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SANOFI

Press Release

UK

SMC recommends Suliqua™▼ (insulin glargine/lixisenatide) for restricted use in combination with metformin for the treatment of adults with type 2 diabetes who are uncontrolled on basal insulin [1]

- Suliqua is a titratable, fixed-ratio combination of insulin glargine and lixisenatide delivered via a single, daily injection[2]
- Suliqua provided greater reductions in blood sugar levels in comparison with insulin glargine 100 Units/mL[3]

READING, ENGLAND – 16 April 2020 – Sanofi has today announced that the Scottish Medicines Consortium (SMC) has recommended Suliqua™ for restricted use in combination with metformin for the treatment of adults with type 2 diabetes in Scotland.[1] It can be used to improve glycaemic control when this has not been provided by metformin alone, or metformin combined with another oral glucose-lowering medicinal product or with basal insulin.[1] The SMC has restricted the use of Suliqua to use in patients who are uncontrolled on basal insulin (glycosylated haemoglobin [HbA1c] > 7.5% [59mmol/mol]) and for whom a GLP-1 receptor agonist is appropriate as an add-on intensification therapy to basal insulin analogues. The combination improved glycaemic control compared with insulin glargine alone in adults with inadequately controlled type 2 diabetes mellitus.[1] By year five of Suliqua being in Scotland, it is estimated that 4,485 people living with type 2 diabetes could be eligible for this treatment.[1]

Currently, between 17% and 38% of patients remain uncontrolled on basal insulin and approximately half of people with diabetes, are not reaching their glycaemic target despite using oral anti-diabetic medications (OADs) and/or basal insulin.[4, 5]

The SMC recommendation of the once-daily injection is based on the phase III study, LixiLan-L. The study found that when added to metformin insulin glargine/lixisenatide demonstrated greater reductions in blood sugar levels (HbA1c) at week 30 in comparison with insulin glargine 100 Units/mL.[3] Suliqua showed greater reductions in HbA1c from baseline compared with insulin glargine (–1.1% vs. –0.6%, P < 0.0001), reaching a mean final HbA1c of 6.9% (52 mmol/mol) compared with 7.5% (58 mmol/mol) for insulin glargine. HbA1c <7.0% (53 mmol/mol) was achieved in 55% of Suliqua patients compared with 30% on insulin glargine.[3] For the secondary outcome of weight change, a reduction of 0.7kg was observed in patients treated with

insulin glargine/lixisenatide versus a 0.7kg increase in those treated with insulin glargine. (Note: the combination is not licensed for weight reduction)

Approximately 257,000 people are currently living with type 2 diabetes in Scotland.[6] Every year, more than 17,000 people are diagnosed with type 2 diabetes,[6] and it is estimated that 500,000 more are at a high risk of developing the condition.[6]

> Prof Mike Baxter, Medical Therapy Area Expert for Sanofi said: *"More than half of people currently living with type 2 diabetes struggle to achieve glycaemic control on current available therapies, so we're delighted to be able to offer a treatment option that may help more people to achieve optimal control. Suliqua offers simple administration of an insulin glargine and lixisenatide fixed ratio combination in a single daily injection. Its availability via NHS Scotland demonstrates Sanofi's continued commitment to addressing the unmet needs in people living with type 2 diabetes."*

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About Suliqua (insulin glargine/lixisenatide)

Suliqua (insulin glargine/lixisenatide), is a once-daily titratable fixed-ratio combination of basal insulin glargine 100 Units/mL and GLP-1 receptor agonist lixisenatide. Suliqua is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise in addition to metformin with or without SGLT-2 inhibitors.

Suliqua is delivered in two pre-filled SoloSTAR® pens, providing different dosing options that may help answer individual patient insulin needs.[2] The differentiation between the pen strengths is based on the dose range and ratios of each pen.[2] The 10–40 SoloSTAR® pre-filled pen will deliver 10 to 40 dose steps of insulin glargine 100 Units/mL in combination with 5 to 20 micrograms of lixisenatide.[2] The 30-60 SoloSTAR pre-filled pen will deliver 30 to 60 dose steps of insulin glargine 100 Units/mL in combination with 10 to 20 micrograms of lixisenatide.[2]

Background on LixiLan-L study

The study was conducted at 187 centers in 18 countries.[3] The trial studied 736 participants, inclusion criteria included a diagnosis of type 2 diabetes mellitus diagnosed at least 1 year before the screening visit and treatment with basal insulin for at least 6 months before the screening visit.[3]

After a 6-week run-in when basal insulin was switched to insulin glargine and/or further titrated, and oral antidiabetic drugs other than metformin were stopped, 736 basal insulin-treated patients (mean diabetes duration 12 years, BMI 31 kg/m2) were randomized 1:1 to open-label, once-daily insulin glargine or insulin glargine/lixisenatide, both titrated to fasting plasma glucose <100 mg/dL (<5.6 mmol/L) up to a maximum dose of 60 units/day.[3] The primary outcome was change in HbA1c levels at 30 weeks.[3]

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About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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References

[1] SMC insulin glargine/lixisenatide (Suliqua®) is accepted for restricted use within NHSScotland. Available at: https://www.scottishmedicines.org.uk/medicines-advice/insulin-glarginelixisenatide-suliqua-full-smc2235/. Last accessed April 2020.
[2] Suliqua™ EU Summary of Product Characteristics, 2020. Available at: https://www.medicines.org.uk/emc/product/9870/smpc, Last accessed April 2020.
[3] Aroda VR, et al. Diabetes Care. 2016, DOI: 10.2337/dc16-1495.
[4] Owens D, et al. Diabetes, Obesity and Metabolism 2017, 19: 1339–1352. Last accessed April 2020.
[5] Raccah D, et al. Diabetes Metab Res Rev. 2016 (online ahead of print) DOI: 10.1002/dmrr.2858/full
[6] Scottish Government. A Healthier Future: type 2 Diabetes prevention, early detection and intervention: framework, Available at: https://www.gov.scot/publications/healthier-future-framework-prevention-early-detection-early-intervention-type-2/pages/4/. Last accessed April 2020.