Hua Medicine
华领医药

2021 Interim Results Presentation

August 2021

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Company Overview

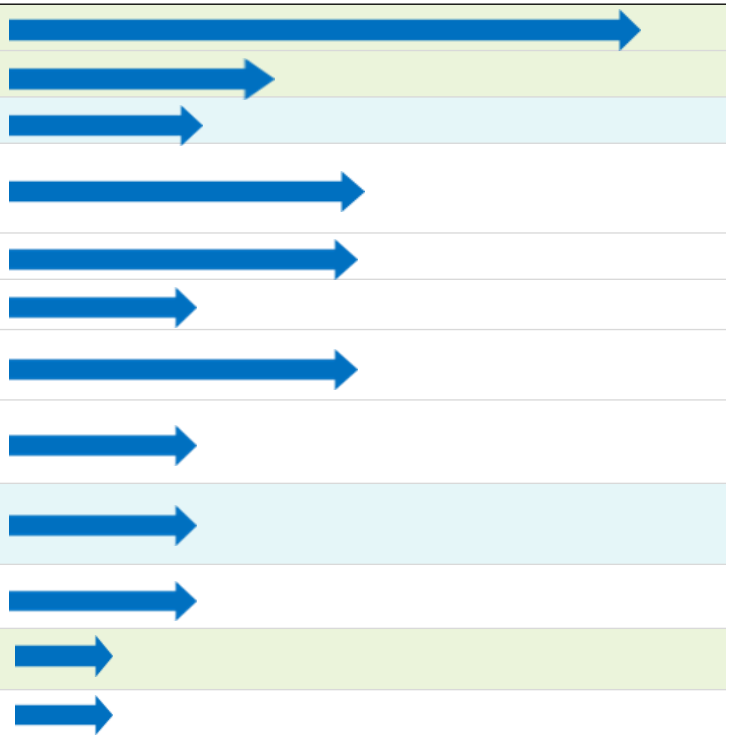
Hua Medicine is a clinical stage biotech company focusing on innovative solution for diabetes and neurodegeneration disease

Dorzagliatin NDA Accepted by China NMPA

- Dorzagliatin NDA was filed as a global **first in class (FIC)** glucokinase allosteric activator for Type 2 Diabetes in March 30, 2021 and accepted on April 23, 2021
  - Mono therapy for drug Naïve T2D
  - Add-on to Metformin for Metformin failed T2D
- **5 characteristics** of Dorzagliatin as a Novel New Drug for T2D
  - Novel concept of treating T2D through rescuing early phase insulin secretion
  - Novel MOA of allosteric activation of glucokinase enzyme
  - Novel chemical structure with ADME advantage for DKD
  - Novel formulation for targeted organ delivery
  - Novel benefit in improving beta cell function and reduction of insulin resistance leads to clinical sustain glycemic control and remission
- CDE, CFDI, CPC and NIFDC at NMPA China are fully engaged in NDA review
- Drug manufacture by CRO-CDMO has been validated and ready for commercial launch
  - New manufacture company has been established at Lingang, Shanghai, China
- Commercial team established at Hua Medicine managing product distribution and market entry
  - Bayer Medical and Marketing Team engages for product launch readiness

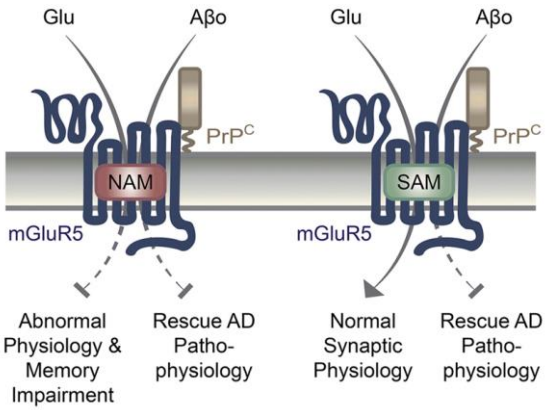
Hua Medicine R&D Pipeline

Product Name	Indication	Development phase
Dorzagliatin HMS5552	T2D	NDA Filed (China)
	DKD	Phase I enabling
	T1D	IND-enabling
HMSFDC 6857 Dorzagliatin + Metformin	T2D	Phase I ready
HMSFDC 6868 Dorzagliatin +Sitagliptin	T2D	Phase I ready
	Insulin Sparing	IND-enabling
HMSFDC 5868 Dorzagliatin +Empagliflozin	T2D CVR	Phase I ready
HMSFDC 5688 Dorzagliatin +pioglitazone	NASH	IND-enabling
HMS 5678 Dorzagliatin + GLP-1	Alzheimer Disease	IND-enabling
HMS 6789 Dorzagliatin + Insulin	Late Stage T2D Insulin sparing	Ph III Design
mGLUR5 NAM	PD-LID	Pre-clinical
Fructose Kinase Inhibitor	Metabolic Disease	Pre-clinical



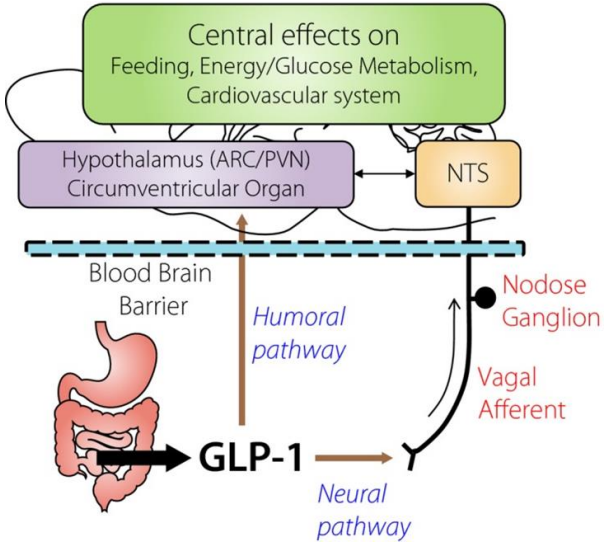
DREAM Study topline data will be presented by Phase III Principal Investigators (Nanjing First Hospital) at the 6th China BioMed Innovation and Investment Conference to be held on September 25-27, 2021 in Suzhou, China.

New Opportunity in Neurodegeneration Disease



mGLUR5 Regulator

Neurodegeneration Diseases

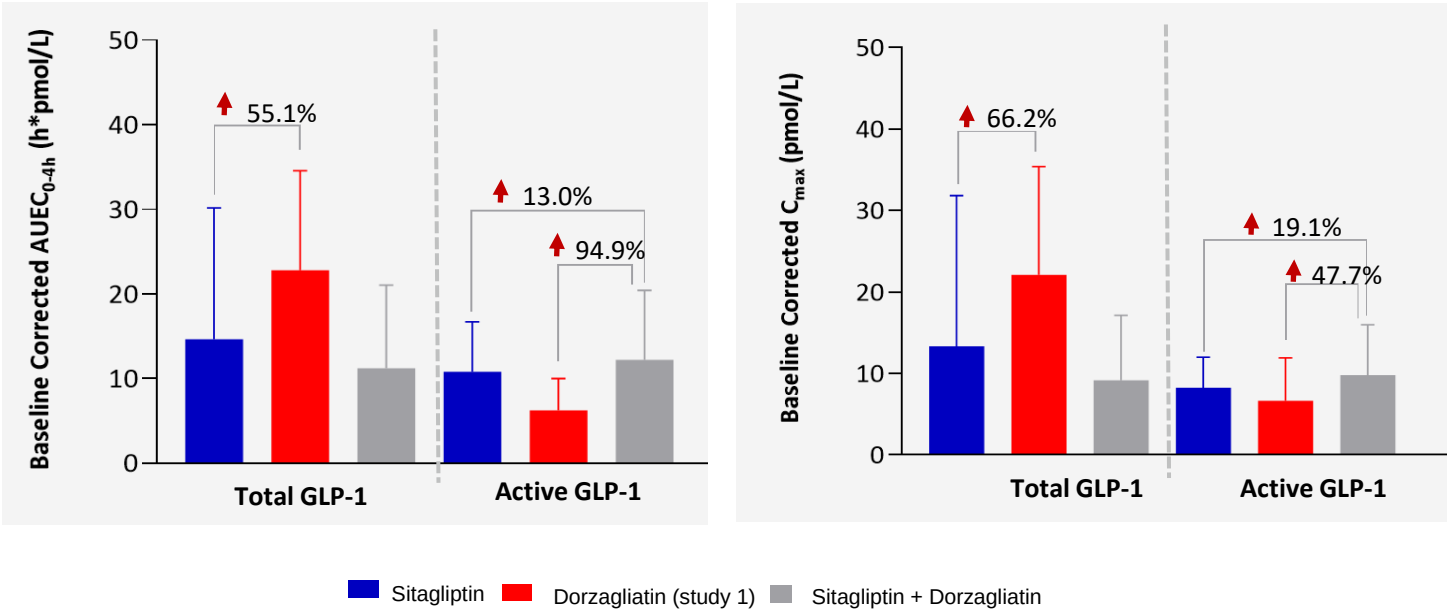


Neuroendocrine Regulation

Neurodegeneration Disease

Improved GLP-1 secretion in T2D Patients (ADA Presentation)

- Dorzagliatin increased total GLP-1 secretion in T2D patients, which is greater than that of Sitagliptin.
- Increase of total GLP-1 was observed in the Dorzagliatin treatment with AUEC0-4h increase of 55.1% and Cmax increase of 66.2% compared with Sitagliptin.
- Dorzagliatin is synergistic with Sitagliptin, to increase circulating active GLP-1 in T2D patients with AUEC0-4h of 94.9% over Dorzagliatin.



ADA 2021 117-LB

The current treatment paradigm for Type 2 diabetes is unsatisfactory... and have to focus on diabetes complications

"Confounding the diabetes epidemic and high costs, ***therapeutic targets are not being met.*** *There is a lack of improvement in reaching clinical targets since 2005 despite advancements in medication and technology treatment modalities.* ***Indeed, between 2010 and 2016 improved outcomes stalled or reversed."***[1]

ADA Guideline 2020

- New recommendations are added on use of the ambulatory glucose profile (AGP) report and **time in range (TIR)** for assessment of glycemic management.
- New evidence and a recommendation were added on early combination therapy for Type 2 Diabetes
- SGLT-2 inhibitors or GLP-1 receptor agonists are introduced in strategy in patients with cardiovascular disease meeting A1C goals for cardiovascular benefit.

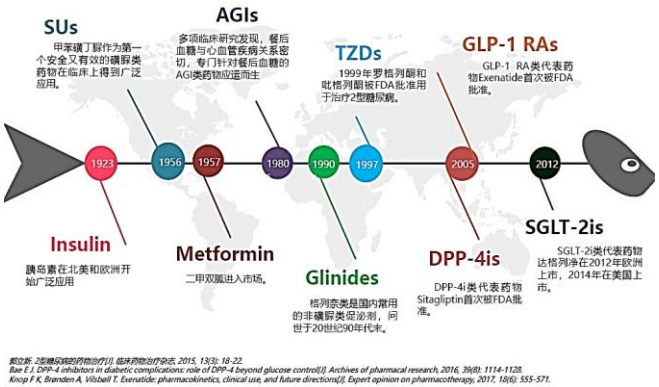
CDS Guideline 2020

- **HbA1c** is incorporated into the diagnostic criteria for diabetes
- **Time in Range (TIR)** added to blood sugar control goals
- The guideline clarifies that lifestyle intervention and metformin are the first-line treatments for hyperglycemia in patients with T2D.
- For patients with T2D with ASCVD or high risk of cardiovascular risk, GLP-1RA or SGLT2i with evidence of ASCVD benefit should be added to metformin treatment.

Source 1: Consensus Report, Diabetes Self-management Education and Support in Adults with Type 2 Diabetes, published in Diabetes Care in July 2020, the American Diabetes Association, et. al.

Global Unmet Medical Needs in Glycemic Control

9 Classes of Drugs

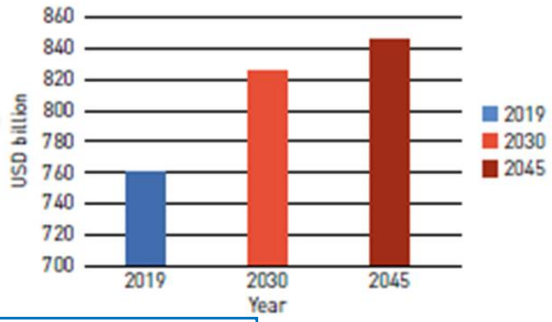


Global Cost
$760 bn USD

450 Mn Diabetes
Many Complications

IDF 2019

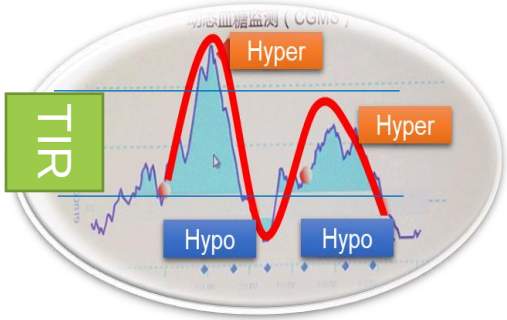
Total diabetes-related health expenditure for adults (20–79 years) with diabetes in 2019, 2030 and 2045



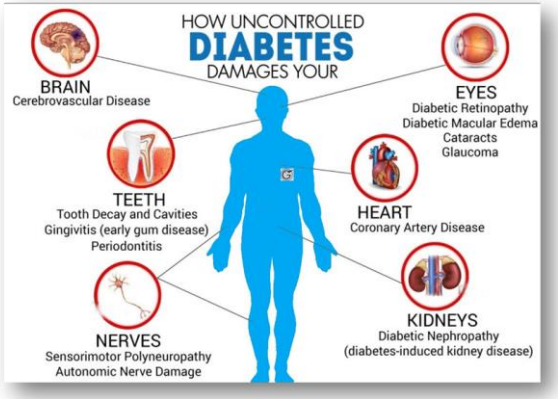
Top 10 Nations

Rank	Country or territory	Total diabetes-related health expenditure in 2019 (USD billion) (20–79 years)
1	United States of America	294.6
2	China	109.0
3	Brazil	52.3
4	Germany	43.8
5	Japan	
6	Mexico	
7	France	
8	United Kingdom	
9	Canada	12.3
10	Russian Federation	10.6

China Cost
$109 bn USD



Blood glucose fluctuation



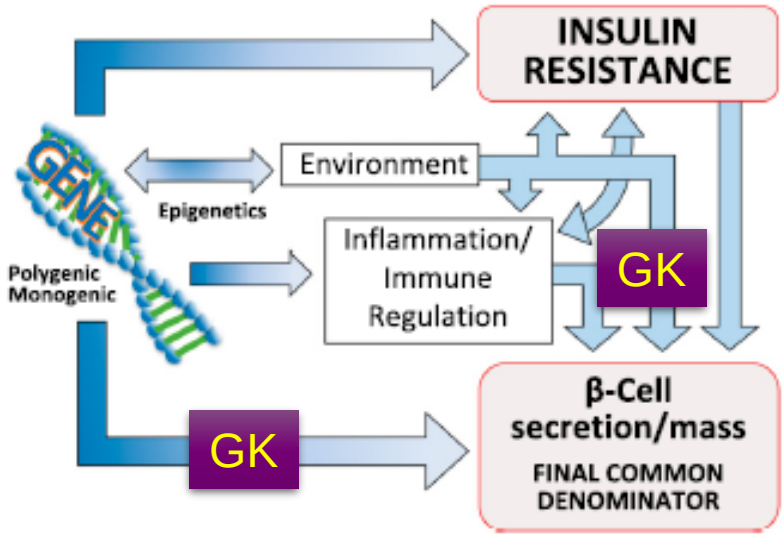
Diabetes Complications

Economic Burden

Source: Cheng YY, Chen L. Global J Obesity, Diabetes and Metabolic Syndrome 2020, 7：018-023
Source: Foos Wang et al Value in Health Regional Issues, 2019, 18: 36-46

Glucokinase plays central rule in diabetes care

- The **root cause of diabetes is** the loss of beta cell secretion function that is regulated by genetic, epigenetic, autoimmunity and insulin resistance, and all these are associated with loss of GK function
- **Metformin, GLP-1 and Insulin** can not restore beta cell secretion function alone nor in combination

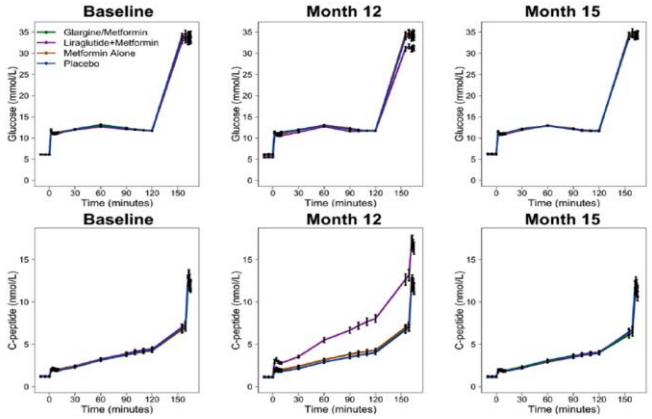


Lack of Durable Improvements in β-Cell Function Following Withdrawal of Pharmacological Interventions in Adults With Impaired Glucose Tolerance or Recently Diagnosed Type 2 Diabetes

The RISE Consortium*

Diabetes Care 2019 Jun; dc190556.
https://doi.org/10.2337/dc19-0556

Check for updates



Treated by

1.Metformin

2. GLP-1 + Metformin

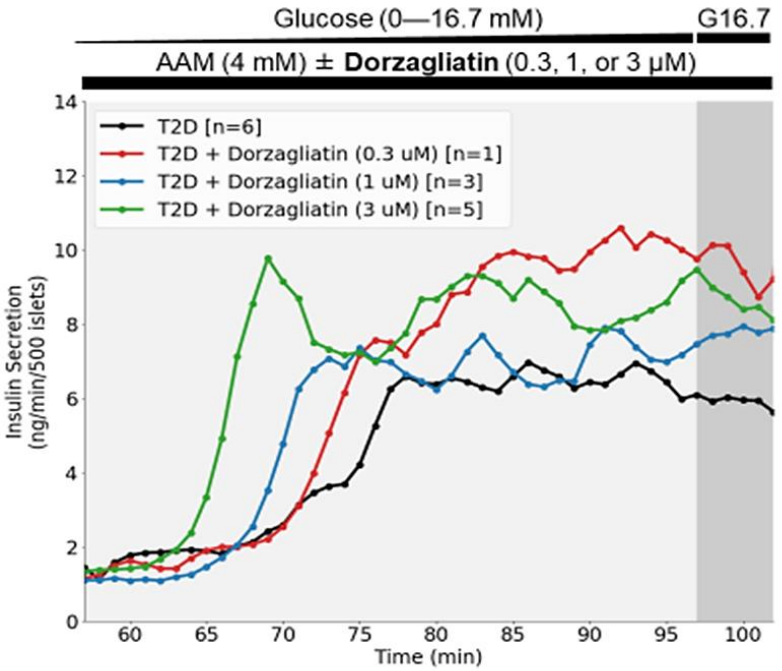
3.Insulin + Metformin

Source: Stanley Schwartz Diabetes Care 2016, 39(2): 179-186
source: RISE Consortium. Diabetes Care. 2019 Sep;42(9):1742-1751.

Dorzagliatin treats the root cause of diabetes

- Dorzagliatin is a novel dual acting full glucokinase allosteric activator that re-models the glucose set point and improves glucose sensitivity in type 2 diabetes patients
- Acts on: glucose sensor GK in pancreas, liver and intestine organs
- Improve glucose dependent insulin, glucagon and GLP-1 secretion in T2D patients
- Improve early insulin secretion and beta cell function to enhance 24hr glycemic range control
- Rescue the beta cell mass and hepatic GK function in animal model
- Completed 17 clinical trials including 2 pivotal Phase III trials in China and USA with excellent glycemic control with minimum hypoglycemia risk, accompanied with improve beta cell function and insulin sensitivity

Dorzagliatin Improves beta Cell Secretion Function in T2D



AI application for Systematic Diabetes Care

- **Dorzagliatin + Antidiabetics offers**
- **Remission + Prevention of Diabetes Complication**

Dorzagliatin glucose dose dependently improves GSIR

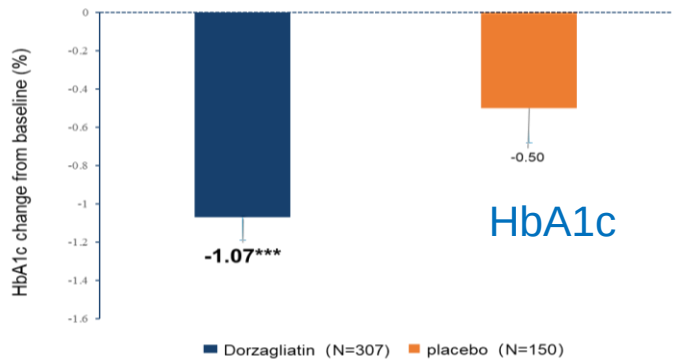
- **A study in islets from T2D patients**

Franz Matschinsky 2021

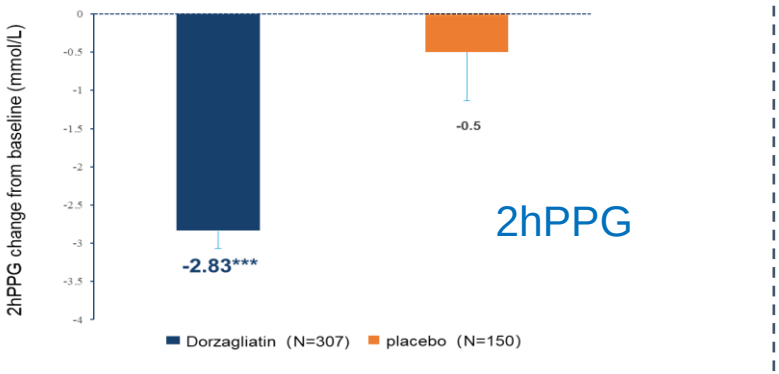
Improved beta cell secretion leads to clinical benefit (ADA Presentation: SEED Study)

Effective glycemic control in drug naïve T2D patients
Improve disease conditions

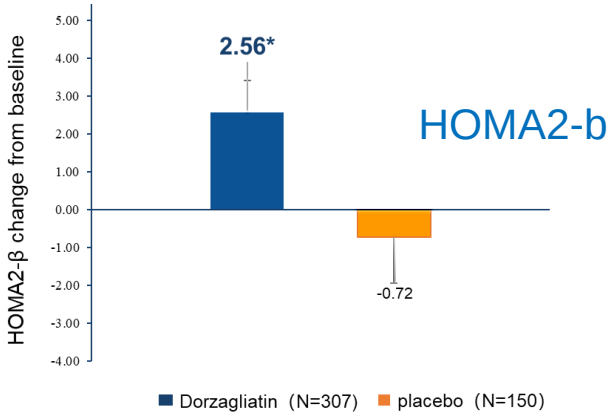
HbA1c change from baseline in week 24



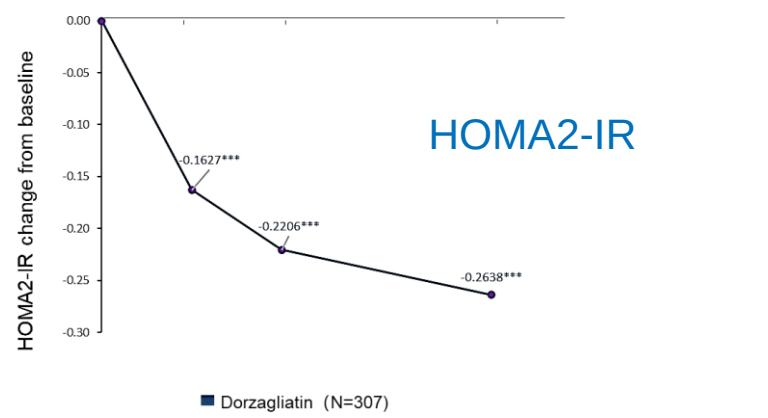
2hPPG change from baseline in week 24



HOMA2-β change from baseline in week 24



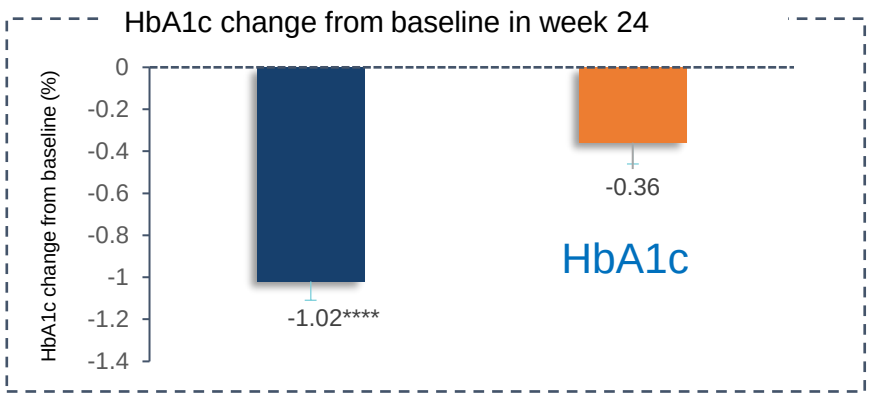
HOMA2-IR change from baseline in week 52

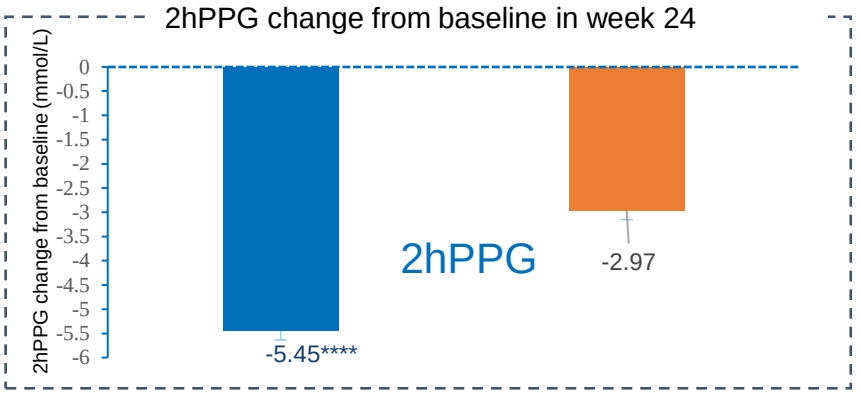


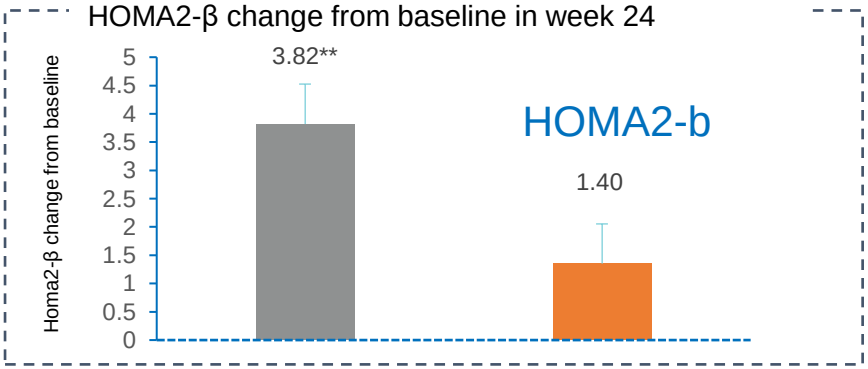
ADA 2021 235-OR

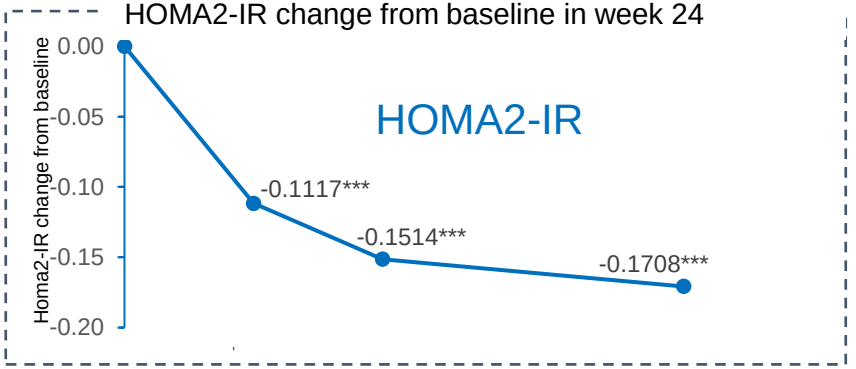
Improved beta cell secretion leads to clinical benefit (ADA Presentation: DAWN Study)

Add-on metformin therapy showed consistent benefit









Dorzagliatin+Metformin 1500mg/d（N=376） Placebo+Metformin 1500mg/d（N=375）

*Note: The bars show lower limits of 95% CIs. ****p<0.0001 vs placebo. **p<0.01 vs placebo. ***p<0.001 vs baseline.*

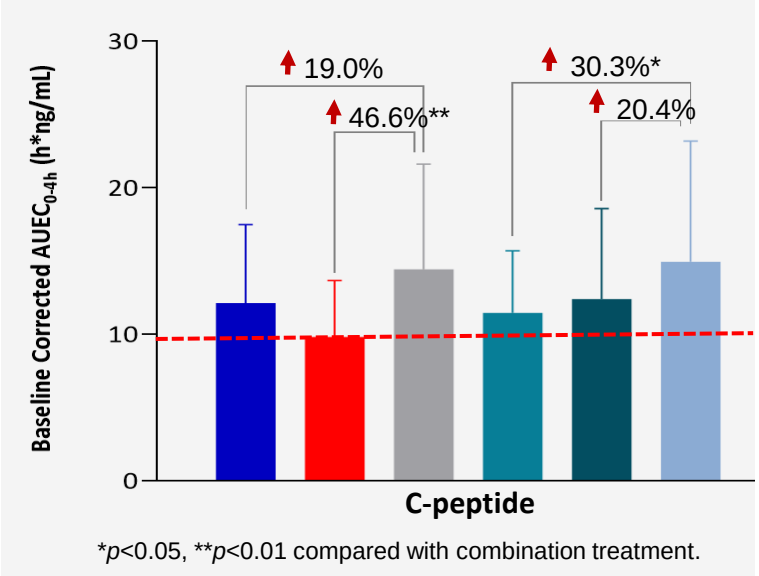
ADA 2021 763-P

Improved beta cell secretion leads to clinical benefit (ADA Presentation)

Study Results

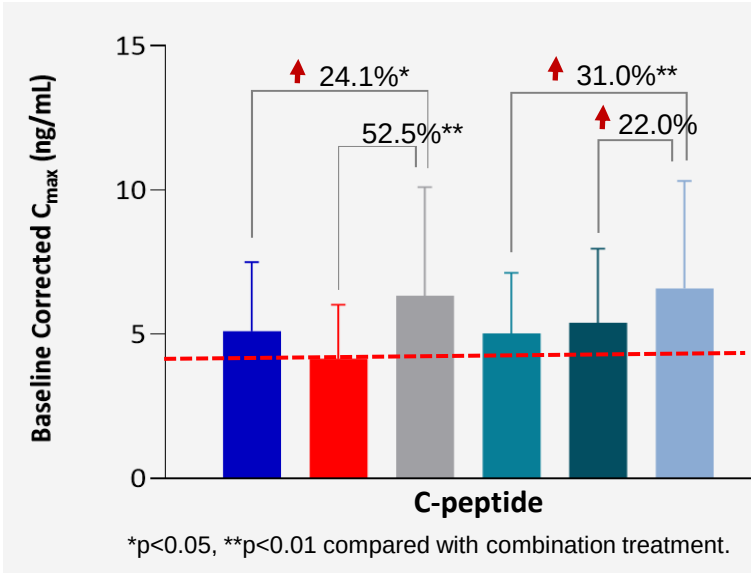
Dorzagliatin is synergistic with Sitagliptin (DPPIV inhibitor) or Empagliflozin (SGLT2 inhibitor) in optimizing beta cell function

$AUEC_{0\text{-}4h}$ of C-peptide between study 1 and study 2



*p<0.05, **p<0.01 compared with combination treatment.

C_{max} of C-peptide between study 1 and study 2



*p<0.05, **p<0.01 compared with combination treatment.

Sitagliptin | Dorzagliatin (study 1) | Sitagliptin + Dorzagliatin | Empagliflozin | Dorzagliatin (study 2) | Empagliflozin + Dorzagliatin

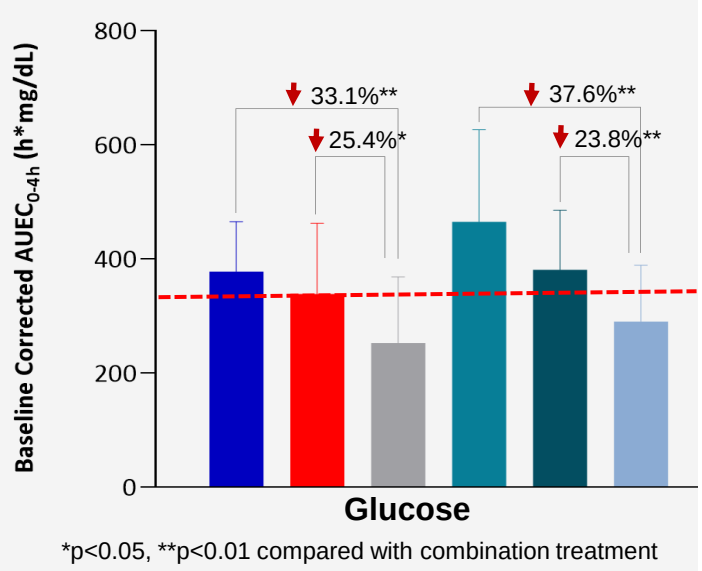
ADA 2021 117-LB

Improved beta cell secretion leads to clinical benefit (ADA Presentation)

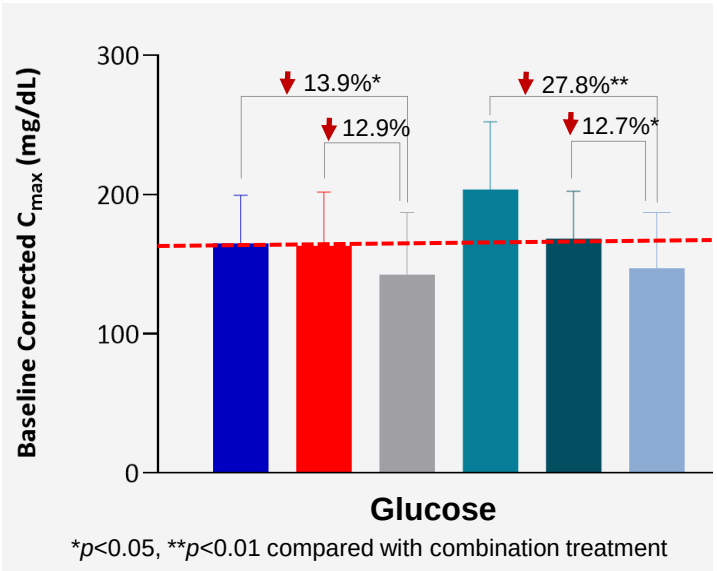
Study Results

The co-administration of dorzagliatin with Sitagliptin or Empagliflozin resulted in a significantly greater reduction of glucose than either monotherapy in the OGTT study

$AUEC_{0\text{-}4h}$ of Glucose between study 1 and study 2



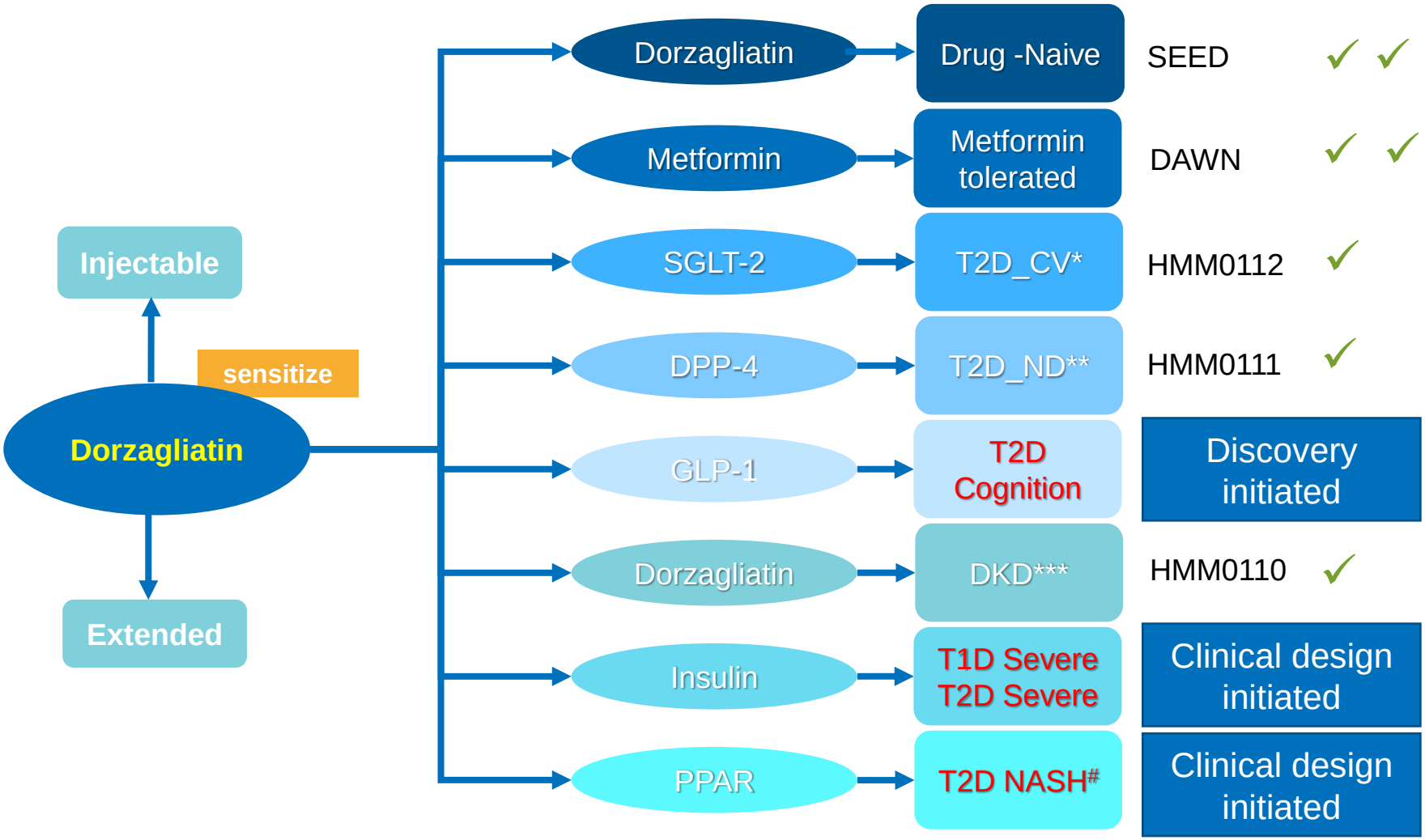
C_{max} of Glucose between study 1 and study 2



Sitagliptin | Dorzagliatin (study 1) | Sitagliptin + Dorzagliatin | Empagliflozin | Dorzagliatin (study 2) | Empagliflozin + Dorzagliatin

ADA 2021 117-LB

New Cornerstone Medication, New Opportunity



*CV cardiovascular disease; **ND neurodegeneration disease; ***DKD diabetes kidney disease
#NASH non-alcoholic steatohepatitis

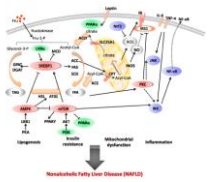
Ongoing Work

Bayer Commercialization Partnership

- Continuing joint medical education, market positioning efforts
- Pricing, pharmacoeconomics, and reimbursement list analysis

Optimizing manufacturing

- Scaling up production levels
- Decreasing cost basis of dorzagliatin



New Drug Discovery

- mGlur5 NAM – Neurodegeneration Diseases
- Fructokinase inhibitor – metabolic syndrome

Hua is well positioned financially

- Strong balance sheet with over RMB 800 million in cash
- Additional milestones upon approval from Bayer, and expected revenue generation starting 2022

Financial Review

Financial Summary

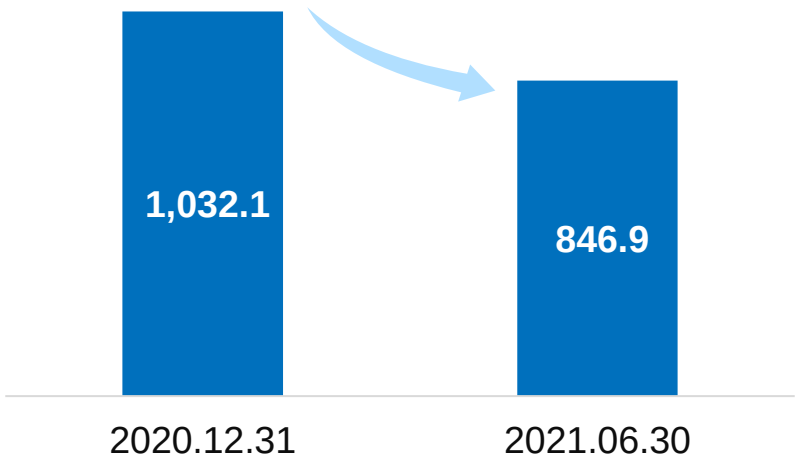
Cash Balance: RMB846.9 million of cash at 06/30/2021 vs. 1,032.1 million at 06/30/2020.

Total cash decrease of RMB185.2 million, consisted of

- Net cash used in operating activities was RMB164.3 million
- Net cash used in investing activities was RMB10.1 million
- Net cash used in financing activities was RMB5.8 million
- Net effect of exchange rate changes was RMB5.0 million

Net cash used in operation activities of RMB164.3 million mainly includes cash payment of RMB 90.9 million for the research and development activities and of RMB73.4 million for the administrative activities.

RMB' million



Financial Summary- continued

Loss before tax of RMB165.3 million in the first half of year of 2021 vs. RMB173.5 million in the first half of year of 2020

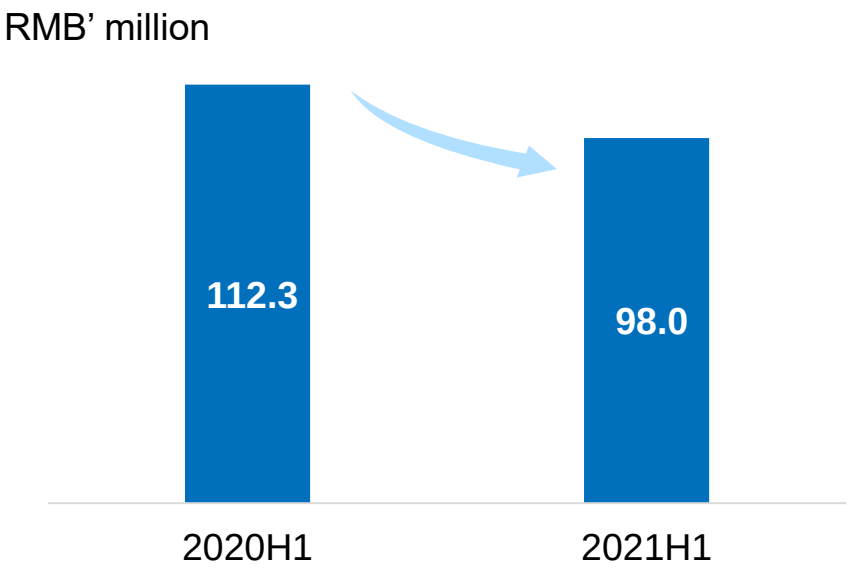
Research and development expenses of RMB98.0 million in the first half of year of 2021 vs. RMB112.3 million in the first half of year of 2020

- A decrease of RMB28.0 million for dorzagliatin clinical trials, which was primarily attributable to decreased costs associated with the last patient out of the 52-week study period of SEED/HMM0301 in March 2020 and DAWN/HMM0302 in September 2020;
- An increase of RMB2.8 million in chemical, manufacturing, and control expenses, which was primarily attributable to the chemical and process research for our fructose kinase inhibitor candidates conducted in the first half of year 2021;
- An increase of RMB3.0 million for dorzagliatin non-clinical studies, which was primarily attributable to the ISS data and analysis expense for NDA filing, FDC efficacy study of dorzagliatin with insulin/acarbose and efficacy study of dorzagliatin in animal model of T2D complicating cognitive disorder.

Financial Summary- continued

Research and development expenses- continued

- An increase of RMB10.2 million for others, which was primarily attributable to the allocation of rental fee, depreciation and amortization expense, property costs, utility cost and other cost related to our new headquarter which came into operation at the end of year 2020.

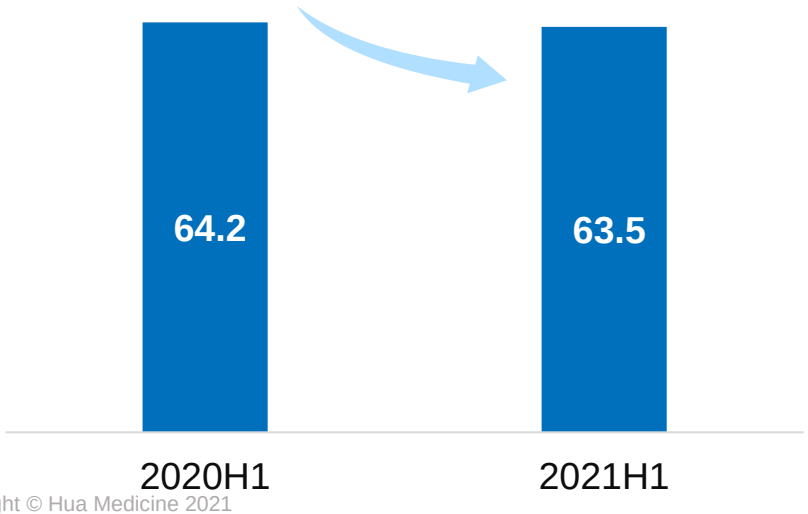


Financial Summary- continued

Administrative expenses of RMB63.5 million in the first half of year of 2021 vs. RMB64.2 million in the first half of year of 2020

- Decrease in labor costs which was attributable to the decrease of RMB4.0 million in share-based payment under the accelerated amortization method;
- Decrease of RMB4.7 million in rental fee, which was mainly due to the allocation method renewal after moving into our new headquarter at the end of year 2020;
- Adjusted for the increase of RMB2.6 million in depreciation and amortization expense, mainly due to the decoration and additional equipment purchased for our new headquarter; increase of RMB1.3 million in meeting fee due to more meeting activities conducted compared to the six months ended June 30, 2020 which was impacted by COVID-19 and increase of RMB1.8 million in other expenses, mainly consisting of cleaning cost, utility cost, security cost, greening cost and other sundry charges related to our new headquarter which came into operation at the end of the year 2020.

RMB' million



Hua Medicine – Global First-in-Class

- **Global rights** to dorzagliatin composition of matter, chemical process, formulation and multiple products in FDC with OADs
- **China strategic partner selected – Bayer Healthcare China**
- **Met Primary Endpoint** in both pivotal Phase III monotherapy and combination with metformin trials at 24-week period, for China regulatory approval purposes; successfully **completed 52-week monotherapy trial** demonstrating sustained & comparable best-in-therapeutics efficacy and safety profile at 52-weeks**, submitted NDA and accepted in April 2021**
- **First-in-Class (GKA) drug** to significantly and sustainably reduce HbA1c safely
- **First Novel Concept** addressing impaired glucose homeostasis - the underlying cause of T2D
- Demonstrated viability in combination with DPP-4 inhibitor & SGLT-2 inhibitor
- Suitable for T2D patients with chronic kidney disease
- **Massive market opportunity** – global T2D population is 453 mm (120 mm in China alone)
- In anticipation of dorzagliatin commercialization, subject to approval of its NDA, in addition to its CMO partnerships, Hua Medicine has **also established Hua Medicine drug manufacture company at Shanghai Lingang Special Area** for ensuring adequate dorzagliatin commercial supply
- **RMB 846.9mn cash** as of June 30, 2021

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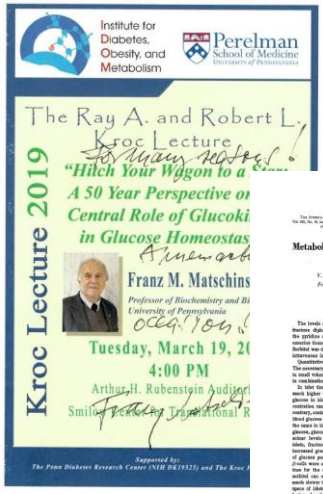
Key Recognitions of Glucokinase

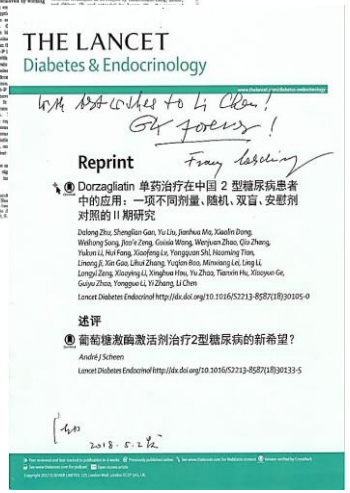
- ✓ Discovered in the 1960s by Dr. Franz Matschinsky, "Godfather of Glucokinase"
- ✓ The 1st GKA Published in Science Magazine in 2003, Roche
- ✓ Dorzagliatin completed POC in 2016, Lancet DE 2018
- ✓ Winner of Rolf Luft Award 2020



Science 2003:

Allosteric Activators of Glucokinase: Potential Role in Diabetes Therapy

"In several rodent models of type 2 diabetes mellitus, GKAs lowered blood glucose levels, improved the results of glucose tolerance tests, and increased hepatic glucose uptake. ***These findings may lead to the development of new drug therapies for diabetes****."*



Lancet 2018: Dailong Zhu and Li Chen

Dorzagliatin Ph II results

A New Hope for Glucokinase Activator for T2D

Rolf Luft Award 2020 awarded to Dr. Franz Matschinsky by Karolinska Institutet

For the discovery that ***glucokinase (GK) is the sensor controlling glucose-stimulated insulin secretion*** *in the pancreatic β-cell. And culminating in the discovery of novel* ***allosteric GK activators*** *currently being assessed in* ***phase III clinical trials****.*

Source: Franz Matschinsky et al . Science: Vol 301, Issue 5631, 18 July 2003