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# EMA committee positive on Teduglutide

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**EMA committee positive on orphan drug Teduglutide**




**Singapore:** The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has adopted a positive opinion for the medicinal product teduglutide (tradename in Europe: Revestive) as a once-daily treatment for adult patients with short bowel syndrome (SBS). The committee has recommended the granting of a marketing authorization, reported Takeda Pharmaceutical and NPS Pharmaceuticals. Teduglutide has orphan drug designation for the treatment of SBS from the European Medicines Agency (EMA) and the US Food and Drug Administration. The marketing authorisation application was submitted in March 2011.

In 2007, NPS Pharmaceuticals, a specialty pharmaceutical company developing innovative therapeutics for rare gastrointestinal and endocrine disorders, granted Nycomed, now acquired by Takeda, the rights to develop and commercialize teduglutide outside the US, Canada and Mexico and Israel. NPS retains all rights to teduglutide in North America.

SBS is a rare and debilitating disease characterised by the body's severely impaired ability to absorb nutrients and fluids through the gastrointestinal tract in people who have had a significant portion of their small intestine removed. SBS typically arises after extensive surgical resection of the bowel due to Crohn's disease, ischemia or other conditions.

"Short bowel syndrome patients suffer from malnutrition and diarrhoea, and often parenteral nutrition is necessary to maintain life," said Professor Palle Bekker Jeppesen, Department of Medical Gastroenterology, Rigshospitalet, University Hospital of

Copenhagen, Denmark. "Revestive is a new, unique and important treatment option for our patients and is adding important value to the limited treatment armamentarium."

"We welcome the positive opinion from the CHMP for teduglutide. This is good news for patients with SBS," said Mr Trevor Smith, head of Commercial Operations, Europe & Canada, of Takeda.