

# Press Release

## **Nissan Chemical Reports Positive Phase IIb study results for NM-702 in Intermittent Claudication**

**Los Angeles, CA – March 13, 2006- /BusinessWire/ )**

Nissan Chemical Industries, Ltd. (Nissan Chemical) announced today positive results of their Phase IIb study NCI-IC-0201 of NM-702 for the treatment of intermittent claudication. The study enrolled 391 patients, who were assessed after six months of therapy. Results from the study showed NM-702 was associated with a statistically significant increase in patients' Peak Walking Time as compared with placebo, the study's primary endpoint. Secondary endpoints were also supportive of NM-702 efficacy.

"We are pleased to announce the statistically significant, robust outcome of the NM-702 study for both the primary and key secondary endpoints." stated Isao Koda, Ph.D., General Manager, Pharmaceutical Division of Nissan Chemical America (US subsidiary of Nissan Chemical). "We intend to submit the final results of the study to the FDA as one of our initial pivotal trials for NDA, and are optimistic these data will guide the successful completion of NM-702 development for this indication".

"We are very encouraged that the study achieved its primary endpoint, and look forward to further development of NM-702", commented Eric Brass, M.D., Ph.D., Department of Medicine, Harbor-UCLA Medical Center, and the chairman of the trial's Steering Committee. The Steering Committee also included William Hiatt, M.D., University of Colorado, and Frederick Cobb, M.D. of the Durham VA Medical Center.

Nissan Chemical is currently partnered with Taisho Pharmaceuticals Co., Ltd. (Taisho), for the joint development of NM-702 in Japan, and support for further studies in the United States to accelerate the global commercialization of this product. Taisho is currently investigating NM-702 in clinical trials for intermittent claudication and asthma in Japan.

Nissan Chemical, in collaboration with Taisho, is seeking an international development and marketing partner for NM-702 for the rest of the world market. This study was conducted by Catalyst Pharma Group, Inc. (Catalyst), a CRO specializing in aiding internationally based companies with limited United States presence. According to Richard Anthony, Ph.D., CEO of Catalyst, "We are pleased that our collaboration with Nissan Chemical has achieved a positive outcome for their product. We are confident in the commercial potential of NM-702 for intermittent claudication and other indications, and are honored to be the CRO, as well as the exclusive international licensing representative, for NM-702."

### **About Intermittent Claudication**

Intermittent claudication is a major symptom of peripheral arterial disease. Intermittent claudication is characterized by exercise-induced lower extremity pain and muscle fatigue that is relieved by rest. Intermittent claudication symptoms are thought to occur when the blood supply is inadequate to meet the demands of lower limb muscle metabolism. This leads to a

severe limitation in walking ability, which in turn adversely affects the social, leisure, and occupational activities of the patient. Approximately four to six million persons in the United States suffer from intermittent claudication, with only about 10% of these patients currently receiving drug therapy to improve their exercise performance.

### **About NM-702**

NM-702 is an orally active inhibitor of phosphodiesterase and thromboxane A<sub>2</sub> synthetase. NM-702 has a unique mechanistic profile of the treatment and chronic management of peripheral arterial disease, as well as other indications, Spinal Canal Stenosis and Asthma.

### **About Nissan Chemical Industries Ltd.**

Since Nissan Chemical was founded in 1887, the company has grown to be a leading manufacturer of a wide range of basic and specialty chemicals, electronic materials, agrochemicals, and pharmaceuticals. In addition to NM-702, Nissan Chemical's pharmaceutical products include anti-hypertensive (LANDEL®), and anti-inflammatory (EPATEC®) agents, and a lipid-lowering agent (LIVALO®) already on the market. More background information on Nissan Chemical is available at the company web site:

<http://www.nissanchem.co.jp/english/pharm/index.html>

### **About Taisho Pharmaceutical Co., Ltd**

Taisho was established in 1912 to develop, produce, and market OTC drugs. In 1955, Taisho began its new drug discovery research for prescription drugs. In particular, Taisho succeeded in discovery and development of clarithromycin, which is now one of the most popular macrolide antibiotics in the world, and launched its product, Clarith® in Japan in 1991. Taisho has licensed-out clarithromycin to U.S. pharmaceutical company, Abbott Laboratories in 1985, and currently, clarithromycin is marketing in over 90 countries in the world. More information on Taisho can be found at <http://www.taisho.co.jp/outline/index-e.htm>.

### **About Catalyst Pharma Group, Inc.**

Catalyst ([www.catalystpharmagroup.com](http://www.catalystpharmagroup.com)) is a contract research organization (CRO) created to specifically meet the needs of companies with limited United States presence who are seeking to develop, approve, and market pharmaceuticals in the U.S. Catalyst considers itself a "drug development platform", specializing in providing contiguous, integrated, cost-effective drug development solutions through three divisions: Catalyst Pharmaceutical Research LLC, Healthcare Discoveries Inc., Adept LTD..

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