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ASIA EDITION

Novartis gets FDA approval for chronic idiopathic urticaria drug

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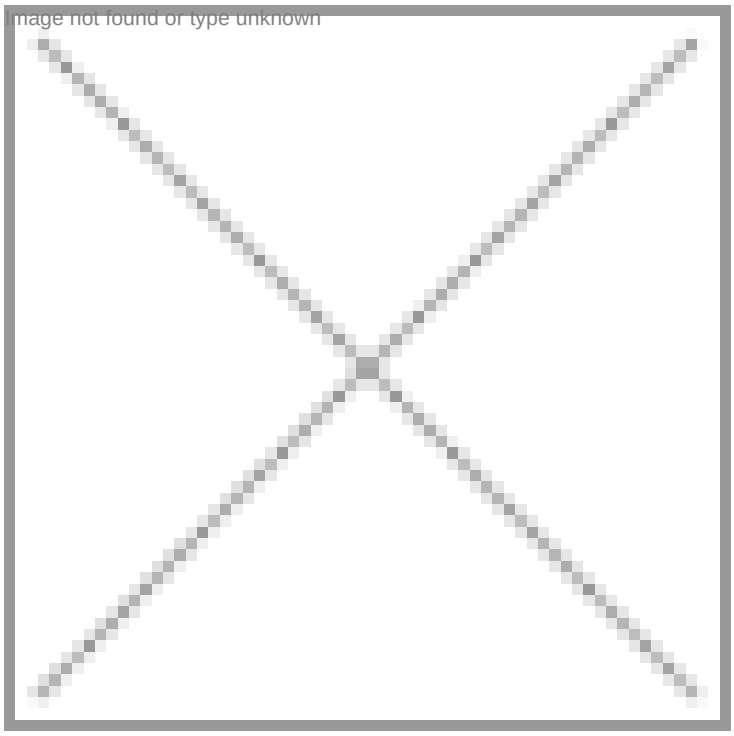

Singapore: US Food and Drug Administration (FDA) has approved Novartis' Xolair (omalizumab) for the treatment of chronic idiopathic urticaria (CIU), an unpredictable and debilitating skin disease that is known as chronic spontaneous urticaria (CSU) outside of the US.

CIU / CSU is a severe and distressing skin condition characterized by red, swollen, itchy and sometimes painful hives on the skin that spontaneously present and re-occur for more than six weeks.

"This approval from the FDA is great news for patients in the US suffering from CIU, a skin disease known as CSU in other parts of the world," said Mr. David Epstein, Division Head of Novartis Pharmaceuticals. "Up to 50% of patients do not respond to approved doses of H1-antihistamines, which up until now have been the only licensed treatment for CIU in the US."

Xolair was recently approved by European Commission (EC) as add-on therapy for CSU in adult and adolescent patients 12 years and above with inadequate response to H1-antihistamines. Xolair has also been approved for the treatment of refractory CSU in eight other countries including Egypt, Turkey, Guatemala, El Salvador, Bangladesh, Pakistan, Ecuador and the Philippines. Regulatory reviews are currently ongoing in more than 20 countries, including Canada, Australia and Switzerland.