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Singapore: The Japanese Ministry of Health, Labor and Welfare has approved a new drug application (NDA) of Lotriga granular capsule 2g (omega-3-acid ethyl esters 90) for the treatment of hyperlipidemia.

Lotriga, discovered by Pronova, is the omega 3-derived prescription drug containing highly concentrated and purified EPA-E (eicosapentaenoic acid ethyl ester) and DHA-E (docosahexaenoic acid ethyl ester). It is already on the market in 60 countries, including the US and Europe. In 2005, Takeda and Pronova entered into a license and supply agreement under which Takeda was granted the exclusive development and marketing right to this product in Japan. Lotriga will be the first prescription medicine in Japan that contains both EPA-E and DHA-E.

The results of the phase III clinical trial conducted in Japan upon submission has evaluated the efficacy and safety of Lotriga for Japanese patients with hypertriglyceridemia in comparison with an active comparator EPA product. The trial demonstrated that 2g (once daily) of Lotriga was equally, and 4g (2g twice daily) of Lotriga was statistically superior to the EPA, in lowering the percent change from baseline in triglycerides. Lotriga was safe and well tolerated, with a safety profile comparable to the EPA.