



Hua Medicine  
华领医药

**2020 Annual Results  
Presentation**  
March 2021

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# Company Overview

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# Advancing innovative solutions for unmet medical needs from China, starting with Type 2 diabetes



## Massive unmet medical need in global T2D

- 1 in 10 are T2D patients
- No drug is focused on addressing underlying cause of T2D, nor prevents or delays complications
- Current approved therapy = unsatisfactory treatment and control rates
- Diabetes complications USD 760B
- Impaired glucose and insulin sensitivity:
  - **$\beta$ -cell secretion and mass**
  - **Insulin resistance**



## Hua Medicine's dorzagliatin (HMS5552)

- Global first-in-class oral-diabetic drug: dorzagliatin
- Profiled for combination with other approved OADs that offer systematic diabetes care
- Successful completion of Phase III with well tolerated and good safety profile
- Improves glucose and insulin sensitivity
  - **Increase Insulin early phase secretion**
  - **Reduce Insulin resistance**
- Leading diabetes partner selected for commercialization
- Launch first in China, then global markets

## 5 Major Activities for 2021

1. China NDA submission for dorzagliatin
2. China commercialization preparation with partner, Bayer AG
3. Advancing dorzagliatin focused pipeline to establish dorzagliatin as cornerstone treatment for diabetes
4. Manufacturing optimization
5. Development and advancement of new molecules: mGlu5 for PD-L1D and FKI for metabolic diseases

## Successful Completion of Phase III Registration Trials in China

5 positive clinical trial study results: 2 Phase III & 3 Phase I

- ✓ Successfully **completed SEED (HMM0301)** Phase III monotherapy trial with sustained efficacy and good safety and tolerability profiles
- ✓ Presented at the American Diabetes Association (ADA) and Chinese Diabetes Society (CDS), demonstrating significant **improvements in  $\beta$ -cell function and 2h-PPG reduction**
- ✓ Successfully **completed DAWN (HMM0302)** Phase III metformin combination study with sustained efficacy, and good safety and tolerability profiles
- ✓ **Completed HMM0110**, indicating the potential use of dorzagliatin with no dose adjustment among T2D patients with diabetic kidney disease
- ✓ **Completed HMM0111**, demonstrating potential for combination with DPP-4 inhibitor, and demonstrated a clear synergistic effect in blood glucose reduction, endogenous GLP-1 release and improvement of  $\beta$ -cell function
- ✓ **Completed HMM0112**, demonstrating potential for combination with SGLT-2 inhibitor, with clear synergistic effect in efficacy of blood glucose reduction and improvement of  $\beta$ -cell function

## Other Corporate Milestones

Manufacturing scale up & commercialization partner ready for drug launch

- ✓ Entered into a commercialization agreement and strategic partnership with Bayer Healthcare Company Limited for mainland China
- ✓ Entered into a commercial supply agreement with Zhejiang Raybow Pharmaceutical as an additional supplier to existing manufacturing partners
- ✓ Granted the Drug Manufacturing Permit for dorzagliatin in China by the Shanghai Municipal Drug Administrative Bureau
- ✓ Announced global operation headquarters and research and development center in Shanghai's Zhangjiang Science City officially established



# Bayer is the Best Partner for Hua Medicine in China



- ✓ **Established Leadership in Diabetes Care** in China for **20+ years**
  - Leading oral anti-diabetic drug in China 1995-2019: Glucobay® cumulative treated > 30 million patients
  - Industry leading market coverage: Glucobay® listed in 13k+ hospitals / CHCs and 10k+ retail pharmacies
  - RMB 40 billion Glucobay® cumulative net sales reported from 2009 - 2019
- ✓ **Full commitment and dedication of Bayer China** to achieve top-selling results for dorzagliatin's launch - no conflicts
  - Potential synergies in the future with Bayer's WaveForm CGM device for studies relating to optimizing time-in-range (TIR)

- Novel first-in-class drug
- Aspiration to cure diabetes



- Leader in diabetes treatment in China
- Integrated diabetes solutions

## ***Collaborate to Cure***

- Hua Medicine: Clinical development, registration, product supply, and distribution
- Bayer: marketing, promotion and medical education activities
- Upfront payment: RMB 300 million – **received in 2020**
- Milestone payments: Up to RMB 4.18 billion
- Bayer: exclusive rights to commercialize product in China, tiered service fee based on net sales



# **Dorzagliatin**

**First-In-Class (FIC) glucokinase activator globally**

**Fix sensor, restore glucose homeostasis, treat diabetes from root cause**

**Synergy with targeted diabetes therapy in disease control**

**Opportunity for personalized diabetes care**

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# Key Recognitions of Glucokinase



- ✓ Discovered in the 1960s by Dr. Franz Matschinsky, “Godfather of Glucokinase”
- ✓ The 1<sup>st</sup> 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.”*



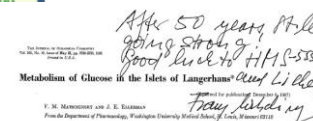
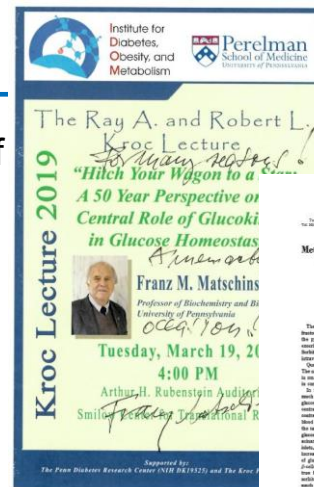
## Lancet 2018: Dalong Zhu and Li Chen

### 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  $\beta$ -cell. And culminating in the discovery of novel **allosteric GK activators** currently being assessed in **phase III clinical trials**. Speech at the Nobel Forum (Stockholm, Sweden) awards ceremony in the spring of 2021***



## THE LANCET Diabetes & Endocrinology



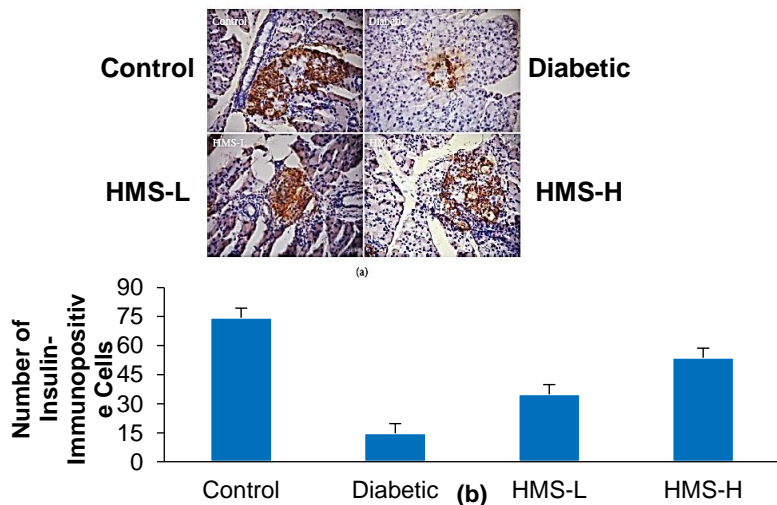


# Dorzagliatin Has the Potential to Repair the Glucokinase Glucose Sensor



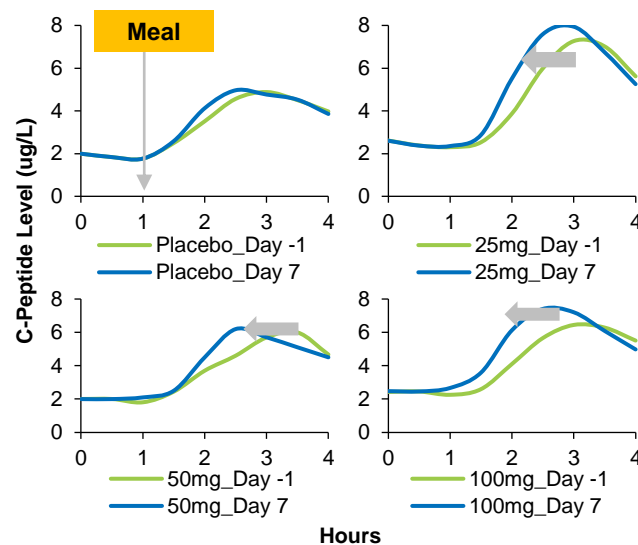
## Type 2 Diabetes Rat Pancreas

Pre-clinical



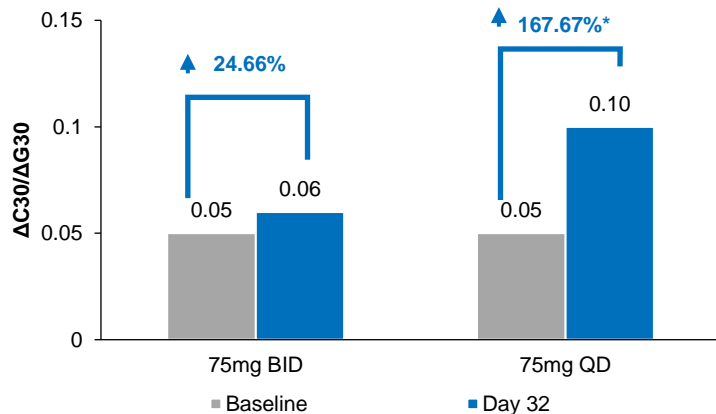
## T2D Patient Early-stage insulin release

Phase Ib



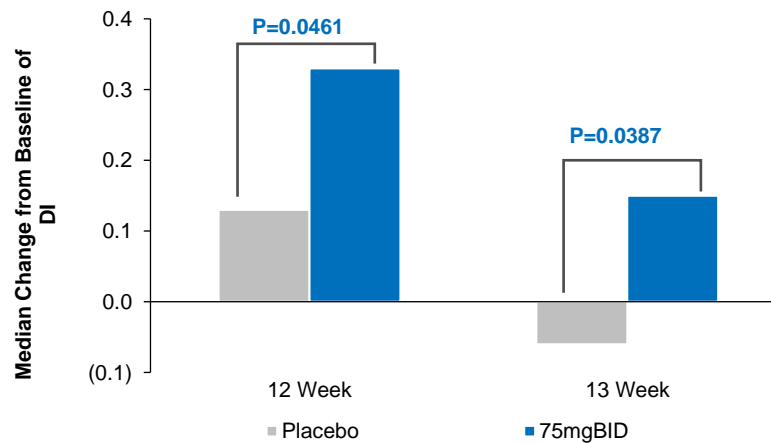
## T2D Patient Early Insulinogenic index

Phase Ic



## T2D Patients Disposition Index

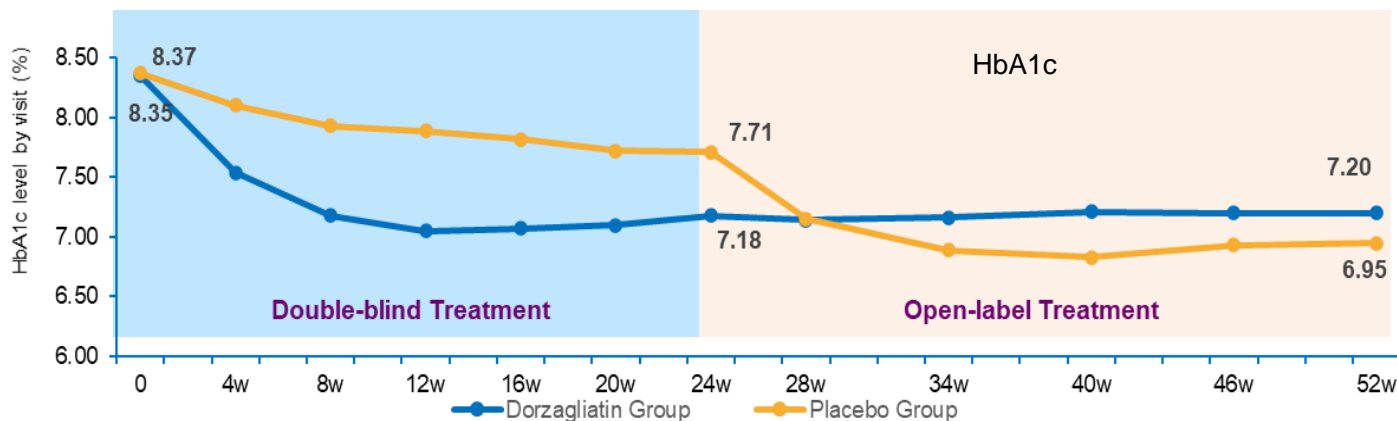
Phase II



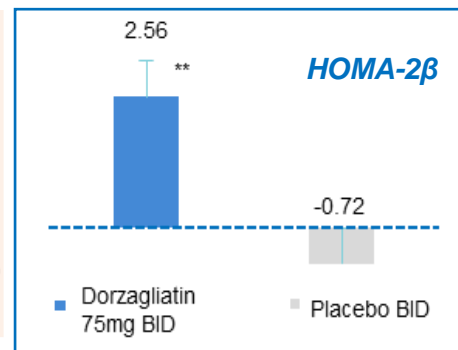
# Dorzagliatin Phase III Results: SEED and DAWN Significantly reduce insulin resistance during 52 week



## SEED HMM0301

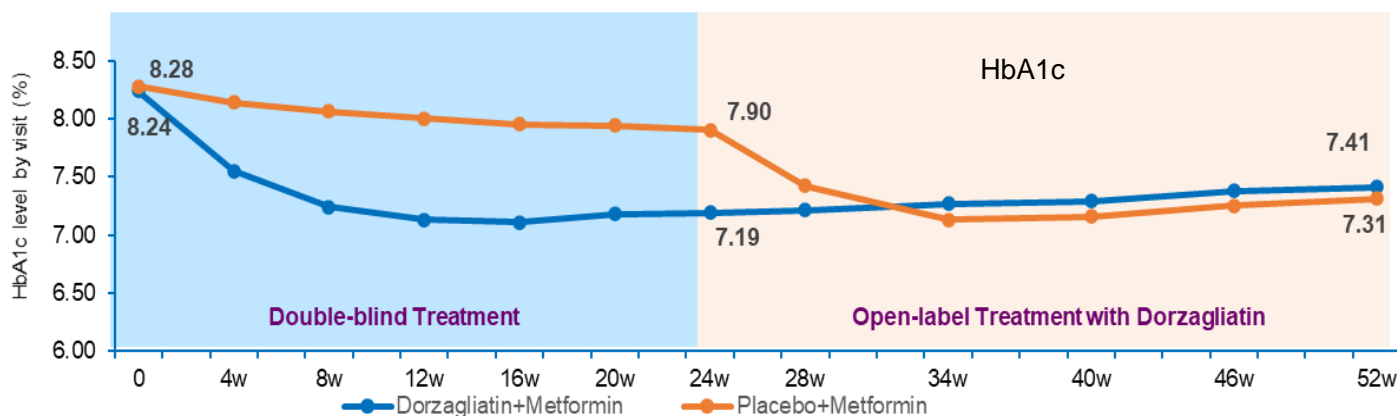


Significantly improve  $\beta$ -cell function at week 24

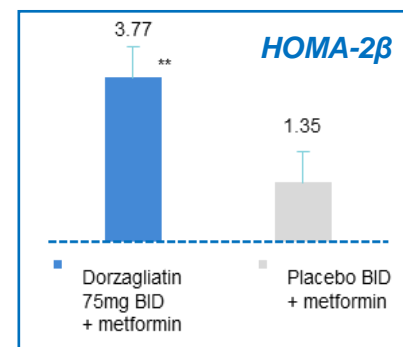


Change from Baseline to Week 24

## DAWN HMM0302



Significantly improve  $\beta$ -cell function at week 24

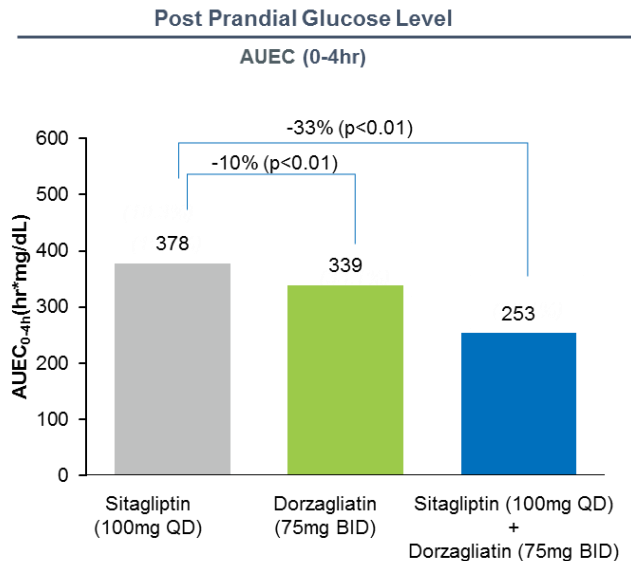


Change from Baseline to Week 24

# Dorzagliatin Has Demonstrated Successful Combination Potential with other Global Top Oral Anti-Diabetic Drugs

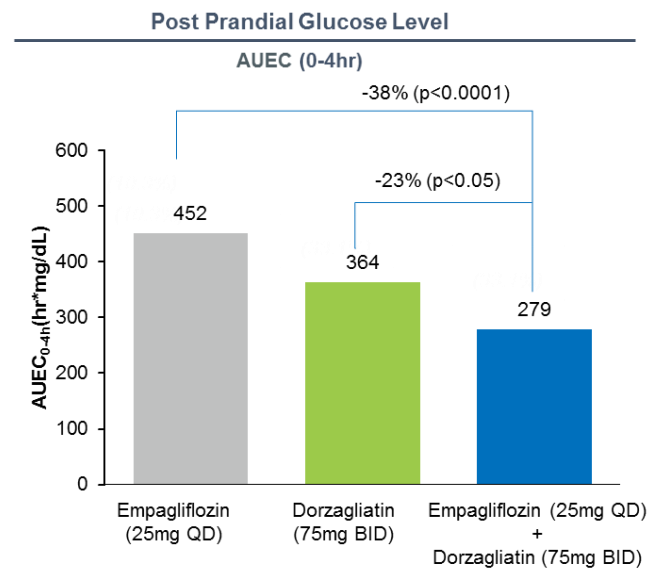


- No drug-drug interaction observed in Phase I trials in USA with sitagliptin (DPP-4 inhibitor) and empagliflozin (SGLT-2 inhibitor)
- **Significant synergies demonstrated in glycemic control and improvement of beta cell function**
  - Data demonstrating dorzagliatin stimulates GLP-1 release in T2D patients, increasing circulating active GLP-1 when used in combination with sitagliptin
  - In both trials, the combined use of sitagliptin or empagliflozin in combination with dorzagliatin increases insulin secretion as measured by C-peptide and reduces glucose over using each of the drugs alone



### DPP-4 inhibitor:

- ✓ US\$ 4B global sales in 2019



### SGLT-2 inhibitor:

- ✓ Fastest growing among OAD with US\$ 6B global sales in 2019 and ~24% yoy growth

Note: AUC represents area under the curve, while AUEC represents area under the effect curve.

# Dorzagliatin has potential to be the **ONLY** oral anti-T2D therapeutic for select DKD patients



## Drug use guidelines for T2D patients with diabetic kidney disease

Dorzagliatin		Oral
Metformin		
DPP-4		
SGLT-2		
GLP-1		Injectibles
Insulin		

- No dose adjustment required
- Dose adjustment required
- Contraindicated

- Patients with diabetic kidney disease make **up 20-40% of the total** T2D patient population globally
- In China, **patients with moderate, severe, and end-stage chronic kidney disease comprise 21.9%** of the T2D patients

### Study:

HMM0110 was conducted in China to evaluate whether dorzagliatin can be readily used in Type 2 diabetes (T2D) patients with impaired renal function.

### Conclusion:

- In subjects with end stage renal disease and are not on dialysis, **the study indicated no significant impact on PK properties in subjects treated with dorzagliatin.**
- This result **supports dorzagliatin as a promising solution and potential supplementary option for T2D patients with moderate, severe and end stage chronic kidney disease** (i.e., stages 3-5 of CKD) which can **provide satisfactory blood glucose control safely and without dose adjustment.**



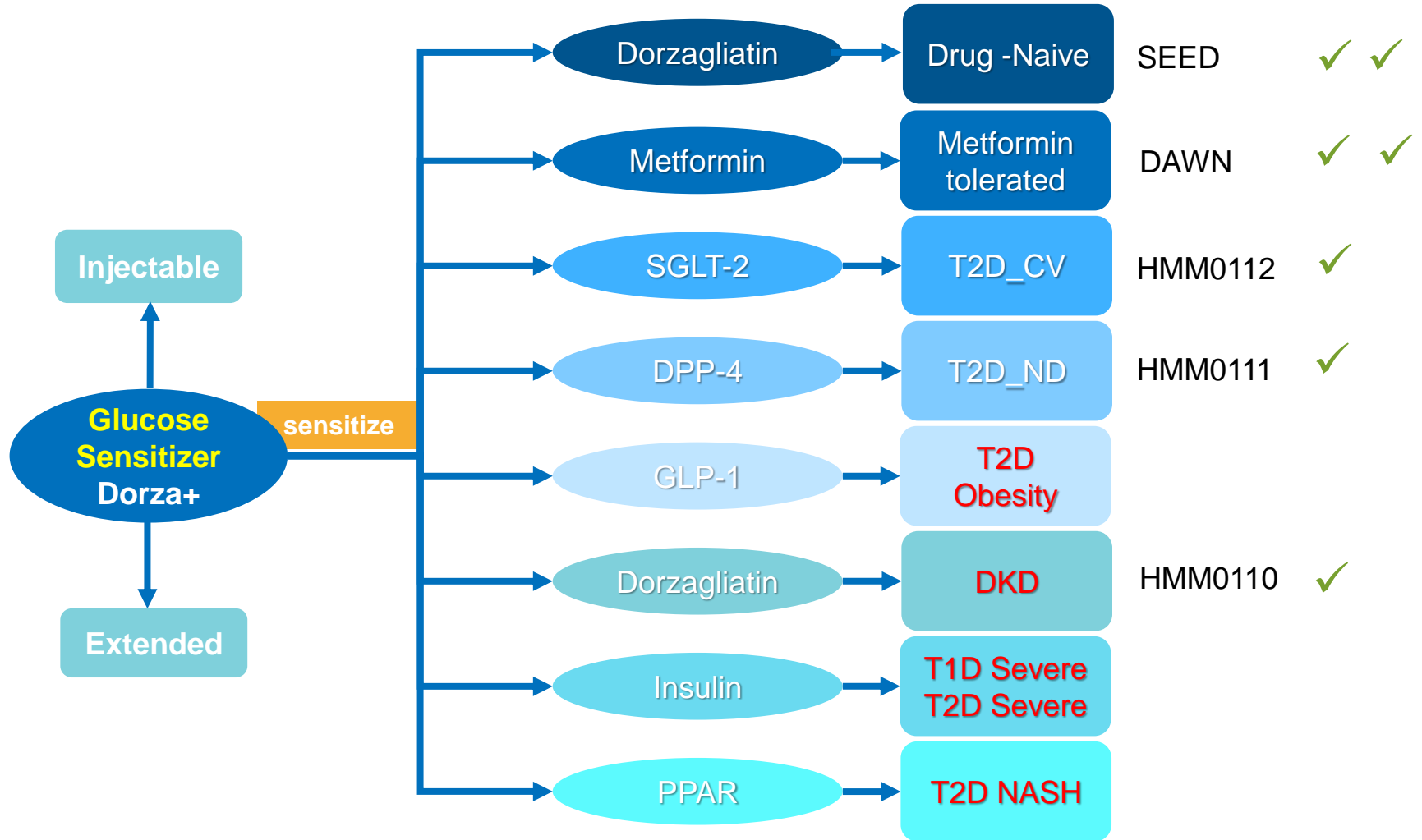
# Outlook

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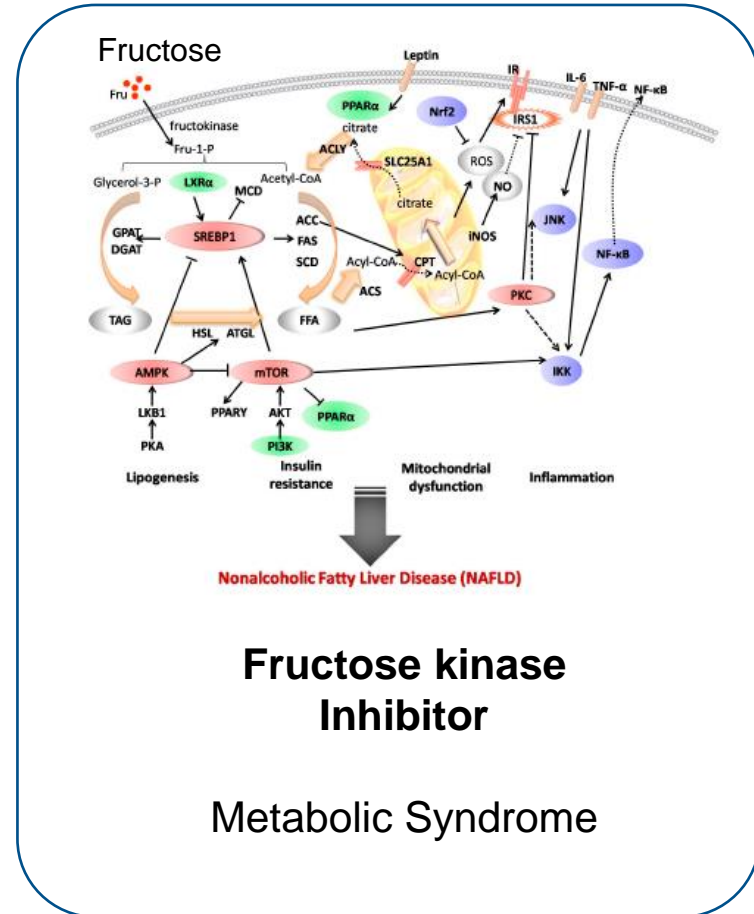
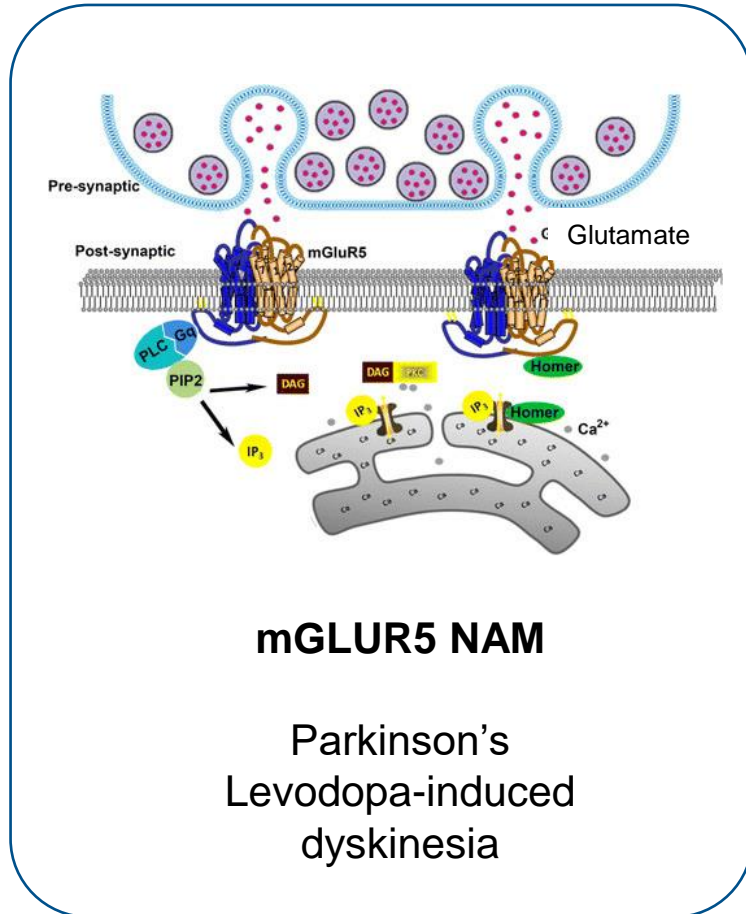


# New FIC Product, New Medication, New Opportunity



Fix Sensor, Repair Homeostasis and Treat Root Cause of Diseases







# Financial Review

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# Financial Summary



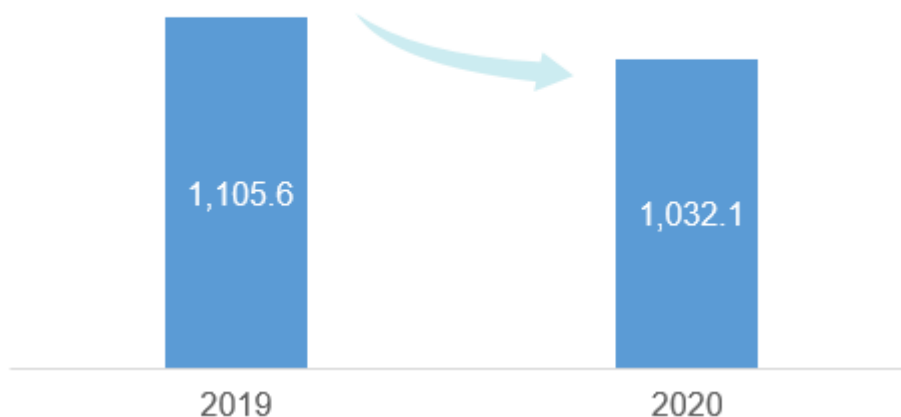
**Cash Balance:** RMB1,032.1 million of cash at 12/31/2020 vs. 1,105.6 million at 12/31/2019.

Total cash decrease of RMB73.5 million, consisted of

- Net cash used in operating activities was RMB20.9 million – accounts for RMB 300 million up front payment from Bayer
- Net cash used in investing activities was RMB14.1 million
- Net cash used in financing activities was RMB7.3 million
- Net effect of exchange rate changes was RMB31.2 million

Net cash used in operation activities of RMB20.9 million mainly includes cash payment of RMB 161.4 million for the research and development activities and of RMB159.5 million for the administrative activities, adjusted for the received upfront payment of RMB300.0 million from Bayer for commercialization and strategic partnership.

(RMB' million)



# Financial Summary- continued

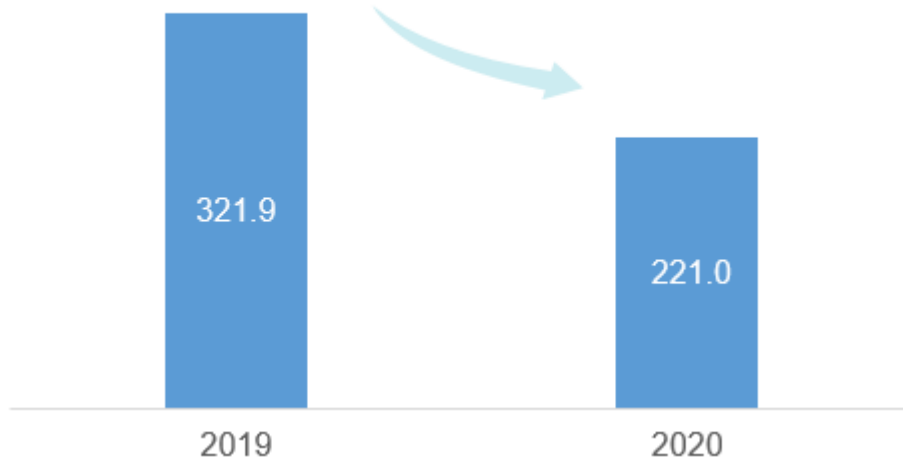


**Loss before tax** of RMB393.1 million in the year of 2020 vs. RMB425.3 million in the year of 2019

**Research and development expenses** of RMB221.0 million in the year of 2020 vs. RMB321.9 million in the year of 2019

- a decrease of RMB78.9 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
- a decrease of RMB23.3 million in chemical, manufacturing, and control (CMC) expenses, which was primarily attributable to scaling-up development, method validation and process validation for spray dried powder (SDP) manufacturing and drug product manufacturing completed in 2019

(RMB' million)





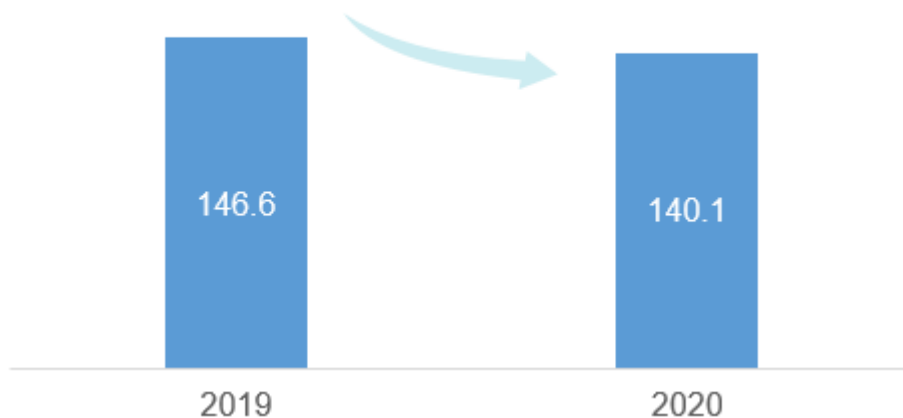
# Financial Summary- continued



**Administrative expenses** of RMB140.1 million in the year of 2020 vs. RMB146.6 million in the year of 2019

- decrease in labour costs which was attributable to the decrease of RMB10.6 million in share-based payment under the accelerated amortization method
- decrease of RMB4.2 million in travelling costs due to the impact of COVID-19 and decrease of RMB2.4 million in recruitment cost based on the recruitment plan
- Adjusted for the rental increase of RMB7.4 million with entering into the tenancy agreement for leasing office building in December, 2019 to establish the Global Operation Headquarters and Research and Development Center in China and Research and Development Center in China and low-value IT consumable expenditure of RMB 1.2million for the office building incurred in the year of 2020.

(RMB' million)



# Hua Medicine – A Global First-in-Class Biotech



## Hua Medicine



**Li Chen**  
CEO & CSO

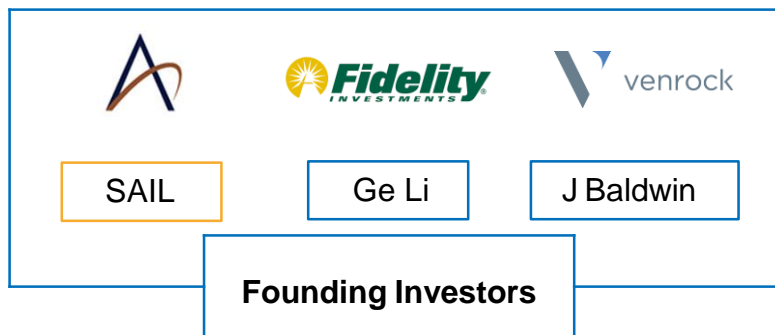


**Bob Nelsen**  
Chairman



## China-Based 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
- **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)
- **RMB 1,032.1mn cash** as of December 31, 2020





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