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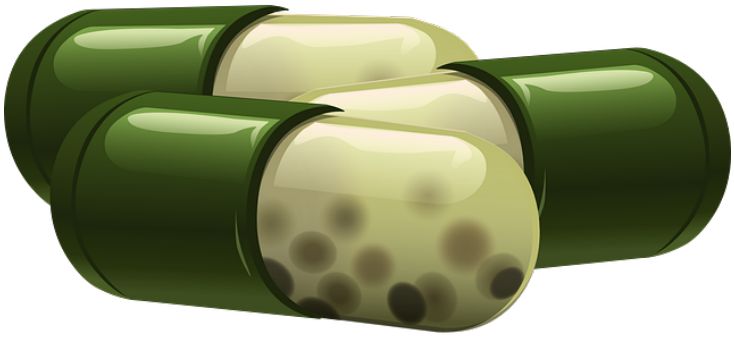

NASDAQ-listed Synageva BioPharma Corp. has submitted the New Drug Application (NDA) for Kanuma (sebelipase alfa) to the Ministry of Health, Labour and Welfare in Japan for the treatment of patients suffering from lysosomal acid lipase deficiency (LAL deficiency).

The candidate enjoyed orphan drug designation in Japan. Hence, the company authorities indicate that the NDA will help the drug receive priority review for marketing authorization, and, if approved, Kanuma would enjoy 10 years of market exclusivity for LAL deficiency. The company also claims that Kanuma would be the first approved therapy for LAL deficiency patients upon its approval.

Currently, Synageva has no approved products in its product portfolio. Kanuma is also under regulatory review in the US and Europe for the treatment of LAL deficiency. The company expects a response from the FDA regarding the approval status of Kanuma by September 8, 2015. Regulatory decision in Europe is expected in the second half of 2015.

Kanuma has received orphan drug designation in the US and Europe. Additionally, it has also received fast track designation and breakthrough therapy designation from the FDA for LAL deficiency in infants.