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Novartis gets positive regulatory feedback for hive drug

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Singapore: Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for the use of Novartis' Xolair (omalizumab) as an add-on therapy for the treatment of chronic spontaneous urticaria (CSU) in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment. The recommended dose is 300 mg by subcutaneous injection every four weeks.

At any given time, the prevalence of chronic urticaria (CU) is up to 1 percent of the world's population, and up to two thirds of these patients have CSU. CSU is also known as chronic idiopathic urticaria (CIU) in the US, and is a severe and distressing skin condition characterized by red, swollen, itchy and sometimes painful hives or wheals on the skin that spontaneously present and re-occur for more than six weeks.

"This positive news from the CHMP brings us one step closer to providing an innovative therapeutic option from our specialty dermatology portfolio to people suffering from this chronic and debilitating disease," said Mr. Tim Wright, Global Head of Development, Novartis Pharmaceuticals. "If approved, Xolair will be the first and only licensed therapy in the EU for up to 50 percent of CSU patients not responding to approved doses of antihistamines."

The European Commission generally follows the recommendations of the CHMP and usually issues its final decision within two months of the CHMP opinion.