



# valeritas

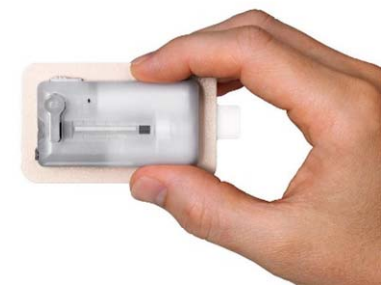


DELIVERING QUALITY OF LIFE

## V-Go<sup>®</sup> Clinical Summary

OTCQB: VLRX

November 2016



# Better Glycemic Control Improves and Extends Lives

## Significant Adverse Health Effects Influenced by Poor Glycemic Control

**Each 1% reduction in mean A1C  
reduces risk for**

**Deaths from Diabetes**

**21%**

**Microvascular  
Complications**

**37%**

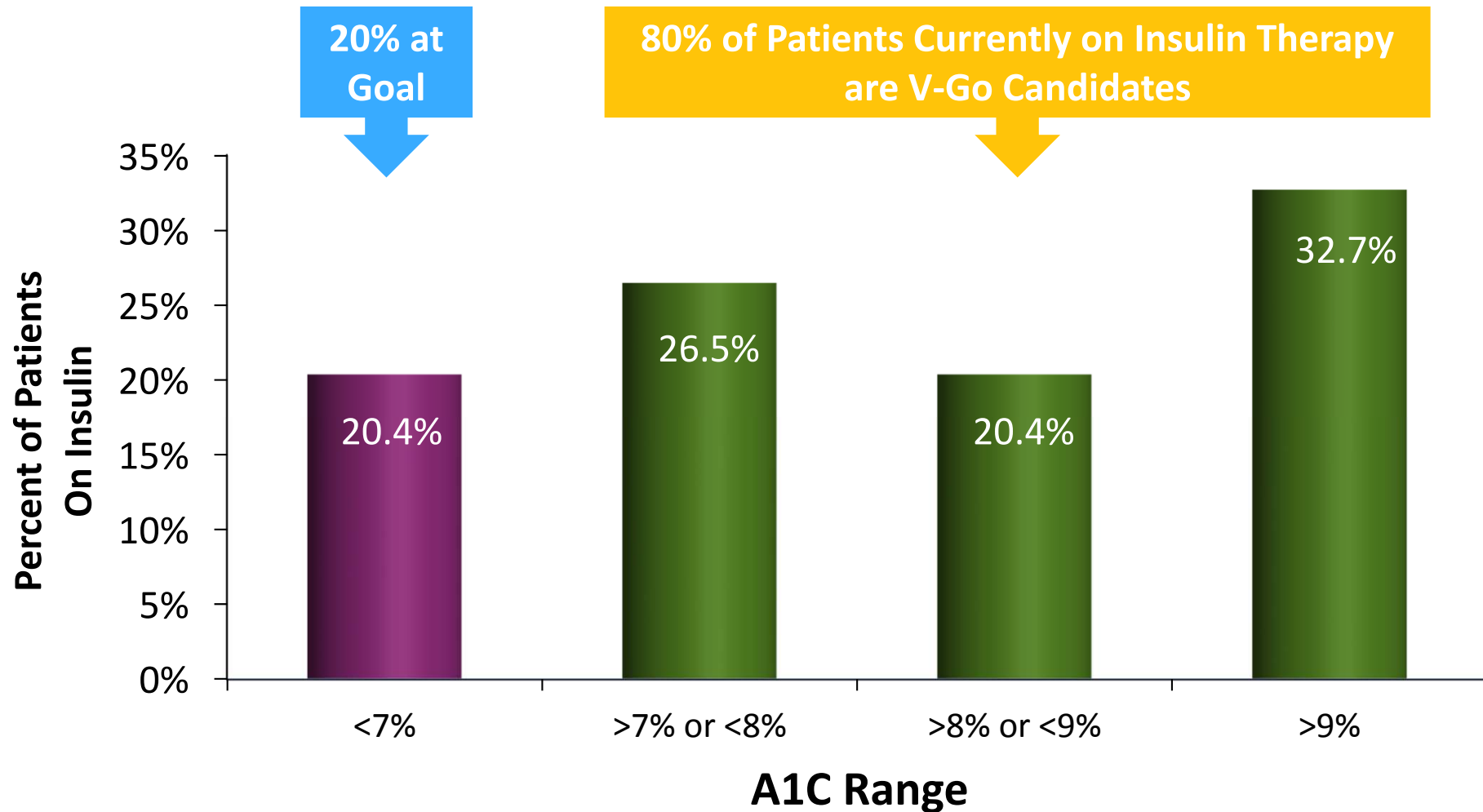
**Heart Attacks**

**14%**

**Peripheral Vascular  
Disease**

**43%**

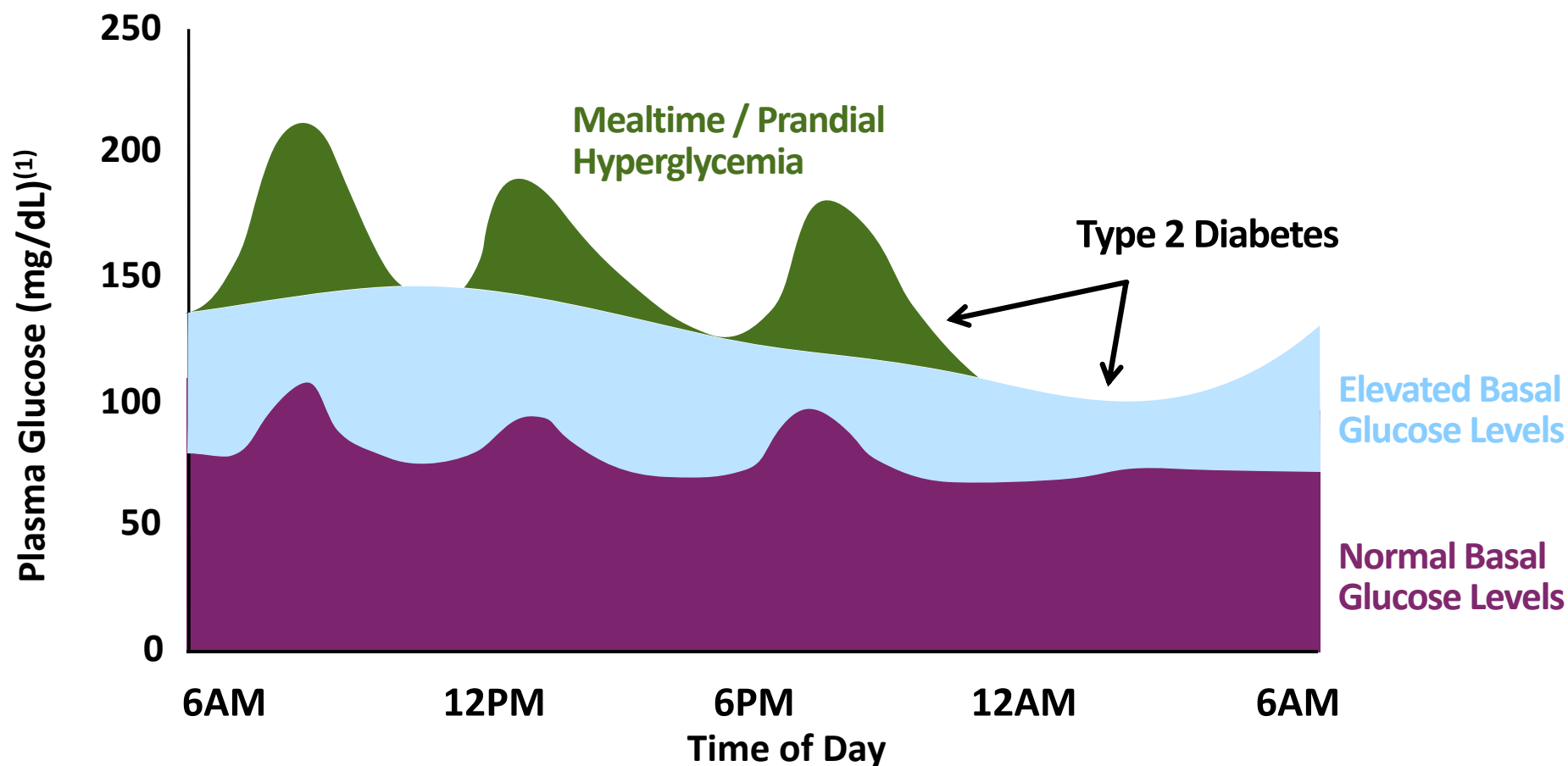
# Large Scale Study Validates 80% of Patients on Insulin\* are Not at A1C Goal and are Ideal V-Go<sup>®</sup> Candidates



2011 Database analysis of 27,897 adult patients with diabetes on insulin

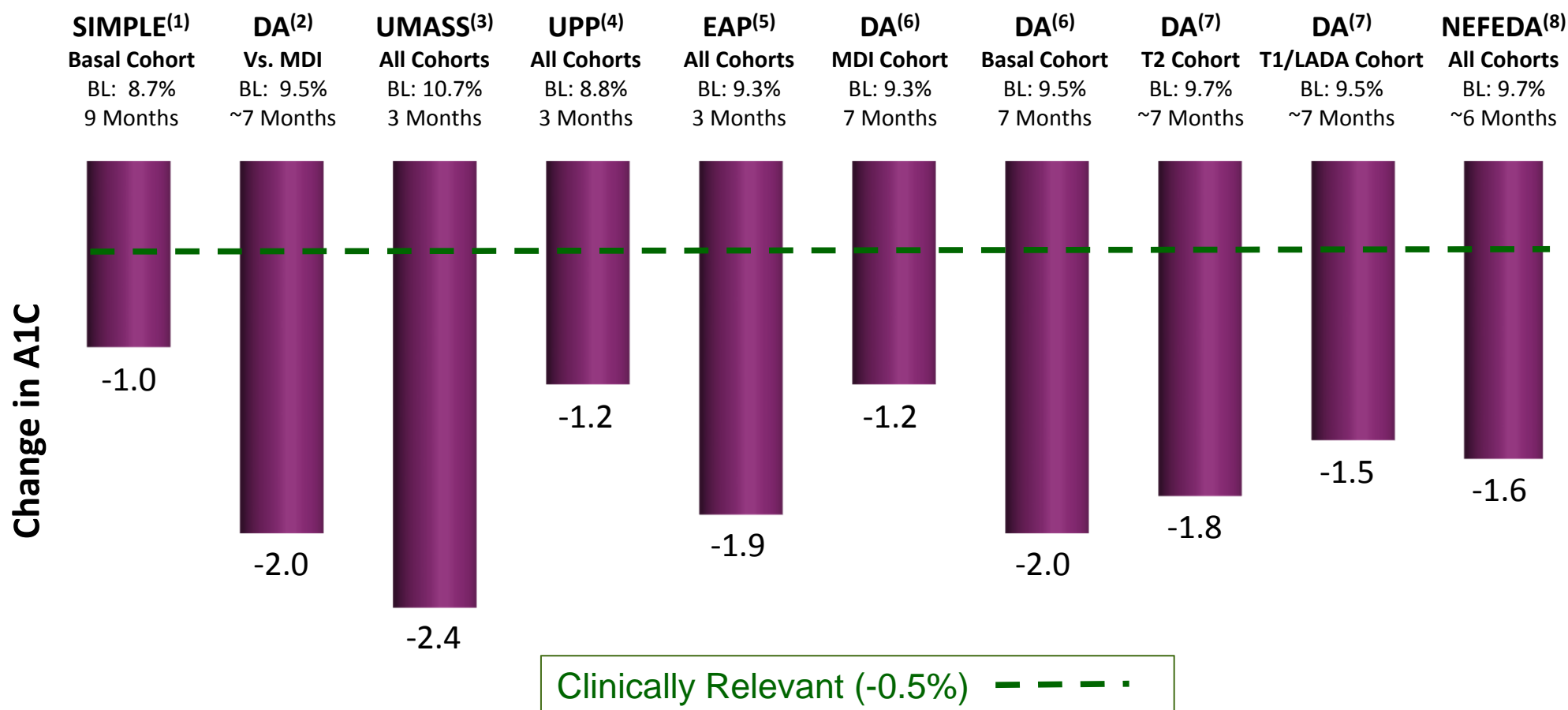
\* Insulin: Basal, Basal plus one, Premixed or MDI. Results data from the Health Core Integrated Research Database.

# Many Patients with Type 2 Diabetes Require Basal and Bolus Insulin Delivery to Maintain Glycemic Control



**82% of Patients with Type 2 Diabetes Initiated on Basal-Only Insulin Regimens Required Mealtime Insulin to Achieve and Maintain A1C Goal<sup>(2)</sup>**

# Robust Clinical Data Validates V-Go<sup>®</sup>'s Ability to Deliver Clinically Relevant Reductions in A1C Levels



BL= Baseline

(1) Grunberger G, et al. Poster presented at: AACE 23rd Annual Scientific and Clinical Congress. May 14-18, 2014; Las Vegas, NV.

(2) Lajara R, Davidson JA, et al. *Endocr Pract.* 2016 June; 22 (6): 726-725.

(3) Omer A, et al. Poster presented at 73<sup>rd</sup> Scientific Sessions of the ADA; June 21-25, 2013; Chicago, IL.

(4) Rosenfeld CR, et al. *Endocr Pract.* 2012; 18 (5):660-667.

(5) Sandberg M, et al. *Practical Diabetology.* 2013;32(3): 6–22.

(6) Lajara R, et al. *Practical Diabetology.* 2016;36(5): 10-15.

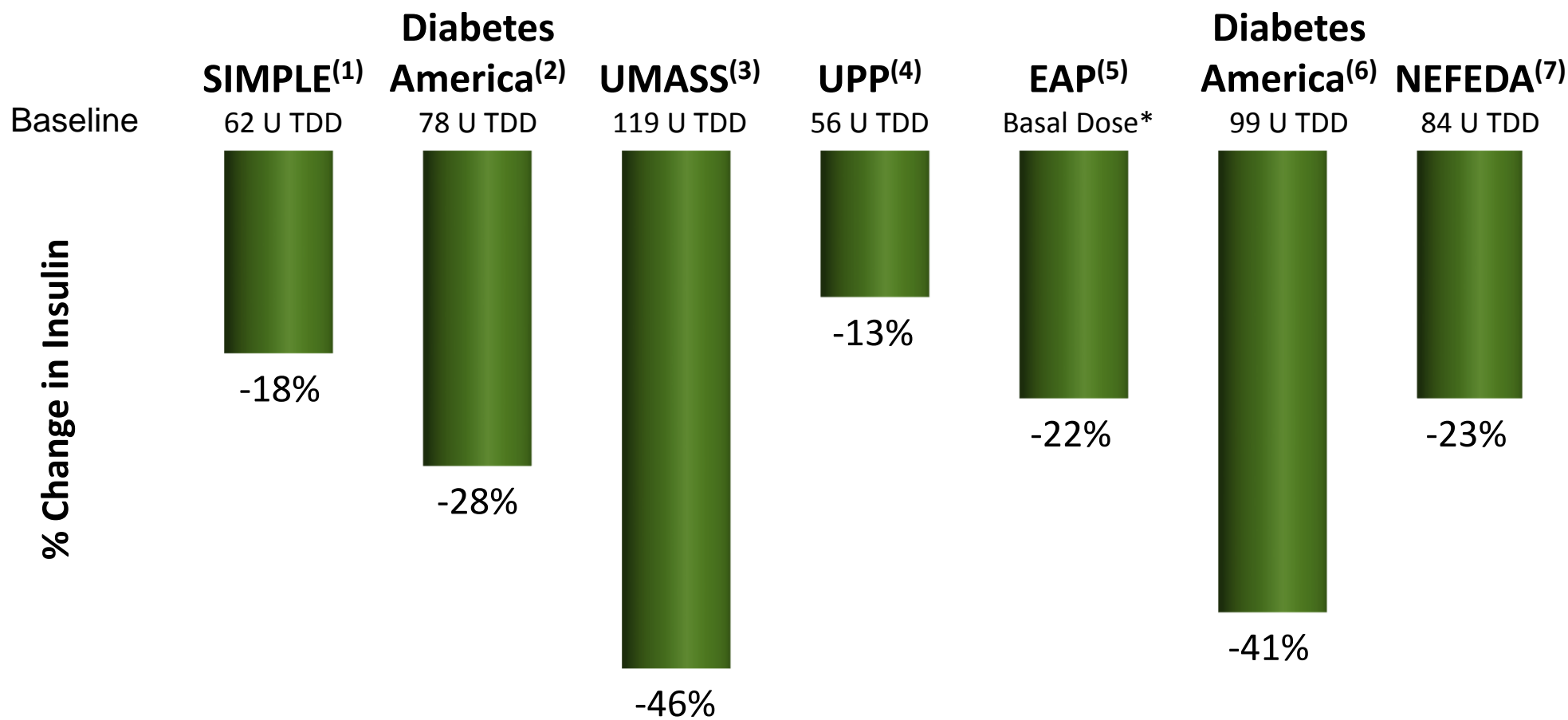
(7) Lajara R, et al. *Diabetes Ther.* 2015;6 (4):531-545.

(8) Sutton D, et al. Poster presented at 76th Scientific Sessions of the ADA; June 10-14, 2013; New Orleans, LA.

Patients naive to insulin reduced A1C by 3.4%<sup>7</sup>



# Switching to V-Go<sup>®</sup> Demonstrated Significant Reductions in Total Daily Insulin Dose (TDD) Across Multiple Studies



(1) Grunberger G, et al. Poster presented at: AACE 23rd Annual Scientific and Clinical Congress. May 14-18, 2014; Las Vegas, NV.

(2) Lajara R, Davidson JA, et al. *Endocr Pract.* 2016 June; 22 (6): 726-725. Difference in mean insulin TDD at end of study MDI 78 U/day vs V-Go 56 U/day.

(3) Omer A, et al. Poster presented at 73<sup>rd</sup> Scientific Sessions of the ADA; June 21-25, 2013; Chicago, IL.

(4) Rosenfeld CR, et al. *Endocr Pract.* 2012; 18 (5):660-667.

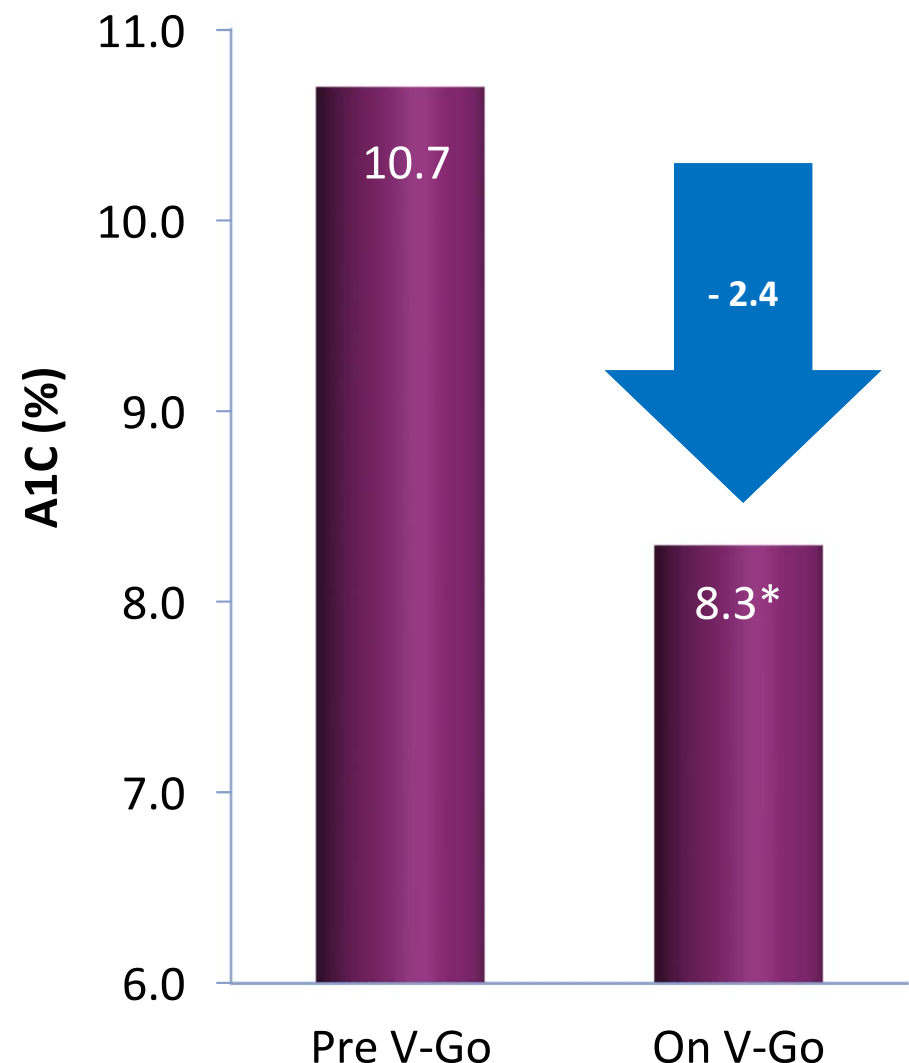
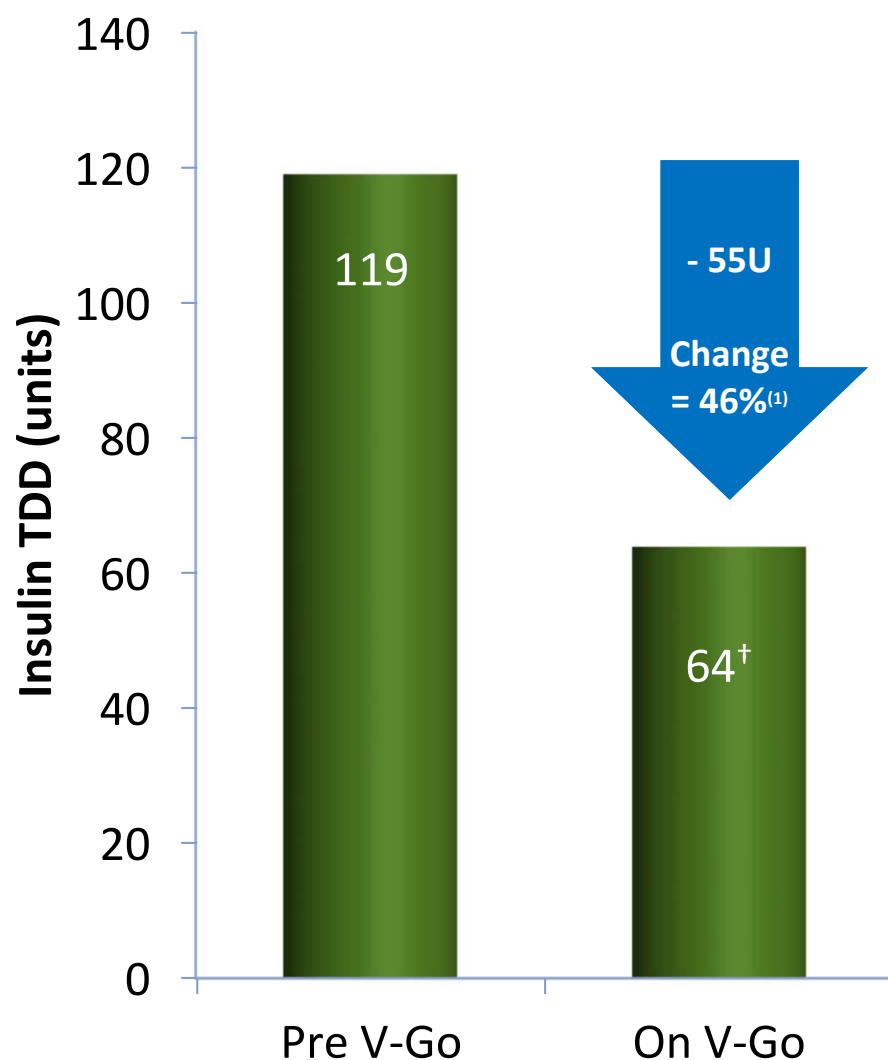
(5) Sandberg M, et al. *Practical Diabetology.* 2013;32(3): 6-22.

(6) Lajara R, et al. *Diabetes Ther.* 2015;6 (4):531-545. Difference based on patients administering insulin at baseline (N=180) compared to V-Go dose at study end.

(7) Sutton D, et al. Poster presented at 76th Scientific Sessions of the ADA; June 10-14, 2013; New Orleans, LA.. Based on office visit 2.

# V-Go<sup>®</sup> Significantly Reduces A1C with Less Insulin

## Key Benefit to Both Patients and Payors



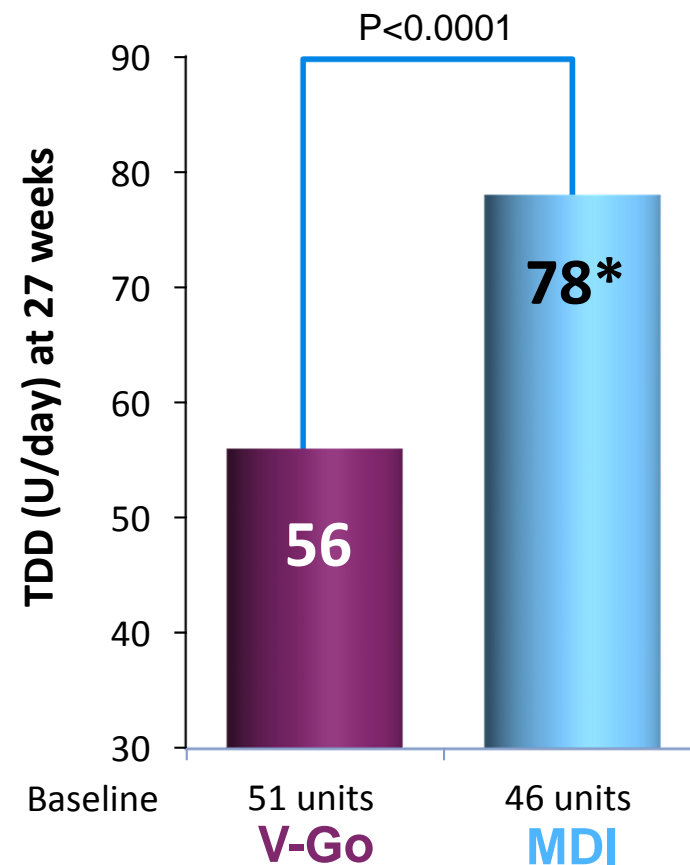
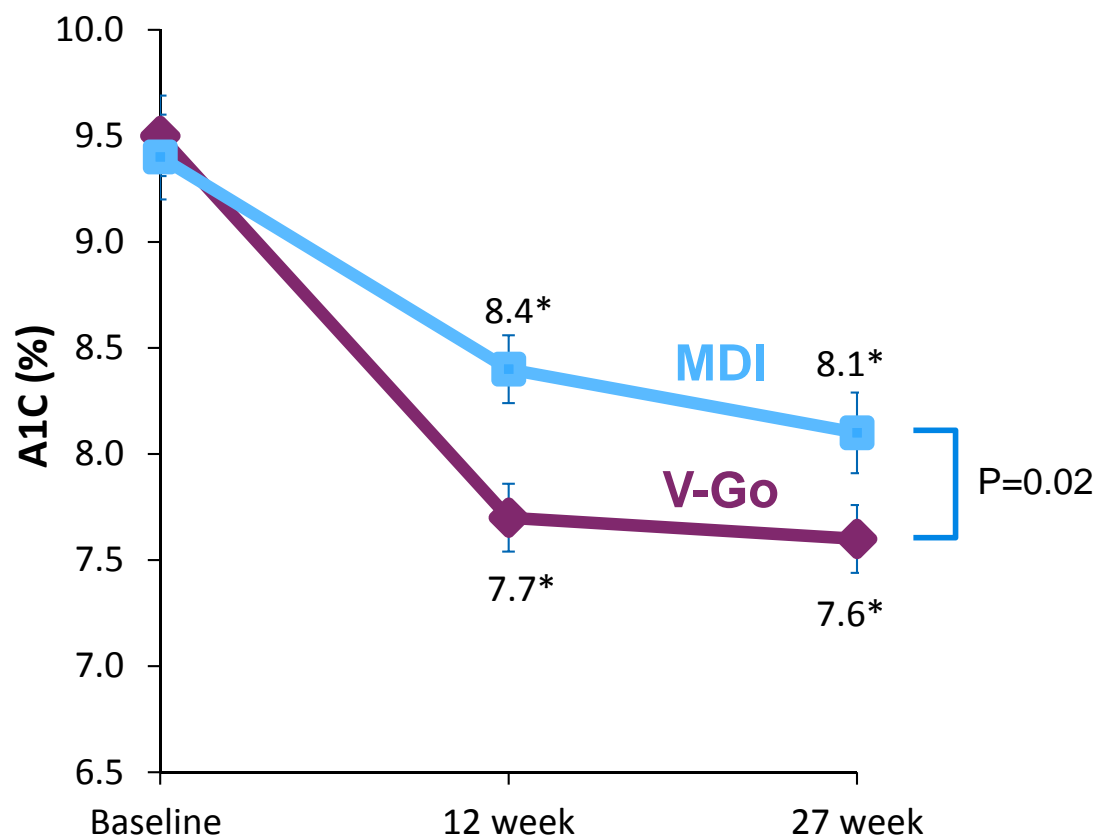
†  $P=0.01$ , \* $P=0.001$

N=14 Average Duration = 88 days

(1) Based on Insulin TDD absolute units.  
Omer, A. et al. Poster presented at 73<sup>rd</sup> Scientific Sessions of the ADA; 2013 June 21-25; Chicago, IL. 980-P.  
UMASS Study.

# V-Go<sup>®</sup> Demonstrates Significant Improvements In Glycemic Control vs Multiple Daily Injections (MDI)

Better Control with Less Insulin vs MDI



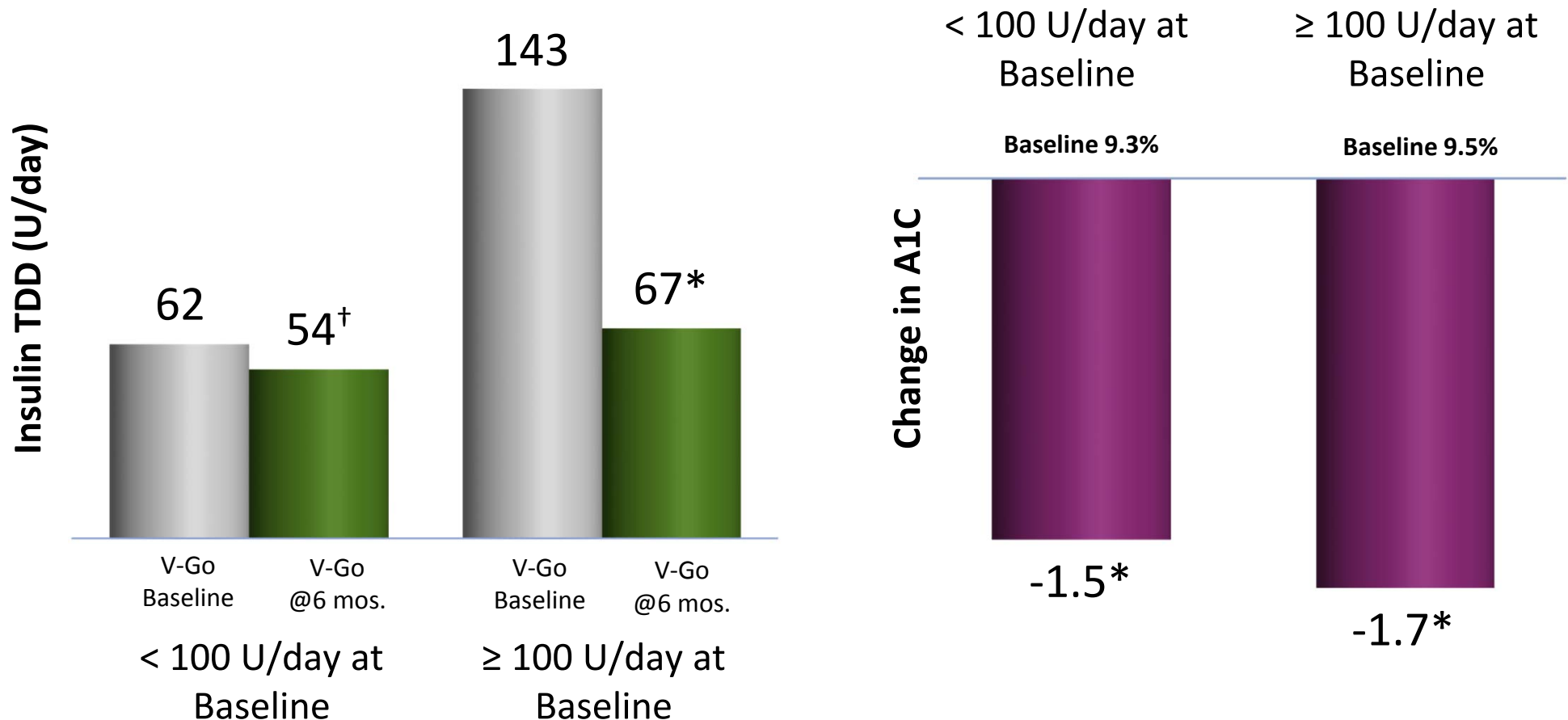
V-Go: N=56 BL A1C- 9.5% BL TDD - 51 U/day, Starting V-Go TDD- 52 U/day, 12 week TDD- 56 U/day, 27 week TDD- 56 U/day  
MDI: N=60 BL A1C- 9.4%, BL TDD- 46 U/day, Starting MDI TDD- 64 U/day, 12 week TDD- 75 U/day, 27 week TDD- 78 U/day  
Data are mean (SE)



# V-Go<sup>®</sup> Appropriate For The Vast Majority of Type 2 Patients

## V-Go Improved A1C Control in Both the Low and High Prior Insulin Dose Groups

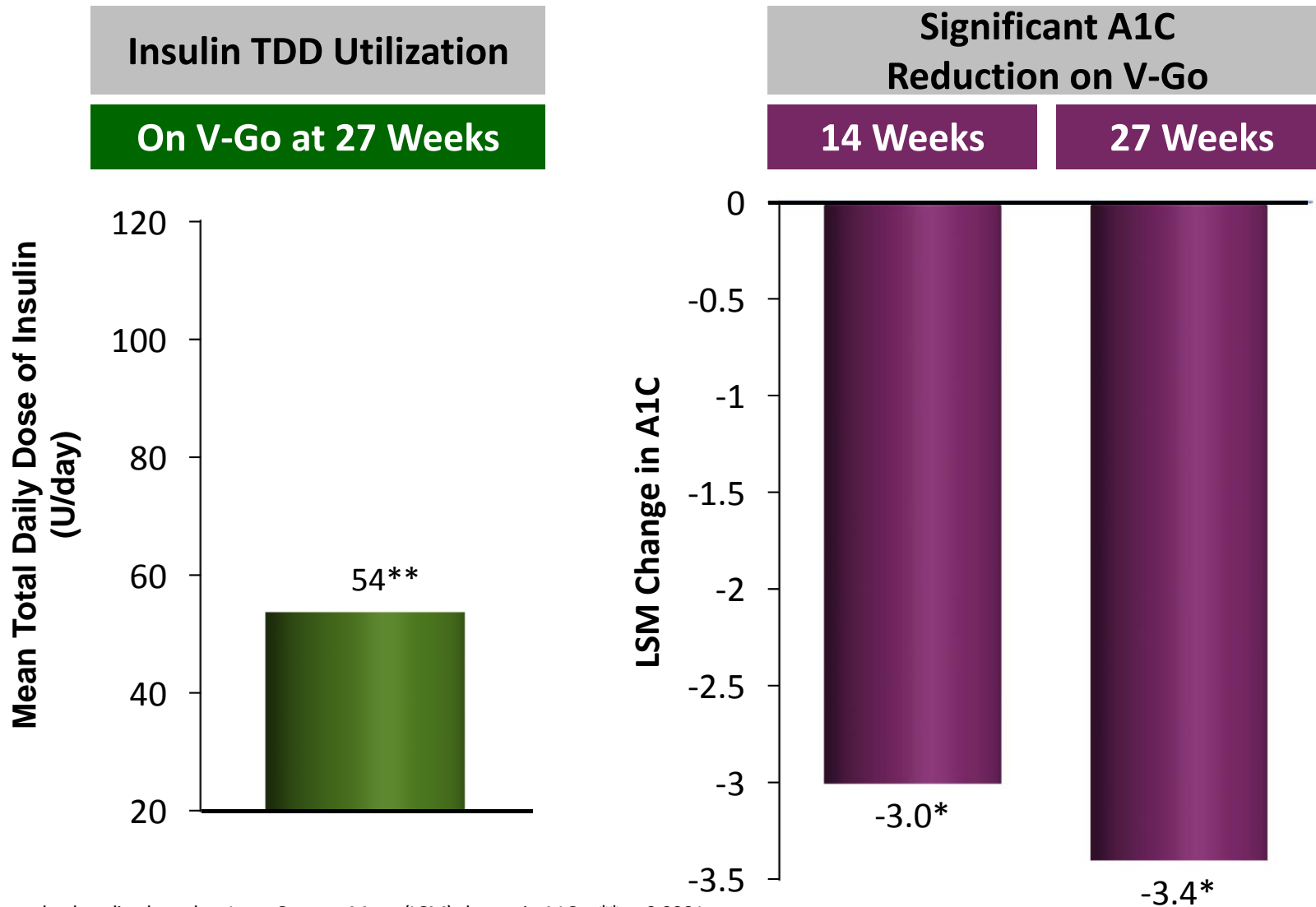
After 6 Months of Using V-Go for Insulin Delivery



N= 66 patients < 100 U/day at baseline and 38 patients ≥ 100 U/day at baseline  
†P<0.05 compared to baseline at 6 months, \*P <0.0001 compared to baseline at 6 months

# Insulin Naïve Patients Could Represent a Significant Market Opportunity for V-Go®

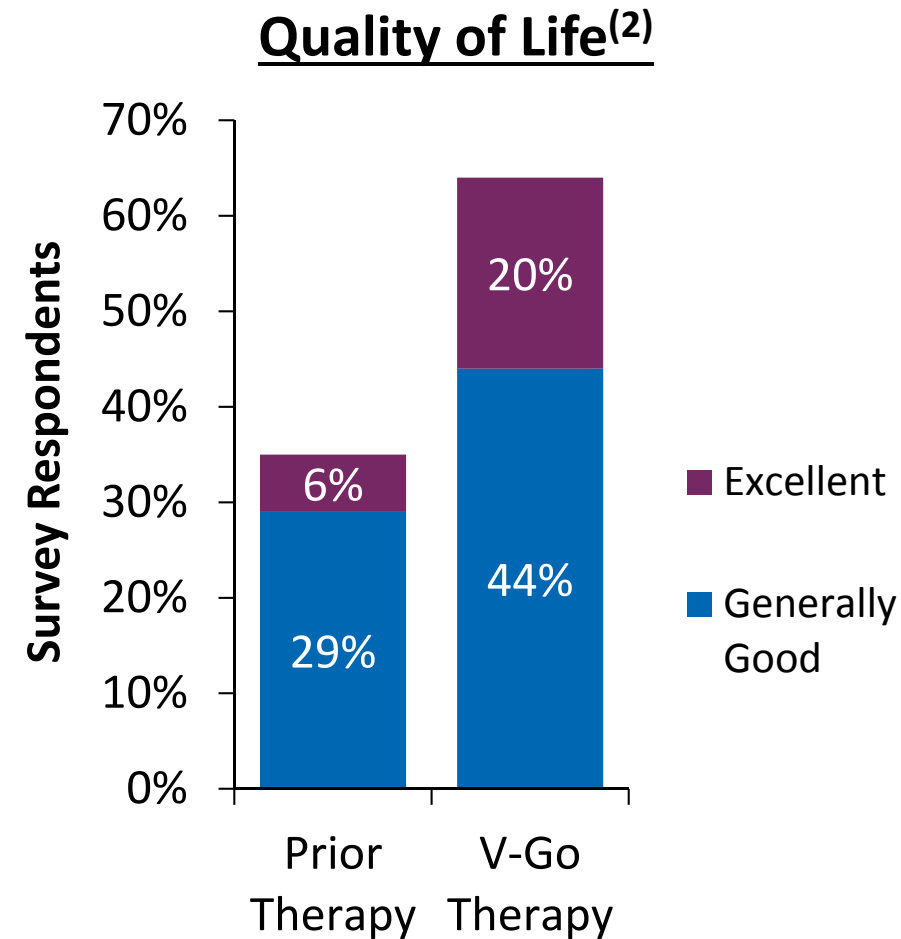
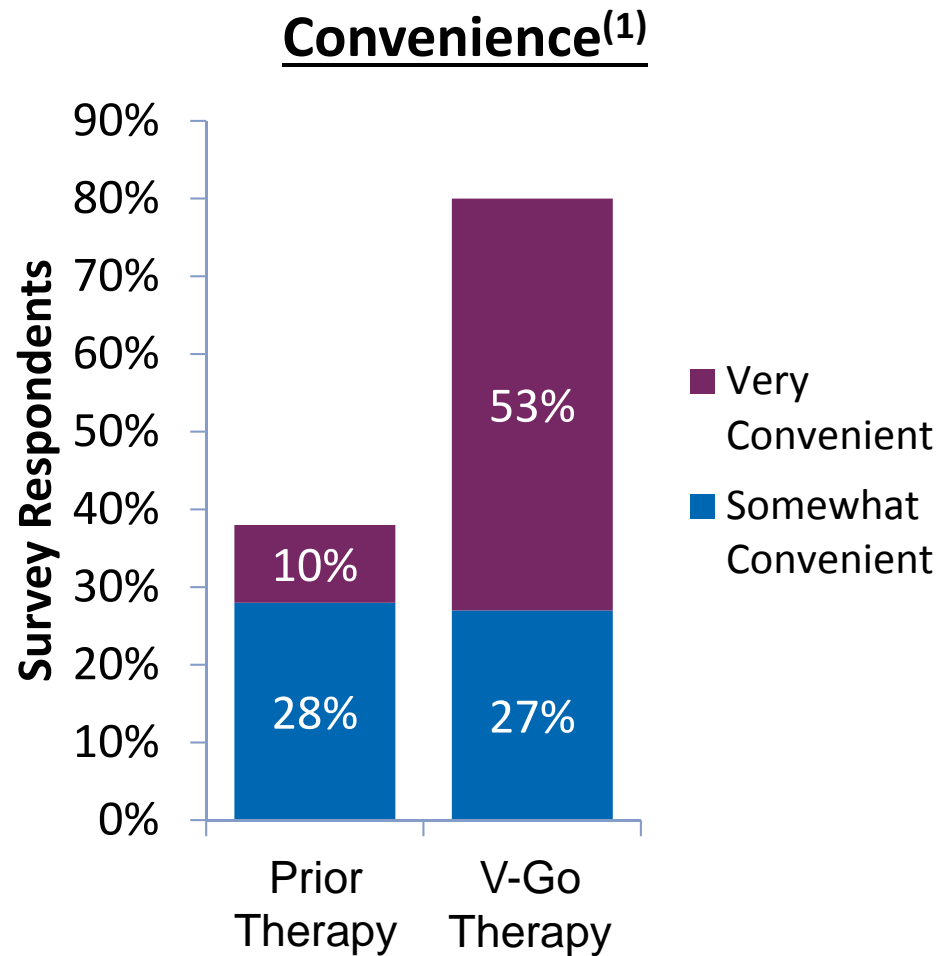
## Potential for V-Go to be First-Line Insulin Therapy



\*p<0.001 compared to baseline based on Least Squares Mean (LSM) change in A1C \*\* p<0.0001

N= 24, Baseline A1C = 11.3%. Time points represent the mean time elapsed between V-Go initiation and follow-up A1C results for the total population.  
Lajara R, et al. Diabetes Ther. 2015;6 (4):531-545

# Patients Rate the Convenience of V-Go<sup>®</sup> and Their Quality of Life as Superior vs. Previous Therapies



How do you feel physically & mentally on a typical day?

(1) Data on File (Valeritas Customer Care).

Note: Patients were surveyed prior to starting V-Go and again ~30 days after being on V-Go.