

Section: Licensing

# Progenics Licenses Relistor® to Salix Outside of Japan

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**Progenics Pharmaceuticals has found a new partner for its opioid-induced constipation (OIC) drug Relistor® (methylnaltrexone bromide) in the form of Salix Pharmaceuticals. Salix receives the global rights to the drug, excluding Japan, in a deal that is potentially worth more than US\$350 M to Progenics. Relistor was previously licensed to Wyeth but Progenics regained the rights to the product in late 2009. Salix will assume development and commercialisation responsibility for the drug from April 2011.**

Gastroenterology specialist Salix Pharmaceuticals has entered into an exclusive agreement with Progenics Pharmaceuticals, which is potentially worth more than US\$350 M, to license Relistor® (methylnaltrexone bromide) for opioid-induced constipation (OIC) (Deal no. 39222). The subcutaneous form of the drug received regulatory approval in the US in 2008 and is approved for use in over 50 countries worldwide. Progenics obtained exclusive worldwide rights to methylnaltrexone in September 2001 from UR Labs (Deal no. 08922), which had earlier licensed the drug from the University of Chicago, where it was discovered, in 1985.

Under the terms of the agreement, Salix will obtain worldwide rights to Relistor, excluding Japan, and the licence grant includes intellectual property from the University of Chicago and Wyeth Pharmaceuticals. In return, Progenics will receive US\$60 M upfront and development milestones that could total US\$90 M, subject to the achievement of certain US regulatory milestones. In the US, Salix will market Relistor directly through its speciality sales force and in the other licensed territories the product will be sublicensed to regional companies. Progenics will also receive sales-based milestones of up to US\$200 M plus royalties on US product sales, based on a percentage ranging from the mid- to high-teens of net sales, and 60% of all revenues from the non-US sublicensees. Salix will fund all development, registration and commercialisation activities for Relistor in markets outside Japan, where Progenics has licensed the drug rights to Ono Pharmaceuticals (Deal no. 31460).

The deal will help Progenics to re-establish Relistor commercially after it regained the rights to the drug from Wyeth in October 2009, following the company's merger with Pfizer (Deal no. 32282). Progenics had earlier licensed global rights to the product to Wyeth in December 2005 as part of a development and commercialisation collaboration potentially worth US\$416.5 M (Deal no. 22932) and the company has been looking for a new partner for the drug since this

deal was terminated. Under the terms of the termination agreement, which has twice been extended, Wyeth agreed to continue to commercialise Relistor in the US until 31 March 2011, although Progenics does not receive royalties on sales of the drug during this transition period. Salix will assume development and commercialisation responsibility from April 2011, although Wyeth will remain responsible for all manufacturing, clinical, medical and regulatory activities for Relistor outside of the US and Japan for an interim period.

Opioid analgesics are widely used for the treatment of acute and chronic pain in patients with advanced illness. Although they are highly effective in treating and managing pain, their frequent use results in OIC in approximately 40–90% of patients. Relistor is the only FDA approved drug for OIC and generated US\$16 M in worldwide sales in 2010. It is currently indicated for the treatment of OIC in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Progenics and Salix are keen, however, to expand use of the drug into larger markets. A sNDA submission for use of Relistor in chronic, non-malignant pain patients with OIC is planned for the first half of 2011 and an oral formulation is currently in Phase III development. In 2010, single-use prefilled syringes of Relistor were approved for use in the US, Canada and the EU.

Sales of Relistor, which have been very modest to date, should benefit from Salix's specialist gastroenterology sales force and the attention the company will give the drug. Salix believes that peak US sales of Relistor could reach approximately US\$1 B if it is able to gain approval for the oral formulation and for expanded use of the drug in the treatment of chronic, non-malignant pain. However, to reach this level of sales, the company will need to target primary care physicians as well as gastroenterologists.