Type 2 Diabetes Mellitus

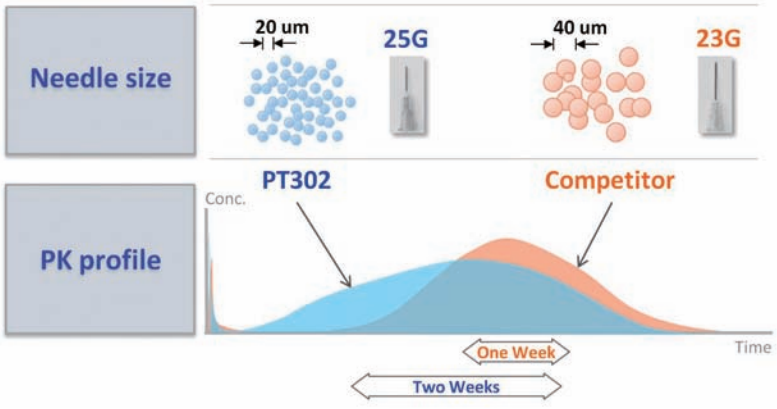
SR-Exenatide
Once Every Two Weeks (PT302) and
Once Monthly (PT302)
Injectable Forms of Exenatide
For the Treatment of Type 2 Diabetes

Background and Rationale

Exenatide is a 39-amino-acid synthetic peptide that mimics the hormone incretin and has biological properties similar to human glucagon-like peptide-1 (GLP-1), a regulator of glucose metabolism and insulin secretion.

The **SmartDepot™** technology to make sustained release formulation features a spray-drying process for the efficient encapsulation of drug into biodegradable carrier, and an ultrasonic nozzle for the homogeneity and size-control of the particle.

Long-acting exenatide manufactured by SmartDepot™ shows ideal PK profile with no lag phase via elaborate control of the initial release. It also has high bioavailability and good injectability with narrow needle size, raising an expectation of more effectiveness and convenience for patients.



Key Benefits & Features of SR-Exenatide

- ➜ SmartDepot™ is Peptron's proprietary ultrasonic spray drying technology for the preparation of sustained release injectable PLGA formulation of drugs.
- ➜ Once weekly and once every two weeks injectable forms of exenatide manufactured by SmartDepot™ technology are under phase II clinical trial. Phase I study on its once monthly form will commence next year.
- ➜ Exenatide by SmartDepot™ has ideal PK profile, outstanding injectability and high bioavailability.

Patent Status

Patent issued in Korea (KR0805208, 12-Feb-2008), Japan, China, India, Canada, Australia, Singapore, Vietnam, Russia, Malaysia, South Africa and Israel.
Patent pending in 6 countries: including US and Europe.

Market

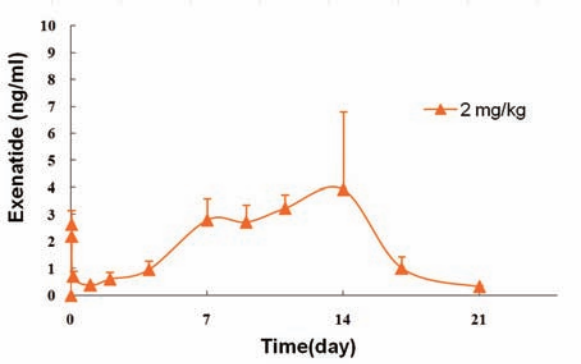
The 2012 estimates released by the International Diabetes Federation (IDF) show that 371 million people have diabetes and this will rise to 550 million by 2030. The global market for products in the management of diabetes currently stands at $39 billion and is on pace to grow to over $58 billion by 2018 (EvaluatePharma, 2012).

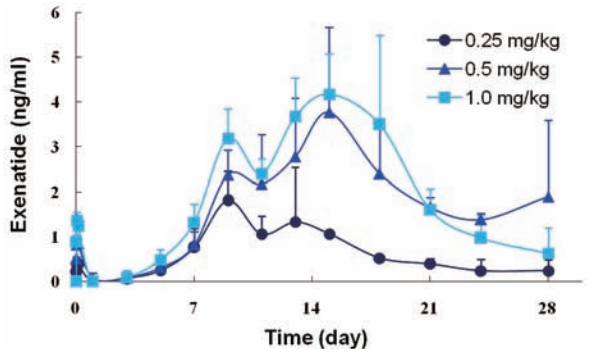
GLP-1 agonists class was expected to grow from $1.6bn to $5.3bn in seven major market sales over 2011–20, at a CAGR of 12.5% and the sales of Bydureon was forecasted to reach $1.4bn in 2020 (Datamonitor, 2012).

PT302 shows excellent efficacy and safety profile, so it has great sustaining potential to replace the Bydureon market.

PT302: Pharmacokinetic Profile

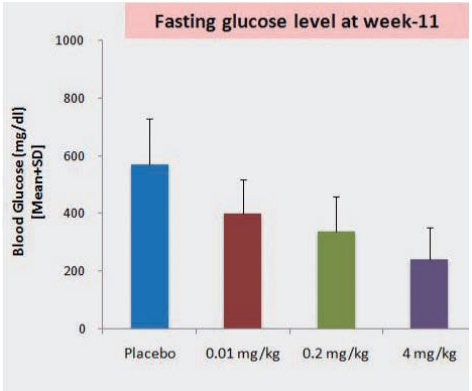
PK profiles of single-dose subcutaneous injection from rat (the figure on the left) and dog (the figure on the right) are well matched with human PK data.





PT302: Efficacy in Diabetic Animal Model

Repeated administration of PT302 showed anti-diabetic effects in diabetic model animals (db/db). After 11 weeks of treatment, fasting plasma glucose and HbA1c were reduced dose-dependently, whereas insulin was increased in proportion to the dose.



PT302	Difference compared to Placebo	
	HbA1C (%)	Insulin (ng/mL)
0.01 mg/kg	-0.28±1.70	1.59±2.78
0.2 mg/kg	-0.47±1.53	2.41±2.29
4 mg/kg	-2.00±1.35	5.92±4.72

PEPTRON: Type 2 Diabetes, May 2014

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