

## Depomed gets gabapentin approval as Abbott spat looms



[Jonathan Gardner](#)

US approval of Depomed's post-herpetic neuralgia (PHN) treatment Gralise should be considered a victory on most counts, and justify a six-month run-up in the share price (*Event - [Depomed leaving pain behind with PHN therapy, January 7, 2011](#)*). Shares rose 33% to a six-year of \$8.27 in early trade today following news that the long-acting formulation of epilepsy drug gabapentin has gotten authorisation in the world's biggest drug market.

Yet the California group must now confront a new problem for this peculiarly snakebitten therapy: the likely need to find a replacement marketing partner for Abbott Laboratories, which is trying to sever its agreement with Depomed. While lining up a licensee for a relatively low-risk approved product does not present the challenge of an early-stage candidate, it has the potential to slow the launch.

### Waiting

In a call with investors today, Depomed chief executive Carl Pelzel did not make a firm prediction of what will happen with the launch of Gralise, branded Serada in the post-menopausal hot flash indication. The company has entered mediation with Abbott, which will take about eight weeks, with binding arbitration to follow if the outcome is not satisfactory to either side.

Such news could be considered portentous and may again raise some uncertainties around the drug: foremost being the unpredictable nature of untangling contractual arrangements as well as the difficulties of finding a new partner or launching with a smaller sales force.

Analysts from Roth Capital Partners reckon there will be a limited launch in the second quarter of 2011, and believe there is a low likelihood that Abbott will stay on as a partner regardless of the results of mediation or arbitration. Mr Pelzel did not commit to either path, choosing to focus on the mediation process.

The dispute centres around launch and marketing obligations that Depomed claims were detailed in its 2008 partnership with Solvay Pharmaceuticals, which was purchased by Abbott last year. Should Abbott fail to launch the drug on time, Depomed could be due \$50m in damages, according to the Roth analysts.

### Positives

Otherwise, Depomed's executive team were largely jubilant. First, the \$48m milestone on approval will be appreciated, padding the already healthy \$67m cash the group had on hand at the end of September 2010.

Second, the label was better than expected, with an explicit statement that Gralise is not interchangeable with other gabapentin products, which should help protect it against generic substitution.

Third, the FDA approved a 30-day starter pack to aid titration to the 1,800mg dosage. This, said Mr Pelzel, should again help differentiate Gralise from gabapentin as the generic formulation has a long and complicated titration schedule that needs to be written explicitly on a prescription. As PHN, caused by an acute episode of herpes zoster, is a disease that afflicts largely the elderly, a simplified titration schedule aided by the starter pack will be important to avoid undermedication.

### Strategic position

Known formerly as DM-1796 for the PHN indication, Gralise and Serada are long-acting formulations of gabapentin that allows Depomed to apply for FDA approval using a standard new drug application plus proprietary delivery technology. The formulation releases over six to eight hours in the upper gastrointestinal tract, rather than a rapid stomach absorption, which is reckoned to reduce side effects and allow for once-daily dosing.

It is similar to the intellectual property strategy used with its already marketed products: long-acting

formulations of diabetes therapy metformin, called Glumetza, and antibacterial cirprofloxacin, known as ProQuin XR. Glumetza itself had a difficult year, with a recall of 500mg dosages in June related to a chemical used in the wood pallets used to transport the drug, a similar problem that befell Johnson & Johnson's Tylenol.

*EvaluatePharma's* consensus has Serada/Gralise royalties of \$80m in 2016, giving it a net present value of \$332m, 75% of Depomed's now swollen market capitalisation of \$440m.

A stock rise of one-third today is an indication of Gralise's potential benefit to Depomed. The company had better hope for a speedy resolution to the Abbott dispute, as well as a successful launch, to prevent that positive investor sentiment from trickling away.

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