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Actavis to sell generic AstraZeneca's Crestor

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Singapore: US-based Actavis reached a settlement agreement with AstraZeneca resolving outstanding patent litigation related to Actavis' generic version of rosuvastatin calcium 5, 10, 20 and 40 mg tablets (the generic version of Crestor tablets), as well as Actavis' rosuvastatin zinc alternate salt product. Under the terms of the agreement, Actavis can launch its generic version of Crestor 67 days prior to July 8, 2016, the expiration of pediatric exclusivity, at a fee of 39 percent of net sales to AstraZeneca. The entry date may be earlier, and the fee eliminated, under certain circumstances.

Egis Pharmaceuticals, Actavis' partner, will also benefit from sales of the product. Launch of Actavis' product is contingent upon the company receiving final approval from the US FDA on its Abbreviated New Drug Application (ANDA) for generic Crestor. The FDA granted tentative approval to Actavis' ANDA on June 6, 2011.

As part of the agreement, Actavis is permitted to launch its rosuvastatin zinc alternate salt product beginning May 2, 2016 or earlier under certain circumstances, however, at this time, the company has made no decision regarding a potential launch.

Actavis' rosuvastatin zinc alternate salt product previously received tentative approval from the FDA in August 2011 but would not be generically substitutable for Crestor and would have required Actavis to convert patients from rosuvastatin calcium. Other details of the settlement are confidential.

Mr Paul Bisaro, president and CEO, Actavis, said that, "This agreement ensures that consumers will benefit from an earlier launch of a rosuvastatin calcium product and eliminates ongoing litigation and uncertainty of marketplace acceptance of a non-generically substitutable product if Actavis had proceeded to launch the alternate product."