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Indigo Licenses Vasodilator INDI-702 From Nissan/Taisho For Peripheral Artery Disease

Indigo Pharmaceuticals hopes to file an NDA by 2010 for INDI-702, a dual-action vasodilator to treat peripheral artery disease, the firm told *"The Pink Sheet" DAILY*. Indigo announced June 1 that it had licensed certain rights to the Phase III compound from Nissan Chemical and Taisho Pharmaceutical.

Indigo obtained rights to develop and market the drug worldwide except in China, Japan, South Korea and Taiwan. In return, Indigo will make a one-time payment followed by milestone payments based on development progress and sales royalties of INDI-702.

The compound has dual action as an inhibitor of phosphodiesterase 3 and thromboxane A2 synthetase. Phosphodiesterase 3 is found in the heart, vascular smooth muscle and platelets. Standard of care includes treatment with statins, ACE inhibitors and cilostazol (Otsuka's *Pletal* and generics), which is also a selective inhibitor of phosphodiesterase 3, Indigo Chief Executive Officer Carol Ann Satler said.

New York-based Indigo plans to begin a Phase III trial in the United States and Europe in 2008. It will study patients with intermittent claudication, pain in the legs caused by peripheral artery disease.

"Our hope is that INDI-702 will offer an improved quality of life for patients who have peripheral arterial disease," said Satler, who until recently was a vice president at Sanofi-Aventis and worked on the development and commercialization of the blood thinner *Plavix* (clopidogrel).

Results of a three-arm, randomized, double-blinded, placebo-controlled Phase II study of the compound at 18 sites in the United States were published in a December 2006 issue of the *Journal of the American College of Cardiology*. A total of 391 subjects over age 50 with intermittent claudication were randomized and followed for 24 weeks.

"One of the key findings was a tremendous impact on their day-to-day ability to function," Satler said. An 8 mg dose given twice daily showed statistically significant improvement in treadmill claudication onset time as compared to placebo, and also improved physical functioning scores.

Indigo estimates that about six million people in the United States and 12 million worldwide suffer from intermittent claudication, but only about 10 percent currently receive treatment.

-Pamela Taulbee (p.taulbee@elsevier.com)

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