BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Noven Pharma files NDA with US FDA

30 August 2012 | News | By BioSpectrum Bureau

Noven Pharma files NDA with US FDA

Singapore: Noven Pharmaceuticals, a wholly-owned subsidiary of Japanese firm Hisamitsu Pharmaceutical, has submitted a new drug application (NDA) to the US Food & Drug Administration seeking approval to market low-dose mesylate salt of paroxetine (LDMP) for the treatment of vasomotor symptoms associated with menopause.

In March 2012, Noven announced completion of the LDMP clinical development program, which included two phase III studies involving an aggregate of 1,180 subjects from more than 130 centers across the US. The results are scheduled to be presented at the North American Menopause Society Annual Meeting in October 2012.

"The submission of the LDMP New Drug Application for consideration by the FDA represents a significant step toward our goal of offering a low-dose non-hormonal therapeutic option for the treatment of menopausal hot flashes," said Dr Joel S Lippman, executive vice president - Product Development and chief medical officer, Noven.