

Simulated-Use Study of a Single-Use Delivery Device for Lanreotide Depot in Untrained Health Care Professionals

Daphne Adelman¹; Beloo Mirakhur²; Alexandria Phan^{2,3}

¹Feinberg School of Medicine, Northwestern University; ²Ipsen Biopharmaceuticals Inc - Basking Ridge, NJ; ³GI Medical Oncology, Houston Methodist Hospital

Background: Lanreotide depot is a long-acting somatostatin analog formulation approved in the US for treatment of unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors to improve progression-free survival. The drug is provided in a unique, prefilled, single-use syringe with integrated passive sharps injury prevention feature. Based on the results of a previous simulated use study, additional modifications were made, to enhance the device's usability. This study evaluated the effects of these changes on the usability of the device in an untrained group of participant health care professionals (HCPs).

Methods: HCPs were given product packaging materials, prefilled device, and IFU; asked to read the IFU; and perform one injection with the device (filled with gel to stimulate injection characteristics of the actual product) using a mannequin. The HCPs were evaluated for understanding of the IFU and correct and safe use of the device.

Results: 100% [16/16] of participant HCPs checked the dose/date in at least 1 location, selected the correct injection site, removed the plunger protector, inserted the needle at 90 degrees, penetrated to the full length of the needle, and compressed the plunger to the bottom in order to inject all the medication, as indicated in the IFU. Most participants (88% [14/16]) correctly maintained pressure on the plunger after delivery of a full dose as indicated, which keeps the needle extended until removed from the patient's body. Not maintaining pressure after delivery of a full dose results in automatic retraction of the needle but has no measurable clinical impact. All participants successfully allowed the needle to retract, placing the needle in a safe state.

Conclusion: In this simulated-use study, untrained HCPs successfully used the prefilled lanreotide depot injection device with integrated sharps injury prevention feature, thus validating the improvements made to the IFU and the device.