neuroendocrine & endocrine tumours and cup

**1144P OCTREOTIDE (OCT) LAR RECONSTITUTED IN A NEW VEHICLE (NV): PHASE 1, OPEN-LABEL, RANDOMIZED, BIOEQUIVALENCE STUDY VS OCT LAR 30 MG (CURRENT VEHICLE)**

S. Sarp¹, K. Roessner¹, A. Brueck-Scheffler², A.P. Tripathi³, J. Roberts⁴
¹Oncology Clinical Development, Oncology Business Unit, Novartis Pharma AG, Basel, SWITZERLAND
²Technical Research and Development, Novartis Pharma AG, Basel, SWITZERLAND
³Biostatistics and Data Management, Novartis India Pvt. Ltd., Hyderabad, INDIA
⁴Oncology Clinical Pharmacology, Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA

**Aim:** The synthetic somatostatin analogue OCT has been marketed for more than 25 years and is successfully used for the treatment of acromegaly and symptoms associated with functional gastroenteropancreatic neuroendocrine tumors (GEP-NET). In addition, OCT shows promising antiproliferative properties, in particular in patients with advanced midgut NET. OCT LAR (long-acting repeatable) is a long-acting depot formulation of OCT administered intramuscularly once every 4 weeks. SMS995L is a formulation in which OCT microparticles are reconstituted in an NV containing a surfactant that, in contrast to the current OCT LAR formulation, allows for shaking during the suspension process and inversion of the vial for withdrawal into the syringe prior to injection. The NV also permits a reduced injection volume (2 mL) vs OCT LAR (2.5 mL) delivered via a smaller-diameter safety engineered needle (0.9 mm vs 1.1 mm), which is provided in the new injection preparation kit. This study was designed to confirm the bioequivalence of SMS995L 30 mg and OCT LAR 30 mg.

**Methods:** This was a single-dose, open-label, randomized, parallel, single-center study involving 2 treatment arms in healthy male volunteers. Over 14 weeks (30 visits), the subjects underwent pharmacokinetic (PK) and safety assessments with a final visit at week 18.

**Results:** 106 subjects were randomized to OCT LAR (n = 52) or SMS995L (n = 54). The 90% confidence intervals for the ratios of geometric means comparing the primary PK parameters (Cmax, AUC0-d98, and AUC0-inf) after single-dose administration were within the predefined boundary (0.80, 1.25), thereby confirming the bioequivalence of the 2 formulations. Reported adverse events were consistent with the established safety profile of OCT LAR. Importantly, there were no relevant differences in the frequency of injection site reactions.

**Conclusions:** SMS995L 30 mg (OCT LAR in an NV) is bioequivalent to OCT LAR 30 mg (current vehicle), with no new safety signals observed. It is anticipated that the NV and the new injection preparation kit (vial adapter and a needle of smaller diameter) will enhance the convenience and safety for the reconstitution and administration of OCT.

**Disclosure:** S. Sarp, Severine Sarp is an employee of Novartis Pharma AG; K. Roessner: Katja Roessner is an employee of Novartis Pharma AG; A. Brueck-Scheffler: Antje Brueck-Scheffler is an employee of Novartis Pharma AG; A.P. Tripathi: Anadya Prakash Tripathi is an employee of Novartis India Pvt. Ltd; J. Roberts: John Roberts is an employee of Novartis Pharmaceuticals Corporation, is a Novartis stock owner, and is a Novartis clinical study team member.