358
First-in-Class Treatment for Hyperinsulinemic Hypoglycemia

January 31, 2017

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Patients Need 358 to Succeed!

Jim R. Neal, Chief Executive Officer and Member of the Board of Directors

Highlights from Proof-of-Concept 358 Studies

- Proof-of-concept established in 14 CHI and 13 PBS patients
- 358 treatment clearly increases glucose levels and reduces hypoglycemia
- Other met objectives enable initiation of multi-dose studies
- Multi-dose protocol approved in UK for CHI patients aged 2 and older

CHI Disease Burden is Significant in Neonatal and Pediatric Population

Disease Burden

- Major emotional burden on families
- Parents in constant fear of hypoglycemic attacks
  - Constant monitoring of blood glucose
  - Irreversible brain damage and permanent developmental issues may result

Economic Burden

- Medical Treatment: **$150,000 / year**
- Cost of Nursing Care: **$200,000 / year**
- In event of pancreatectomy: **$1,000,000**
  - Type 1 diabetics post-pancreatectomy

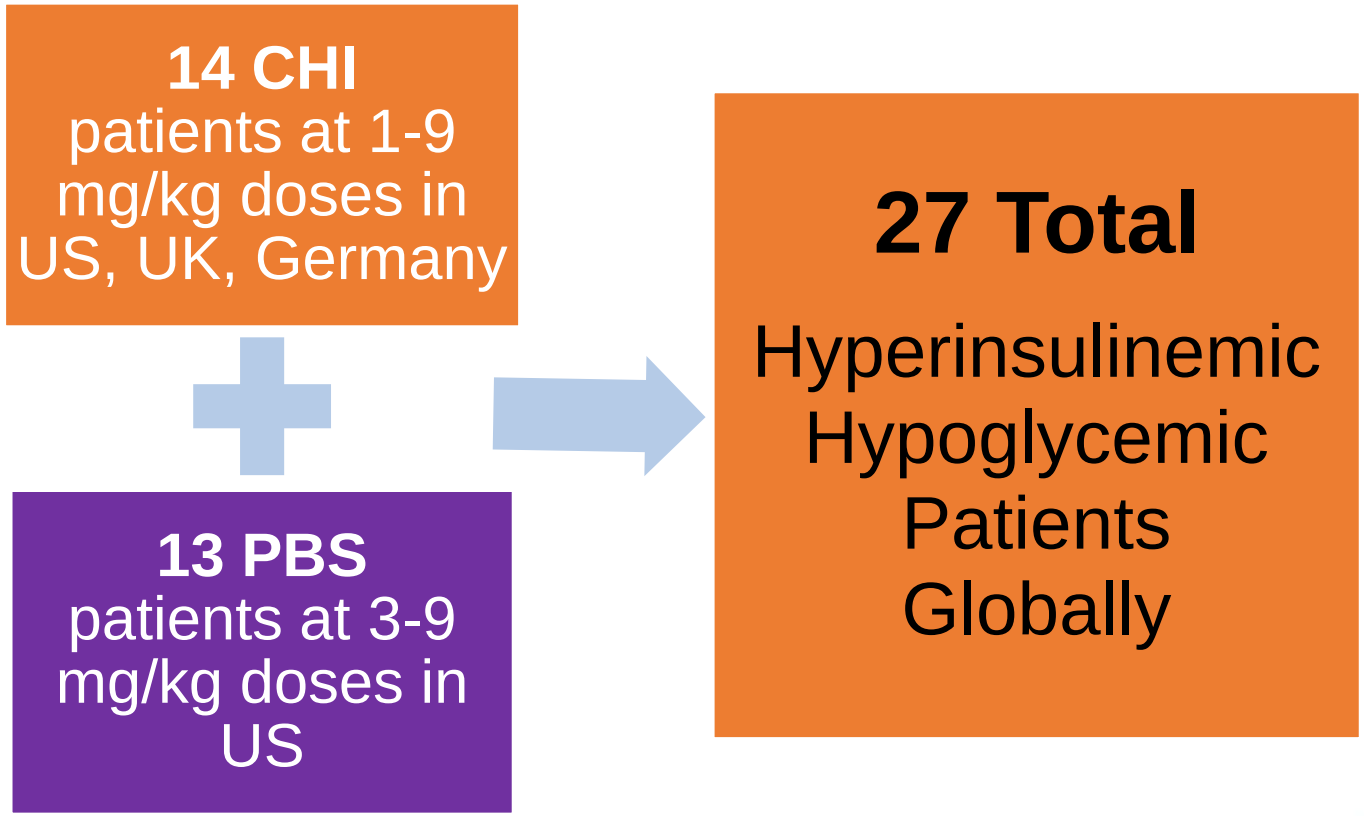
Healthcare System Burden

- Patients may require medical treatment for many years
- Significant costs incurred over patient's lifetime
- Long-term care requirements: epilepsy, permanent brain damage
- CHI centers of excellence: 5 in U.S., 8 outside U.S.

Source: Arnoux, Jean-Baptiste. Congenital Hyperinsulinism: Current Trends in Diagnosis and Therapy. Orphanet Journal of Rare Diseases. 10/03/2011. http://www.ojrd.com/content/6/1/63 McLaughlin, Tracey.

The Global Phase 2 Patient Data Set

Triple the N described in mid-September and well-distributed across both indications and dose levels



Low Blood Sugar is the Major Problem *and* Unmet Need in these Hyperinsulinemic Disorders

- Hypoglycemia is commonly defined as glucose values <70 mg/dL

- Glucose levels were monitored, often in parallel, by:
  - bedside glucometer
  - serum laboratory
  - Continuous Glucose Monitoring (CGM)

By CGM:

- CGM durations of blood glucose below 70 mg/dL for ≥2 hr/day is abnormal[1]
- An improvement of ~50% is considered "clinically meaningful"[2]

1. Accuracy of Continuous Glucose Monitoring Measurements in Normo-Glycemic Individuals. PLOS One October 7, 1-13, 2015. JDRF, Diabetes Care 33:1297, 2010. Brynes AE, Brit JAkintola, A.A. Accuracy of Continuous Glucose Monitoring Measurements Nutr 93:179, 2005

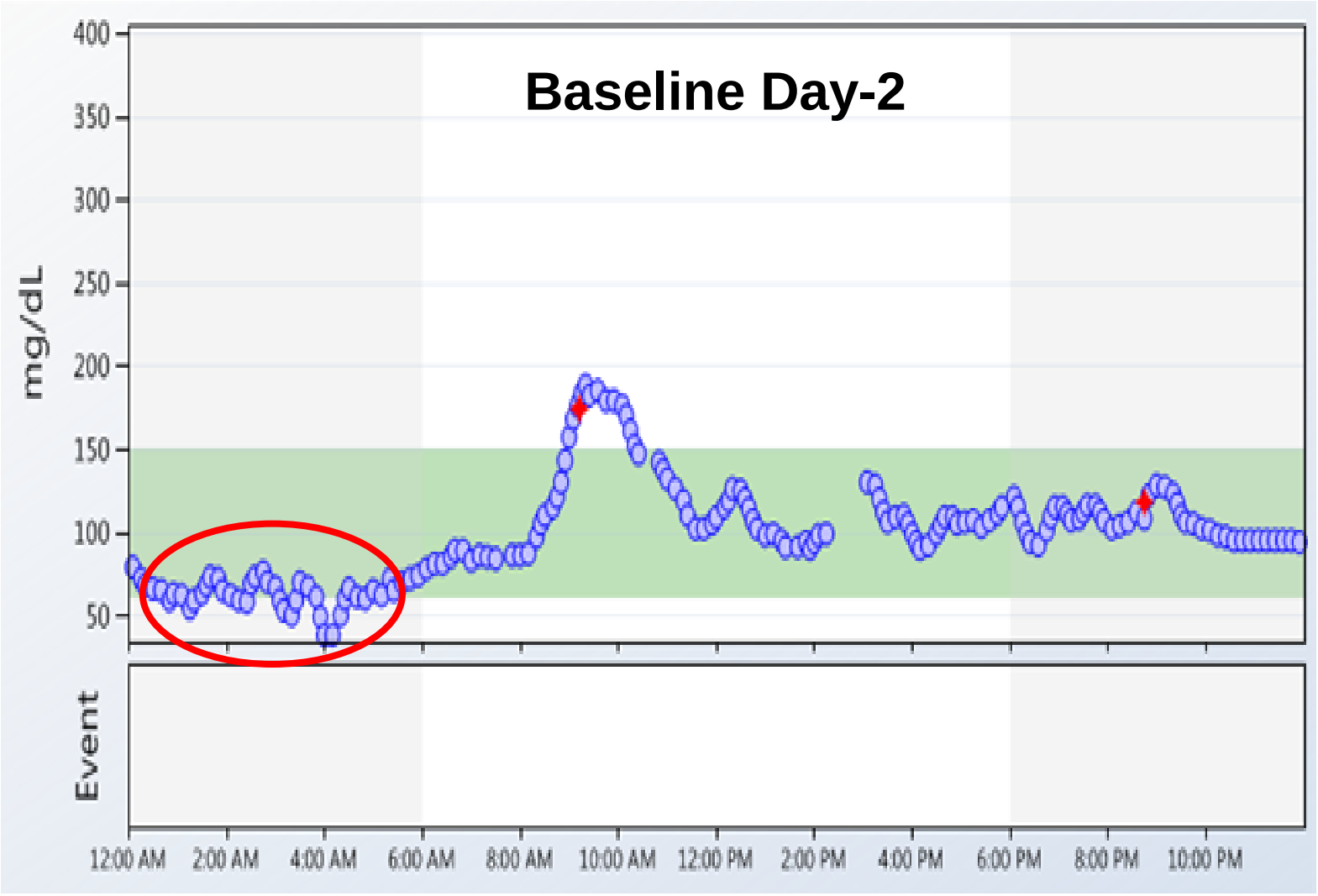
2. CHI Key Opinion Leaders and Principal Investigators

CHI

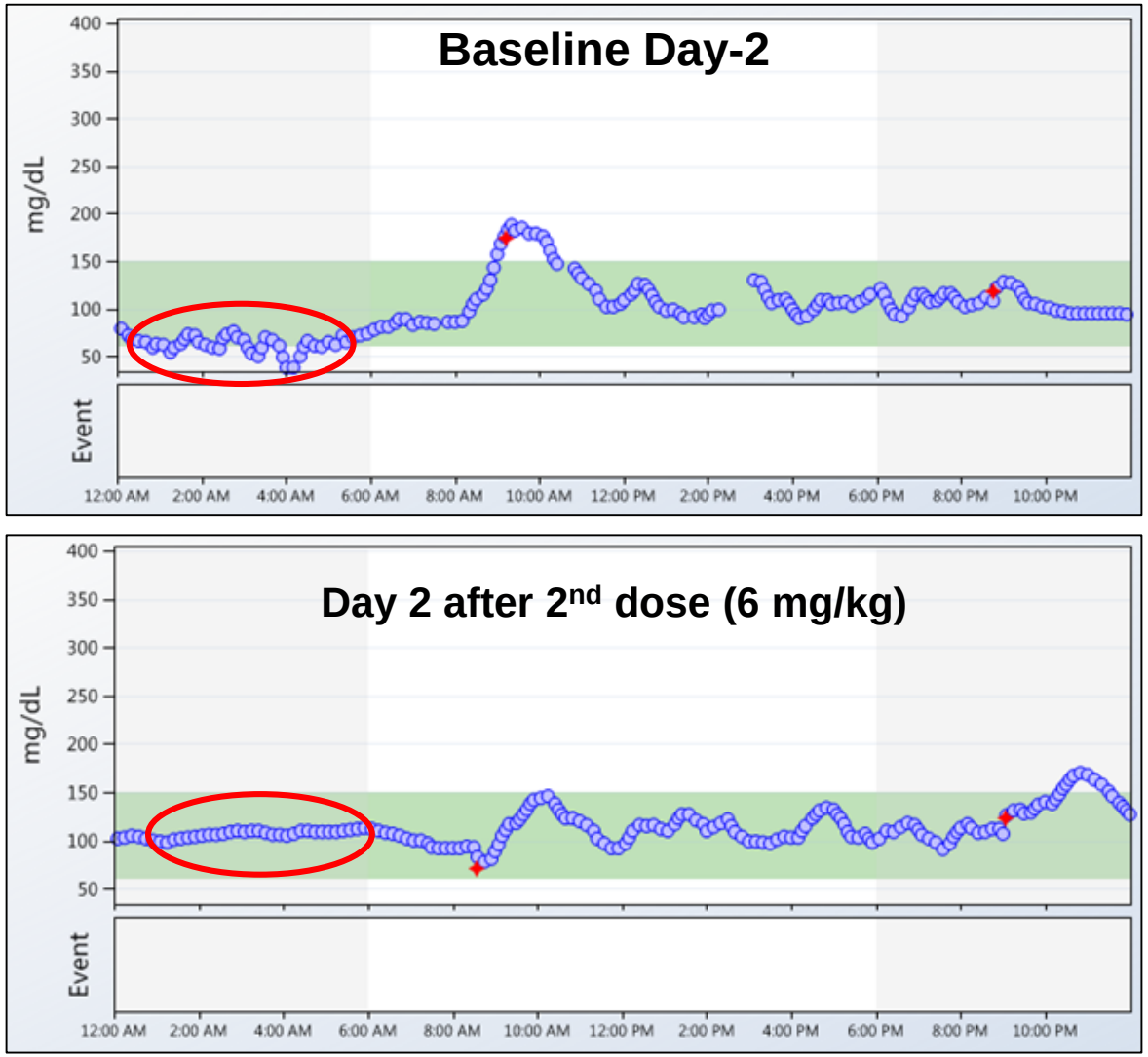
Enrolled Adolescent & Adult Patients were Consistent with CHI Disease Population

- **6 Females + 8 Males**
- **Aged 12-37**
- **CHI mutation profile consistent with disease population**
  - Majority K-ATP mutations
- **Washed out of pre-existing drugs (e.g. diazoxide, octreotide) and studied in-unit for 4 baseline days and 12 days post-358**

Nighttime hypoglycemia is common in CHI. For example, the 24hr CGM profile of a 12 year-old CHI Patient



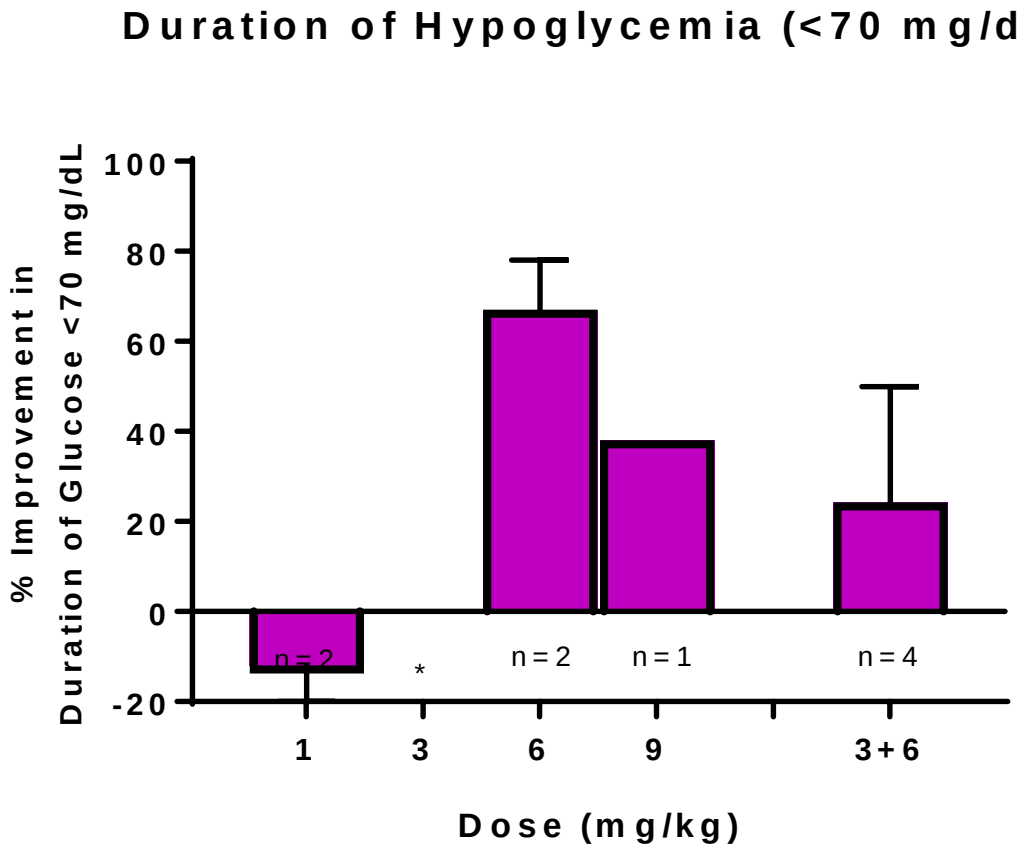
Normalization of Glycemia in the 12 year-old CHI Patient Following 358 dosing



★ = calibration

358 Reduced Duration of Hypoglycemia by 25% - 70%

9/14 Patients with baseline durations of 24hr CGM <70 mg/dL for ≥120 min Change in Post-358 Days 2,4,6 vs Non-challenge Baseline Days -2 & -1



* Excluded from analysis as they did not meet this CGM criteria

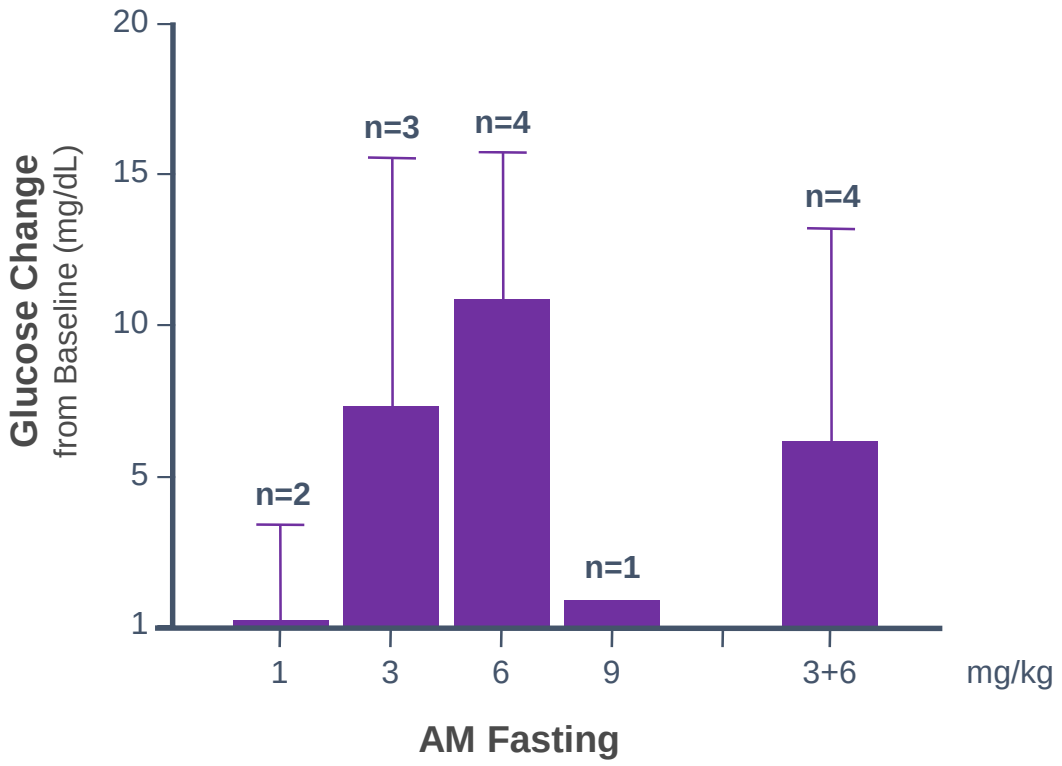
Improvement of the AM Fasting Glucose Level is a Goal in CHI Management

- Overnight fasting glucose measurements are a common laboratory test
- Hyperinsulinemic patients tend to have low fasting blood glucose values

358 Treatment Increased AM Fasting Glucose Levels in CHI Patients

Change Post-358 on Days 2,4,6 vs Baseline Days -2 & -1

(mean bedside glucose, all patients)



Completed CHI Studies Support Advancement to Repeat Dose Protocol Phase

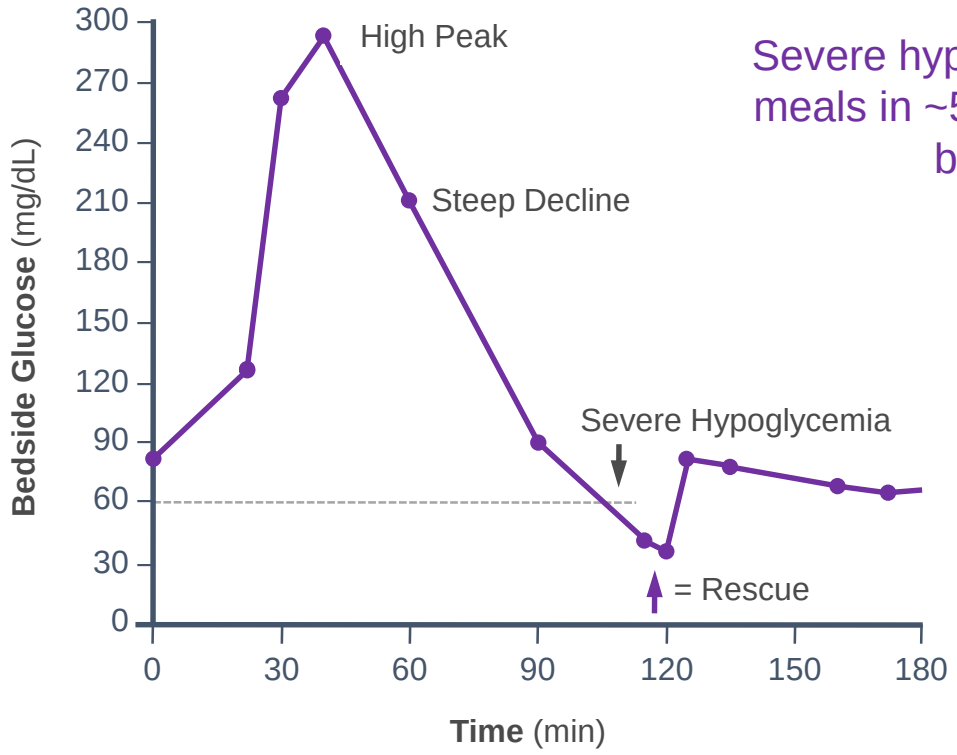
- **Single-dose data in CHI patients established a beneficial dose range with predictable pharmacokinetics and acceptable safety**

- **Program is ready for advancement to a repeat-dose phase**
  - Experience with relevant endpoints
  - Protocol involving 3-month dosing of CHI patients aged 2 and up is completing all regulatory approvals in UK

PBS

Post-meal Glycemic Crashes are the Major Issue in Hyperinsulinemic PBS Patients

Typical Profile of Blood Glucose vs Time Post-Meal

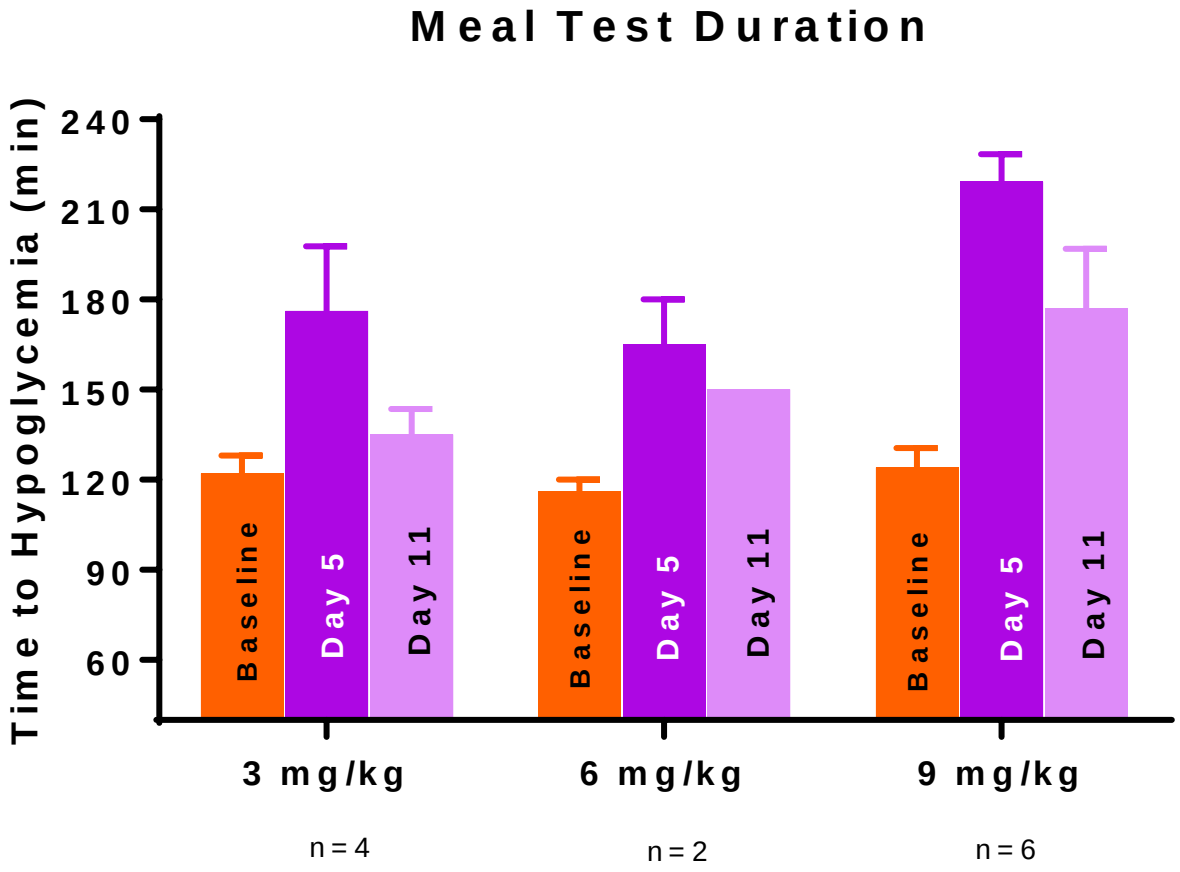


Severe hypoglycemic risk following meals in ~5% of Roux-en-Y gastric bypass patients

Enrolled Patients were Representative of Typical PBS Patients

- 12 Females + 1 Male
- Aged 42-68
- Body weight 62-112 kg
- Washed out of pre-existing drugs (e.g. diazoxide, octreotide, acarbose) and studied in-unit for 4 baseline days and 12 days post-358

358 Significantly Improves Glucose Control in PBS Patient Meal-Challenge Tests



Mean ± SEM

Duration of Meal Tolerance and Magnitude of Improvement Increase with Increasing Dose

Nighttime Hypoglycemia is Evident in PBS, too, and is Meaningfully Improved in the Majority Following 358

9 mg/kg Cohort, 4 baseline days vs 4 post-358 Days 3-6

	Avg Glucose (mg/dL)	
Patient #	Baseline	Post-X358
1002	87	82
1003	68	79
3005	71	81
4002	64	76
4003	61	73
4004	68	93

Also, the duration of hypoglycemia at nighttime was reduced ~50% in all these patients

Completion of Single-dose Phase Enables Further Development

- **Single-dose data in PBS patients established a broad active dose range. Pharmacokinetics mimic healthy volunteers and there were no drug-related safety issues**
- **Program is ready for advancement to a repeat-dose phase**
  - Experience with relevant endpoints
- **Next step: Initiating repeat-dose protocol under US IND**

Achievement of 358 Proof-of-Concept in CHI & PBS

√ **Administration of 358 resulted in clinically meaningful improvement in glucose levels:**

- improved AM fasting glucose levels
- reduced daily periods of hypoglycemia
- improved time to hypoglycemia in meal tests in PBS
- correction of nighttime hypoglycemia

√ **The post-358 improvement occurs in a majority of the patients treated at 3-9 mg/kg doses**

√ **The duration of action ranged 1-2 weeks**

√ **Additional serum markers in PBS & CHI affirm attenuated insulin action following 358 treatment**

Phase 2 Safety Summary

Safety Findings Support Further Clinical Development

Across all Phase 1 and Phase 2 Trials 358 was determined to be generally safe and well-tolerated

In the Phase 1 healthy volunteer studies of ascending single doses of 358 (N=22)

- No deaths and no serious adverse events
- No clear positive anti-drug antibody titers seen
- No clinically significant changes in laboratory parameters, ECGs, physical examinations or vital signs.

In the CHI and PBS studies (N=27)

- All patients completed studies. No deaths. 2 serious adverse events unrelated to study drug. 1 serious adverse event related to study drug but consistent with pre-trial history.
- No clear positive anti-drug antibody titers seen
- No clinically significant changes in laboratory parameters, ECGs, physical examinations or vital signs.

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Thank You