-12; rHuIL-12) has a remarkable ability to increase survival from death using a single, low dose at 24 hours after radiation injury in both mice and rhesus monkeys. The survival benefits of HemaMax™ administration can be attributed to four main effects: 1) generation of early immune competency following lymphodepletion, 2) regeneration of the bone marrow following aplasia, 3) protection of gastrointestinal tract and 4) release of erythropoietin, which provides anti-oxidant and anti-apoptotic, general tissue protection.

In addition to this unprecedented pre-clinical data, the company began dosing healthy volunteers in a first-in-human, Phase I study last year to evaluate the safety, tolerability, and pharmacokinetics of HemaMax™. The initial Phase I study, in which results are expected by the end of March 2012, will be followed by subsequent, larger safety studies in healthy human volunteers, prior to submission of a Biologic License Application (BLA) to the FDA. The company expects to be ready to submit its HemaMax™ BLA to the FDA by the end of 2016. To date, the Phase I study in healthy volunteers has demonstrated that the safe human dose is within the predicted efficacious human dose range, as determined from the animal efficacy studies, thus indicating that HemaMax™ has an excellent safety profile.

Lena A. Basile, PhD, JD, President & CEO of Neumedicines and co-author of the paper, said, “We believe this is the first study demonstrating potent mitigation by a single agent, using a single dose, at protracted time points, such as 24 hours or longer, following acute radiation exposure and in the absence of supportive care. We have now demonstrated efficacy in our preclinical studies and safety from our Phase I human studies, and because there are no approved therapies capable of increasing survivability or restoring immune system recovery from radiation, we are moving with urgency to complete pivotal animal studies and expanded human safety studies, so as to be ready to submit a BLA under the Animal Rule within four years.”

Following a similar dosing regimen used in lethally irradiated mice, Neumedicines’ researchers determined the survival rate of 39 rhesus monkeys exposed to an LD50/30 of total body radiation (6.7 Gy) by following treatment with 100 ng/Kg or 250 ng/Kg of HemaMax™ (rHuIL-12) administered at 24 hours or at 24 hours and 7 days post radiation in the absence of any supportive care, including antibiotics. The doses of HemaMax™ (rHuIL-12) were chosen based on PK/PD studies in rhesus monkeys and were equivalent to rmuIL-12 doses of...
8 ng/mouse and 20 ng/mouse, respectively. HemaMax™ at both doses, using either one or two doses, mitigated death due to irradiation to the same extent. Overall survival rates were 71% in the 100 ng/Kg single dose group (n = 7) and 75% in all other groups receiving rHuIL-12 (n = 8) compared to 50% in the vehicle group. Between-group differences in survival rates of HemaMax™ treated animals were not statistically significant, most likely because of the small number of animals in each group (n = 7 or 8), but also because both HemaMax doses are likely within the efficacious dose range. Analysis of the survival rates regardless of the HemaMaxTM dosing regimen indicated that when pooled together, monkeys receiving HemaMaxTM had a significantly higher survival rate than those receiving vehicle (75% vs 50%, respectively; P = .05)

HemaMax™ is being developed by Neumedicines under the FDA’s Animal Efficacy Rule to treat the Hematopoietic Syndrome of ARS (HSARS) or radiation poisoning from any exposure to radiation, such as a nuclear or radiological weapon or from a nuclear accident. This approval pathway requires demonstration of efficacy in representative animal models and safety, pharmacokinetic and pharmacodynamic testing in healthy human volunteers.

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About HemaMax™ (rHuIL-12)
The therapeutic under development by Neumedicines Inc., HemaMax™ (NMIL12-1), is based on rHuIL-12 (recombinant human interleukin–12). Scientists from Neumedicines discovered the previously unexplored hematological properties of IL-12 by demonstrating the potent survival effects of single, low dose IL-12 on hematopoietic recovery following lethal radiation. HemaMax™ is a new therapeutic that is predicted to be administered to humans in very low, nanogram per kilogram doses to achieve potent radiomitigation effects. To date, Neumedicines Inc. has demonstrated that HemaMax™ can increase survival in mice and non-human primates who receive the therapeutic in single, low doses 24 hours after lethal radiation exposure. The safety of HemaMax is currently being assessed in healthy volunteers in a First-in-Human (FIH) trial. The predicted efficacious human dose of HemaMax has been found to be safely administered to healthy volunteers in the FIH trial.

About Neumedicines Inc.
Neumedicines Inc. is a privately held, early-stage company developing protein therapeutics that address unmet clinical and societal needs in the fields of oncology, hematology, and immunology. The company’s lead product candidate, NMIL12-1 (recombinant human interleukin-12; rHuIL-12), functions as to target multiple pathways of hematopoiesis and innate immunity and is being developed to address a range of clinical indications. At Neumedicines, we are committed to developing and maximizing the scientific, clinical, and commercial potential of our product pipeline.

Neumedicines is developing NMIL12-1 under the trade name HemaMax™ as a biodefense radiation medical countermeasure. NMIL12-1 is also being developed for indications in hematology/oncology, such as chemotherapy-induced thrombocytopenia. The company operates from its headquarters and laboratories in Pasadena, California.

This press release contains certain forward-looking statements relating to our business, including our plans to develop new therapeutics and our financial resources. Actual events or results may differ from the expectations
set forth herein as a result of a number of factors, including uncertainties inherent in pre-clinical studies, clinical trials and product development programs (including, but not limited to, the fact that pre-clinical and clinical results referenced in this release may not be indicative of results achievable in other trials or for other indications, that the studies or trials may not be successful or achieve the results desired, that pre-clinical studies and clinical trials may not commence or be completed in the time periods anticipated, that results from one study may not necessarily be reflected or supported by the results of other similar studies and that results from an animal study may not be indicative of results achievable in human studies), the availability of funding to support continuing research and studies in an effort to prove safety and efficacy of our therapeutics, the adequacy of our capital resources, the availability or potential availability of alternative therapies or treatments for the conditions targeted by the company or its collaborators, including alternatives that may be more efficacious or cost-effective than any therapy or treatment that the company and its collaborators hope to develop, evaluation of potential opportunities, issues involving product liability, issues involving patents and whether they or licenses to them will provide the company with meaningful protection from others using the covered technologies, whether such proprietary rights are enforceable or defensible or infringe or allegedly infringe on rights of others or can withstand claims of invalidity and whether the company can finance or devote other significant resources that may be necessary to prosecute, protect or defend them, the level of corporate expenditures, assessments of the company’s technology by potential corporate or other partners or collaborators, capital market conditions, the impact of government healthcare proposals and other factors. There can be no assurance that any product in Neumedicine’s pipeline will be successfully developed or manufactured, that final results of clinical studies will be supportive of regulatory approvals required to market licensed products, or that any of the forward-looking information provided herein will be proven accurate.

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