

**Brand Name:** Onglyza

**Generic:** saxagliptin

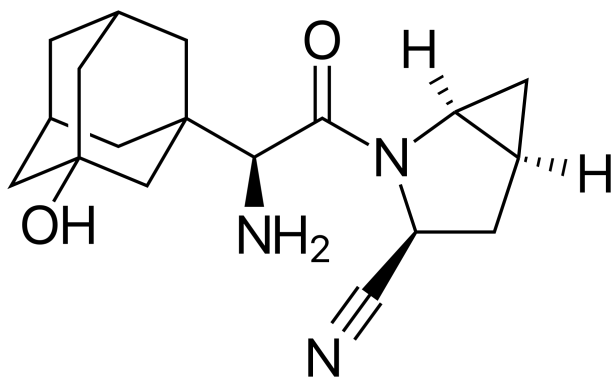
**Type:** small molecule

**Year Accepted/Phase:** 2009

**Mechanism:**

Moxetumomab pasudotox is a CD22-directed cytotoxin that binds to CD22 on the surface of B cells, delivering a cytotoxic agent to the cell and causing cell death.

**Chemical Structure:**



**Indication:**

Onglyza is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It can be used as monotherapy or in combination with other antidiabetic agents.

## **Clinical trials:**

### **SAVOR-TIMI 53 Trial (Phase IV)**

**Pubmed:** <https://pubmed.ncbi.nlm.nih.gov/23992601/>

**Purpose:** Evaluate the cardiovascular safety of saxagliptin in patients with type 2 diabetes who have a high risk of cardiovascular events.

**Dates:** Conducted from 2010 to 2013.

**Results:** The SAVOR-TIMI 53 trial showed that saxagliptin did not significantly increase or decrease the risk of major adverse cardiovascular events (MACE) compared to placebo. However, there was an observed increase in the risk of hospitalization for heart failure.

**Impact:** These results provided crucial information on the cardiovascular safety profile of saxagliptin, which is essential for the management of patients with type 2 diabetes and high cardiovascular risk.

### **Clinical Trials Leading to FDA Approval:**

#### **Initial Phase III Trials:**

**Purpose:** Assess the efficacy and safety of saxagliptin as monotherapy and in combination with other antidiabetic agents.

**Dates:** Conducted from 2006 to 2008.

**Results:** These trials demonstrated that saxagliptin significantly improved glycemic control, as measured by reductions in HbA1c, fasting plasma glucose, and postprandial glucose levels. The safety profile was comparable to that of placebo, with a low incidence of hypoglycemia.

**Impact:** These results supported the efficacy and safety of saxagliptin, leading to its approval for the treatment of type 2 diabetes.