Once-Weekly Exenatide in Youth with Type 2 Diabetes: A Pivotal Phase III Randomized Study.

Tamborlane W V, Bishai R, Geller D, et al. Diabetes Jun 2021, 70 (Supplement 1) 91-LB

Background: There is an alarming rise in the incidence of Type 2 diabetes in children and adolescents. We need better treatment options that can prevent the hyperglycaemia-related complications of Type 2 Diabetes in youth. Exenatide, a glucagon-like peptide 1 (GLP-1) receptor agonist, has been approved in the treatment of Type 2 Diabetes in adults and can be conveniently administered once-weekly.

Aim: To evaluate the efficacy and safety of once-weekly Exenatide (EQW) in Youth with Type 2 Diabetes (T2D).

Methods: Phase III study, participants (aged 10 to <18 years) were randomized (5:2) to Exenatide (EQW) 2mg or placebo. Setting: 27 sites in 6 countries. Primary efficacy endpoint was change from baseline in HbA1c at week 24 & secondary endpoints were changes in fasting glucose, body weight & blood pressure.

ACADEMIC P.E.A.R.L.S

Pediatric Evidence And Research Learning Snippet

Once-Weekly Exenatide Improves Disease Control in Youth with Type 2 Diabetes

Results:Of the 83 trial participants (EQW: 59 Vs. placebo:24), 72 completed the 24-week treatment.

- At 24 weeks, EQW was superior to placebo in lowering HbA1c; the least squares mean (LSM) change in HbA1c was -0.36% for EQW and +0.49% for placebo (between-group difference: -0.85%; P= 0.012)
- The proportion of patients who met the secondary endpoint of HbA1c <7% was significantly higher in the treatment group vs. placebo group (31% Vs. 8.3%; P=0.02)
- Nonsignificant LSM differences from baseline to 24 weeks favoring EQW were observed for fasting glucose (-21.6 mg/dL; 95%CI: -49.0, 5.7; P=0.119), SBP (-2.8 mmHg; 95% CI: -8.0, 2.4; P=0.284) and body weight (-1.22 kg; 95% CI:-3.59, 1.15; P=0.307)
- Exenatide was well tolerated; adverse events occurred in 61.0% and serious events in 3.4%.

Conclusion: In youth with Type 2 diabetes sub-optimally controlled with current treatments, Exenatide was effective in improving metabolic control. Exenatide was well-tolerated and no adverse events led to treatment discontinuation.

Key message: Once-Weekly injection of glucagon-like peptide 1 (GLP-1) receptor agonist, Exenatide, reduced HbA1c levels versus placebo at week 24 in children and adolescents with Type 2 Diabetes.

EXPERT COMMENT

“Over the past decade, glucagon-like peptide 1 (GLP-1) receptor agonists with a dual competitive advantage of lower risk of hypoglycaemia and better weight loss, have expanded the treatment options of children and adolescents with Type 2 Diabetes. This study provides evidence for the efficacy of Exenatide, as an adjunct to diet and exercise in youth with Type 2 Diabetes. However, the long-term safety is yet to be established. It is noteworthy that FDA has approved it’s use for children aged 10 to 17 years with Type 2 Diabetes.”

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With warm regards,

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Reference

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