



Innovent Biologics Clinical Data Update

Mazdutide (IBI362) Higher Dose 9mg

Phase 2 Clinical Study in Obesity

May 11, 2023

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Prof. Linong Ji

Leading PI; Peking University People's Hospital

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Dr. Lei Qian

VP, Non-oncology Clinical Development

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Prof. Linong Ji, MD

Leading Principal Investigator; Peking University People's Hospital



- Professor Linong Ji is **Director of Peking University Diabetes Center and Director of the Department of Endocrinology and Metabolism**, Peking University People's Hospital, Beijing, China.
- He is also **President of Specialty Committee of Clinical Research on Diabetes and Metabolic Drugs of China Pharmaceutical Innovation and Research Development Association (PhIRDA)**, Past Vice President of International Diabetes Federation (IDF), Past Chair of International Diabetes Federation Western Pacific Region (IDF-WPR), Past President of the Chinese Diabetes Society (CDS), Vice President of the Chinese Endocrinologist Association (CEA), President of Chinese Geriatric Endocrine and Metabolism Society, Executive board member of Asia Association for the Study of Diabetes (AASD).
- He is **Chief Editor of Chinese Diabetes Journal** and an editorial board member of **Journal of Diabetes, Diabetes Research and Clinical Practice, Diabetes Technology & Therapeutics, Metabolism, International Journal of Diabetes**.
- He is the leading principal investigator of 60+ clinical studies. He published 500+ articles in peer-reviewed journals.



Obesity and Overweight in China

Prof. Linong Ji

Leading PI; Peking University People's Hospital

Obesity — a Growing Public Health Issue in China



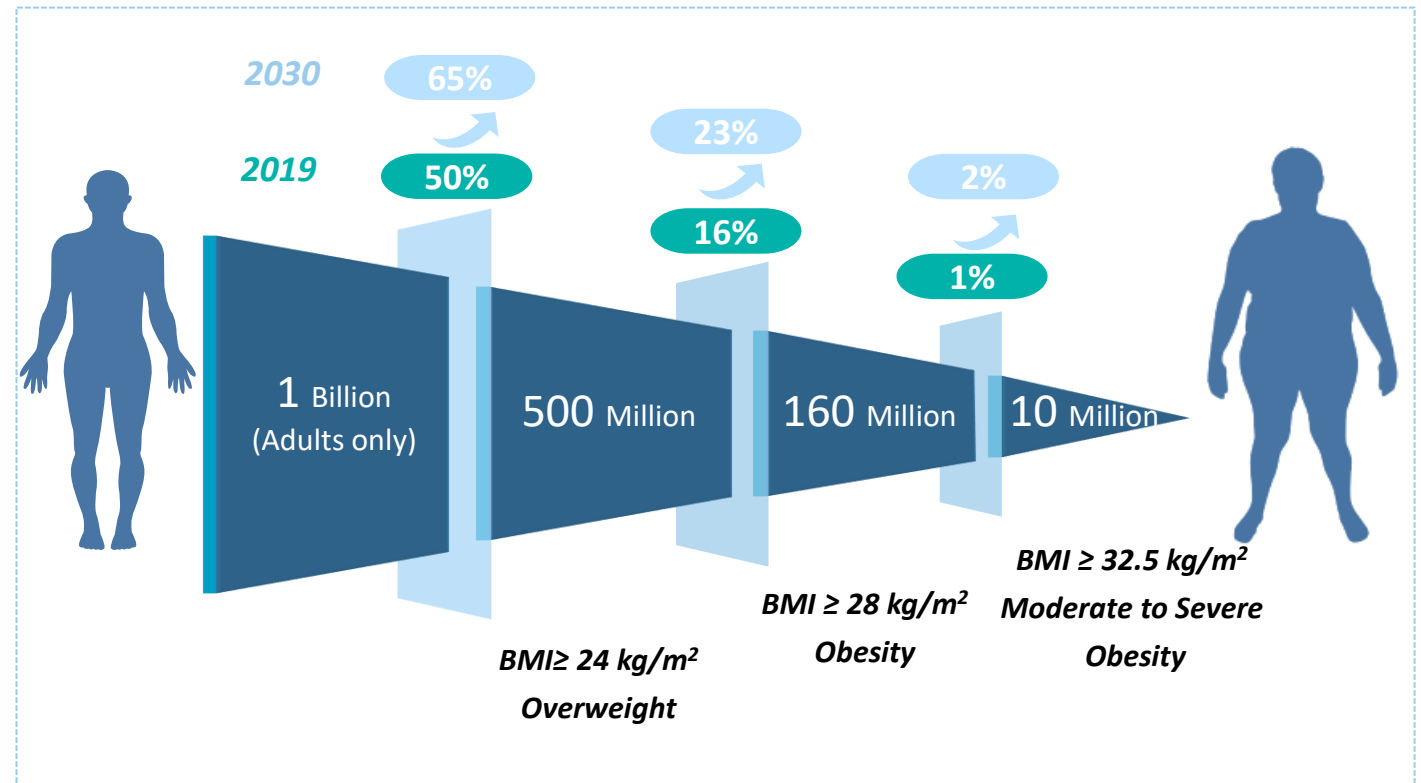
1. Pan XF, Wang L, Pan A. Epidemiology and determinants of obesity in China. Lancet Diabetes Endocrinol. 2021 Jun;9(6):373-392. doi: 10.1016/S2213-8587(21)00045-0. Erratum in: Lancet Diabetes Endocrinol. 2021 Jul;9(7):e2. PMID: 34022156.
2. Wang Y, Zhao L, Gao L, Pan A, Xue H. Health policy and public health implications of obesity in China. Lancet Diabetes Endocrinol. 2021 Jul;9(7):446-461. doi: 10.1016/S2213-8587(21)00118-2. Epub 2021 Jun 4. PMID: 34097869.
3. Institute for Health Metrics and Evaluation. Global Health Data Exchange. GBD results tool. <http://ghdx.healthdata.org/gbd-resultstool> (accessed Jan 10, 2021).

China Has the Largest Obese and Overweight Population

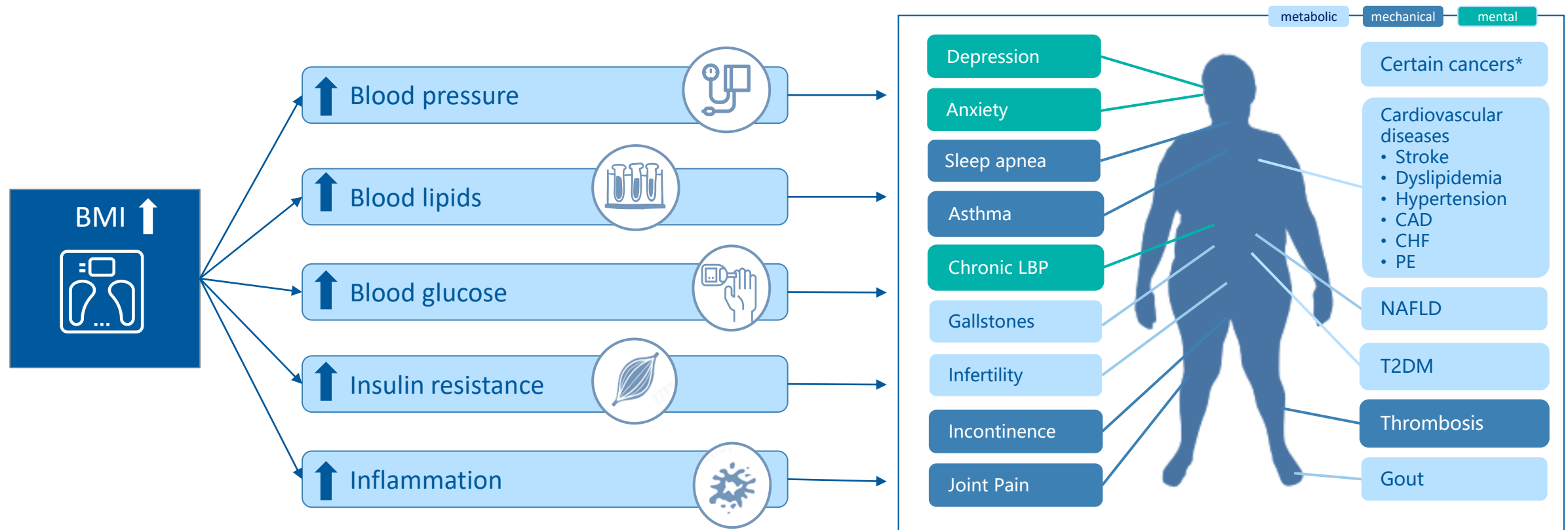
~500M adults in China are living with obesity or overweight, **potentially the largest in the world**^{i,1}.

- Overweight (BMI 24-27.9kg/m²): 340M
- Obesity (BMI ≥ 28kg/m²): 160M
- Moderate to severe obesity (BMI ≥ 32.5kg/m²): 10M

ⁱ: WHO criteria define overweight in adults as a BMI of 25.0–29.9 kg/m² and obesity as a BMI of 30.0 kg/m² or higher. However, accumulated evidence has shown that Chinese people are likely to have higher percentages of body fat (as shown via imaging techniques) and higher rates of cardiovascular risk factors and all-cause mortality than White people at given BMI levels.



Raised BMI is a Major Risk Factor for >200 Non-communicable Diseases



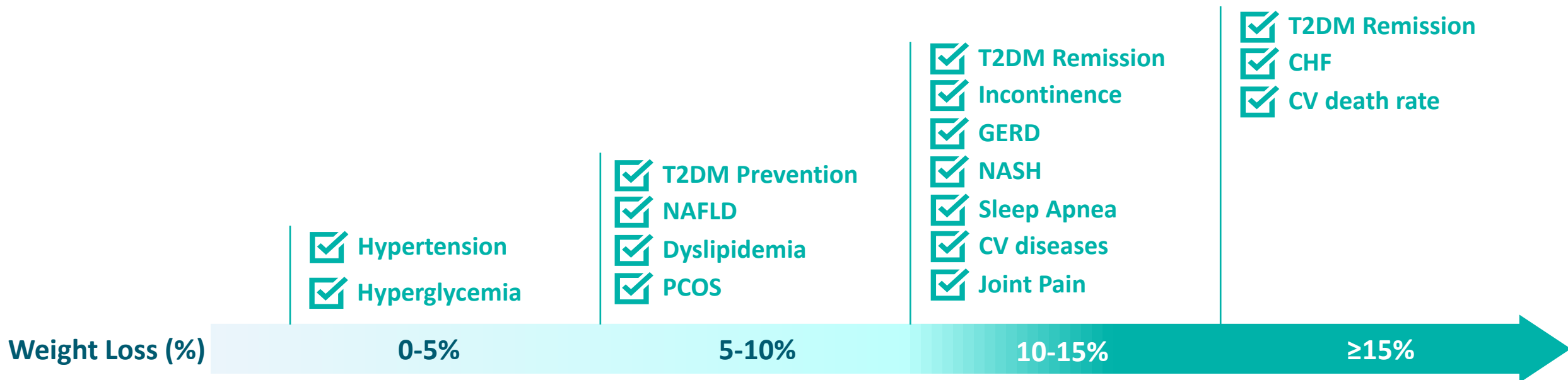
*Including breast cancer, colorectal cancer, ovarian cancer, cervical cancer, esophageal cancer, renal cancer, prostate cancer, etc.
 CAD: coronary artery disease CHF: congestive heart failure PE: pulmonary embolism LBP: Low Back Pain
 NAFLD: nonalcoholic fatty liver disease

- Overweight and obesity contribute to **11.1% of deaths** associated with non-communicable diseases;
- Overweight and obesity are also associated with **significantly increased morbidity**, which can affect almost every organ system. The organs affected by obesity can be broadly grouped into three classes: metabolic, mechanical, and mental.

Obesity Management Could Reverse Disease Trajectory

5%
~15%

- 5%-15% weight loss within 6 months is recommended for patients with obesity or overweight with complications.
- Increased weight loss percentage is associated with increased improvements in obesity-related risk factors and comorbidities, and could be of significant benefit for patients.



1. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY COMPREHENSIVE CLINICAL PRACTICE GUIDELINES FOR MEDICAL CARE OF PATIENTS WITH OBESITY; Endocr Pract. 2016 Jul;22 Suppl 3:1-203. doi: 10.4158/EP161365.GL. Epub 2016 May 24 .

PCOS: polycystic ovary syndrome NASH: Non-alcoholic steatohepatitis
GERD: gastroesophageal reflux disease

Obesity Management is Highly Beneficial in T2DM Treatment

Two digit or more significant weight loss may lead to the remission of T2DM

~50% T2DM adult patients
in China are living with overweight or obesity



T2DM incidence rates in Chinese population:

- 8.8% in BMI < 25 group;
- 13.8% in 25 ≤ BMI < 30 group;
- **20.1% in BMI ≥ 30 group.**

1. JAMA. 2021 Dec 28;326(24):2498-2506. doi: 10.1001/jama.2021.22208. Prevalence and Treatment of Diabetes in China, 2013-2018

2. Chinese Diabetes Society, Guideline for the prevention and treatment of type 2 diabetes mellitus in China (2020 edition)

3. American Diabetes Association; 8. Obesity Management for the Treatment of Type 2 Diabetes: Standards of Medical Care in Diabetes—2021. Diabetes Care 1 January 2021; 44 (Supplement_1): S100–S110.

4. Hou X, Lu J, Weng J, Ji L, Shan Z, Liu J, et al. (2013) Impact of Waist Circumference and Body Mass Index on Risk of Cardiometabolic Disorder and Cardiovascular Disease in Chinese Adults: A National Diabetes and Metabolic Disorders Survey. PLoS ONE 8(3): e57319.

5. Ameena Meerasa, Satya Dash; Weighing in on Type 2 Diabetes Remission. Diabetes Care 5 January 2022; 45 (1): 28–30.



- **T2DM prevention:** There is strong and consistent evidence that **obesity management can delay the progression from prediabetes to T2DM.**
- **Beneficial in T2DM treatment:** In patients with T2DM who also have overweight or obesity, modest and sustained weight loss (>5%) has been shown to **improve glycemic control, reduce the need for glucose-lowering medications and result in metabolic benefits** including lowering of blood pressure and blood lipids, improving insulin resistant and β -cell function.
- **Potential of T2DM remission:** Increased weight loss percentage was associated with increased odds of T2DM remission, starting with 10–15%.

Lack of Satisfactory Measures Calls for Breakthrough in Obesity Management for Huge Population in China



Lifestyle Intervention

Low Compliance

Lack of established approach

Intensive time commitment

Self-management disparities

Non-ideal outcome

China is in lack of established and comprehensive lifestyle intervention approach for widespread use



Pharmacotherapy

<1% treated

Lack of effective medicines

Insufficient response

Safety and tolerability issues of current therapy

Concomitant medications limit

Only Orlistat is approved for weight loss use in China. It is difficult to meet various clinical needs and has limited efficacy and serious adverse effects.



Bariatric Surgery

~0.25% treated

Psychological resistance

Considerable cost

Weight rebound

Short / long term complications

The adoption of bariatric surgery in China faces many obstacles, such as a series of serious postoperative complications



Mazdutide Development Overview and Clinical Update

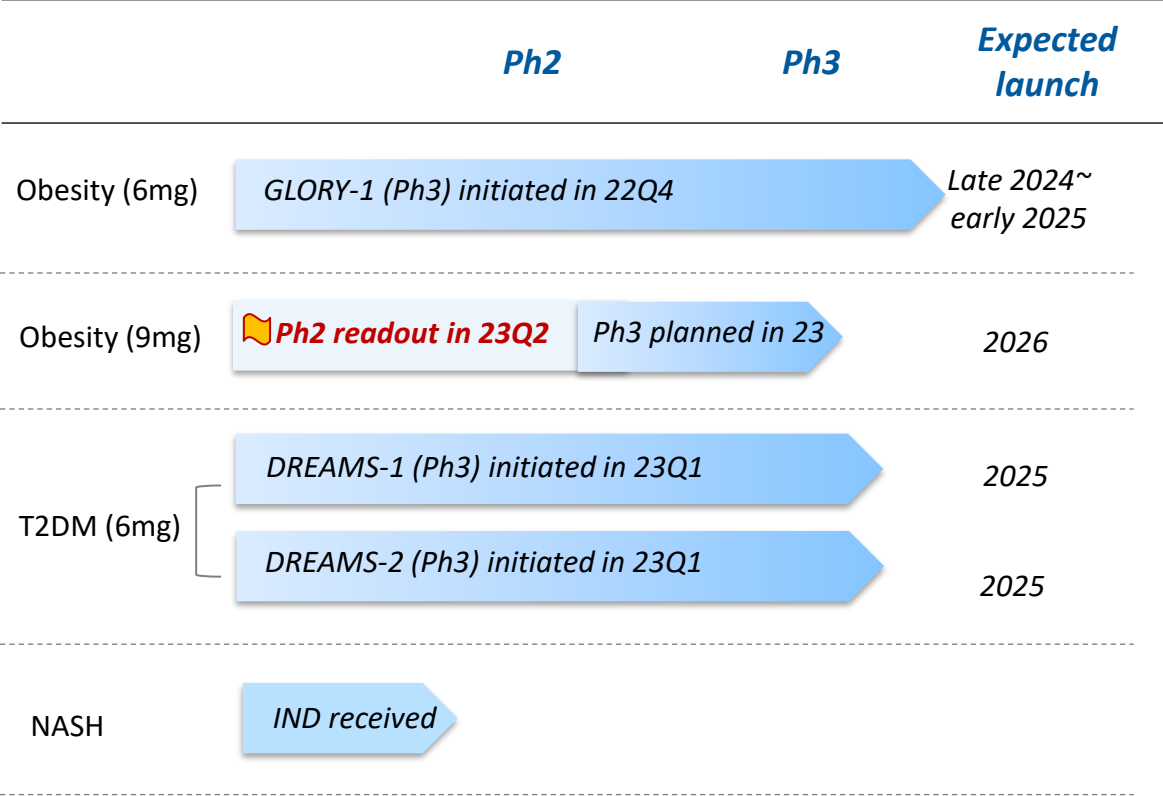
Dr. Lei Qian

VP, Non-oncology Clinical Development

Mazdutide (IBI362) : Globally First GLP-1R/GCGR Dual Agonist in Phase 3

Potentially best-in-class therapy for obesity and diabetes

Mazdutide Development Overview



- Potential best-in-class therapy to change treatment regimen for huge obese and overweight population
- Unique clinical development strategy to address needs of different population
 - 6mg for obesity and overweight: Phase 3 ongoing since 22Q4; robust weight loss effect for broad obese and certain overweight population
 - 9mg for obesity: Phase 2 achieved primary endpoint in 23Q2 with potentially bariatric surgery equivalent efficacy for moderate to severe obesity
 - 6mg T2DM: Phase 3 ongoing since 23Q1; both weight loss and glycemic control for long-term disease management benefits of diabetes

Mazdutide 9 mg Phase 2 in Chinese Adults with Obesity

A potentially more ideal treatment for moderate to severe obesity than surgery

Among the GLP-1 class drugs approved and under clinical development globally, mazdutide 9mg is...



The **first** study suitable for **moderate to severe obesity** where metabolic surgery is the only main treatment option today



The **first** dual-target agonist achieved **>15%** weight loss in 24-week treatment, showing **surgery-equivalent** weight loss efficacy



The **first** to develop different dose regimes for **different degrees of obesity**, with robust weight loss in both 6mg and 9mg mazdutide



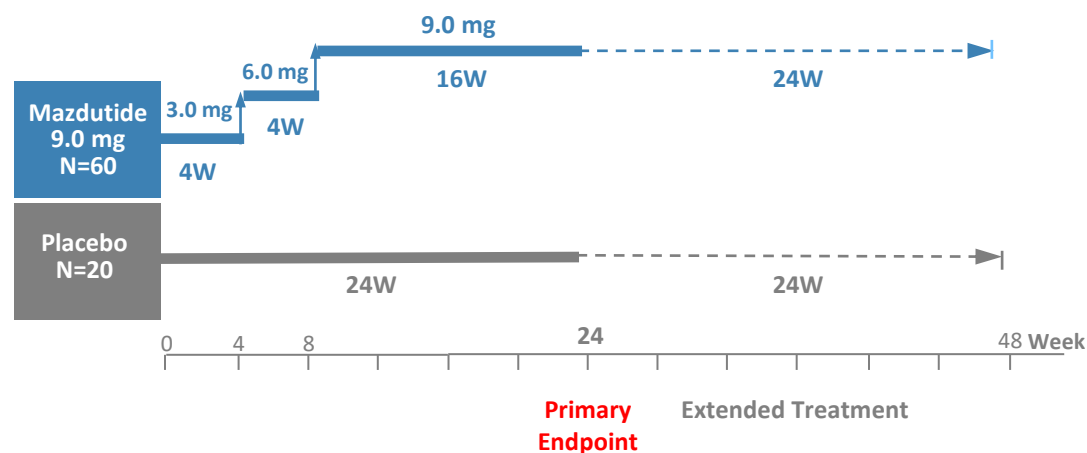
Consistently favorable tolerability and safety profile in 9mg mazdutide as previously seen in 6mg mazdutide

Mazdutide 9 mg Phase 2 in Chinese Adults with Obesity

Study design

Inclusion criteria

BMI ≥ 30 kg/m² without diabetes



Baseline characteristics

			
Mean Age	Mean Height	Mean Weight	Mean BMI
34 yrs	168.0 cm	96.9 kg	34.3 kg/m ²

- A randomized, double-blind, placebo-controlled Phase 2 clinical study (NCT04904913).
- Primary endpoint: percentage change in body weight from baseline versus placebo after 24 weeks of treatment.
- The study will also extend treatment to 48 weeks.

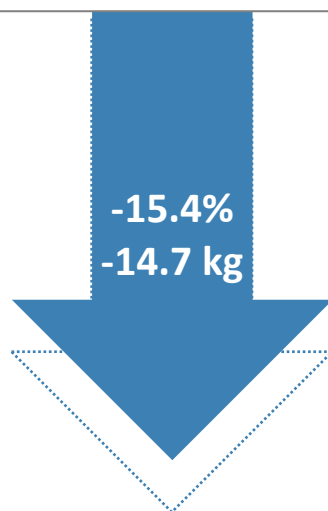
Mazdutide 9 mg Phase 2 in Chinese Adults with Obesity

Positive topline results with 15.4% mean weight loss versus placebo

Primary Endpoint

Placebo-adjusted mean body weight
change from baseline:
mazdutide 9mg at Week 24

mean baseline weight 96.9 kg



Mazdutide 9 mg

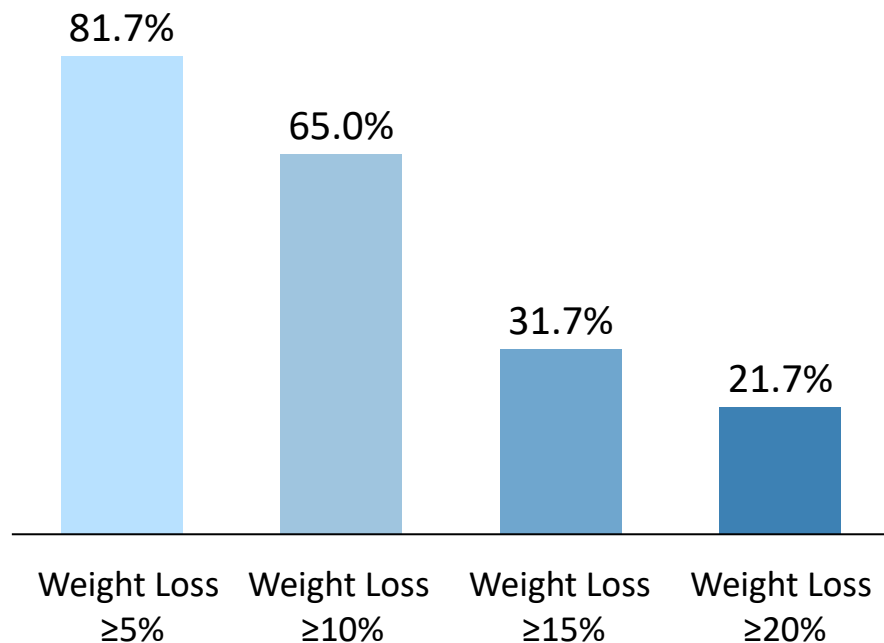
- **Mazdutide 9mg demonstrated superior body weight loss to placebo.**
- After 24 weeks, treatment difference of mazdutide 9mg versus placebo:
 - -15.4% (95%CI: -18.8%, -11.9%) mean body weight percent change from baseline, $P < 0.0001$;
 - -14.7 kg (95%CI: -17.9 kg, -11.5 kg) mean body weight change from baseline, $P < 0.0001$.
- **A trend of continuous decline of body weight was observed at Week 24 and we expect longer treatment will bring more weight loss.**

Mazdutide 9 mg Phase 2 in Chinese Adults with Obesity

21.7% participants achieved $\geq 20\%$ weight loss at Week 24

Key Secondary Endpoint

Proportion of participants achieved $\geq 5\%$ weight loss from baseline: mazdutide 9mg at Week 24



- At Week 24, 81.7%, 65.0%, 31.7% and 21.7% of participants in the mazdutide 9 mg group achieved $\geq 5\%$, $\geq 10\%$, $\geq 15\%$ and $\geq 20\%$ weight loss, respectively.
- No subject in placebo group lost 5% or more of body weight.

Mazdutide 9 mg Phase 2 in Chinese Adults with Obesity

Overall tolerability and safety profile was favorable



- Except for COVID-19 infection, the most commonly reported adverse events were gastrointestinal-related adverse events, most of which were **mild or moderate and transient**.



- The **drop-out rate** of the mazdutide group was **lower than** that of the placebo group.



- **No subject** in the mazdutide group discontinued treatment due to adverse events.



- **No serious adverse events occurred.**

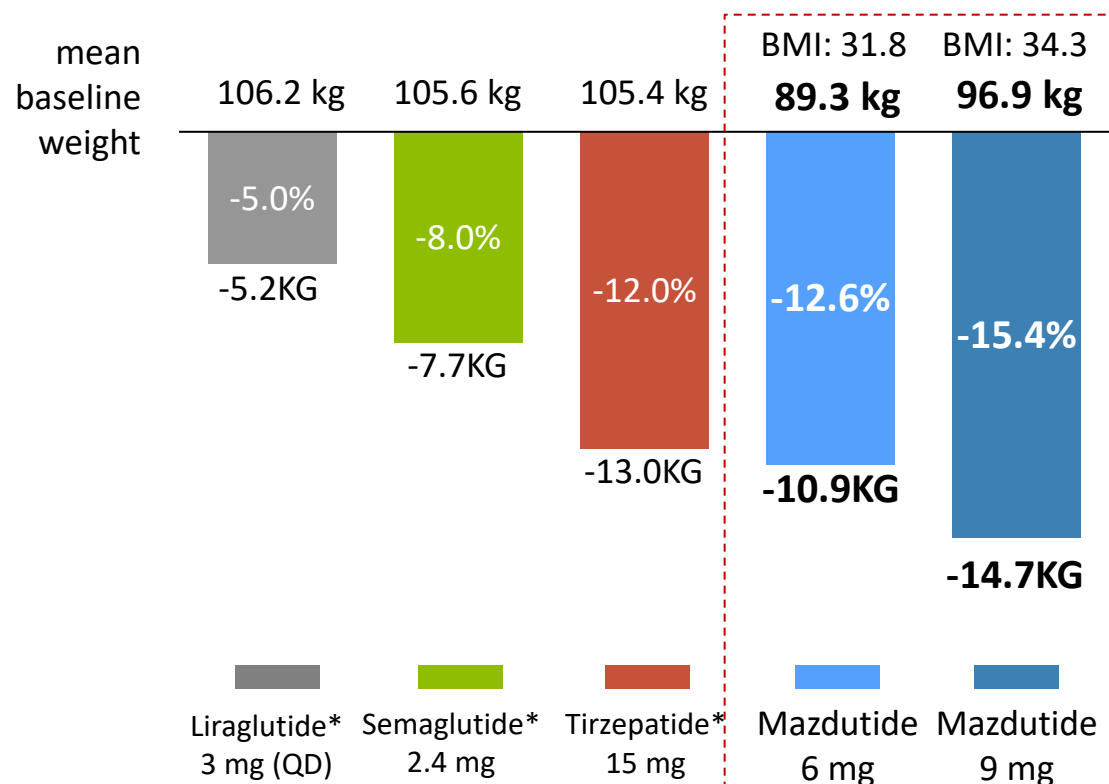
The study is still in progress. Full data and analysis of primary endpoints, other secondary and exploratory endpoints, and safety profile will be further analyzed and disclosed after the completion of the study.

Mazdutide in Obesity or Overweight

Potentially best-in-class weight reduction

Indirect comparison of GLP-1 class drugs

Placebo-adjusted mean body weight reduction at Week 24



- After 24 weeks of treatment, mazdutide 6 mg & 9 mg regimens can induce a weight loss of 12.6% (10.9kg) and 15.4% (14.7kg) respectively in different baseline group.
- The results are **competitive to** the most effective multi-target GLP-1 receptor agonist drug.
- Mazdutide 9mg even demonstrated **bariatric surgery equivalent efficacy**. Single-target GLP-1 drugs have limited efficacy in this population and hardly can achieve placebo-adjusted 15% weight loss.

* Not approved in China for obesity

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24-week weight loss data of liraglutide 3 mg, semaglutide 2.4 mg and tirzepatide 15 mg were estimated from published results of SCALE¹, STEP-1² and SURMOUNT-1³ study, respectively.

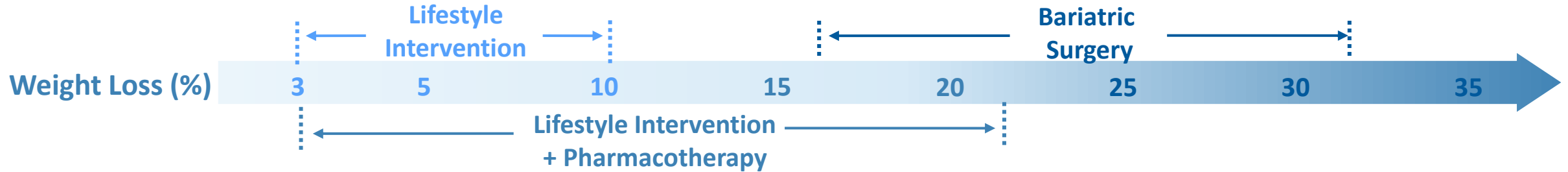
¹Pi-Sunyer X, et al. *N Engl J Med*. 2015. ²Khoo TK, et al. *N Engl J Med*. 2021. ³Jastreboff AM, et al. *N Engl J Med*. 2022

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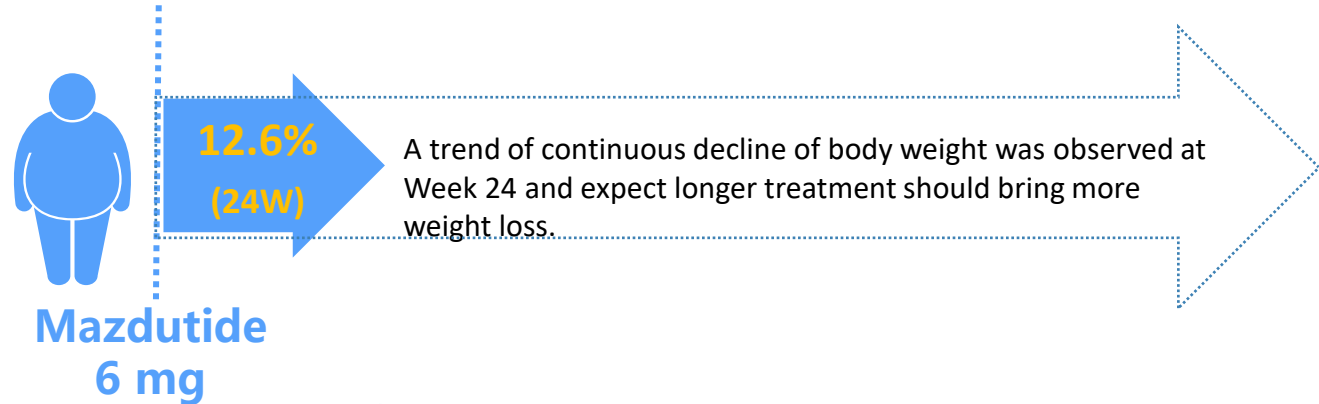
Mazdutide 9mg and 6mg

Developing two dose regimens to treat different degrees of obesity

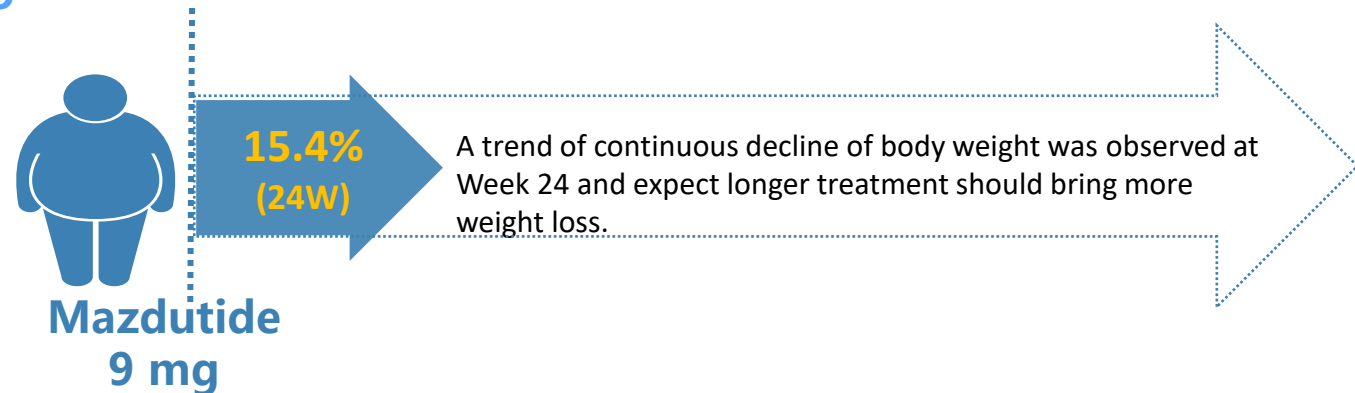


- Potential best-in-class weight loss efficacy
- Broader coverage indicated for obese ($\text{BMI} \geq 28 \text{ kg/m}^2$) and certain overweight ($24 \text{ kg/m}^2 \leq \text{BMI} < 28 \text{ kg/m}^2$) * population

*Body mass Index (BMI) ≥ 28 kilograms per square meter (kg/m^2), or $\geq 24 \text{ kg/m}^2$ and previous diagnosis with at least one of the following comorbidities: hypertension, dyslipidemia, obstructive sleep apnea



- Superior, bariatric-surgery-like efficacy
- Filling the pharmacotherapy gap for moderate and severe obese population with substantial unmet need.

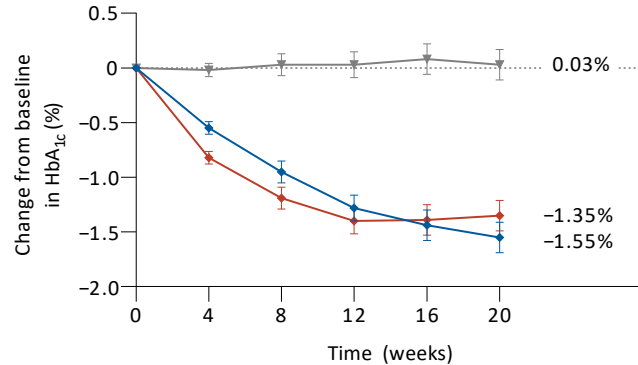


Mazdutide 6mg Phase 2 in Chinese T2DM Patients

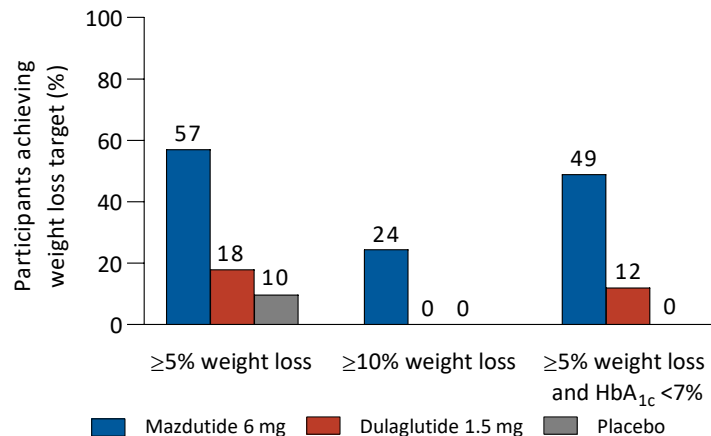
Achieve both weight loss and glycemic control for long-term benefits

Primary & Key Secondary Endpoints

HbA_{1c} reduction from baseline at Week 20



Proportion of participants achieving HbA_{1c} and weight loss targets at Week 20



- HbA_{1c} reduction trend is sustained in patients receiving 6mg mazdutide at Week 20.
- At Week 20, 49% patients in the mazdutide 6mg group achieved HbA_{1c} <7.0% and body weight reduction ≥5% from baseline, compared to 12% in dulaglutide 1.5mg group and 0% in placebo group, while weight loss is highly beneficial in T2DM treatment and may even lead to T2DM remission.
- Multiple metabolic benefits observed in patients receiving mazdutide including reduction in waist circumference, BMI, blood pressure, lipid levels and serum uric acid.

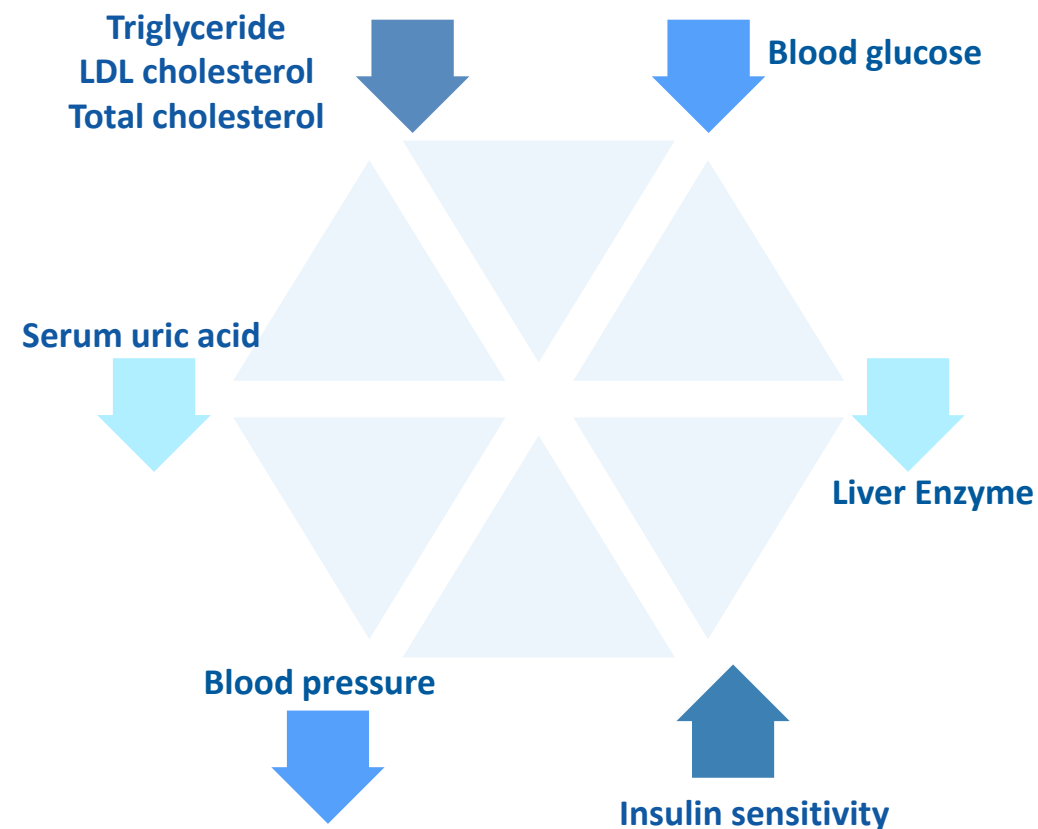
Overall Safety Profile and Metabolic benefits Observed for Mazdutide

Overall tolerability and safety profiles are favorable

- Favorable and tolerable safety profile in over 1000 subjects exposed to mazdutide in all clinical programs; the most common adverse reactions (AEs) were gastrointestinal related AEs, most of which were mild to moderate and transient.
- Overall safety profiles are similar to other GLP-1 based therapies as reported.

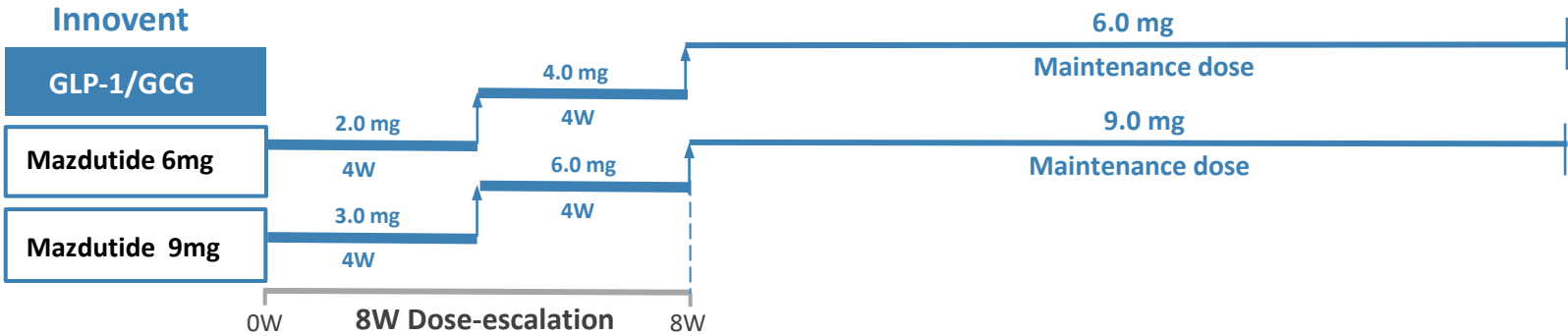
More data and full analysis of Phase 2 study of mazdutide 6mg for obesity and Phase 2 study of mazdutide 6mg for T2DM is planned to be disclosed in future academic journals.

Multiple metabolic benefits observed



Mazdutide Simplified Dose-Escalation Regimen

Only two steps to enter maintenance dose



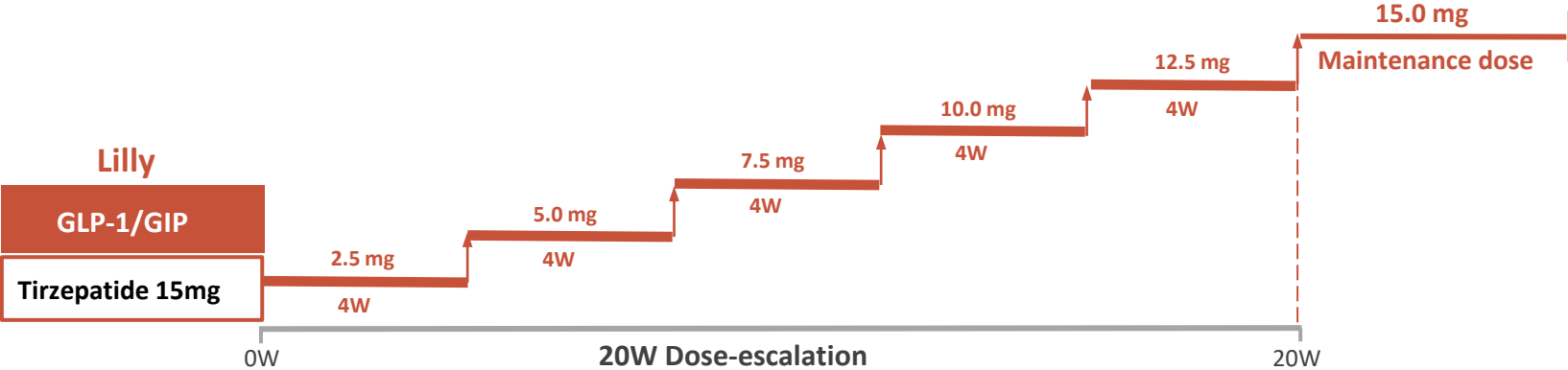
Mazdutide 6mg/9mg

- 3 strengths (pens)
- 8-week dose-escalation



Semaglutide 2.4mg

- 5 strengths (pens)
- 16-week dose-escalation



Tirzepatide 15mg

- 6 strengths (pens)
- 20-week dose-escalation

Summary and Key Takeaways

Substantial Unmet Medical Need in Obesity and T2DM in China

- Overweight and obesity are established risk factors for major NCDs
- Over 500m adults, including 50% T2DM patients live with obesity or overweight in China, with huge unmet need for effective weight management measures

Superior Clinical Profile of Mazdutide

- Best-in-class weight loss effect; both glycemic control and weight loss for diabetes management benefit
- Favorable and tolerable safety profile in over 1000 subjects exposed to mazdutide in all programs
- Multiple metabolic benefits observed

Frontrunner to Potentially Change China's Obese Treatment Standard

- No GLP-1 class drug has filed NDA in China for obesity till now
- One of the only two dual agonists in registrational stage in China; NDA planned in end-23 to early-24
- High quality and efficient product development platform to advance mazdutide development on track

Reliable Supply and Commercialization in Plan

- Established manufacturing capacity in plan to meet the potential huge demand
- Product potential backed by Innovent's differentiated CVM portfolio and commercialization capability



Q&A

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