

## Nuron Biotech Inks Vaccine License with Mitsubishi Tanabe

By Marie Powers  
Staff Writer

Privately held Nuron Biotech Inc. hooked a big fish for its first licensing deal. The Exton, Pa.-based company signed an agreement with Mitsubishi Tanabe Pharma Corp. (MTPC), of Osaka, Japan, to commercialize its HibTiter vaccine (*Haemophilus b* conjugate vaccine [diphtheria CRM197 protein conjugate]) in Japan, both as a single entity and for combination product use.

Financial terms were not disclosed, but MTPC will be responsible for development and regulatory approval costs and pay undisclosed up-front, pre-commercial milestones, Nuron founder and CEO Shankar Musunuri told *BioWorld Today* at the close of the 2012 J.P. Morgan Healthcare Conference in San Francisco. Nuron also will receive what Musunuri described as "significant" royalties on commercial sales in Japan.

The HibTiter vaccine is a previously marketed pediatric vaccine using glycoconjugate technology for which Nuron acquired rights in the U.S., Japan and other markets from Wyeth LLC. The vaccine "still represents a considerable global opportunity, especially in markets like Japan, where there is only one approved vaccine for *Haemophilus influenzae* type b (Hib) bacteria," Musunuri said.

The license with "the No. 1 vaccine company in Japan" affirms the small biotech's development and delivery capabilities, he added, while providing Nuron with additional resources to accelerate its relaunch strategy for the vaccine in the U.S. market, where the company already has held productive talks with the FDA.

Based on guidance from the FDA, Nuron plans to initiate a bridging trial for the HibTiter vaccine this year, file in 2013 and, following approval, launch the vaccine in the U.S. market in 2014, according to Musunuri.

That timetable also benefits MTPC, which plans to use data generated in the U.S. trial toward a filing in Japan, he said.

Nuron, founded in 2010, has been hot right out of the gate. In addition to vaccines – where the company hopes to make HibTiter the first in a growing portfolio – Nuron is developing central nervous system candidates. Its flagship compound, NUI00, is a recombinant human interferon beta-1b (IFN beta-1b) for the treatment of multiple sclerosis (MS). The new molecular entity is a liquid product with an auto-

injector that is essentially aggregate-free, compared to other marketed interferon beta products.

Remarkably, Nuron already has a randomized, double-blind, placebo-controlled Phase III of NUI00 under way. Launched in November 2011, the study is evaluating the safety and efficacy of NUI00 in patients with relapsing-remitting multiple sclerosis. The pivotal trial is expected to involve 500 patients at sites in Europe and Asia randomized to NUI00, a marketed IFN beta-1b or placebo over a 12-month period, with data expected late next year.

The trial is geared toward a filing with the European Medicines Agency, Musunuri said, with a second trial oriented toward an FDA filing scheduled to begin this year.

A second compound, NU400, is a long-acting version that combines NUI00 with pegylation technology called TheraPEG, developed by PolyTherics Ltd., of London. Nuron hopes that NU400 will marry the benefits of NUI00 with reduced injection frequency – potentially semimonthly or monthly injection – for improved patient compliance.

The company plans to complete the preclinical work on NU400 and launch early stage trials this year, according to Musunuri.

In combination, the two products support Nuron's "long-term life cycle strategy" for MS, Musunuri said.

To support that level of growth and keep projects on schedule, the company plans to more than double its work force this year, from 19 to approximately 40 full-time employees.

"We're at a late stage already, so we have a lot of work to do – not only on the clinical and manufacturing side, but also with process validations and whatever we need for filings," Musunuri said.

Among small biotechs, Nuron has another distinguishing characteristic: The company already has a commercial production process in place to manufacture NUI00.

"We're trying to think into the future," Musunuri said.

The company's deep management expertise – including former executives from Pfizer Inc., Wyeth, Johnson & Johnson and Merck & Co. as well as former FDA officials on its scientific advisory boards – gives Nuron a big-picture view of the factors needed to succeed in the biopharma space.

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To that end, the company is keeping its long-term options open. Although Nuron is proceeding with the Phase III in NUI00, the company hopes to partner with a big pharma that has a strong interest in MS to commercialize the compound “so that we can launch, penetrate the market and grow market share as rapidly as possible,” Musunuri said.

In contrast, the biotech may proceed alone in the U.S. on the HibTiter vaccine. “It’s not a one-size-fits-all strategy,” Musunuri said. “As we move along as a company, we’ll look

at those options.”

Part of that business strategy will depend on finances. To date, the company has raised \$48 million, mainly from private investors. Although Musunuri declined to provide the company’s runway, he indicated that Nuron will seek additional funding this year to launch the HibTiter vaccine, which is expected to generate sufficient revenues to support the NUI00 product development. ■