

The in Vitro and in Vivo Pharmacology of AB101, a Potential Once-Weekly Basal Subcutaneous Insulin

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Disclosures

All authors are employees and stock option holders of AntriaBio, Inc., the sponsor/company developing AB101

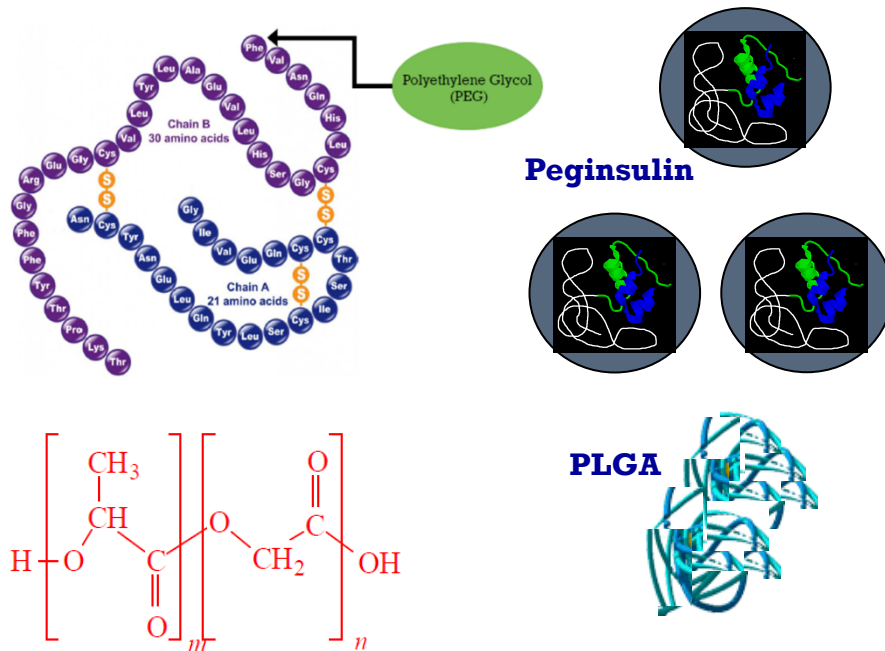
AB101 Addresses an Unmet Need for a Longer-Acting Basal Insulin

- **Barriers to adequate insulin utilization may include**
 - Insulin/needle-averse patients
 - Safety concerns, including hypoglycemia
 - Weight gain
- **A longer-acting basal insulin represents a convenient, effective, and safe treatment option**
 - AB101 is being developed as a once-weekly subcutaneous insulin injection
 - In contrast to currently available basal insulin analogs, AB101 requires no modification to the native recombinant insulin structure

AB101 is a Slow Release Microsphere Encapsulated Peg (5 kDa)-insulin

PEG+ native Insulin = soluble insulin

5 kDa PEG attached to the N-terminus of insulin's B-Chain using site-specific amine PEGylation.

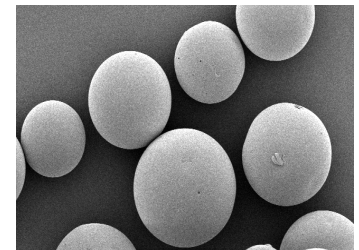
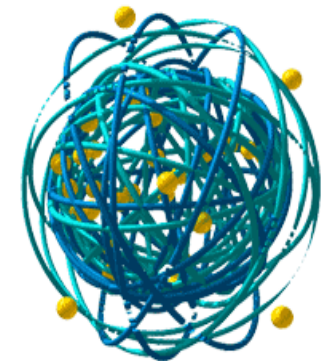


Poly(lactic-co-glycolic acid) (PLGA)

Peginsulin + PLGA = slow release microspheres

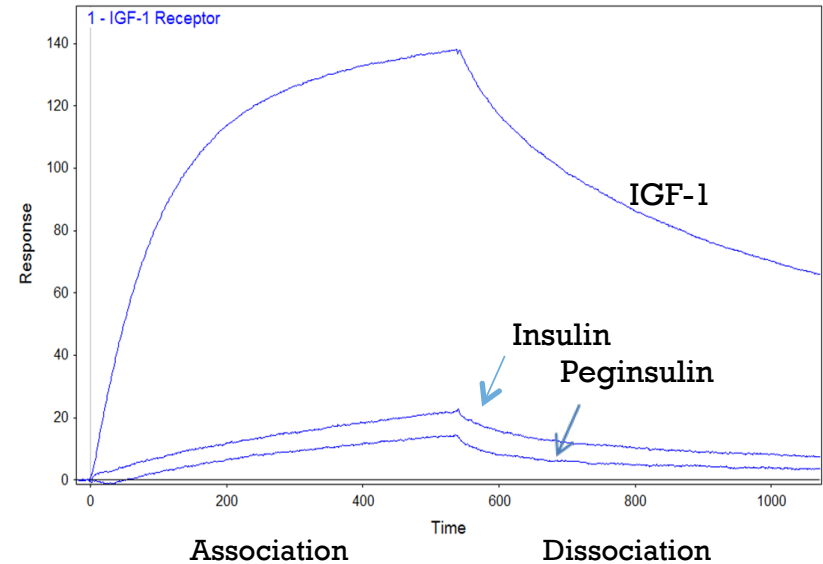
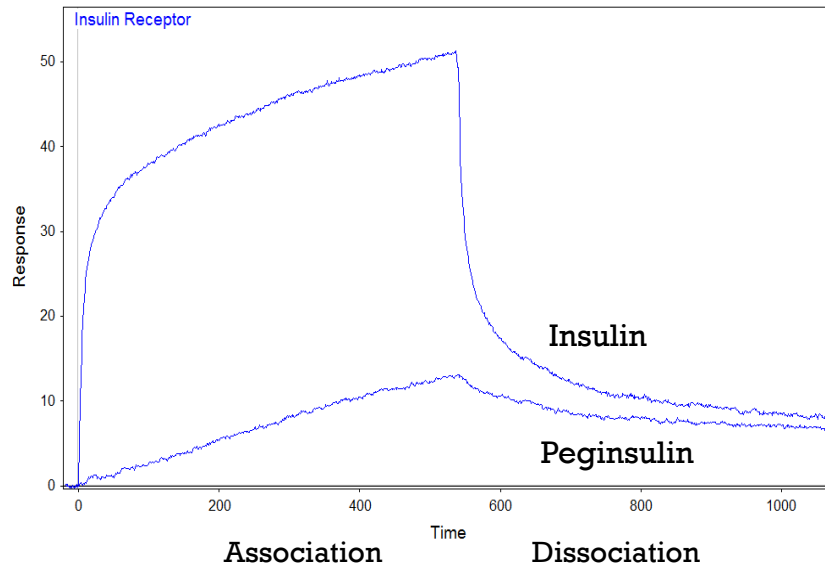
Emulsion Process

End Result: AB101
Drug dispersed evenly throughout microspheres



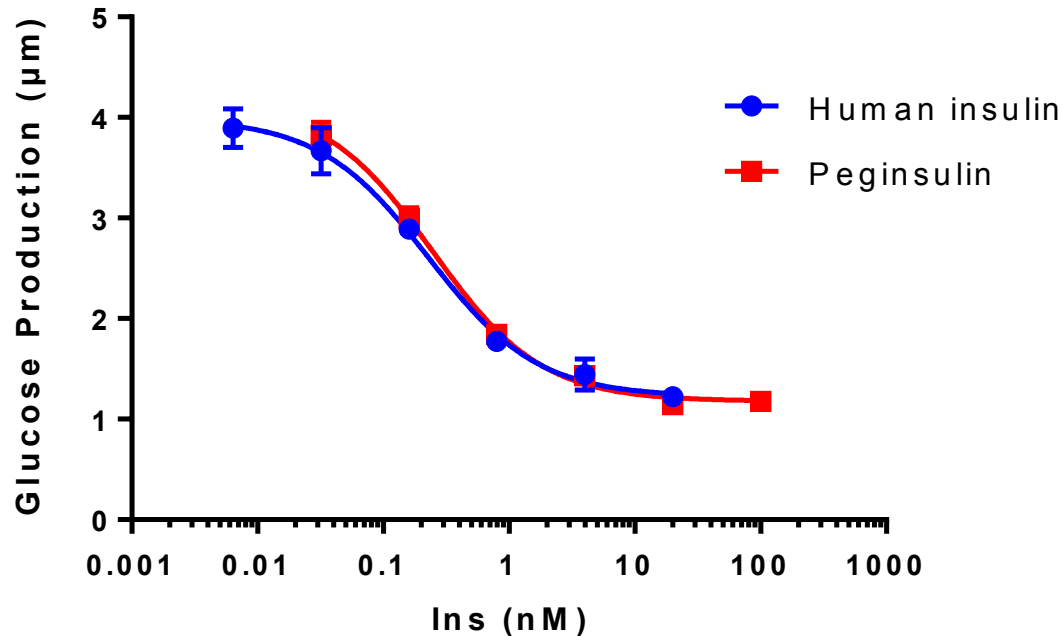
Peginsulin (Drug Substance) Exhibits Receptor Binding Kinetics Predictive of Desired Pharmacology with Low Mitogenic Potential

Insulin and IGF-1 receptor binding kinetics Using Surface Plasmon Resonance (Biacore 3000)



Peginsulin (Drug Substance) Exhibits in Vitro Pharmacology Comparable to Regular Insulin

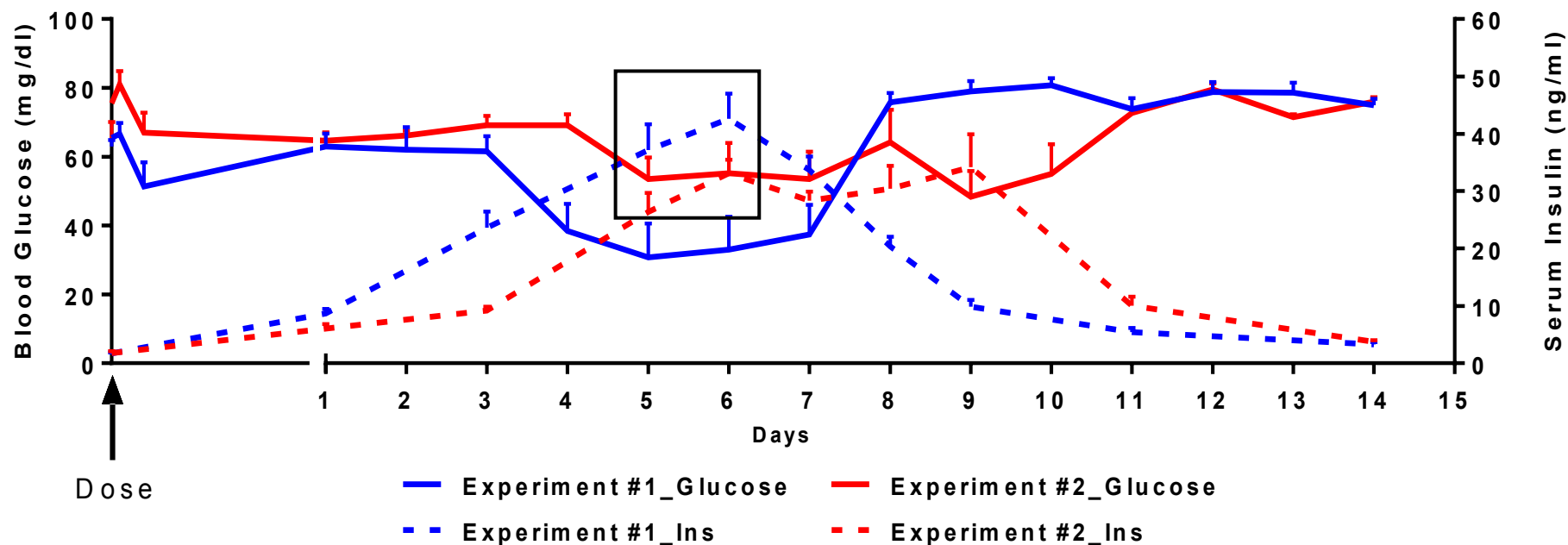
Glucose Production:
Cultured Rat Liver Cell Line (H4IIE)



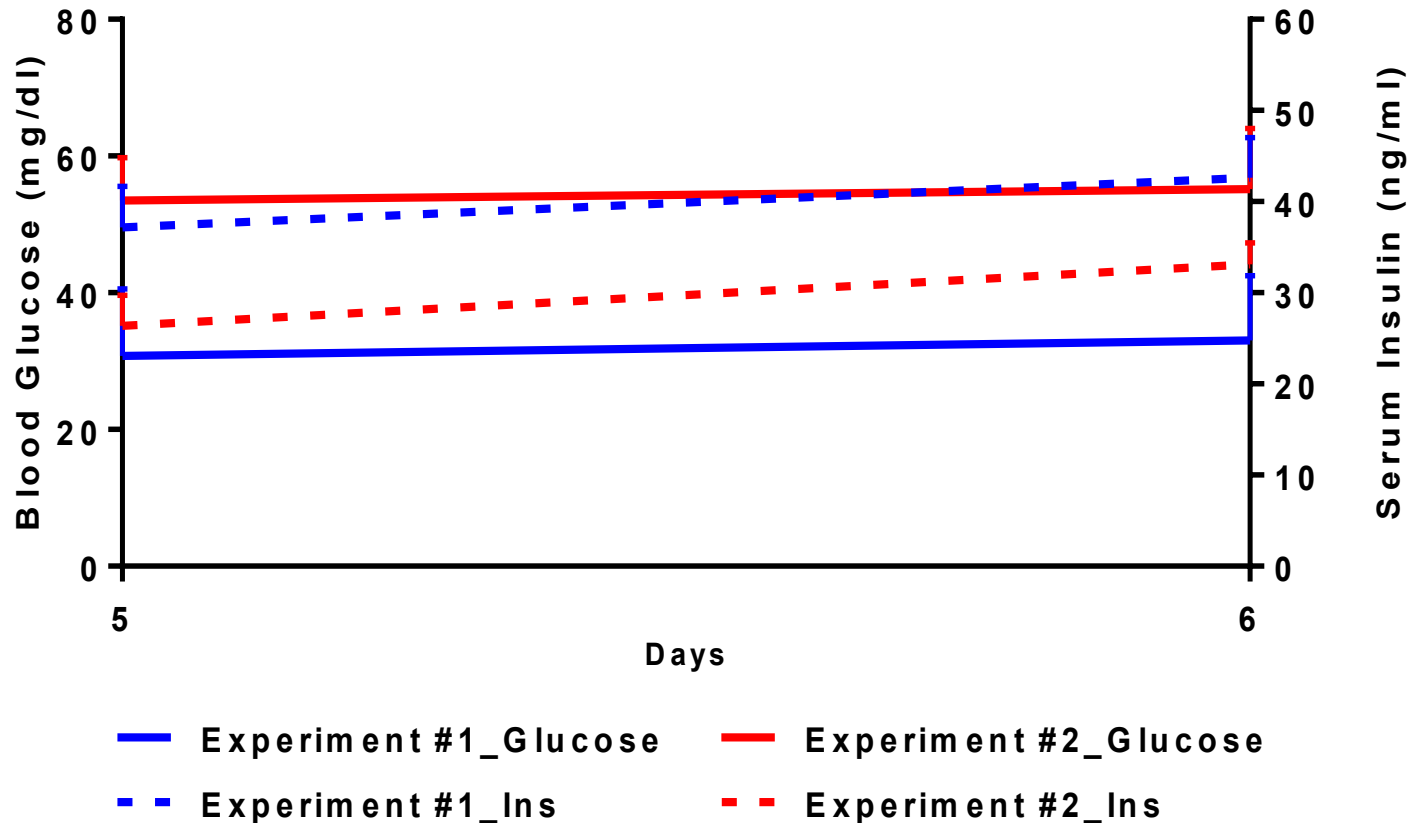
	Human insulin	Peginsulin
IC50 nM	0.2285	0.2445

AB101 Single Dose SC Administration to Normal Rats Results in Slow Onset, Sustained PK-PD

Serial Fasting Glucose and Insulin Measurements After a Single Dose of 37.5 mg/kg in Normal Sprague Dawley Rats (N=6)

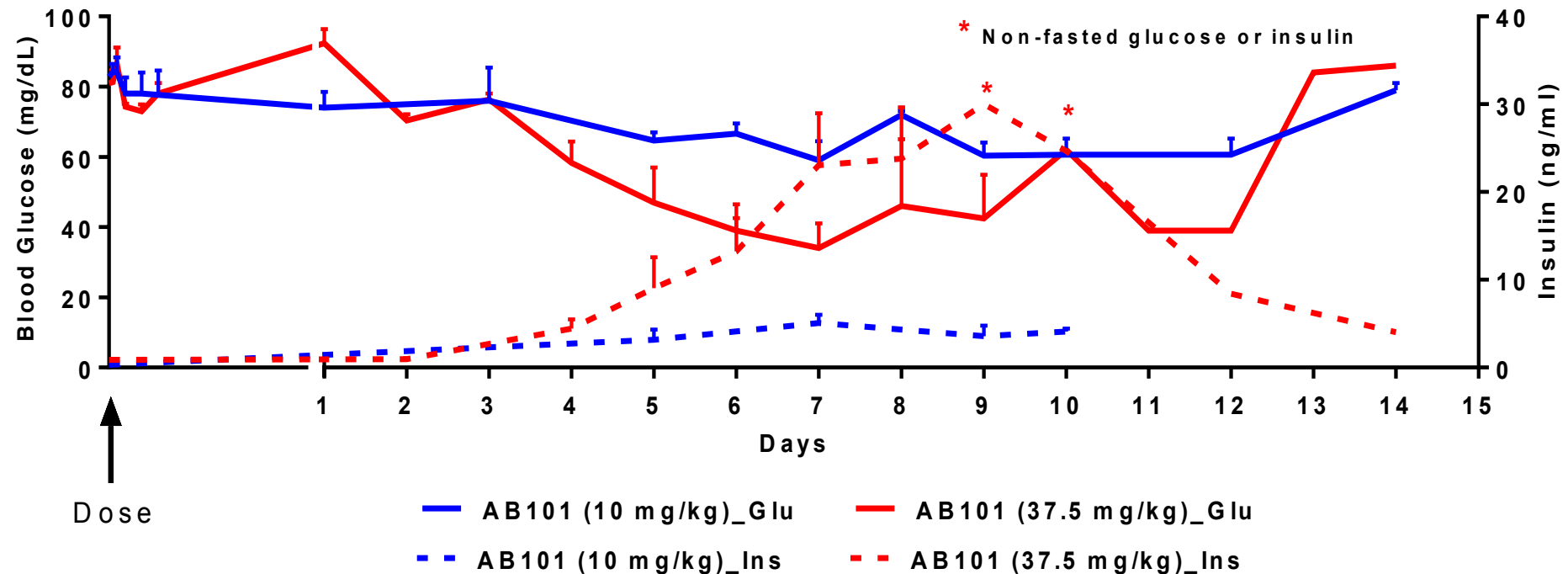


AB101 Produces Peakless Pharmacology Over the Time-Action Duration Associated with Currently Available Basal Insulins (24h)



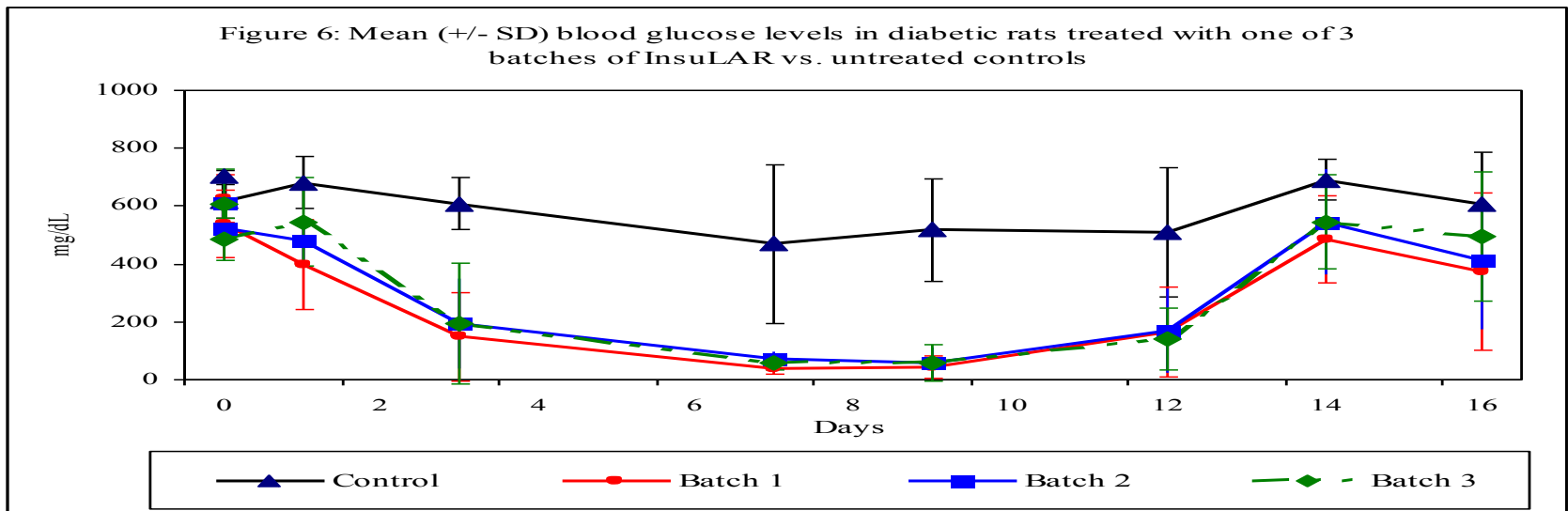
AB101 Single Dose SC Administration to Normal Dogs Results in Slow Onset, Sustained PK-PD

Serial Fasting Glucose and Insulin Measurements After a Single Dose in Normal Beagle Dogs (N=3/dose group)



Pharmacology Summary

- Potency and activity are comparable to recombinant human insulin
- Slow onset, sustained insulin increases and corresponding glucose reductions over the course of ~1 week in 2 species (rats and dogs)
- No acute insulin release or glucose reduction observed
- Data support weekly dosing as a basal insulin
- To our knowledge, only non-analog (native human insulin) to have an extended duration of action
- Similar results previously reported in a STZ-induced diabetes rat model



How Does this Translate to the Treatment of Diabetes?

- Inter-species homology of insulin/receptor predicts insulin activity in humans
- No expected differences in activity in diabetes compared to non-diabetes (time-action profile or pharmacodynamics)
- Pharmacology in dogs observed at predicted doses based on:
 - Typical daily insulin needs supplied over one week
 - Allometric predictions
 - Adjustments for minor differences in receptor potency/activity
- Efficacious doses in dogs can be readily translated to human clinically relevant doses
- Projected human doses can be administered via acceptable volumes and needle gauge
- IND-enabling work is ongoing and an IND application for clinical trials is forthcoming

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