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GSK seeks Japanese approval for NDA

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Singapore: GlaxoSmithKline has submitted a regulatory application to the Japanese Ministry of Health, Labour and Welfare (MHLW) for umeclidinium (UMEC), a long-acting muscarinic antagonist (LAMA), administered using the Ellipta dry powder inhaler.

The New Drug Application(NDA) has been submitted to the MHLW for UMEC monotherapy (62.5mcg), as a once-daily inhaled dry powder maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

UMEC has recently been granted market authorisation in the US, Canada and Europe, with the approved trade name Incruse Ellipta. Regulatory filings in other countries will take place throughout 2014 and onwards.
UMEC is not currently approved in Japan and is not licensed anywhere outside of the US, Canada and the European Union.