

# Exenatide in Youth with Type 2 Diabetes

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## Background

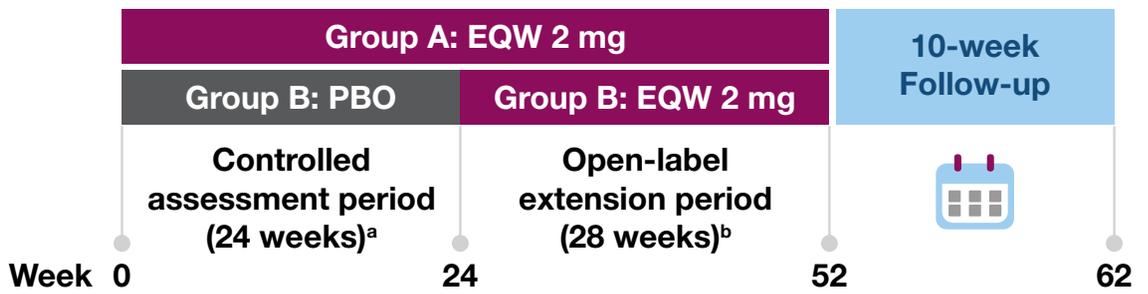
- Approximately **half of youth with type 2 diabetes fail metformin monotherapy** within 1 year of treatment initiation,<sup>1</sup> and insulin therapy is associated with challenges,<sup>2</sup> necessitating **alternative therapies**
- Exenatide, a glucagon-like peptide-1 receptor agonist, is the first agent approved in adults with type 2 diabetes that can be given once weekly<sup>3</sup>

## Objective

To evaluate the **efficacy and safety of exenatide weekly injections** in youth aged 10 to <18 years with type 2 diabetes

## Methods

- This **parallel-group, phase III study** randomized patients in a 5:2 ratio (Week 0) to receive **once-weekly exenatide 2 mg** or **placebo**

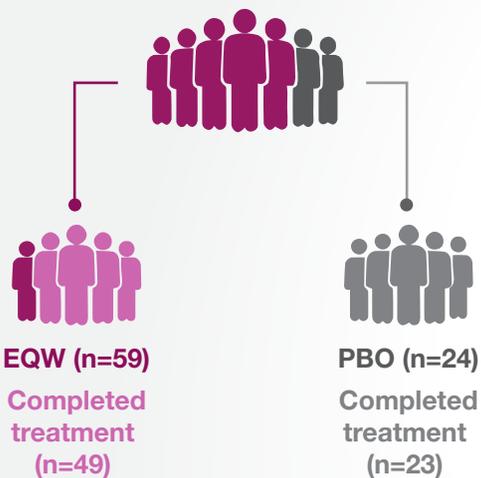


- Primary endpoint:** Change in HbA1c levels from Weeks 0 to 24 with once-weekly exenatide vs placebo; **safety endpoints:** descriptive evaluation of AEs, laboratory investigations and vital signs

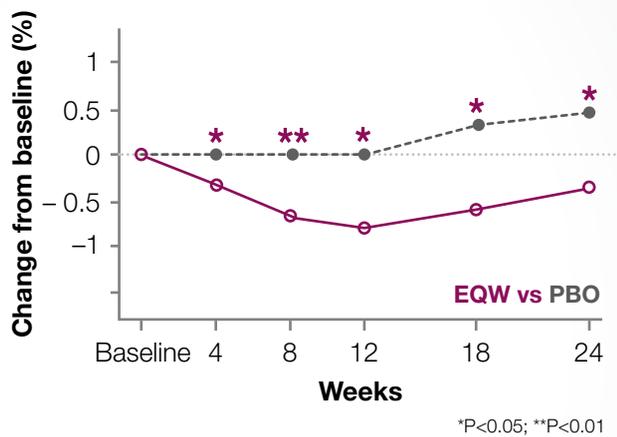
<sup>a</sup>Double-blind, placebo-controlled period to examine the efficacy and safety of EQW 2 mg (Group A) or placebo (Group B).  
<sup>b</sup>Open-label, uncontrolled period to examine the long-term safety and efficacy of EQW. Patients assigned to EQW 2 mg (Group A) continued EQW 2 mg during the open-label extension period. Patients randomized to placebo (Group B) received EQW 2 mg at the start of the open-label extension period until Week 52.

## Results

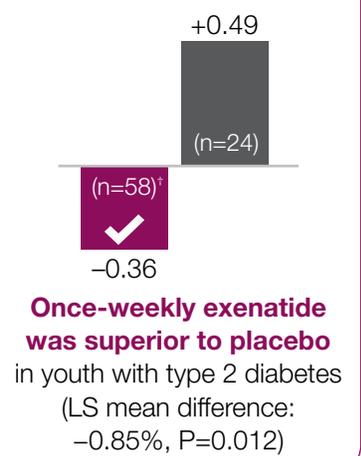
Randomized (N=83)



Change in HbA1c over time

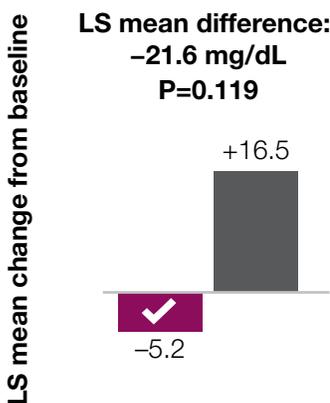


LS mean change in HbA1c at Week 24



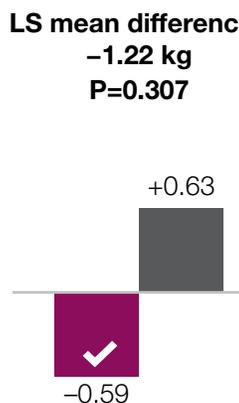
Fasting plasma glucose

LS mean difference:  
-21.6 mg/dL  
P=0.119



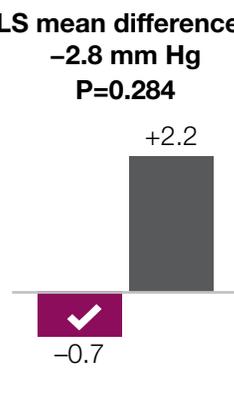
Body weight

LS mean difference:  
-1.22 kg  
P=0.307

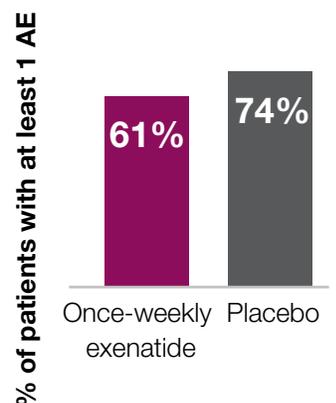


Systolic blood pressure

LS mean difference:  
-2.8 mm Hg  
P=0.284



Adverse events



Reductions in fasting plasma glucose, body weight, and systolic blood pressure were observed with **once-weekly exenatide** (once-weekly exenatide (n=58)<sup>†</sup> placebo (n=24))

## Conclusion



**Once-weekly exenatide was effective and safe in youth with type 2 diabetes and offers a new convenient treatment option for this population**

<sup>†</sup>One patient who was randomized to once-weekly exenatide did not receive any study medication due to an AE of vomiting which led to study discontinuation before the first exenatide dose.

AE, adverse event; EQW, once-weekly exenatide; PBO, placebo; HbA1c, glycated hemoglobin; LS, least squares

1. TODAY Study Group. *N Engl J Med.* 2012;366(24):2247-2256; 2. Cameron FJ, et al. *Lancet.* 2015;385:2096-2106; 3. Genovese S, et al. *Adv Ther.* 2017;34:1791-1814.