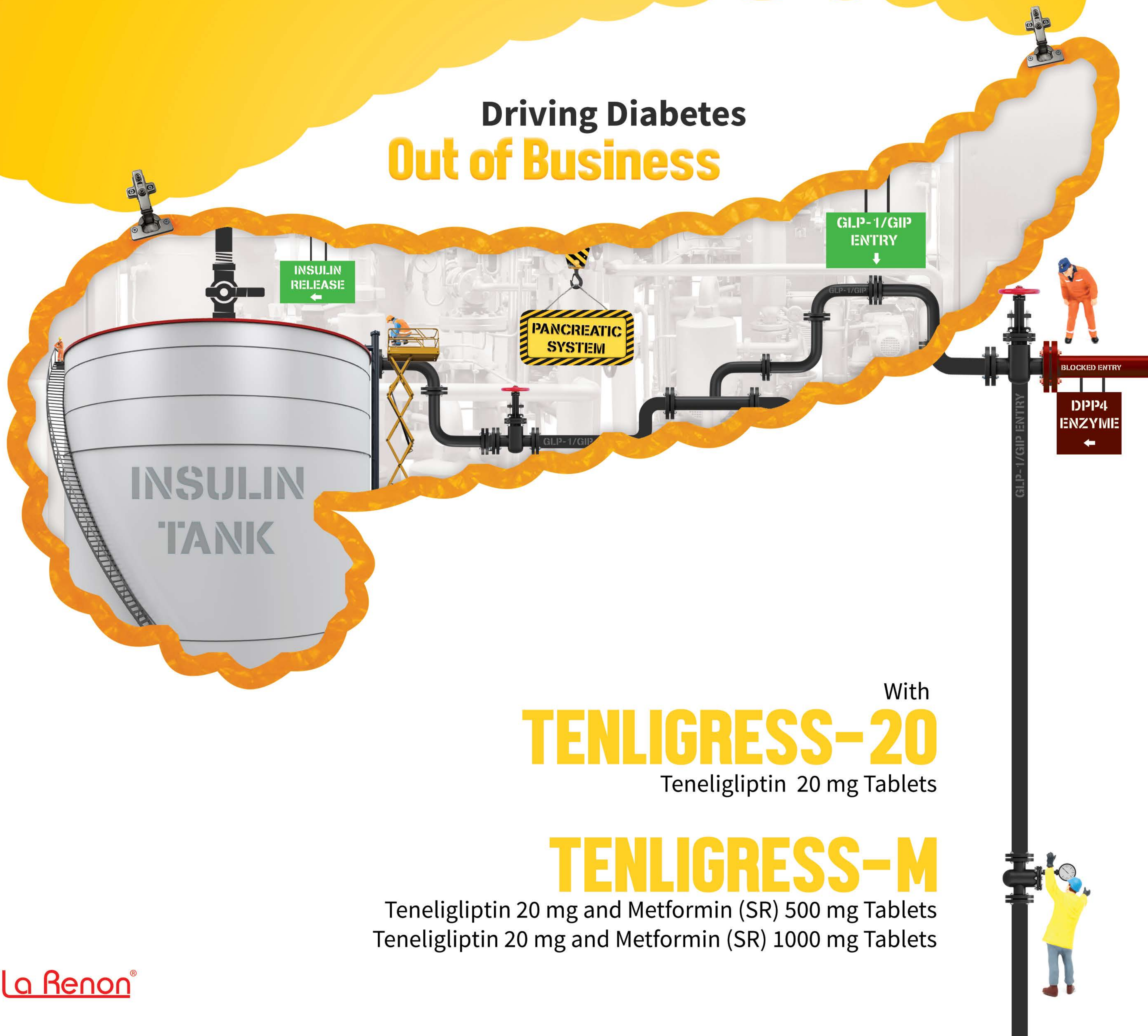


Driving Diabetes Out of Business



With
TENLIGRESS-20
Teneligliptin 20 mg Tablets

TENLIGRESS-M
Teneligliptin 20 mg and Metformin (SR) 500 mg Tablets
Teneligliptin 20 mg and Metformin (SR) 1000 mg Tablets

Clinical Studies: *Teneligliptin Monotherapy*

1 Efficacy, safety and dose-response relationship of teneligliptin in type 2 diabetes mellitus patients

- A randomized, double-blind, placebo-controlled, parallel-group study, on 324 Type 2 DM patients.
- Teneligliptin 10, 20 or 40 mg, or placebo, once daily given for 12 weeks.
- The primary endpoint was the change in hemoglobin HbA1c from baseline to week 12.
- All teneligliptin-treated groups showed significantly greater reductions in HbA1c and fasting plasma glucose (FPG) than did the placebo group.
- The differences between the teneligliptin 10, 20 or 40 mg groups and the placebo group for the change in HbA1c were -0.9%, -0.9% and -1.0%, respectively. The respective means for FPG were -17.8, -16.9 and -20 mg/dl.

Conclusion

Treatment with teneligliptin provided significant and clinically meaningful reductions in HbA1c and FPG across the dose range studied and was generally well tolerated in T2DM patients.

Reference: *Diabetes Obes Metab.* 2013 Sep;15(9):810-8.

2 Effects of once-daily teneligliptin on 24-h blood glucose control and safety in type 2 diabetes mellitus

- A randomized, double-blind, placebo-controlled, parallel-group study to assess blood glucose control over 24-h
- 99 patients were administered teneligliptin 10 or 20 mg or placebo before breakfast for 4 weeks
- Both teneligliptin-treated groups showed significantly smaller 2-h postprandial glucose (2-h PPG), 24-h mean glucose and fasting plasma glucose values than the placebo group.
- The differences between the teneligliptin 10 mg and placebo groups in changes in 2-h PPG after each meal were -50.7 ± 7.8 , -34.8 ± 9.2 and -37.5 ± 7.5 mg/dl at breakfast, lunch and dinner. The differences between teneligliptin 20 mg and placebo were -38.1 ± 7.8 , -28.6 ± 9.2 and -36.1 ± 7.5 mg/dl, respectively.
- Both doses of teneligliptin increased postprandial plasma active GLP-1 concentrations compared with placebo.

Conclusion

Once-daily teneligliptin improved blood glucose levels over 24 h without hypoglycaemia.

Reference: *Diabetes Obes Metab.* 2012 Nov;14(11):1040-6.

TENLIGRESS-20

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Combination Therapy:

Teneligliptin added to Metformin

■ A total of 204 patients with Type 2 Diabetes Mellitus (T2DM) with inadequate glycemic control

■ **Group A:** Teneligliptin + Metformin (N=136)

■ **Group B:** Placebo + Metformin (N=68)

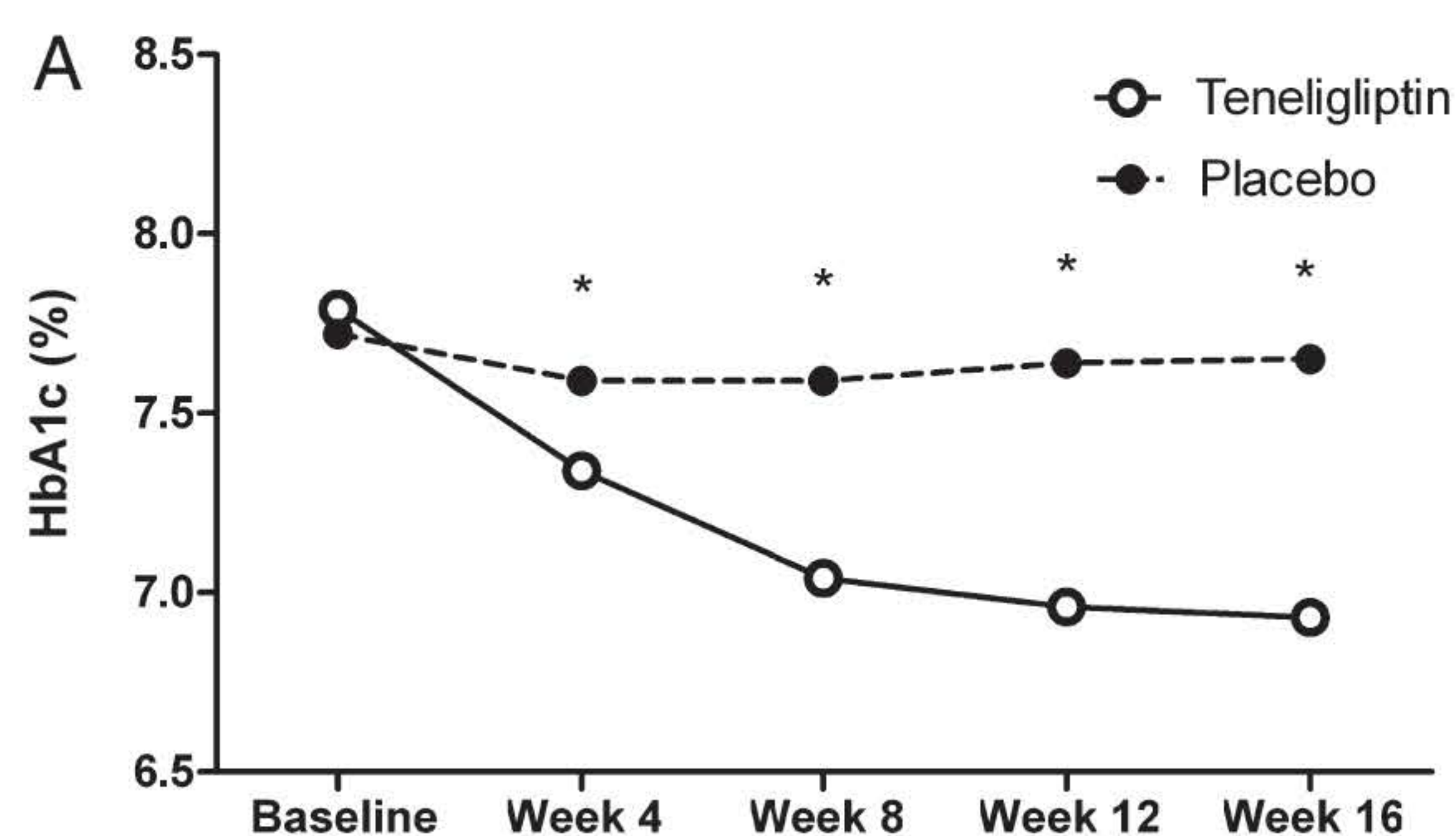
■ **Duration:** 16 weeks

■ Higher percentage of patients achieved goal (HbA1c <7%) in teneligliptin plus metformin group than placebo plus metformin group (64.71% vs 13.24%, respectively).

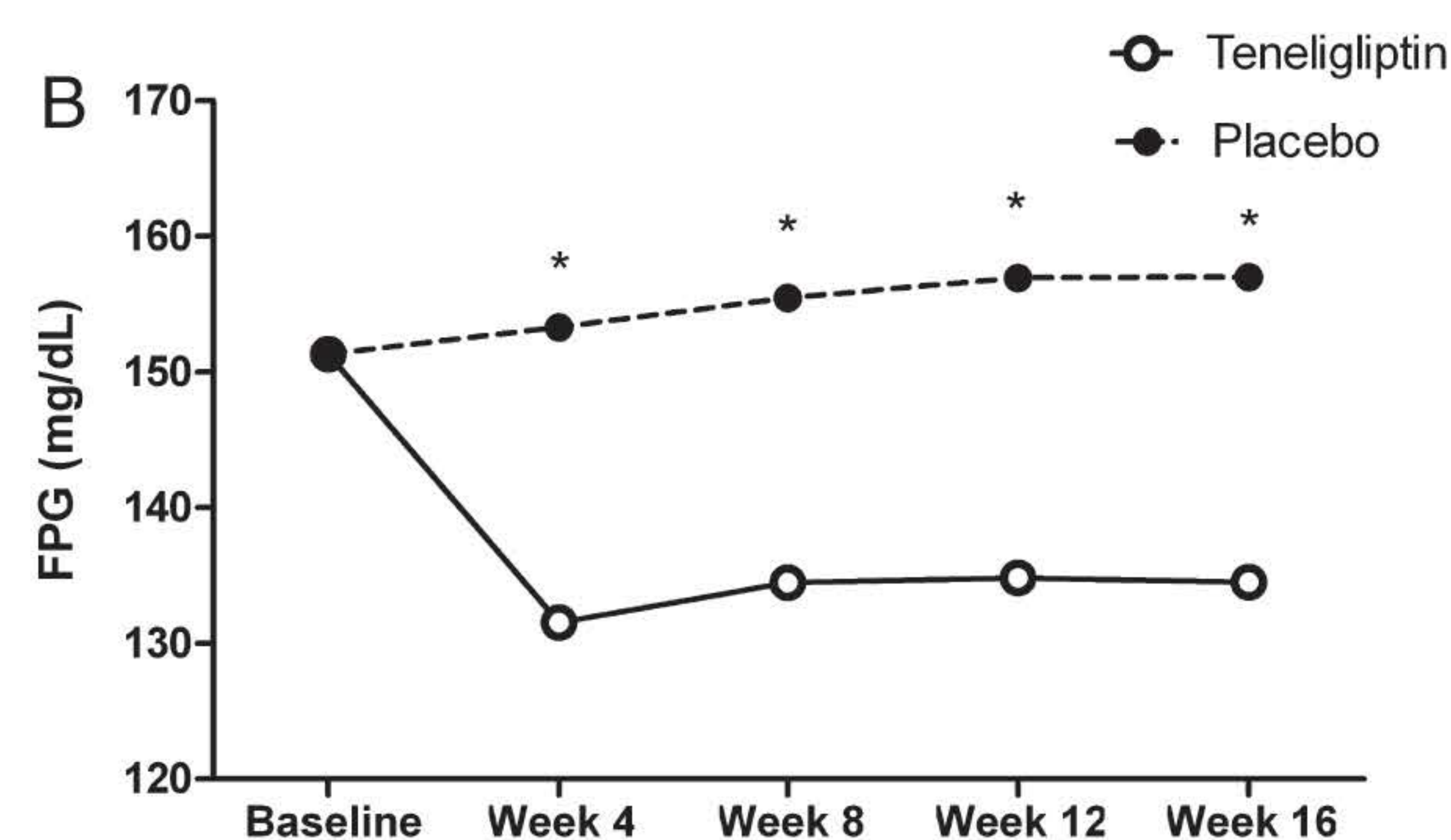
Greater increase in β -cell function and improvement in insulin resistance were noted in teneligliptin plus metformin group than placebo plus metformin group.

Glycemic Parameters at Final Visit (16-Week Study) for Teneligliptin (20 mg) in Add-on Combination Therapy with Metformin

Glycemic Parameters	Teneligliptin + Metformin	Placebo + Metformin
HbA1c (%)	(N=136)	(N=68)
Baseline	7.79	7.72
Change from baseline	-0.87	-0.06
Patients (%) achieving A1C < 7%	64.7	13.24
FPG (mg/dL)		
Baseline	151.17	151.17
Change from baseline	-16.79	5.8



Change in HbA1C in patients treated with teneligliptin plus metformin or placebo plus metformin



Change in FPG in patients treated with teneligliptin plus metformin or placebo plus metformin

Conclusion

The addition of teneligliptin to metformin treatment was effective in controlling blood glucose and well tolerated in patients with T2DM.

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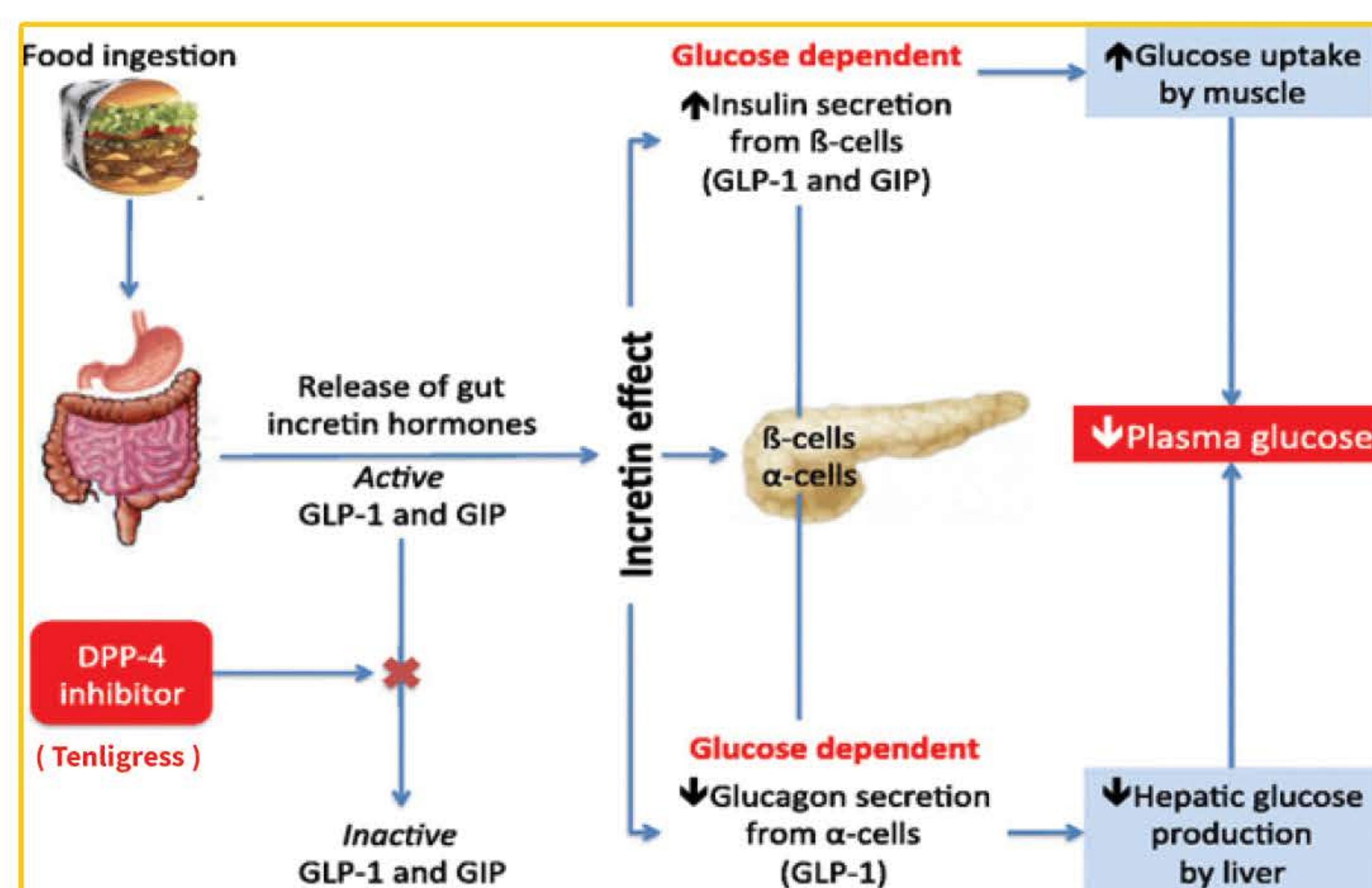
TENLIGRESS-M

PRODUCTION LINE

Description

Tenligress contains Teneligliptin 20 mg used for the treatment of type 2 diabetes mellitus. It belongs to the class of anti-diabetic drugs known as dipeptidyl peptidase-4 inhibitors or "gliptins". Tenligress-M is combination of Teneligliptin 20 mg and Metformin (SR) 500/1000 mg.

How Tenligress Works ?



Indication

Tenligress and Tenligress-M are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Important Features

- Higher potency compared to other DPP-4 Inhibitors ¹
- Long half-life (24.2 hrs) ²
- Safe in renal patients ³
- Safe in hepatic patients ⁴

Dosage

The usual adult dosage of Tenligress-20 and Tenligress-M is once daily. If efficacy is insufficient, the dose may be increased up to 40 mg daily while closely monitoring the clinical course.

Reference:

1. *Biochem Biophys Res Commun.* 2013 May 3;434(2):191-6
2. *Drugs Today (Barc).* 2013 Oct;49(10):615-29
3. *Int Urol Nephrol.* 2014 Feb;46(2):427-32.
4. *Clin Pharmacol Drug Dev.* 2014 Jul;3(4):290-6

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HELLO

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Mail me at _____