



**ADOCIA**

innovative medicine  
for everyone, everywhere



## Advancing Mealtime Insulin Therapy: Phase 3 Results for BC Lispro in Type 2 Diabetes

Virtual KOL Event  
June 16, 2026



# Agenda

**10:00 am** Welcome and Opening Remarks

*Steve Daly,  
CEO, TIXiMED*

**10:05 am** Introduction to Adocia

*Olivier Soula,  
Adocia CEO and cofounder*

**10:10 am** The BioChaperone® Technology Platform

*You-Ping Chan,  
Adocia R&D Director*

**10:15 am** Current Mealtime Insulin Treatment Paradigm for Diabetes and Limitations

*Dr Tim Heise,  
Profil*

**10:25 am** Ultra-Rapid Insulin BC Lispro Phase 3 Data in Type 2 Diabetes

*Dr Tim Heise,  
Profil*

**10:40 am** Next Steps and Potential Value Creation

*Olivier Soula,  
Adocia CEO and cofounder*

**10:45 am** Q&A



# Speakers



**Tim Heise, MD**

Lead Scientist, Chairman of the Board of Directors and co-founder of the private research institute Profil in Neuss, Germany. Profil has gained an international reputation for performing early-phase studies, in particular glucose clamp studies, investigating experimental diabetes treatments and medical devices. Dr. Heise has led numerous studies on the pharmacology of novel anti-diabetic agents and insulins. Before establishing Profil, Dr. Heise worked for more than 7 years at the Clinic for Nutrition and Metabolic Diseases at the Heinrich-Heine-University Düsseldorf (Head Prof Michael Berger). During this time, he was responsible for the diabetes and obesity outpatient clinics and took care of patients in structured teaching and treatment programs for type 1 and type 2 diabetes. Dr. Heise has published more than 250 scientific papers and reviews. He is a member of the Editorial Boards of Diabetes, Obesity and Metabolism, and Diabetes Technology & Therapeutics.

**Steve Daly**

CEO at TIXiMED, a clinical stage company developing a first in class oral disease modifying therapy for T1D.

Over 30 years of pharma and biotech experience, including, 21 years focused on diabetes and metabolism, spanning commercial, operational and C-suite roles at Amylin Pharmaceuticals and Adocia, where he served six years as US General Manager during the development of BC lispro.



**Olivier Soula**  
PhD, MBA,  
**ADOCIA**  
CEO, Co-founder

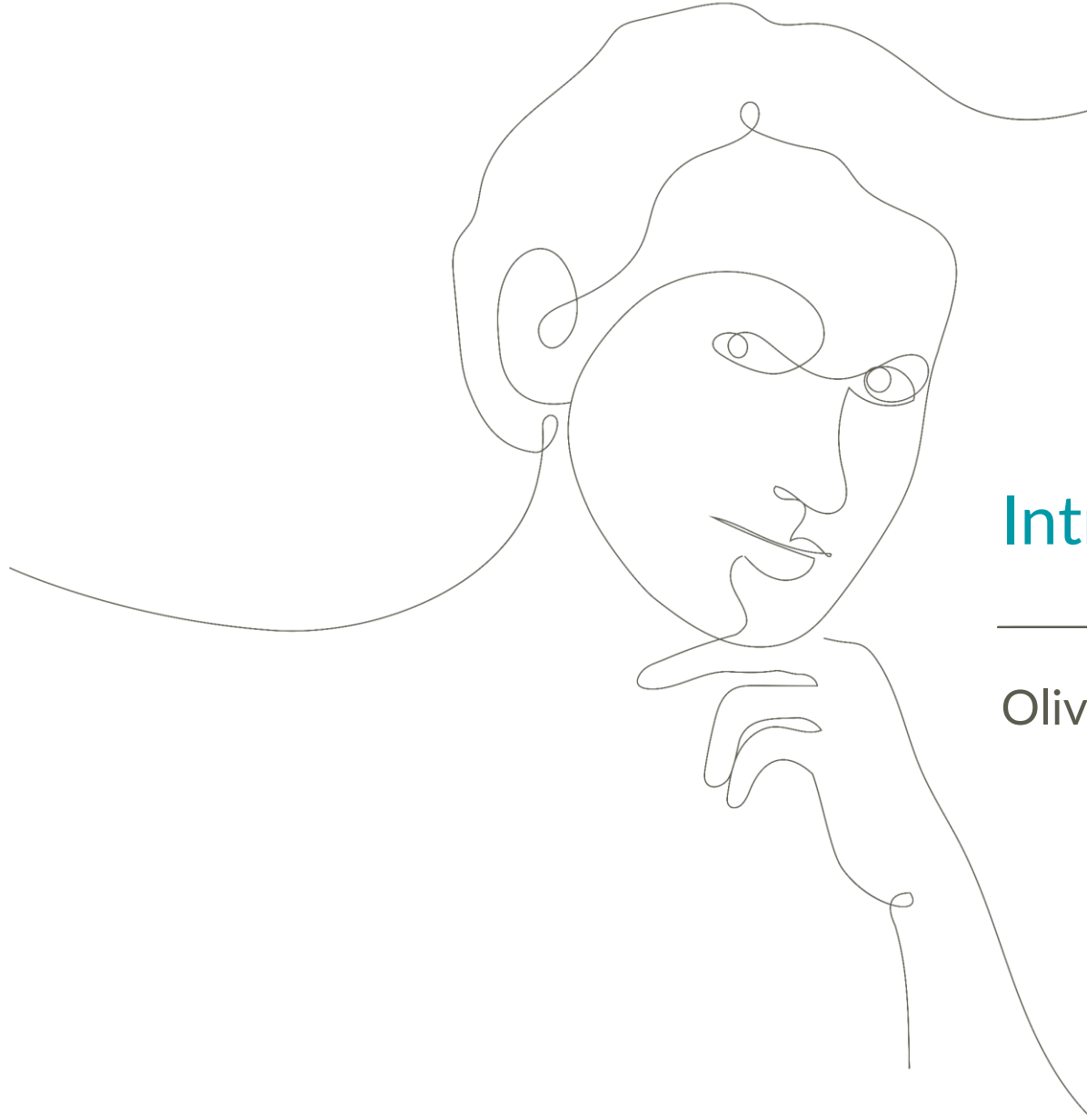


**You Ping Chan**  
PhD, MBA  
**ADOCIA**  
R&D Director



**Martin Gaudier**  
PhD  
**ADOCIA**  
R&D Director





# Introduction to Adocia

---

Olivier Soula



# Diabetes and Obesity: significant unmet needs in peptide-based therapies

## THE METABOLIC DISEASES MARKET



Diabetes: 589 million<sup>1</sup>



Obesity: 1 billion<sup>2</sup>

## THE ROOT CAUSE

Peptides dysregulation



Insulin  
Amylin  
GLP-1  
Glucagon

...

## CURRENT SOLUTIONS

Peptide  
Replacement Therapies

✓ Efficient  
✓ Safe

✗ Delivery  
Challenges

## CURRENT CHALLENGES

Ensure the long-term use of  
these treatments

Ensure mass distribution of  
obesity drugs

## OUR SOLUTION

ADOCIA



Expert in innovative  
peptide delivery

## STRATEGIC IMPACT



Close the gap between  
healthspan and lifespan

1. IDF Atlas, 11th Edition, 2025  
2. World obesity atlas 2025



# From a mature market with few players to a fast growing market with many newcomers

## Insulin Mature Market



- First porcine insulin: 1922
- Faster, longer and combination of insulins
- 80 million insulin users<sup>1</sup>
- \$20 B market size in 2024<sup>2</sup>
- 3 key players, Lilly, Novo, Sanofi



## GLP-1, Amylin... Fast Growing Market



- First GLP-1 and amylin: 2005
- Longer, oral and combinations of peptides
- 1 billion obese people in the world in 2025<sup>3</sup>
- \$150 B expected in 2030<sup>4</sup>
- 2 leaders Novo, Lilly and more than 30 players

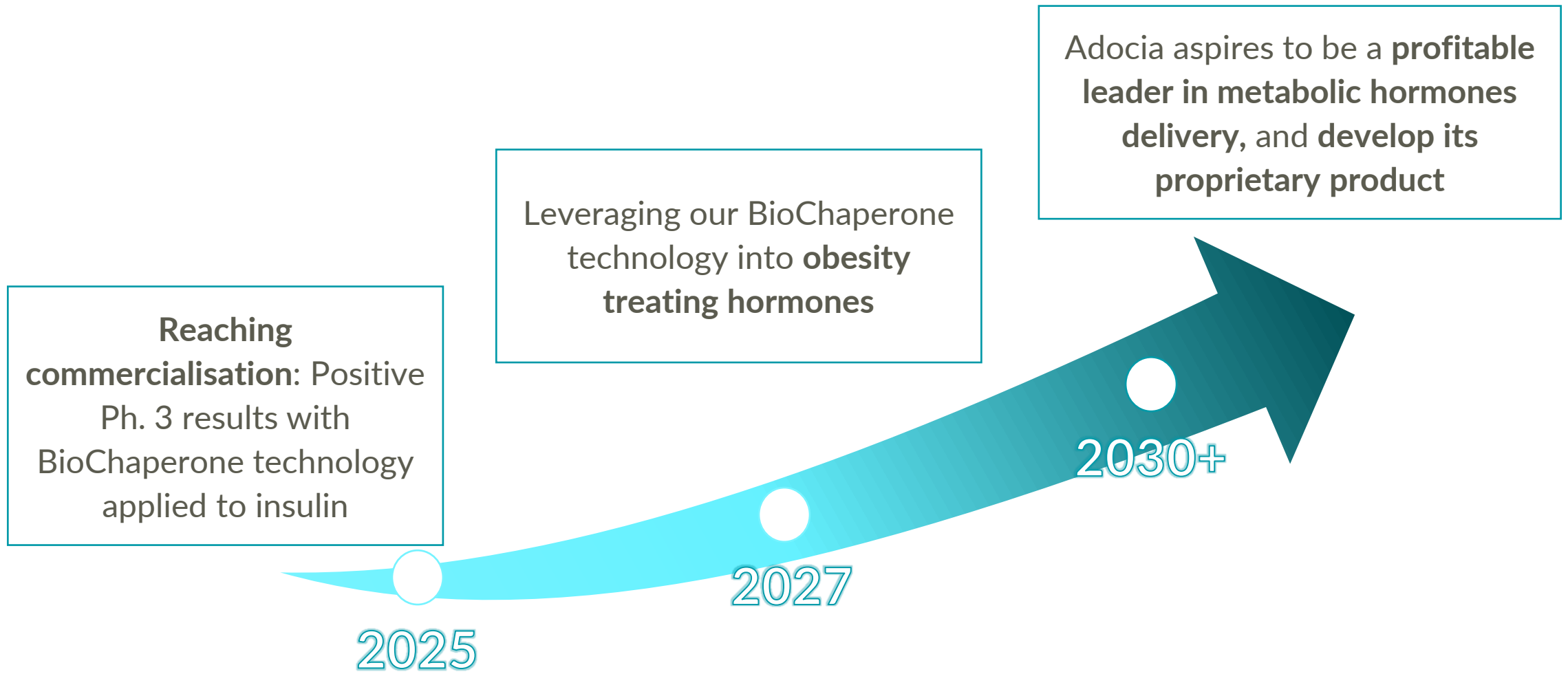


Capitalizing on its insulin track record, Adocia is best positioned to innovate in the delivery of peptides of the metabolism

1. More than 150 million people worldwide depend on insulin therapy for health. ([BMJ Open Diabetes Research & Care](#), 2021); Only 50% of people who need insulin have access to it. ([Doctors Without Borders](#), 2024) 2. Grand View Research Insulin Market (2025 - 2030) 3. World obesity atlas 2025 4. Grand View Research GLP-1 Receptor Agonist Market (2025 - 2030)



# Building leadership in advanced metabolic peptide delivery: capitalizing on insulin success





# Introduction to Adocia's BioChaperone<sup>®</sup> Technology Platform

---

You-Ping Chan



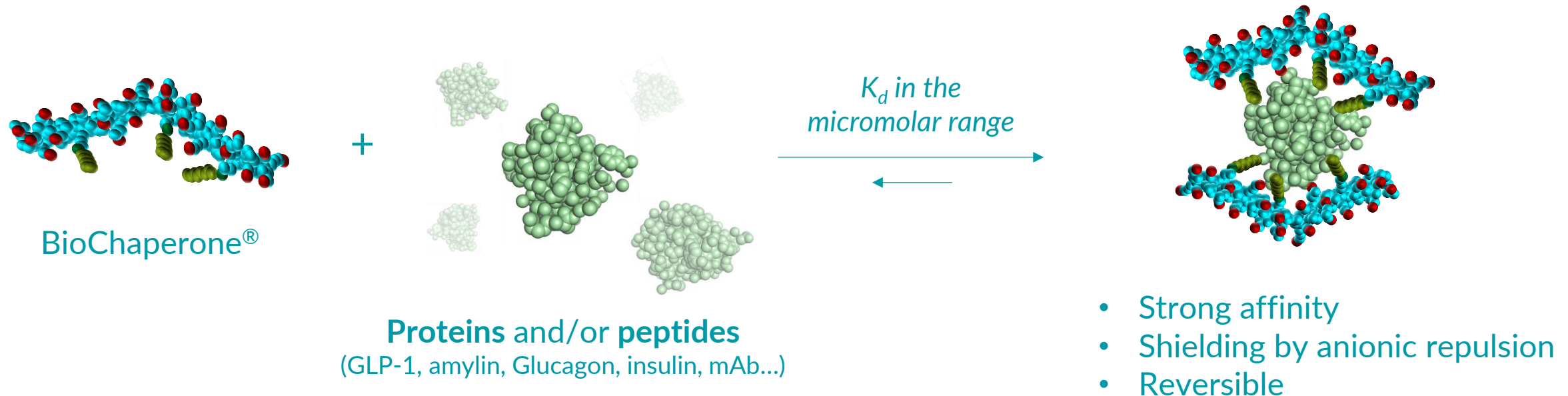
# BioChaperone® technology: a toolbox to formulate peptides

- More than 800 BioChaperone® novel proprietary polymer excipients
- > 30 positive clinical trials involving BioChaperone®
- 2 most advanced BioChaperone: BC449 and BC222

	BC 449	BC 222
Molecule	<ul style="list-style-type: none"> <li>• Acylated polyglutamate</li> </ul>	<ul style="list-style-type: none"> <li>• Acylated oligosaccharide</li> </ul>
Properties	<ul style="list-style-type: none"> <li>• Proteins and Peptides stabilisation and combinations</li> </ul>	<ul style="list-style-type: none"> <li>• Accelerating absorption</li> </ul>
Development stage	<ul style="list-style-type: none"> <li>• Phase 3 ready package</li> <li>• 3 clinical trials</li> <li>• Large scale GMP manufacturing in place</li> </ul>	<ul style="list-style-type: none"> <li>• BC Lispro ready for submission</li> <li>• &gt;10 clinical trials</li> <li>• Commercial production in place</li> </ul>
Application	<ul style="list-style-type: none"> <li>• BC CagriSema</li> <li>• 3 feasibility studies (peptides and peptides combination) with undisclosed partners</li> </ul>	<ul style="list-style-type: none"> <li>• BioChaperone® Lispro</li> </ul>



# BC449 designed to improve peptide co-formulations



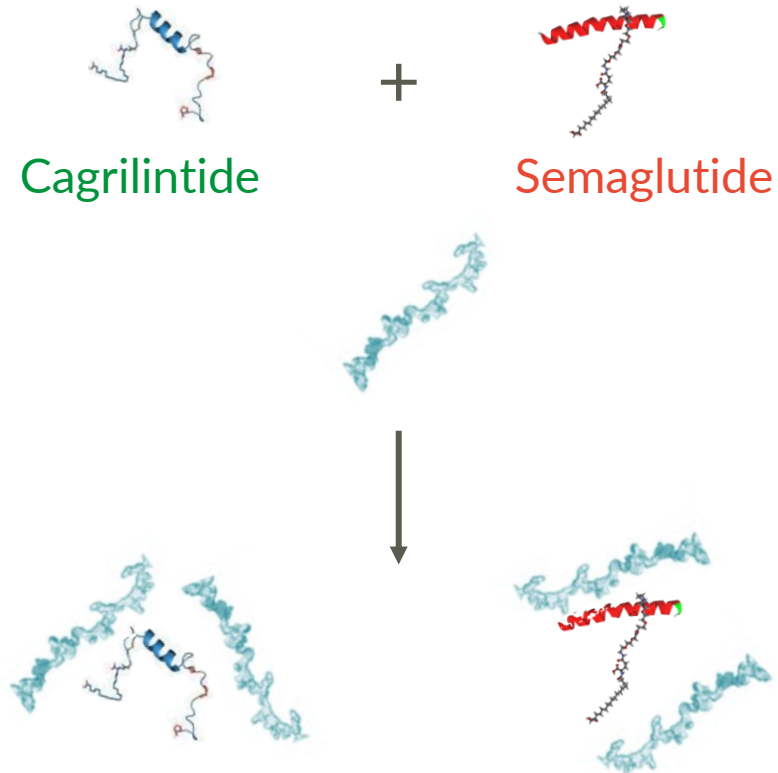
Redefining physicochemical identity to solve formulation challenges:

- Physical and chemical stability
- Compatibility with preservatives for multiple-use



# BioChaperone® GLP-1 / Amylin - BioChaperone® CagriSema

## Application of BC449: stable co-formulation of semaglutide and cagrilintide



4 double-chamber pens  
/ 4 weeks



1 multi-use pen  
/ 4 weeks



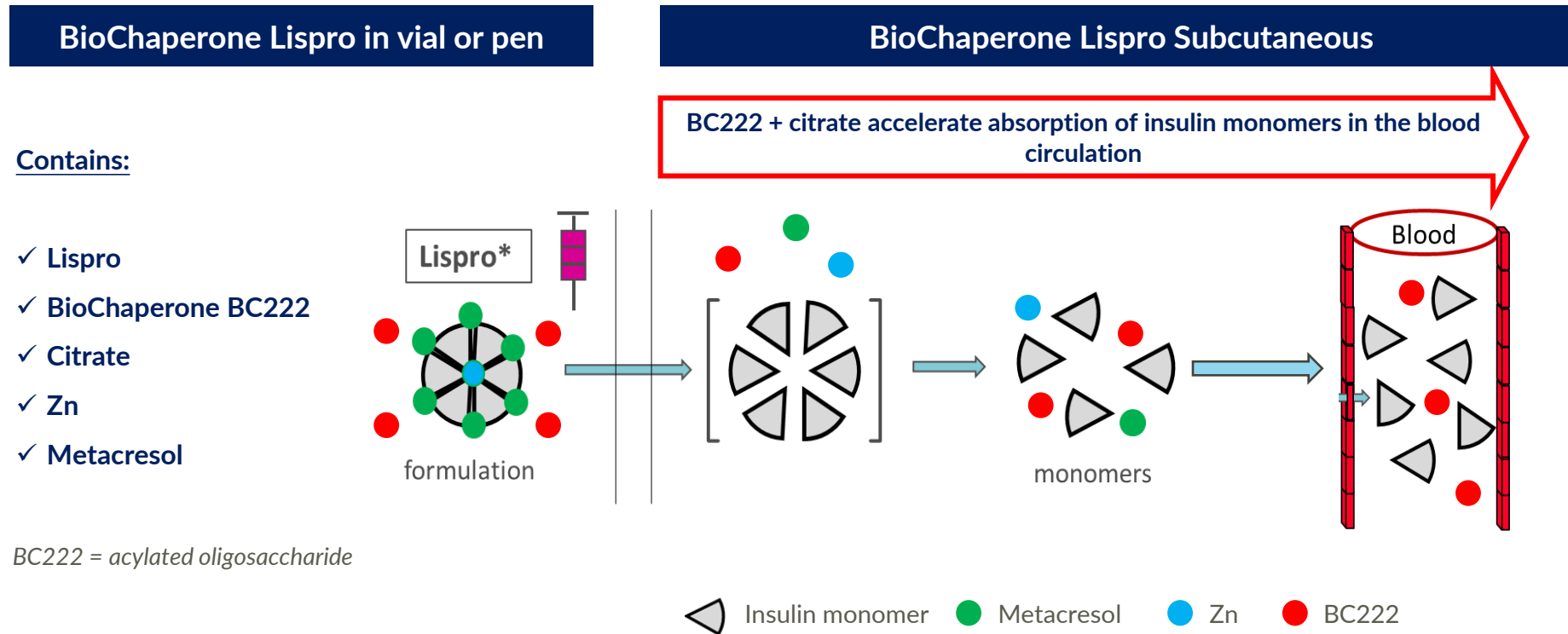
- ✓ Manufacturing cost ↓
- ✓ Manufacturing capacity ×4 ↗
- ✓ Capital Expenditure ↓
- ✓ Flexible dosing
- ✓ Environmental footprint ↓
- ✓ Intellectual property<sup>1</sup>: 2045 ↗

A holistic improvement throughout the product lifecycle

1. WO2025172605 & WO2025172606 – filed February 17, 2025 – no phase entries yet. The patent term is anticipated.

## BC Lispro

## Application of BC222: accelerating insulin lispro absorption



BC222 transforms Rapid-Acting insulin lispro into Ultra-Rapid insulin lispro



**profil**  
WE DELIVER SOLUTIONS

# Current Mealtime Insulin Treatment Paradigm for Diabetes and Limitations

Tim Heise

**AN UNRIVALLED COMBINATION OF SCIENCE AND  
PROFESSIONAL CLINICAL CONDUCT.**

**WE DELIVER SOLUTIONS.**

**WE ARE UNIQUE.**

# Disclosures



TH's institution received research funds from Afon Technology, AstraZeneca, Betagenon, Biocon, Civica, Corteria, Cytoki Pharma, DiogenX, Eli Lilly, Enyo, Gan&Lee Pharmaceuticals, Nanexa, Neodyne, Novo Nordisk, Roche Diagnostics, Sam Chun Dang, Spiden, Sun Pharma, and Zealand Pharma.

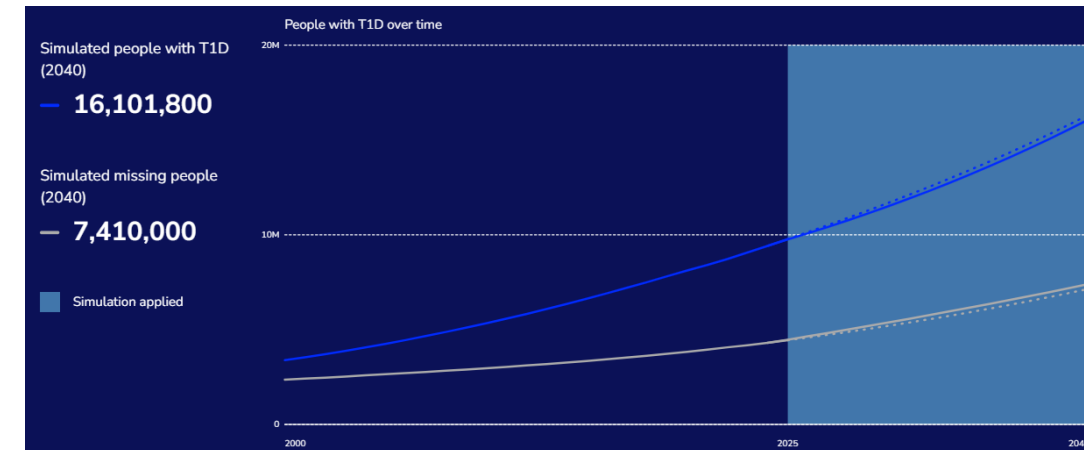
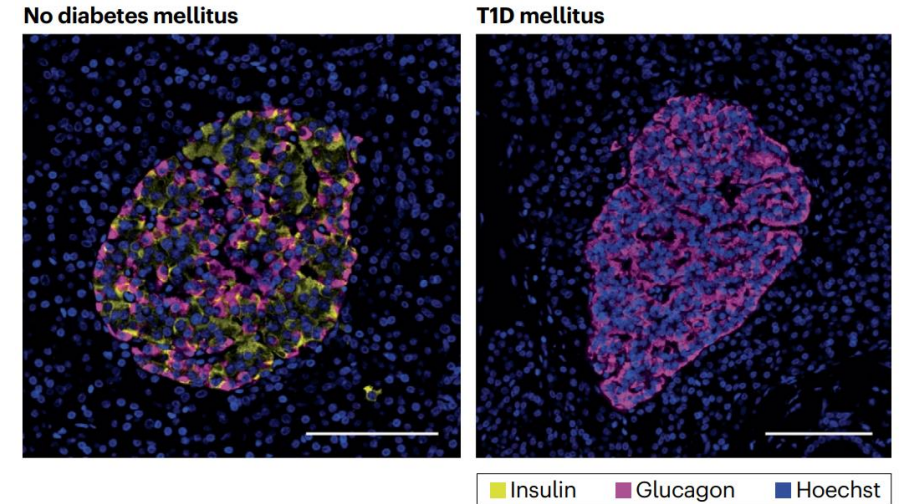
TH received speaker honoraria from Eli Lilly and Novo Nordisk, travel grants from Zealand Pharma and is a consultant to Gan&Lee Pharmaceuticals and i2o Therapeutics

# Type 1 diabetes mellitus (T1DM)

## Causes and Prevalence



- Autoimmune disease with destruction of beta cells
- Usually rapid progression to complete loss of endogenous insulin secretion capacity
- Occurs mostly in childhood or early teen years (peak ages are 4-7 years and 10-14 years), but can occur at any age
- Causes are still poorly understood but include
  - Genetics (collection of HLA genes)
  - Environmental factors (climate and geography)
  - Viral infections
- About 9.5 million people live with T1DM
  - Incidence rising for unknown reasons
  - 4.1 million premature deaths due to T1DM
  - 34 years of healthy life lost on average per person with T1DM



# Treatment paradigm and limitations



- ◆ Insulin therapy has been standard of care since 1922

# Insulin discovery and evolution

One evolution every 10-20 years to better match endogenous insulin secretion



Isolation of insulin  
(Banting/Macleod)

1921



Protamine-retarded  
insulin

1936



Insulin  
sequence

1955



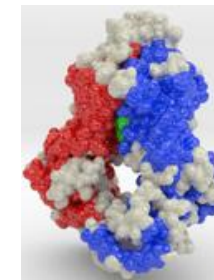
Insulin  
structure

1969



Short-acting  
analogues

1996



2013  
Basal analogues  
2<sup>nd</sup> generation



1923

Animal insulin  
preparations



1940s

NPH insulin



1952

Lente insulin



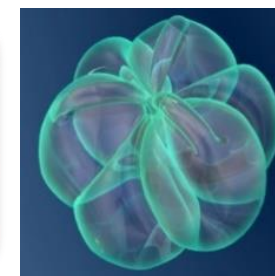
1977

Recombinant human  
insulin



2000

Basal insulin  
analogues



2018

“Ultra Rapid” insulin  
analogues



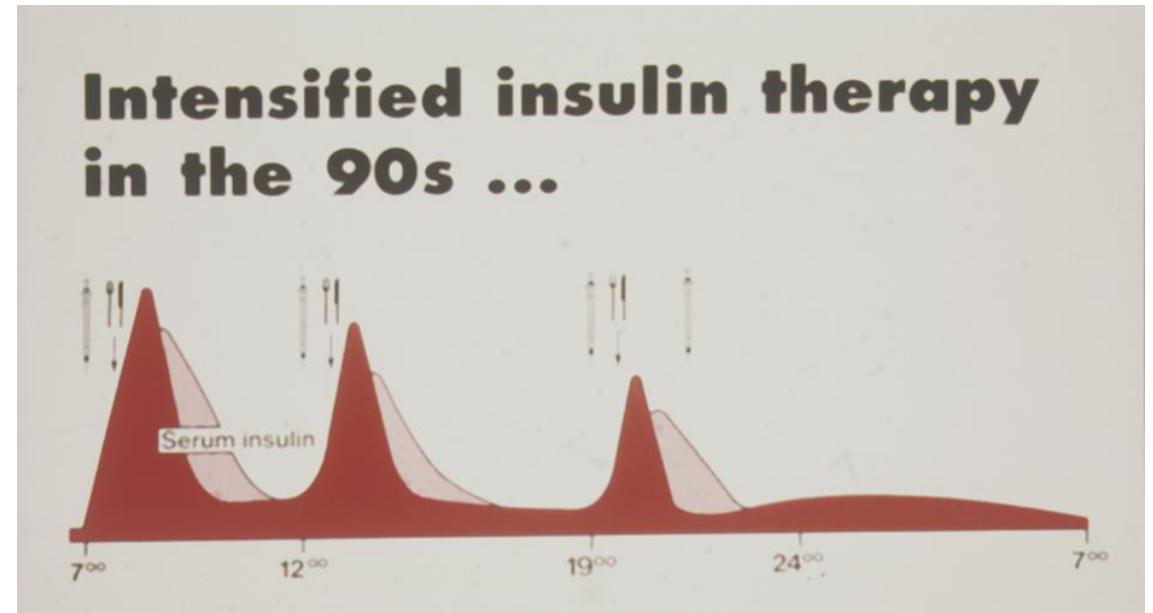
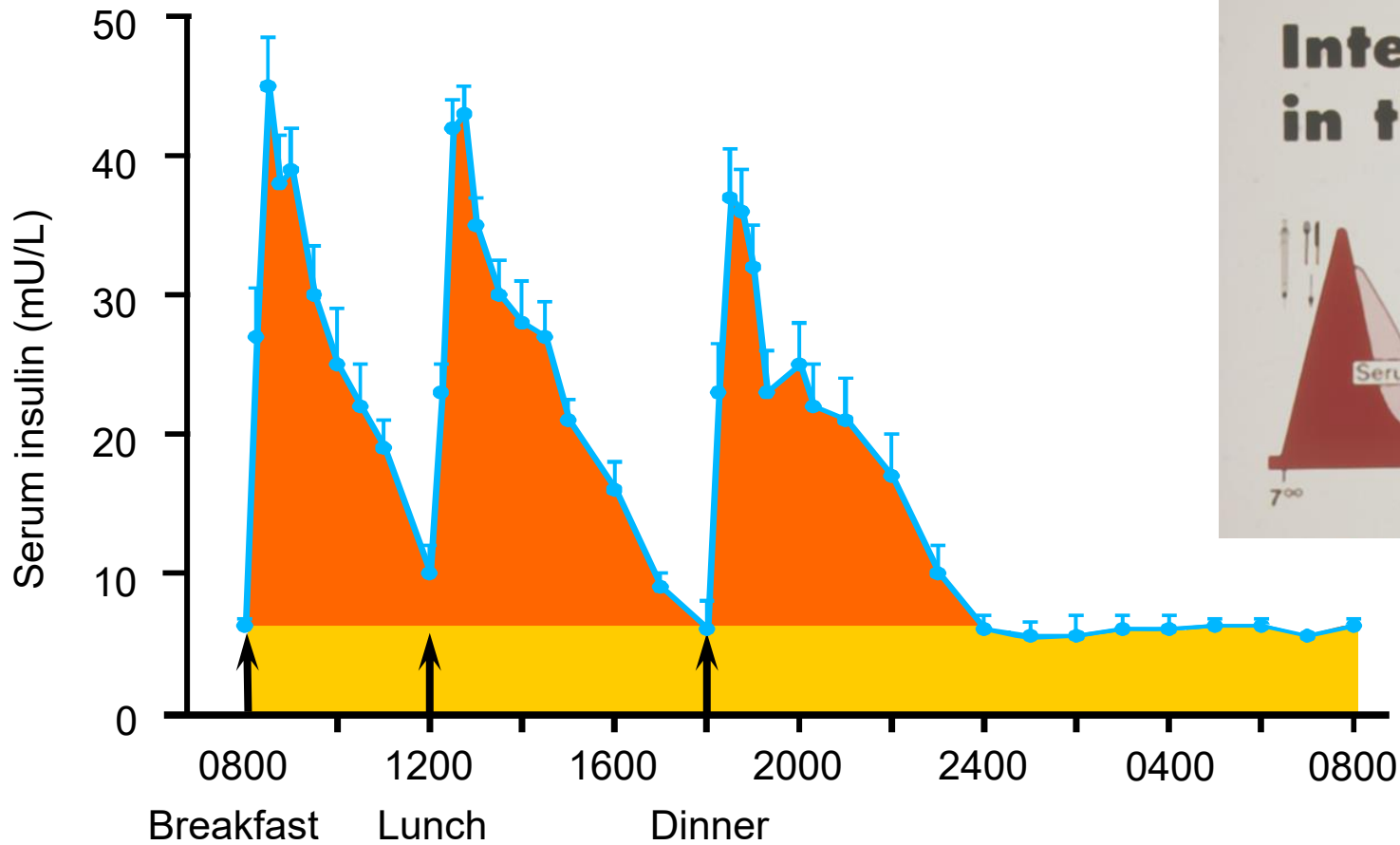
# Treatment paradigm and limitations



- ◆ Insulin therapy has been standard of care since 1922
- ◆ Since the 1990ies, insulin therapy regimens aim at physiological insulin supplementation, i.e., mimicking endogenous insulin secretion

# Intensified insulin therapy

## Physiological insulin supplementation



# Treatment paradigm and limitations



- Insulin therapy has been standard of care since 1922
- Since the 1990ies, insulin therapy regimens aim at physiological insulin supplementation, i.e., mimicking endogenous insulin secretion
- Standard of care today: MDI with modern insulins or insulin pumps

Injected insulin regimens	Flexibility	Lower risk of hypoglycemia	Higher costs
MDI with LAA + RAA or URAA	+++	+++	+++
Less-preferred, alternative injected insulin regimens			
MDI with NPH + RAA or URAA	++	++	++
MDI with NPH + short-acting (regular) insulin	++	+	+
Two daily injections with NPH + short-acting (regular) insulin or premixed	+	+	+

Continuous insulin infusion regimens	Flexibility	Lower risk of hypoglycemia	Higher costs
Hybrid closed-loop technology	+++++	+++++	+++++
Insulin pump with threshold/predictive low-glucose suspend	++++	++++	++++
Insulin pump therapy without automation	+++	+++	++++

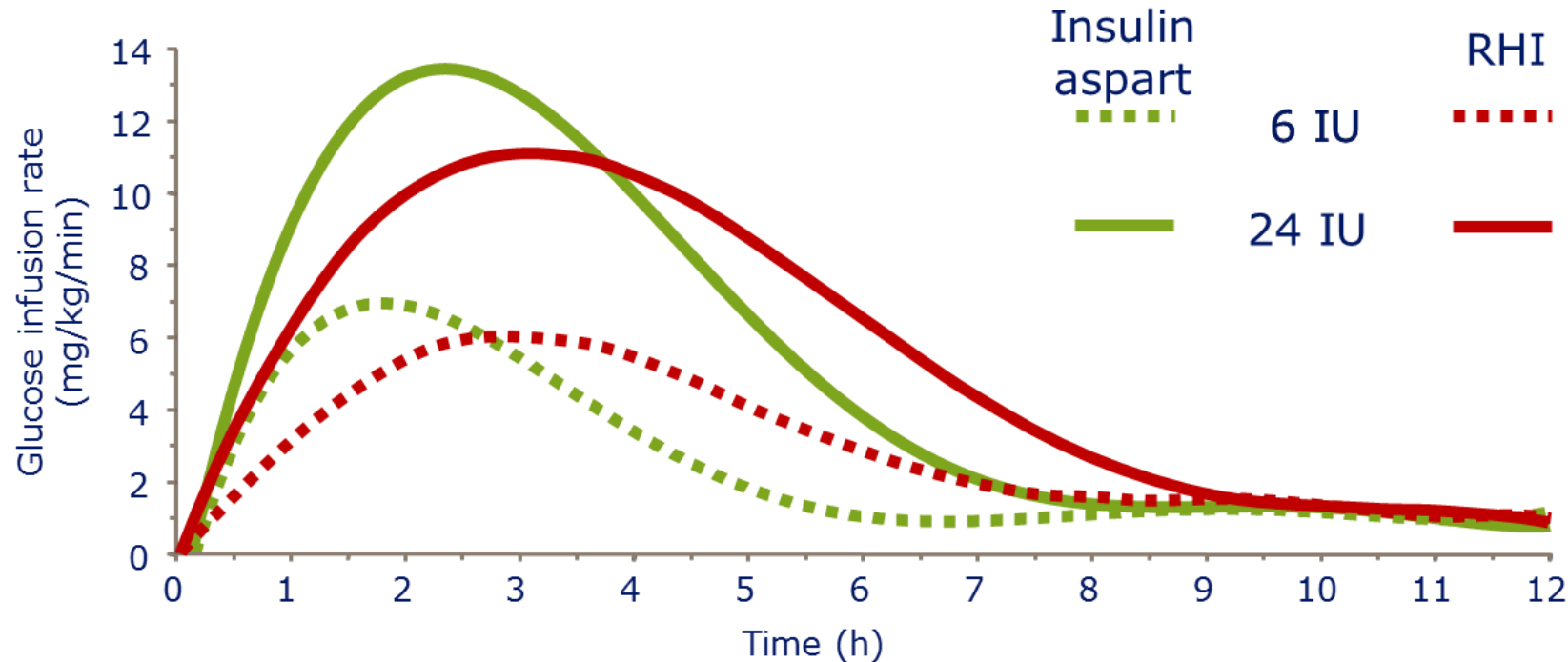
Holt RIG et al. Diabetes Care 2021; 44:2589-2625

MDI : Multiple daily injections, LAA: Long Acting Analogs, (U)RAA: (Ultra) Rapid Acting Analogs.

# Treatment paradigm and limitations



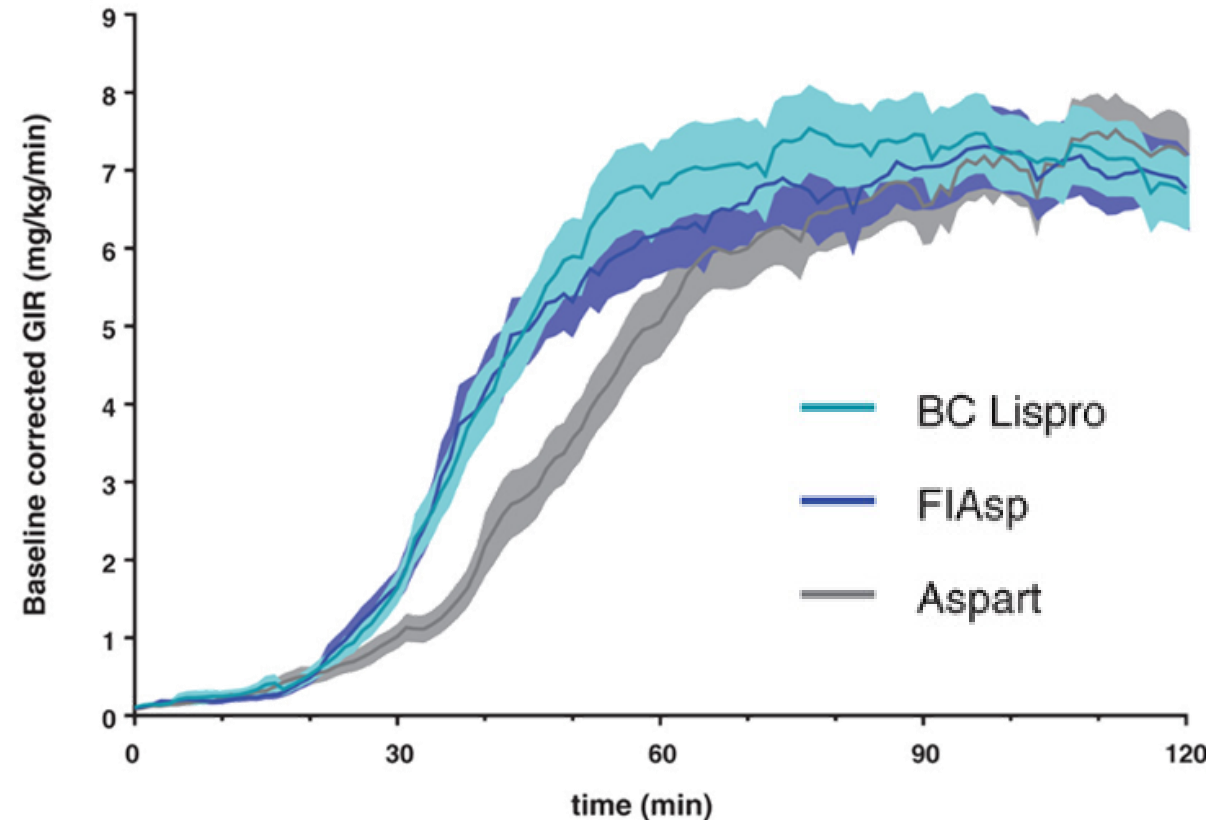
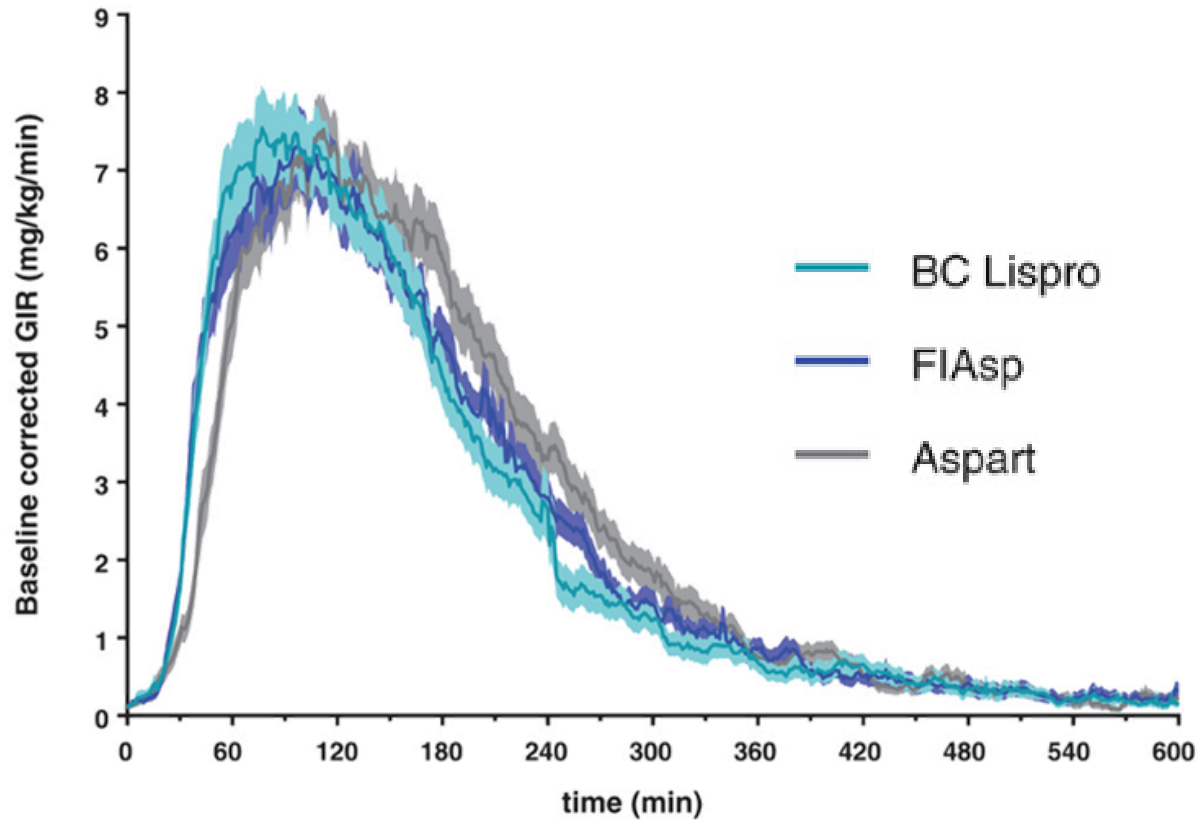
- ◆ Insulin therapy has been standard of care since 1922
- ◆ Since the 1990ies, insulin therapy regimens aim at physiological insulin supplementation, i.e., mimicking endogenous insulin secretion
- ◆ Standard of care today: MDI with modern insulins or insulin pumps
- ◆ Physiological insulin supplementation is limited by the pharmacodynamics of prandial insulins, which have a slow onset and a long duration of action



RHI: Regular human insulin

Nosek L et al. Diabetes Obes Metab 2013;15:77-83

# Biochaperone (BC) Lispro has a faster onset and a shorter duration of action than both aspart and FIAsp



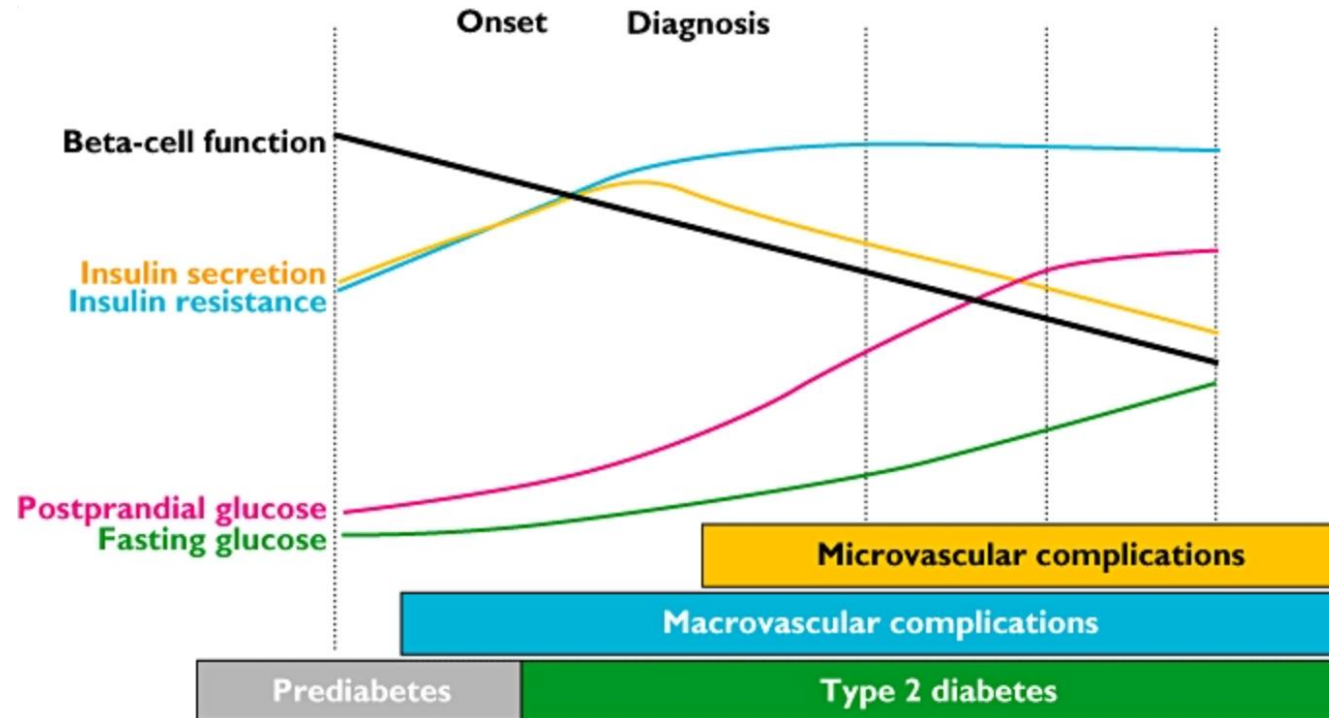
- Nine studies with BC Lispro confirm ultrarapid onset and short duration of action vs available rapid-acting or ultrarapid-acting insulins

# Type 2 diabetes

## Causes



- Caused by insulin resistance with compensatory insulin hypersecretion
  - Progressive beta-cell failure leads to hyperglycaemia
  - Beta-cell function continues to deteriorate requiring treatment intensification in the course of the disease



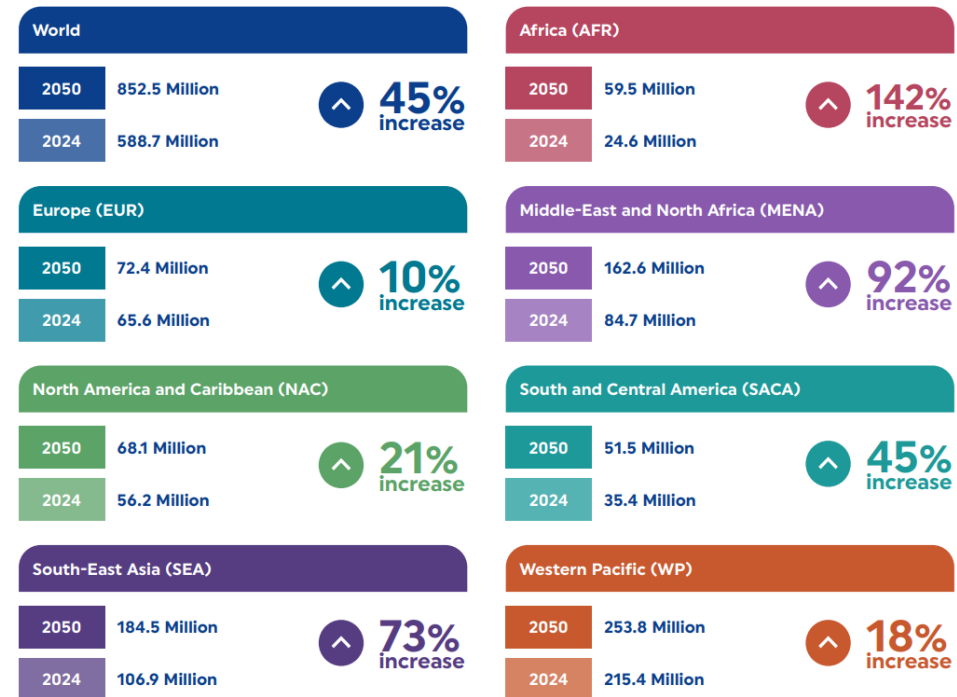
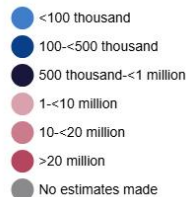
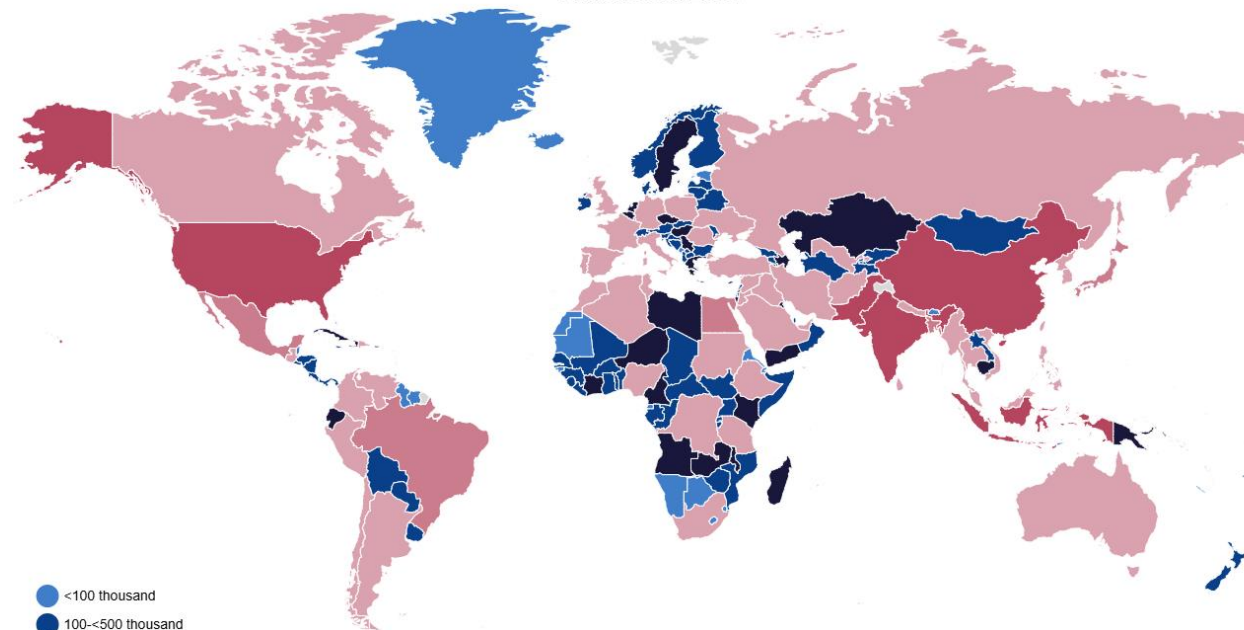
# Type 2 diabetes

## Prevalence



- High prevalence (data from 2024, IDF diabetes atlas)
  - 589 million adults (20-79 years) are living with diabetes worldwide – 1 in 9.
  - The total number of adults with diabetes is predicted to rise to 853 million by 2050 – 1 in 8.
  - Diabetes caused 3.4 million deaths in 2024 – 1 every 9 seconds.

Estimated total number of adults (20–79 years) with diabetes in 2024

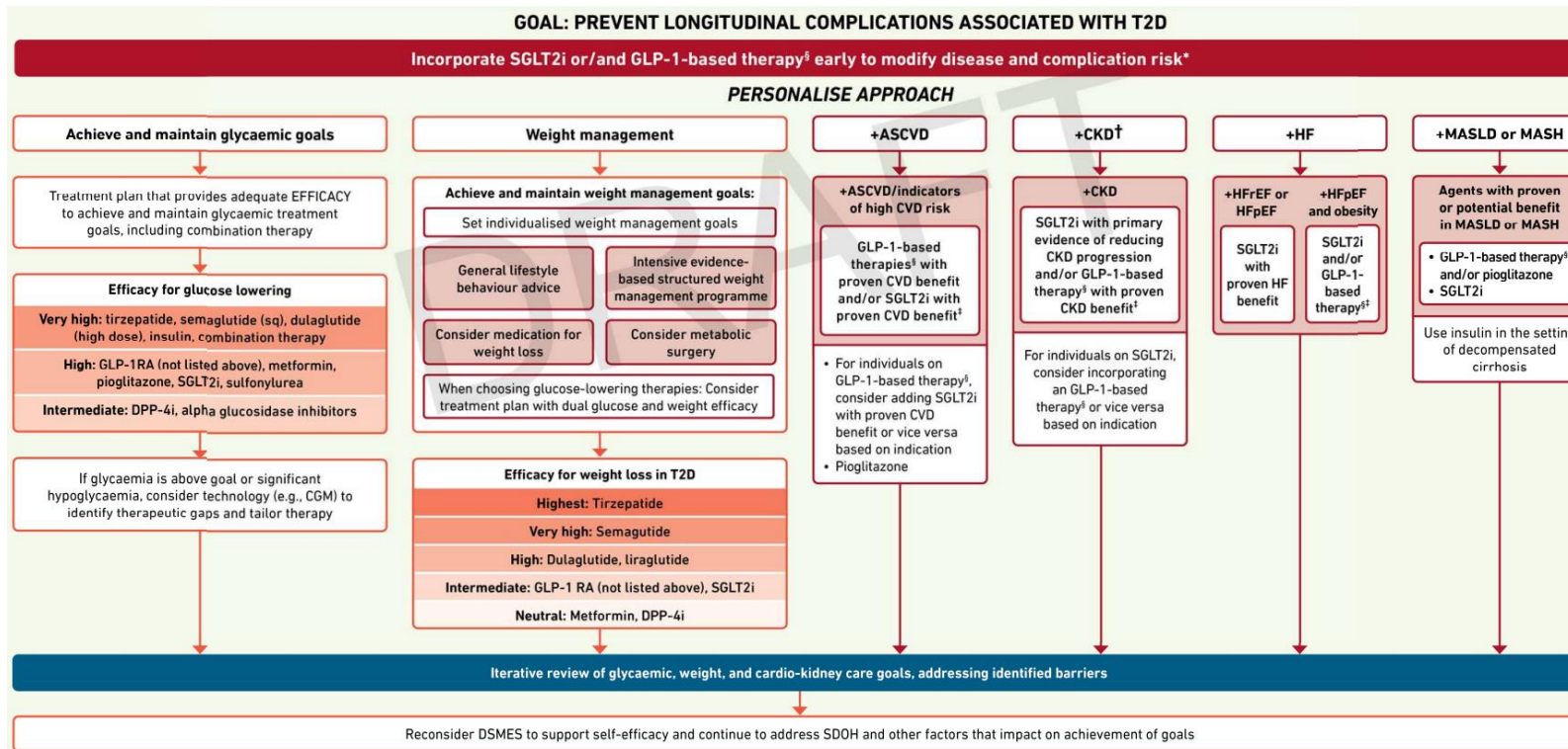
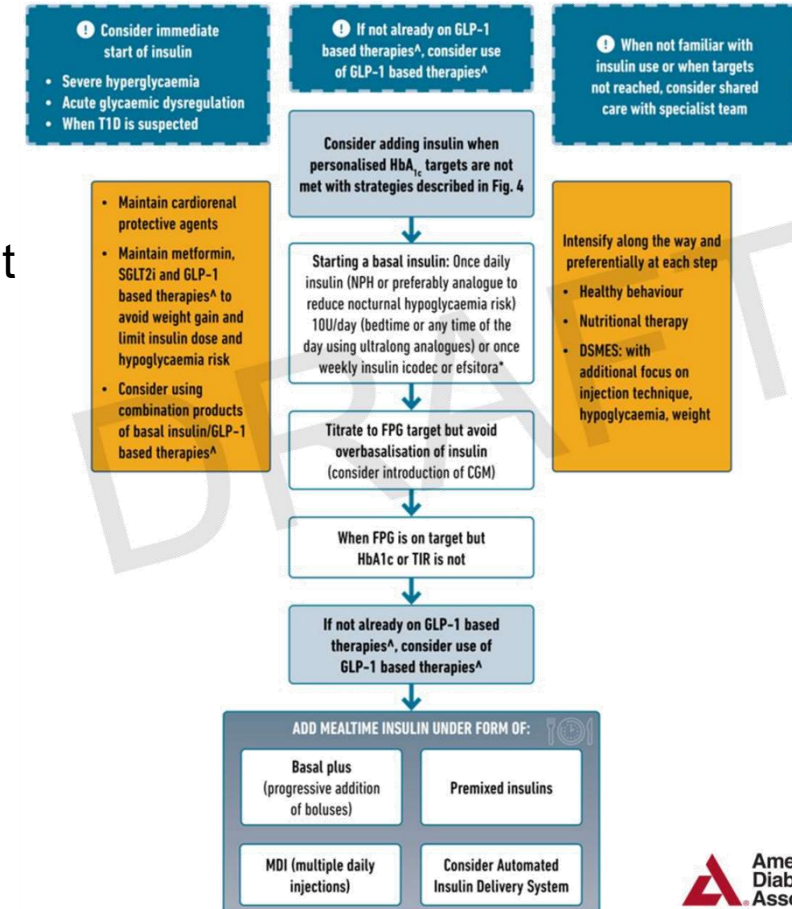


# Type 2 diabetes

## Treatment (ADA/EASD consensus presented at ADA 2026)



- GLP-1-based and SGLT2-inhibitors most important because of proven cardiovascular benefits
- Insulin still-rated as therapy with very high efficacy
  - Start with basal insulin, add mealtime insulin, if needed
  - Progression of T2DM might eventually lead to insulin treatment



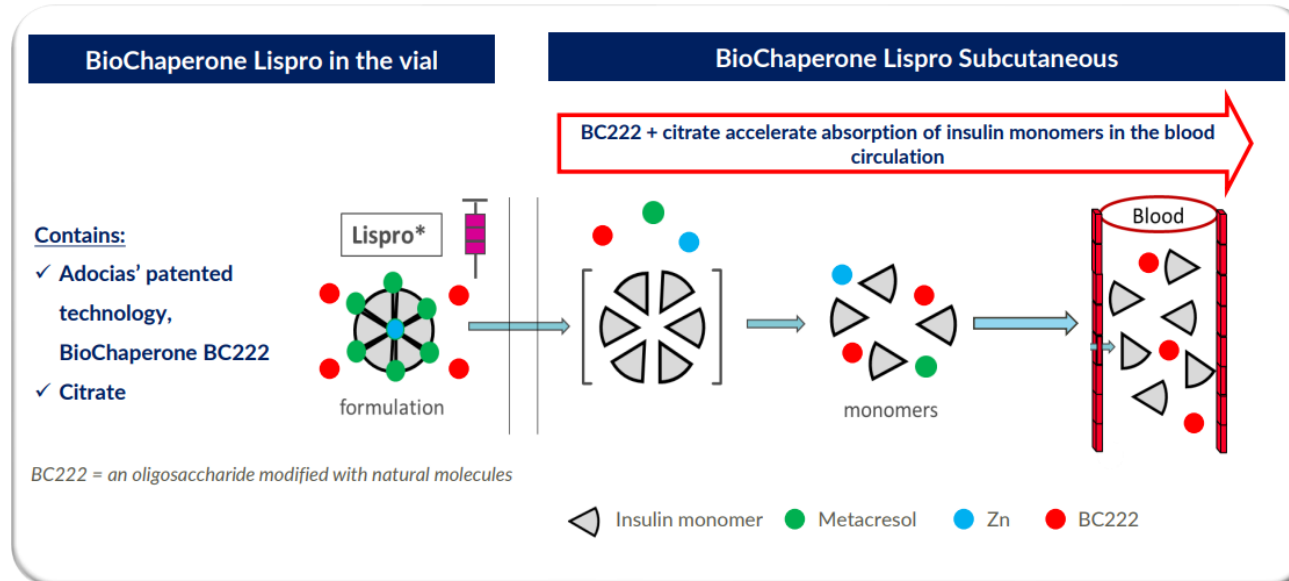
Ultra-Rapid insulin BC Lispro Phase 3 Data on Type 2  
Diabetes

---



# Introduction and Study objectives

THDB0206 (BioChaperone<sup>®</sup> Lispro, BCLIS) is an-ultra-rapid insulin lispro formulation containing the novel excipient BC222 and citrate.



## Aims of the study

- To evaluate the efficacy and safety of THDB0206 (BioChaperone Lispro, BCLIS) administered at mealtime, versus mealtime insulin lispro (LIS), both in combination with insulin glargine, in Chinese people with type 2 diabetes (T2D).
- Phase 3, 26-week, multicenter, randomized, treat-to-target, open trial



# Study Design and Inclusion/Exclusion criteria

## Key Inclusion Criteria:

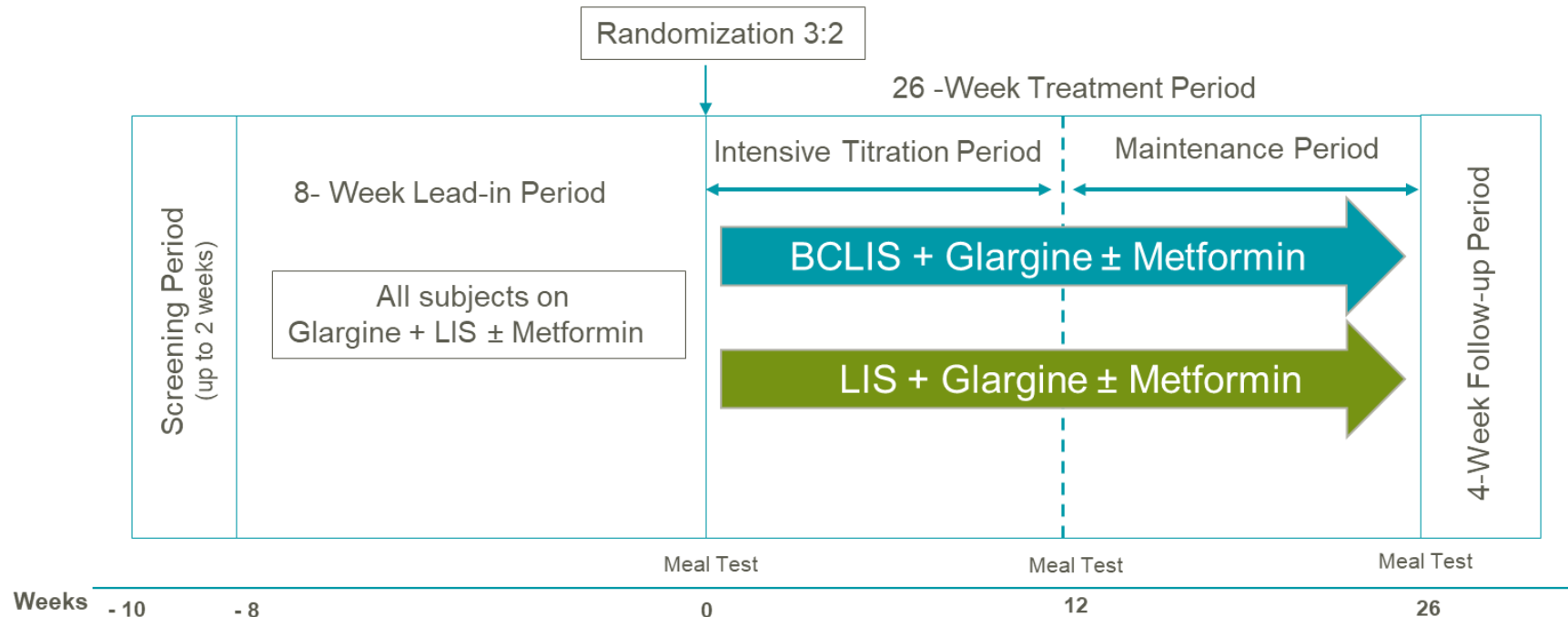
- People with T2D  $\geq 6$  months
- Male or female aged 18 to 75
- Stable insulin treatment  $\geq 3$  m either on basal +  $\geq 1$  bolus/day or on premix  $\geq 2$ /day with or without oral antidiabetic treatment
- HbA1c between 7% and 11% inclusive
- BMI between 18 and 35 kg/m<sup>2</sup> included

## Primary endpoint:

- HbA1c change from baseline 26 weeks after randomization

## Key secondary endpoints:

- 1-h Post Prandial Glucose Excursion after a meal test at week 26
- 2-h Post Prandial Glucose Excursion after a meal test at week 26



# Demographics

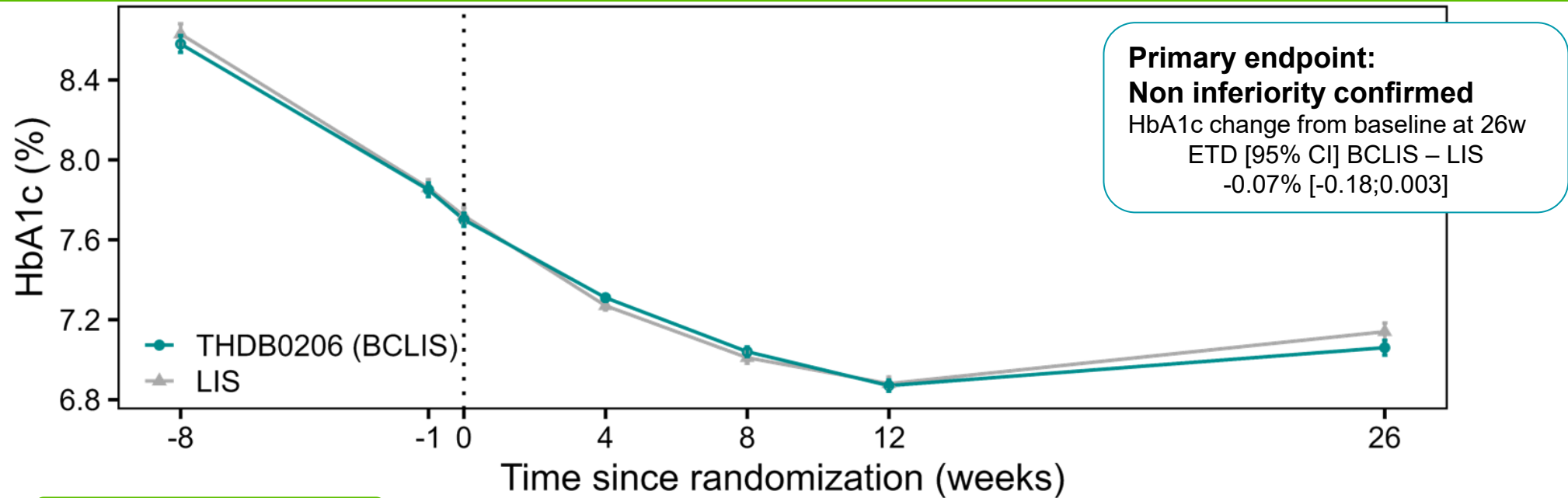


Parameter	BCLIS (N=623)	LIS (N=415)
Age, years	59.0 ± 8.65	59.2 ± 9.43
Gender, n(%) male	340 (54.57)	221 (53.25)
Body weight (kg)	69.95 ± 11.202	70.57 ± 11.599
BMI (kg/m <sup>2</sup> )	25.71 ± 3.063	25.98 ± 3.105
Duration of diabetes, years	13.53 ± 7.154	13.91 ± 7.373
Baseline HbA1c (%)	7.70 ± 0.807	7.72 ± 0.815
Baseline FPG, mmol/L	7.17 ± 1.751	7.23 ± 1.838
Treatment Completion Rate, n(%)	581 (92.96)	396 (95.42)

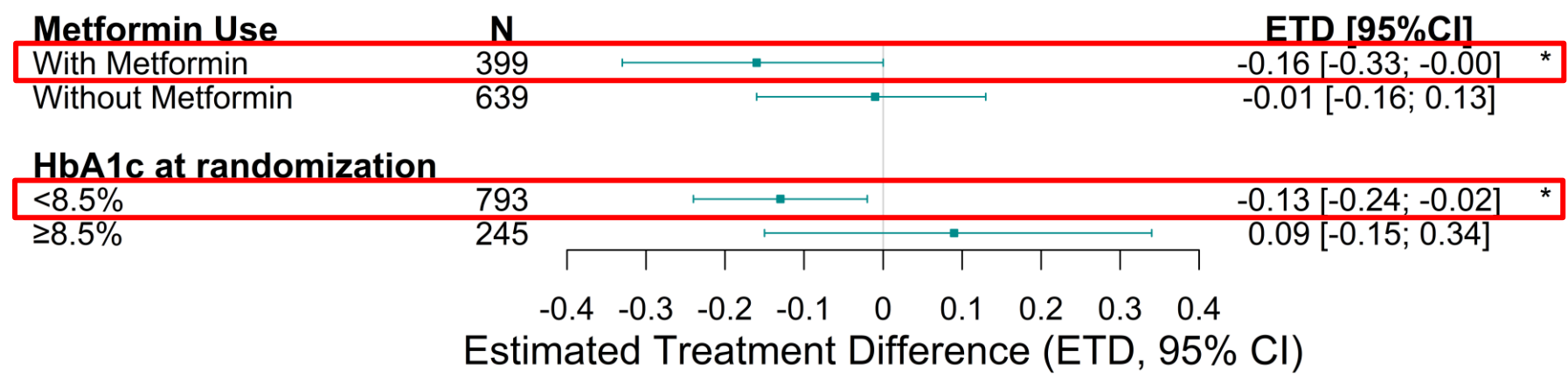
Data are presented as mean ± SD unless specified differently



# Glycemic control during the study



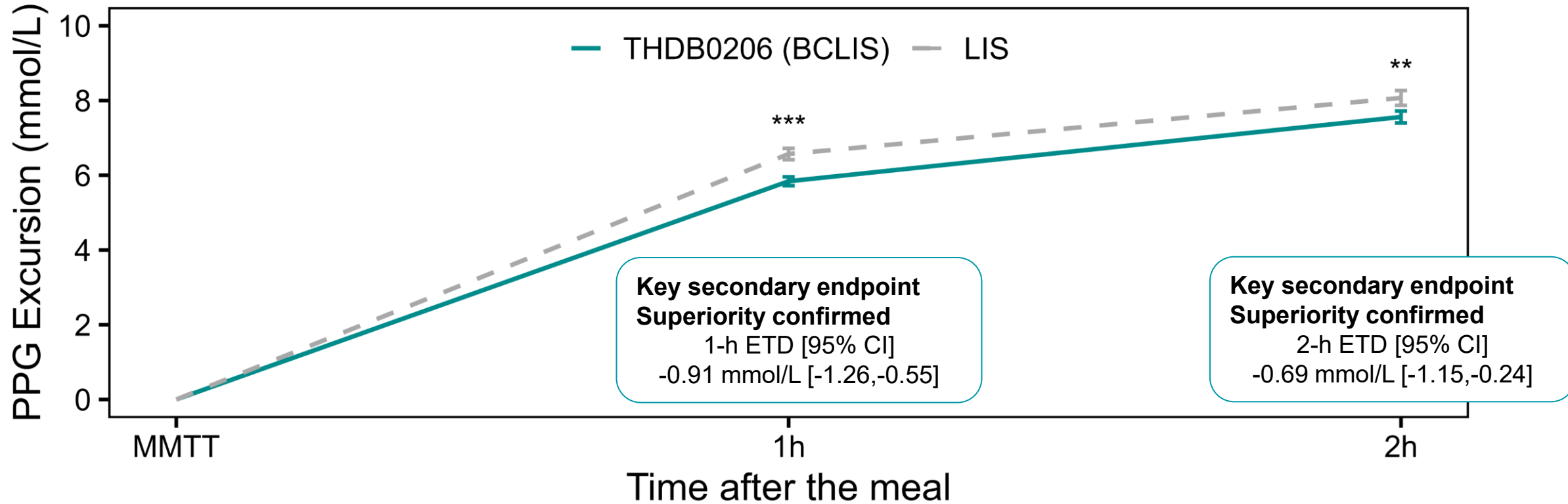
## Superiority for BCLIS



Data are represented as mean ±SE. ETD : estimated treatment difference, \* p<0.05

# Mixed Meal Tolerance Test

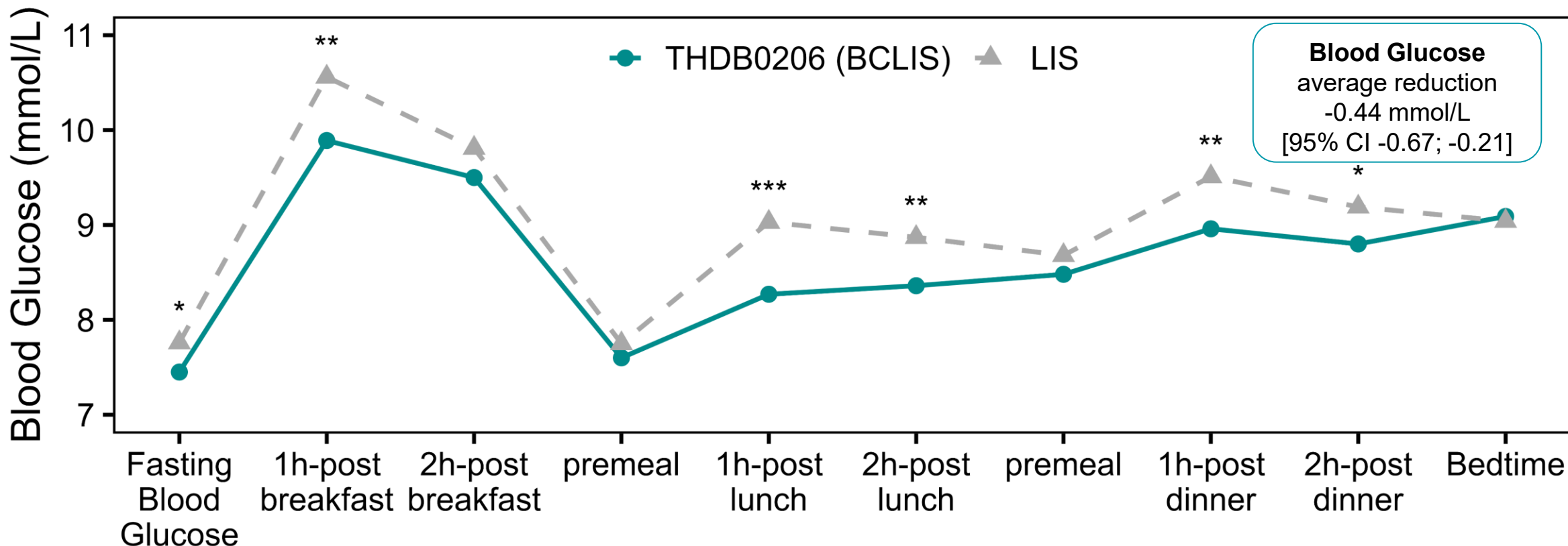
## Postprandial excursions at week 26



Data are represented as mean  $\pm$ SEM. ETD, estimated treatment difference; \*  $p < 0.05$ , \*\*  $p < 0.01$ , \*\*\*  $p < 0.001$

# Glucose control

## 10-point SMBG at 26 weeks



**Superior glucose control throughout the day with improvement after each meal**

\* p<0.05, \*\* p<0.01, \*\*\* p<0.001

# Safety profile



- ◆ Similar TEAE profile
- ◆ Injection site reactions were low and similar between both treatments (N =5 (0.8%) vs 2 (0.48%), BCLIS vs LIS)
- ◆ Similar hypoglycemia rates during 26 weeks of treatment

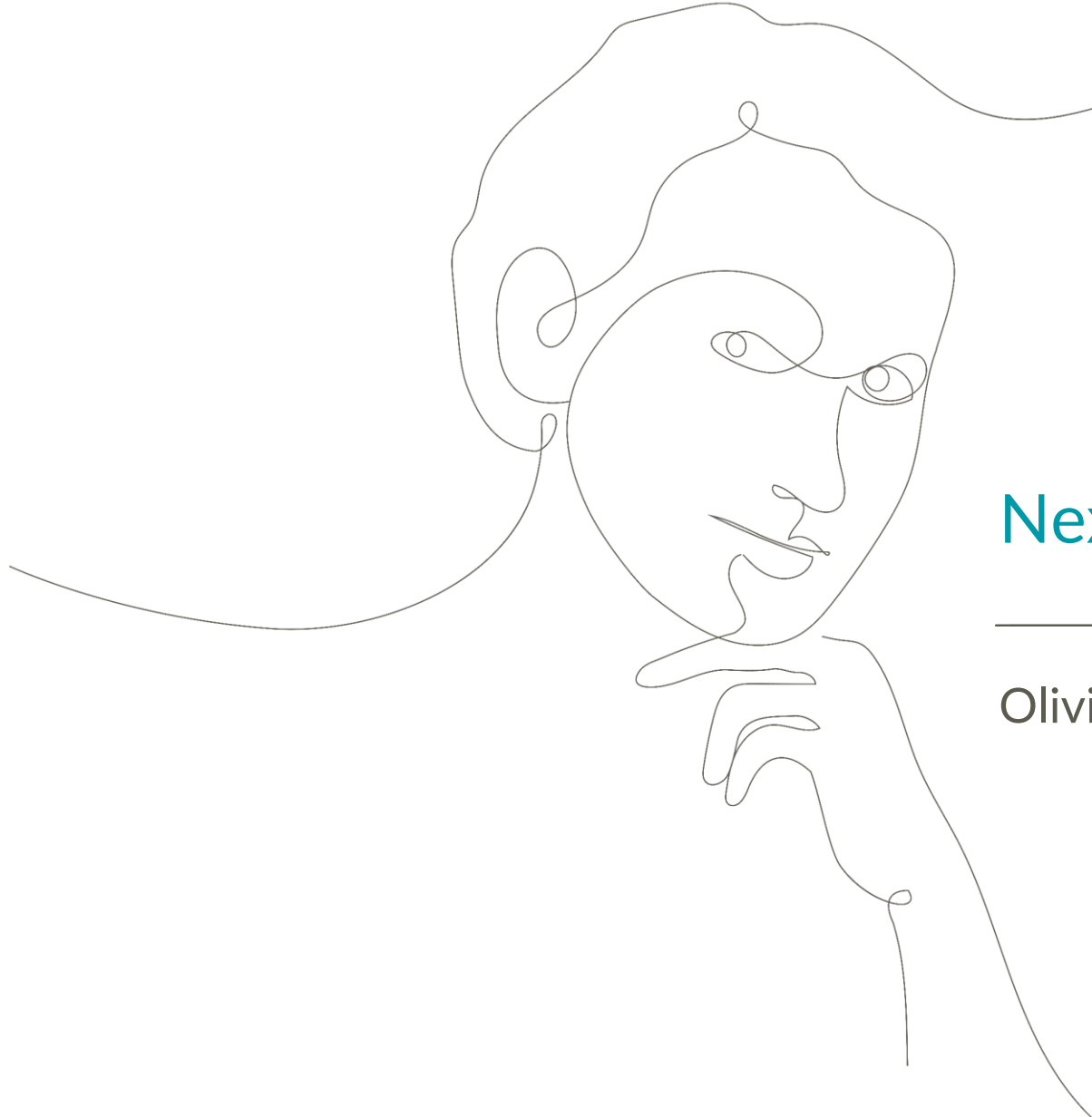
# Summary of this study in 1040 Chinese people with T2D



Ultra-rapid THDB0206 (BCLIS) in comparison with insulin lispro, showed:

- ◆ Superior HbA1c improvements in people using metformin or with HbA1c < 8.5%
  - ◆ Significantly more people achieving HbA1c target below 7%
  - ◆ Similar (non-inferior) HbA1c improvements for the whole population
- ◆ Superior blood glucose control
  - ◆ throughout the day (mean BG)
  - ◆ after each meal (SMBG/MMT)
- ◆ Similar safety and tolerability





# Next Steps and Potential Value Creation

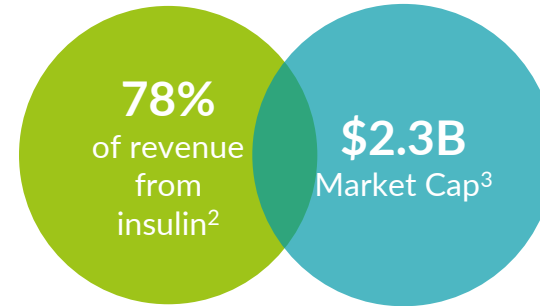
---

Olivier Soula



# China Phase 3 clinical part completed, filing under preparation

Partnered with



## Licensed for development & commercialization in China and other Asian territories<sup>1</sup>:

- ✓ \$10M upfront
- ✓ \$5M milestone - 1<sup>st</sup> patient on the Phase 3 trial in China
- ✓ \$10M milestone - Phase 3 Last Patient Last Visit, Dec. 2024
- \$20M additional milestones - 1<sup>st</sup> marketing approval in China
- Double-digit royalties on sales

## Recent & Upcoming

- ✓ Phase 3 positive topline results on people with T2D
- ✓ Phase 3 positive topline results on people with T1D
- Market Authorization submission in China expected

The company expects BioChaperone<sup>®</sup> Lispro to become the best-in-class mealtime insulin  
Adocia has retained rights for licensing BC Lispro outside THDB territories<sup>1</sup>

1. China and other territories (excluding US, EU, Japan), Press Release, Apr. 26, 2018: Adocia and Tonghua Dongbao Announce a Strategic Alliance for BioChaperone<sup>®</sup> Combo and BioChaperone<sup>®</sup> Lispro in China

2. Data THDB

3. July 2025



# BC Lispro U100 pen for T1D and T2D: commercial distribution

## China and other Asian countries covered by the contract with THDB

THDB holds full responsibility for registration and commercialization activities in these territories.

### ❑ Next steps:

⇒ China : Market Authorization submission by Tonghua Dongbao

## Countries eligible for a simplified registration procedure

Health authorities may accept a registration dossier based on Chinese clinical and regulatory data, without requiring a large-scale Phase III study

Notably includes several countries in the Middle East, LATAM...

## EU/US : Regulated markets requiring a new Phase III study

Regulatory agencies (EMA and FDA) require a new Phase III clinical study to demonstrate efficacy and safety in a local population or in accordance with their methodological standards

Subject to signing a partnership

Development in other territories are subject to the signing of a partnership agreement



## Perspectives: other potential applications

### BC Lispro U100 pen

- ✓ 6 Phase 1 clinical trials (EU ≈ 200 patients)
- ✓ 2 Phase 3 clinical trials (CN - > 1500 patients)
- ☐ **Next steps:**
  - ⇒ China : Market Authorization submission by Tonghua Dongbao

### BC Lispro U100 insulin pump

- ✓ 2 Phase 1 clinical trials (EU ≈ 100 patients)
- ☐ **Potential next step:**
  - ⇒ A pivotal phase 3 trial in T1D/T2D patients using CSII

### BC Lispro U200 insulin pump and pen

- ✓ BC Lispro U200 is bio-equivalent to BC Lispro U100 in a preliminary clinical study
  - T2D infuse high doses of insulin, reducing the duration of the pump which is a limitation for T2D pump use
- ☐ **Potential next steps :**
  - ⇒ A bioequivalence study, and a
  - ⇒ Pivotal phase 3 trial in T1D/T2D patients using CSII / pens

Subject to THDB or signing a partnership

Beyond commercialization of BC Lispro U100 in pen, BC Lispro could be developed for pump and at U200 concentration, subject to THDB or signing a partnership



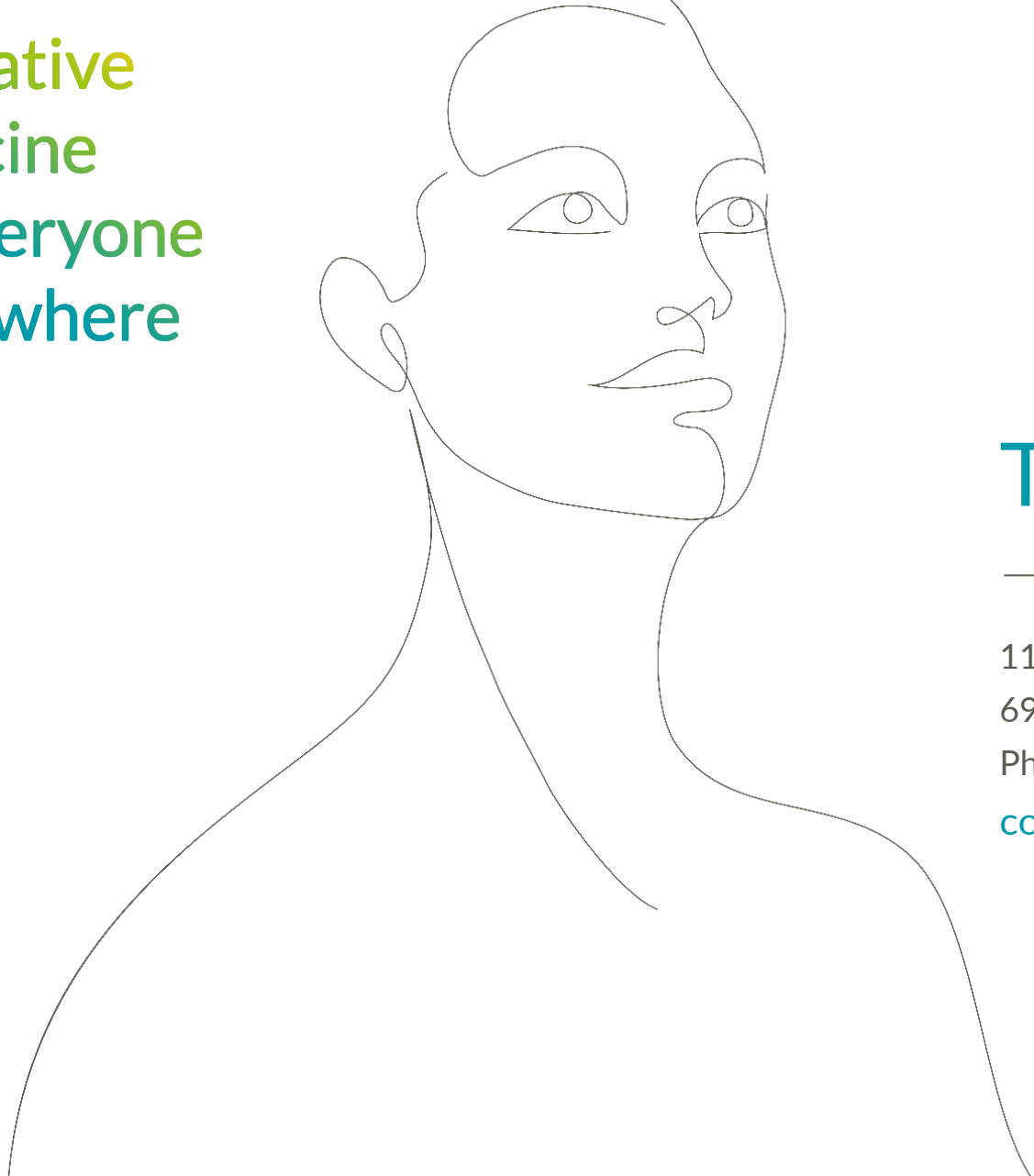


## Q&A

---



Innovative  
Medicine  
for everyone  
everywhere



# Thank you

---

115 avenue Lacassagne  
69003 Lyon - FRANCE  
Ph.:+33 4 72 610 610  
[contact@adocia.com](mailto:contact@adocia.com)