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Singapore: The European Commission (EC) has granted European market authorization for the medicinal product teduglutide (Revestive in Europe) as a once-daily treatment for adult patients with short bowel syndrome. The marketing authorization follows a positive opinion issued on June 21, 2012, by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). Following the authorization, Takeda Pharmaceutical intends to provide patient access to Revestive within Europe initially through a Named Patient Program.

In 2007, NPS Pharmaceuticals granted Nycomed, acquired by Takeda in October 2011, the rights to develop and commercialize teduglutide outside the US, Canada and Mexico and Israel.

The Named Patient Program is a facility that enables the distribution or supply of a medicine for the treatment of an individual patient, at the specific request of his/her healthcare provider, in cases where the medicine is currently not licensed or reimbursed.

"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."

"Teduglutide is the first approved treatment in Europe for this debilitating disease and offers an important new treatment option to patients who are reliant on parenteral nutrition," said Mr Trevor Smith, head of Commercial Operations, Europe & Canada, of Takeda.

"The granting of European marketing authorization for teduglutide is welcome news for patients who suffer from short bowel syndrome," said Dr Francois Nader, president and chief executive officer of NPS Pharmaceuticals. "We look forward to

supporting our partner Takeda as it works to launch this important therapy for patients in Europe."

The marketing authorization will be held by Nycomed Danmark and is valid in the current EU member states. National approvals are expected in Iceland and Norway within 30 days. It is based on data obtained from the STEPS pivotal phase III safety and efficacy trial, a double blind, placebo controlled study in patients with SBS, who required parenteral nutrition.