



Sangamo BioSciences Presents Positive Phase 2 ZFP Therapeutic Data at ADA 2009

RICHMOND, Calif., June 8, 2009 /PRNewswire via COMTEX News Network/ -- Analysis of Subjects with Moderately Severe Diabetic Neuropathy Shows Statistically Significant Improvement in Multiple Quantitative Neurological Endpoints

RICHMOND, Calif., June 8 /PRNewswire-FirstCall/ -- Sangamo BioSciences, Inc. (Nasdaq: SGMO) announced today the presentation of as yet unreleased positive Phase 2 clinical data from its ZFP Therapeutic(TM) program to develop SB-509 as a treatment for diabetic neuropathy (DN) at the 69th Annual Scientific Sessions of the American Diabetes Association (ADA), held in New Orleans, LA, from June 5 to 9, 2009. Data from Sangamo's SB-509-601 and SB-509-701A Phase 2 clinical trials demonstrated that SB-509 treatment resulted in statistically significant and clinically relevant improvements in subjects with moderate and severe DN as compared to placebo. SB-509 was well-tolerated in both multi-dose studies.

"We have learned a great deal from these data, which demonstrate positive activity of SB-509 in multiple clinically relevant measurements of nerve health," stated Dale Ando, M.D., Sangamo's Vice President of Therapeutic Development and Chief Medical Officer. "Data from our Phase 1 and both Phase 2 clinical trials have shown us that the dual angiogenic and neurotrophic effects of SB-509 are most effective in the later stages of DN when both diabetic microvascular disease and metabolic neuropathy are evident. The statistically significant improvement in SB-509-treated subjects across multiple independent clinical endpoints for DN has enabled definition of a responder group and is particularly encouraging for future trials in this patient population."

"SB-509 is the first drug candidate of its type designed to harness the body's own regenerative potential to address DN, a significant complication for diabetic patients," stated Alan Lewis, Ph.D., President and Chief Executive Officer of the Juvenile Diabetes Research Foundation (JDRF). "A significant part of JDRF's patient-centric funding efforts support the development of therapies to stop or reverse the impact of diabetic complications and we are very pleased to be involved in the SB-509-601 study with Sangamo. Additionally, JDRF funded an ancillary study by Dr. Polydefkis to investigate the effects of SB-509 on nerve fiber density improvement and nerve regeneration. We are very encouraged that SB-509 was associated with an improvement in clinical outcomes in the more severely affected subjects in the trial and that this group showed increased nerve fiber density and nerve regeneration. In future trials we hope these important and encouraging positive effects of SB-509 are reproduced on a broad range of clinically relevant endpoints and translate into real functional gains for people with diabetes."

SANGAMO ABSTRACTS PRESENTED AT THE ADA MEETING

Details of Poster Presentation of Data from Sangamo's SB-509-601 Study (Abst# 859-P): "Vascular Endothelial Growth Factor Zinc Finger Protein Activator (SB-509) in Mild to Moderate Diabetic Peripheral Neuropathy Patients. Interim Phase 2 Results (SB-509-0601 Study)" presented on Saturday, June 6 at 11:30 am CT (12:30 pm ET).

Overall, no difference was seen at 180 days between placebo and SB-509-treated subjects in Sangamo's double-blind, repeat dosing Phase 2 clinical study of SB-509 (SB-509-601) in the following measures of nerve health and function: Abbreviated Neuropathy Impairment Score in the Lower Limbs (A-NIS-LL), Nerve Conduction Velocity (NCV), and Quantitative Sensory Testing (QST). However, analysis of the data demonstrated that subjects entering the SB-509-601 trial had significantly milder DN by neurologic exam (A-NIS-LL) and NCV than subjects in either the Phase 1 SB-509-401 or Phase 2 SB-509-701 studies (p value = 0.0001). Further analysis of the data revealed that subjects with moderate to severe DN had a statistically significant and clinically relevant positive response to treatment with SB-509 over the six-month test period. In addition, new top-line data were presented from epidermal (skin) nerve fiber density (ENFD) and nerve fiber regrowth (ENFDR) studies carried out in collaboration with Michael Polydefkis, M.D., Associate Professor of Neurology, Johns Hopkins University School of Medicine and supported by funding from the Juvenile Diabetes Research Foundation International (JDRF).

ENFD has been shown to be a direct measure of nerve health and growth in DN. Subjects entering the SB-509-601 trial with a median ENFD of less than 18 fibers/mm, a value that separates moderate from mild DN, demonstrated parallel improvement between median sensory (sural) NCV (Δ 1.0 M/s) and ENFDR at day 210 (Δ =2.0 fibers/mm) with a multi-endpoint p value of 0.05.

Baseline measurements considered to define the threshold of mild and moderate DN of sural NCV ($<$ 47.5 M/s), QST ($>$ 7.5 vibration units) and A-NIS-LL ($>$ 10) were also used to define SB-509 responder groups within the total population of SB-509 treated subjects. The data from these sub-groups were analyzed and all groups demonstrated clinically relevant improvement in the neurological exam by A-NIS-LL.

Specifically, the following clinically relevant improvements in A-NIS-LL in SB-509-treated subjects compared to placebo at Day 180 were seen for subjects entering the study with the following baseline measurements:

- Sural NCV of <47.5 M/s, we observed an improvement of 1.1 points compared to 0.2 point worsening for the placebo group (a delta in A-NIS-LL of 1.3 points, p value= 0.08);
- QST of >7.5 v.u., there was a 2.3 point improvement compared to a 1.5 point worsening in the placebo group (a delta in A-NIS-LL of 3.8 points, p value=0.005);
- A-NIS-LL of >10 points, we observed improvement in A-NIS-LL of 2.5 points in SB-509 treated subjects compared to a 0.3 point worsening when compared to SB-509 treated subjects entering the study with a baseline A-NIS-LL of <10 (a delta in A-NIS-LL of 2.8 points, p value=0.003).

In addition, in subjects entering the trial with A-NIS-LL>10 points, we observed sural nerve NCV preservation of 0.02 M/s in SB-509 treated subjects compared to a 2.4 M/s worsening in the placebo-treated group (p value = 0.09).

Details of Oral Presentation of Data from Sangamo's SB-509-701-A Study (Abst# 243-OR, presented 06/07/09): "Reappearance of Nerve Potentials in Severe Diabetic Peripheral Neuropathy Patients with Unmeasurable Nerve Conduction Using Vascular Endothelial Growth Factor Zinc Finger Protein Activator (SB-509): Interim Phase 2 Results (SB-509-0701 Study)" presented on Sunday, June 7 at 6:00 pm CT (7:00pm ET).

Data from the first cohort of Sangamo's single-blind, repeat dosing Phase 2 study of SB-509 (SB-509-701-A) demonstrated that subjects with at least one nerve for which an NCV could not be measured showed a clinically relevant improvement at Day 180 in two NCV-based analyses of SB-509 versus placebo-treated subjects.

Proportional analysis of the percentage of responding subjects with a measurable nerve at 180 days that could not be measured at baseline or who demonstrated a greater than 7 M/s improvement for a baseline measurable nerve revealed a two-fold improvement with SB-509 treatment (47%) compared to placebo (27%) (p value = 0.20).

The mean change in sural NCV at Day 180 compared to baseline demonstrated a clinically relevant improvement in subjects treated with SB-509 compared to placebo-treated subjects (2.8 m/s SB-509, 1.3 m/s placebo, p value=0.20). In addition, relative improvements in sural NCV were maintained at 240 days (3.81 M/s SB-509, 1.98 m/s placebo, p value = 0.24).

"SB-509 has shown unprecedented restoration of NCV in subjects that began the study with nerves for which no induced electrical activity could be measured, a clinical condition that would normally be considered irreversible and untreatable," commented Dr. Ando. "There is both a vascular as well as a neurologic component to severe peripheral neuropathy which appears to be addressed by the activation of VEGF-A by SB-509. It is also very encouraging that effects have been observed across multiple endpoints such as NIS-LL and NCV in the 601 study and NCV in the 701 study which are measurements that have been used as endpoints in previous pivotal large scale trials of other non-analgesic approaches for diabetic neuropathy."

About SB-509

SB-509 is an injectable plasmid encoding a DNA-binding Zinc Finger DNA-binding Protein (ZFP) Transcription Factor (ZFP TF (TM)) designed to upregulate the endogenous expression of the gene encoding vascular endothelial growth factor (VEGF-A). VEGF-A has been demonstrated to have direct angiogenic, neurotrophic and neuroprotective properties. In preclinical animal efficacy studies in a diabetic rat model (Diabetes, June 1, 2006; 55(6): 1847-1854), SB-509 has proven effective in protecting motor and sural nerve function from disease-induced nerve damage. Sangamo has completed a Phase 1b clinical trial (SB-509-401) that demonstrated statistically significant and clinically relevant improvements in several measurements of nerve health and function in subjects with diabetic neuropathy. For more information about SB-509, visit www.sangamo.com and for further information on Sangamo's clinical trials of this drug visit <http://www.clinicaltrials.org>.

About Diabetic Neuropathy

Diabetic neuropathy is a progressive degenerative disease that is one of the most frequent complications of diabetes, affecting between 14 and 16.5 million Americans in 2007. High blood glucose levels lead to nerve damage over time, primarily affecting peripheral nerves. Symptoms include numbness, tingling sensations and pain particularly in the toes or feet, which gradually evolve to loss of sensation and motor function as nerve damage progresses. Ulcers and sores may appear on numb areas of the foot as pressure wounds or injuries go unnoticed. Despite palliative treatment, these areas of trauma frequently become infected and this infection may spread to the bone, necessitating amputation of the leg or foot. More than 60 percent of non-traumatic lower-limb amputations in the United States occur among people with diabetes. In 2004, this translated to

approximately 71,000 amputations. Diabetes is a growing problem. The Centers for Disease Control estimates that from 1980 through 2007, the number of Americans with diabetes increased from 5.6 million to 23.6 million and that of those about 60 percent to 70 percent have mild to severe forms of neuropathy.

About Sangamo

Sangamo BioSciences, Inc. is focused on researching and developing Zinc Finger DNA-binding Protein (ZFP) Technology for therapeutic gene regulation and modification. By engineering ZFPs that recognize a specific DNA sequence Sangamo has created ZFP transcription factors (ZFP TF(TM)) that can control gene expression and, consequently, cell function. Sangamo is also developing sequence-specific ZFP Nucleases (ZFN(TM)) for gene modification. The most advanced ZFP Therapeutic(TM) development program is currently in Phase 2 clinical trials for evaluation of safety and clinical effect in patients with diabetic neuropathy and ALS. Sangamo also has a Phase 1 clinical trial to evaluate safety and clinical effect of a ZFP Therapeutic for the treatment of HIV/AIDS. Other therapeutic development programs are focused on cancer, neuropathic pain, nerve regeneration, Parkinson's disease and monogenic diseases. Sangamo has established strategic partnerships with companies in non-therapeutic applications of its ZFP Technology, including Dow AgroSciences, Sigma-Aldrich Corporation Genentech and Pfizer. For more information about Sangamo and the ZFP Technology, visit www.sangamo.com.

This press release may contain forward-looking statements based on Sangamo's current expectations. These forward-looking statements include, without limitation, references to the clinical trials of SB-509, research and development of novel ZFP TFs and ZFNs and therapeutic applications of Sangamo's ZFP technology platform. Actual results may differ materially from these forward-looking statements due to a number of factors, including uncertainties relating to the initiation and completion of stages of the SB-509 clinical trials, whether the SB-509 clinical trials will validate and support tolerability and efficacy of SB-509, technological challenges, Sangamo's ability to develop commercially viable products and technological developments by our competitors. See Sangamo's SEC filings, and in particular, the risk factors described in its Annual Report on Form 10-K and its most recent Quarterly Report on Form 10-Q. Sangamo BioSciences, Inc. assumes no obligation to update the forward-looking information contained in this press release.

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