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Depomed Signs $395M Deal with Solvay for Phase III Pain Drug

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Staff Writer

Depomed Inc. granted an exclusive license to Solvay Pharmaceuticals Inc. for North American rights to DM-1796 (formerly Gabapentin GR) in pain indications. The drug – an extended-release version of the active ingredient in Pfizer Inc.'s marketed seizure and pain drug, Neurontin – is in Phase III trials for postherpetic neuralgia (PHN).

Menlo Park, Calif.-based Depomed stands to get $25 million up front and as much as $370 million in milestone payments, $70 million of which are triggered by regulatory events and $300 million of which are tied to sales. Solvay Pharmaceuticals Inc., a subsidiary of Brussels, Belgium-based Solvay SA, also will pay Depomed a 14 percent to 20 percent royalty on sales.

Depomed President and CEO Carl Pelzel said the deal resulted from a "highly competitive" partnering process that involved multiple parties over the past year and culminated in a "perfect scenario" for Depomed.

First, the deal only includes rights to DM-1796 in the U.S., Canada, Mexico and Puerto Rico, leaving Depomed open to negotiate with other partners in Europe, Asia and the rest of the world. Pelzel pointed out that such deals can be quite lucrative. XenoPort Inc. was able to negotiate an $85 million deal with Astellas Pharma Inc. for Asian rights to its gabapentin derivative, XP13512. (See *BioWorld Today*, Dec. 2, 2005.)

But more importantly, Depomed's deal with Solvay covers only pain applications for DM-1796 – leaving Depomed with all rights to the drug in hot flashes. Depomed started two pivotal Phase III hot flash trials this fall with Gabapentin GR, which it refers to as DM-5689 in the hot flash indication. (See *BioWorld Today*, Sept. 18, 2008.)

Under the deal, Depomed will complete its ongoing Phase III trial of DM-1796 in PHN before handing the program over to Solvay. The randomized, double-blind, placebo-controlled, 450-patient pivotal study was initiated in March and is expected to wrap up next year.

A previous Phase III study of DM-1796 in PHN missed statistical significance, which Pelzel explained likely resulted from a "huge" placebo effect. He noted that the ongoing trial includes more patients and is powered to detect a smaller difference in pain reduction with a less stringent statistical hurdle. (See *BioWorld Today*, July 11, 2007.)

Another neuropathic pain drug to fail in Phase III due to a stronger-than-expected response in the control group was NeurogesX Inc.'s capsaicin patch, NGX-4010, which missed its endpoint in a trial of HIV patients with peripheral neuropathic pain. Yet NGX-4010 had met its endpoint in two previous Phase III PHN trials, and NeurogesX pushed forward with its NDA filing last month. (See *BioWorld Today*, Feb. 29, 2008.)

Even more setbacks have plagued contenders for treating diabetic peripheral neuropathy (DPN), for which DM-1796 is in Phase II trials. Pelzel said DPN is a "much harder indication" than PHN because the pain "fluctuates to a much greater extent."

Earlier this month, XTL Biopharmaceuticals Ltd. saw its stock fall almost 95 percent after a Phase II study of its bicifadine for DPN failed, and shares of Sangamo BioSciences Inc. dropped 65 percent when its Phase II DPN trial for SB-509 failed. Additionally, Astellas stopped a Phase II DPN trial of XenoPort's XP13512 after an interim analysis showed it was unlikely to succeed. (See *BioWorld Today*, Nov. 7, 2008, Nov. 12, 2008, and Nov. 19, 2008.)

Despite all the setbacks, neuropathic pain remains an attractive target for biotech and pharma companies, with a market value estimated to reach $5 billion in 2010 for the U.S. alone. Depomed believes DM-1796's slow and steady delivery may be able to provide less-frequent dosing and reduced side effects compared to existing treatments. Pelzel noted that DM-1796 has demonstrated lower rates of dizziness and somnolence compared to Neurontin, Lyrica (pregabalin, Pfizer Inc.) and XP13512, although the drugs have not been compared in head-to-head trials.

Beyond PHN and DPN, Solvay has the right to develop DM-1796 for other types of pain. If the pharma decides to pursue the drug for fibromyalgia, Depomed has a right of first negotiation for co-promotion rights in the OB/GYN field.

Pelzel explained that retaining the OB/GYN co-promo-

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tion option fits Depomed's near-term strategy of "pulling together a group of products that could be promoted to OB/GYNs" using a niche sales force.

That basket of products also would include DM-5689 for hot flashes and the FDA-approved diabetes drug Glumetza (metformin hydrochloride extended-release tablets). Depomed partnered Glumetza with Santarus Inc. earlier this year but retained the option to co-promote the drug to OB/GYNs, which prescribe it for gestational diabetes, among other conditions. (See *BioWorld Today*, July 23, 2008.)

Depomed's pipeline also includes the approved antibiotic Proquin XR (ciprofloxacin hydrochloride extended-release tablets), which is marketed by Watson Pharmaceuticals Inc. for uncomplicated urinary tract infections; the Phase II gastroesophageal reflux disease drug DM-3458, which is actively being partnered; and the preclinical Parkinson's disease drug DM-1992, which is slated to begin clinical trials later this year or early next year.

Shares of Depomed (NASDAQ:DEPO) gained 25 cents, or 20.2 percent, to close at $1.49 on Friday. ■

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