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Daiichi commits up to $650M to Charleston Labs for nausea drugs

By Michael Fitzhugh, Staff Writer

Daiichi Sankyo Co. Ltd. is investing up to $650 million in a Charleston Laboratories Inc. subsidiary to back development and U.S. commercialization of its hydrocodone combination drug portfolio, including CL-108, a late-stage therapy providing the pain relief of hydrocodone without the common nausea and vomiting associated with the widely prescribed opioid.

CL-108 combines 12.5 mg of immediate-release promethazine with 7.5 mg of hydrocodone and 325 mg of acetaminophen. Charleston stopped a phase III trial studying the drug early last year when an interim analysis revealed that it hit its primary endpoints relative to pain reduction and the symptoms of opioid-induced nausea and vomiting.

The deal provides Charleston $100 million up front, $100 million for hitting a near-term milestone, plus up to $450 million in additional milestone payments connected to U.S. filing and approval events, including submission of the company's anticipated new drug application for CL-108 late next year. (See *BioWorld Today*, Oct. 29, 2013.)

Jupiter, Fla.-based Charleston could also receive an escalating, tiered, double-digit share of the gross operating margin from products sold under the arrangement and retains an option to co-promote products of the collaboration in the U.S.

More important than the money, Charleston Labs original founder, president, and CEO Paul Bosse told *BioWorld Today*, the deal was a strong cultural fit and the ability to leverage Daiichi's substantial primary care salesforce, helping it access that medical area in which most pain management is handled.

"We connected really well with all the different arms of their organization – their business development, scientific, regulatory, clinical and commercial teams," said Bosse. "That really struck a chord with us. Daiichi was on our white board as one of the best potential partners back in September when we went on our educational outreach."

Talks gained momentum at January's JP Morgan Healthcare Conference in San Francisco, Bosse said, making it clear that the two companies shared a similar vision, something that was especially important since other programs in Charleston's pipeline "may line up with where Daiichi wants to go," he said.

Once talks took off, Charleston's team was able to move quickly, due in large part to the agility it gains from being privately backed, Bosse said. Before now, the company has sought no venture or private equity investments, relying instead on a small group of wealthy backers with broad industry experience to fund and guide its development.

Hydrocodone is the most widely prescribed medication in the U.S., with more than 131 million prescriptions annually, according to Charleston. Opioid-induced nausea affects up to 30 percent of people taking hydrocodone, with about 15 percent experiencing vomiting.

Bosse said the company has a strong pipeline of other opioids not included in the Daiichi collaboration. In addition to the development of the pain platform, the company is rapidly advancing products in other therapeutic areas. Chief among them are CL-H1T, a migraine product that the company is also looking to partner, and a hydrocodone liquid-based product for cold-related cough and respiratory symptoms.

CL-H1T is a fixed-dose formulation of a triptan combined with an anti-emetic in a proprietary release technology that the company is investigating as a treatment for migraine headaches and the reduction or elimination of migraine induced nausea and vomiting

Some potential partners have already expressed interest in CL-H1T, and the company will be pursuing those talks ahead of beginning a phase I pharmacokinetic study of the drug later this fall.

Charleston is putting a high priority on incorporating abuse-deterrent technologies into its products, Bosse pointed out, something that it's investigating internally and in a collaboration with Stanford University School of Medicine. //