Hua Medicine
华领医药

2019 Annual Results Presentation

March 17, 2020

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Company Overview

Mission, Vision and Strategy

A leading, clinical-stage innovative drug development company in China focused on developing novel therapies for the treatment of diabetes

Mission

- Establish dorzagliatin as the cornerstone therapy for the treatment of diabetes by restoring glucose homeostasis in Type 2 diabetes patients

Objectives

- Become a global diabetes care company
  - By launching dorzagliatin commercially, first in China and then globally
  - Either as monotherapy or in combination with approved anti-diabetes drugs
  - Employing AI to develop personalized treatment for the entire heterogenic universe of Type 2 diabetes patients worldwide

Strategy

- Leverage Hua's internal team and strong partnership network to continue advancing our current pipeline
- Partner with either China-based or international pharmaceutical companies to make dorzagliatin available to patients, in both China and regions outside of China

2019 Highlights

Clinical trials:

- **Achieved primary efficacy endpoint** in a 24-week double blinded placebo controlled Phase III trial in drug naïve T2D patients in China, **with very low hypoglycemia incidents and good safety profile**
- **Completed enrollment** in a metformin add on Phase III registration trial
- Completed HMM0110, which demonstrated desirable pharmacokinetics profile in patients with end stage chronic kidney disease, indicating the potential use of dorzagliatin among T2D patients with moderate, severe and end stage chronic kidney disease (i.e. stages 3-5 of CKD)
- Completed HMM0111, investigating the PK and PD parameters of dorzagliatin either alone or in combination with sitagliptin in T2D patients in the United States, with positive results

Other:

- Granted a formulation patent for dorzagliatin in China
- Filed six patent applications covering the IPR of fixed dose combination of dorzagliatin with six classes of oral-antidiabetic drugs
- Initiated a formal collaboration with Dr. Franz Matschinsky, recipient of 2020 Rolf Luft Award
- Presented AI based machine learning results at the American Diabetes Association's 79th Scientific Sessions, providing a non-biased methodology to sub-classify T2D patients
- Announced that global operation headquarters and R&D center will be established in Shanghai's ZhangJiang Science City
- Fully validated cGMP commercial manufacturing processes for API and drug product to support the China launch of dorzagliatin
- Former U.S. FDA Officer Dr. Fuxing Tang joined Hua Medicine as Chief Technology Officer, VP of Formulation R&D and Product Development
- Cash position as of December 31, 2019: RMB 1.1bn

Phase III Topline Results were Presented in the Keynote Lectures of 2019 CDS Plenary Session

Professor Zhu Dalong, Chairman of CDS, hosting 2019 CDS plenary session

Dr. Yang Wenying, ex-Chairwoman of CDS, attending the 2019 CDS plenary session

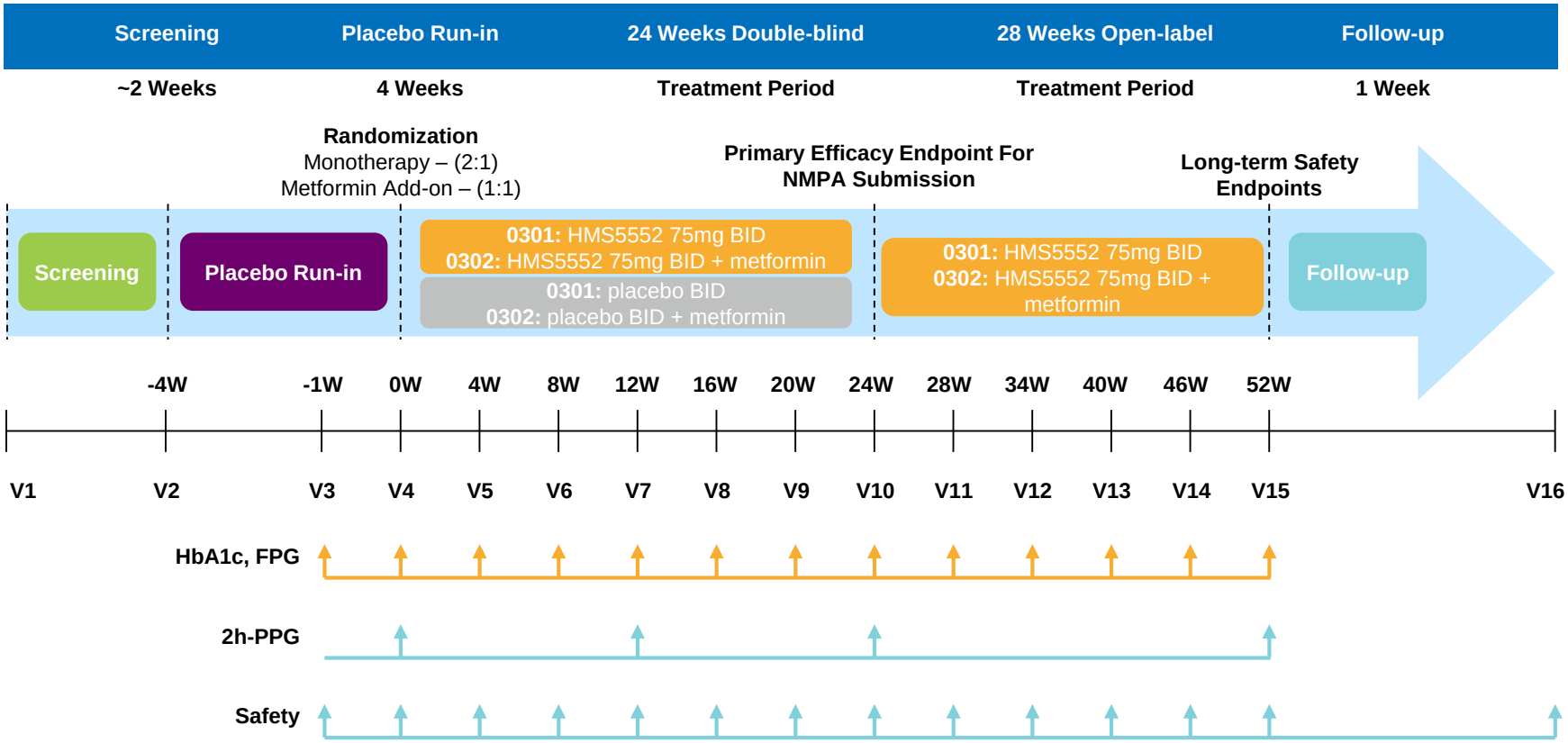
Professor Zhu Dalong, presenting dorzagliatin Phase III topline data at the 2019 CDS plenary session

2019 CDS Plenary Session audience members

Ongoing Phase III Trials: HMM0301 / HMM0302 Study Design

Study Design for:

- HMM0301: 52-week completed March 2, 2020
  Dorzagliatin Mono-therapy Trial for Drug Naïve T2D Patients (463 Patients)
- HMM0302: 24-week completed February 16, 2020
  Dorzagliatin Metformin Add-on Therapy Trial for Metformin Users (766 Patients)



Primary endpoint of HbA1c reduction of 0.4% over placebo, p-value < 0.05

Update from COVID-19

Clinical Achievements

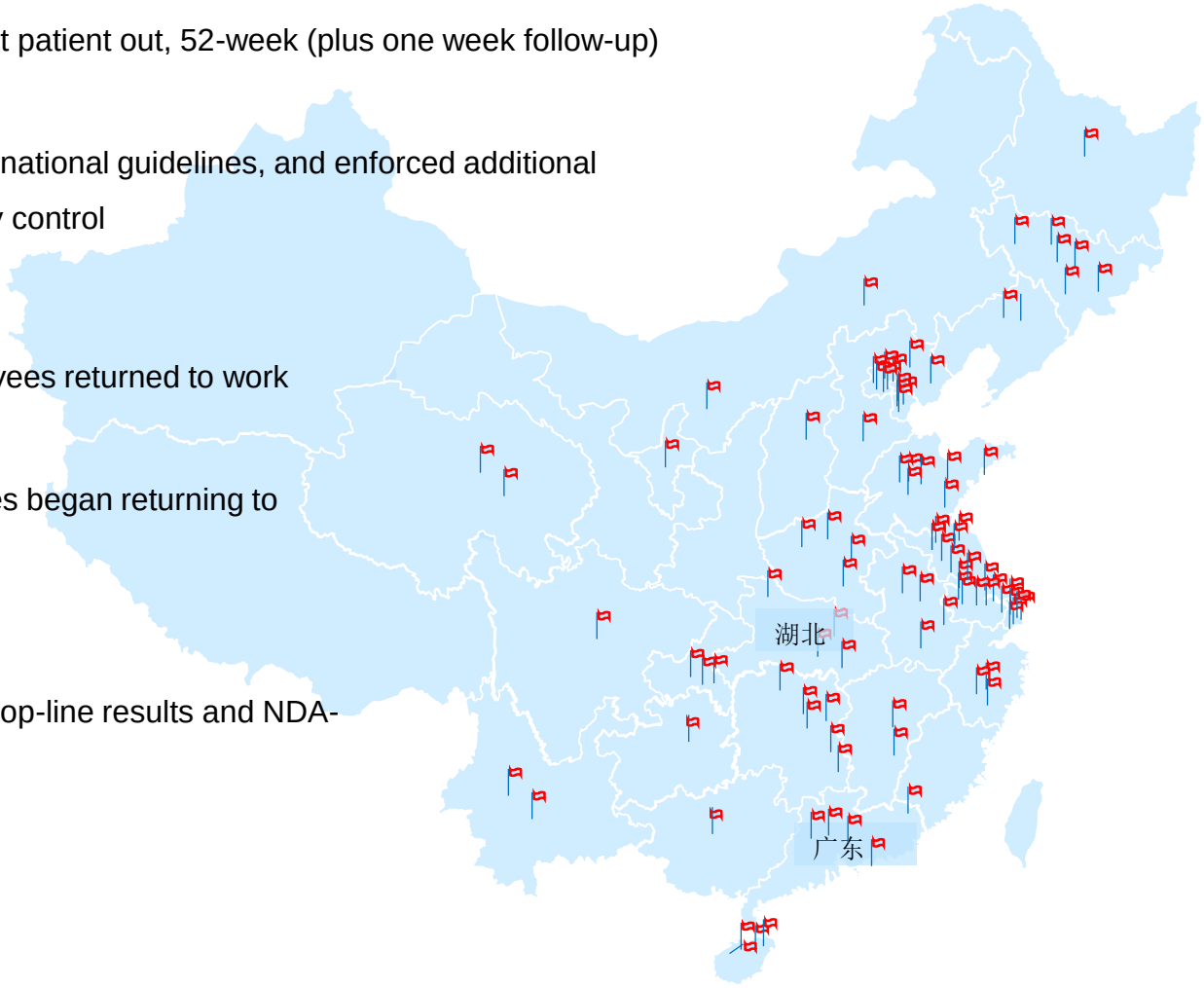
- February 16, 2020: Completed last patient out, 24-week patient visit for HMM0302
- March 2, 2020: Completed last patient out, 52-week (plus one week follow-up) patient visit for HMM0301
- Continued strict adherence to national guidelines, and enforced additional pharmacovigilance and quality control

Other

- February 3, 2020: Hua employees returned to work remotely
- March 2, 2020: Hua employees began returning to offices in China

Things to note

- Potential delays in release of top-line results and NDA-enabling work



2020 Outlook

Clinical trial readout:

- HMM0301 monotherapy Phase III trial 52-week results
- HMM0302 combination with metformin Phase III trial 24-week, 52-week results
- HMM0112 combination with empagliflozin Phase I trial results

Other:

- Initiate studies of dorzagliatin for other potential indications
- Prepare and finalize NDA submission in China
- Expand and prepare commercialization, sales and marketing team for planned 2021 product launch in China
- Engage international and China-based pharmaceutical companies in discussions regarding partnership for China and ex-China territory

Dorzagliatin

A First-in-Class Anti-Diabetic Therapy Focused on Treating the Underlying Cause of Type 2 Diabetes

Current State of the Type 2 Diabetes Landscape

Large market

- Over **450 million** people with type 2 diabetes, globally; **120 million+ in China alone**
- Over **US$80 billion** plus of pharmaceutical sales globally every year

What is the unmet need?

- **Not one** approved drug **currently treats the underlying cause** of type 2 diabetes – loss of glucose sensitivity and impairment of glucose homeostasis
- **Restoring the function of impaired glucokinase** is the only scientifically validated means to restore glucose sensitivity in homeostasis

Why hasn't anyone else developed a GK?

- Most large multinational pharmaceutical companies with a metabolic disease franchise have tried to create a viable and safe glucokinase activator (GKA) to treat type 2 diabetes, **none have entered phase III**
- Dorzagliatin is the **first GKA to achieve the primary efficacy endpoint with desirable safety profile** at 24-weeks in a Phase III trial
- **Targeting the glucose sensor role of GK, dorzagliatin is conceptually differentiated** from previous GKA which worked on lowering the blood glucose and treated GK as a glucose processor only

How Do We Stop Type 2 Diabetes?

Goal in treating diabetes:

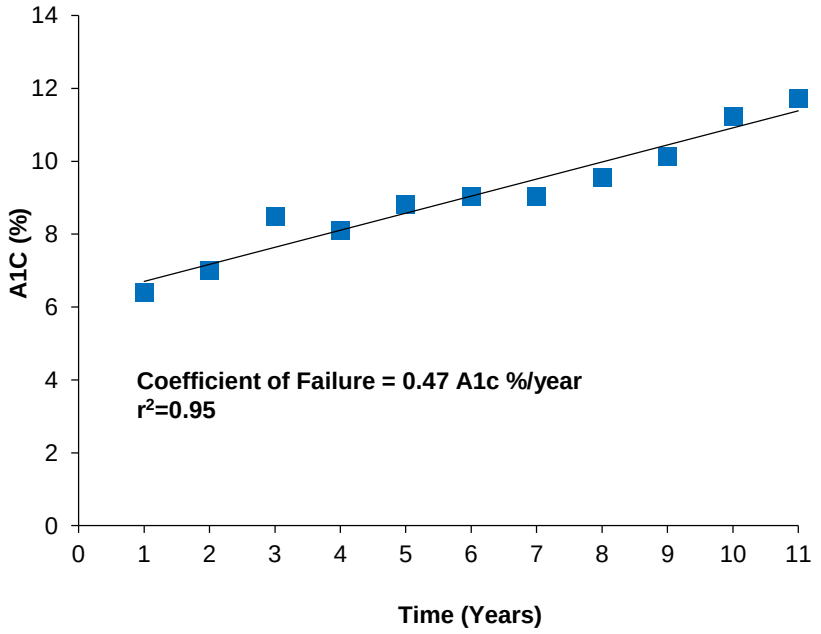
To maintain blood glucose levels within a healthy range, achieving ***glucose homeostasis***

Lowering blood glucose levels alone will not stop the progressive degenerative nature of diabetes, leading to complications

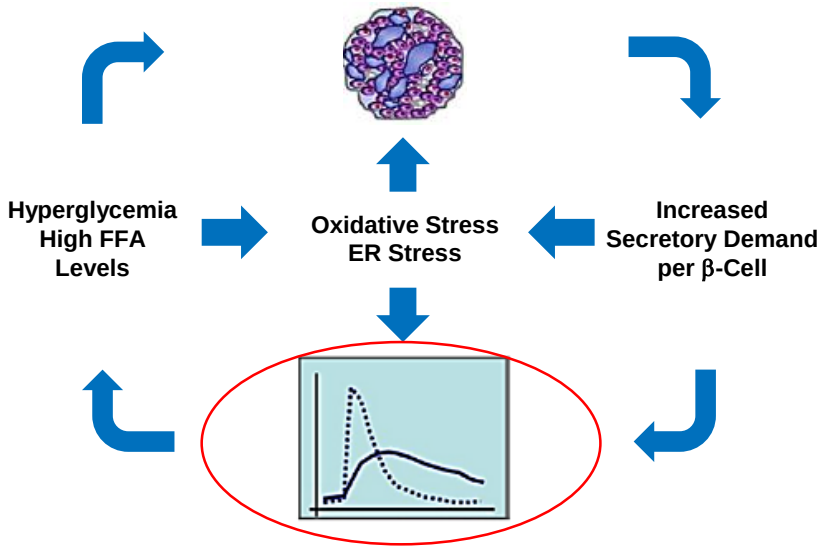
T2D is a Progressive Disease with Degeneration of β Cell Function and Increasing Insulin Resistance

- Type 2 diabetes is a progressive disease with deterioration of β cells function
- Loss of glucose sensitivity in Type 2 diabetes patients is the first step in the progressive destruction of β cells
- Impaired β cells function results in hyperglycemia stress which causes progressive damage of β cells
- Deterioration of the 1st phase insulin secretion is the leading cause of impaired glucose homeostasis

Patients with Monotherapy: HbA1c Increased by 1% Every 2 Years, β-Cell Function Decreased Accordingly[1]



Impaired β-Cell Function Results in Hyperglycemia Stress which Causes Progressive Damage of β Cells



- Deficiency in the ability of glucose to trigger insulin release
- Cells have lost glucose sensitivity and early phase insulin release is reduced
- Reduction in glucose sensitivity is the key culprit behind Type 2 Diabetes

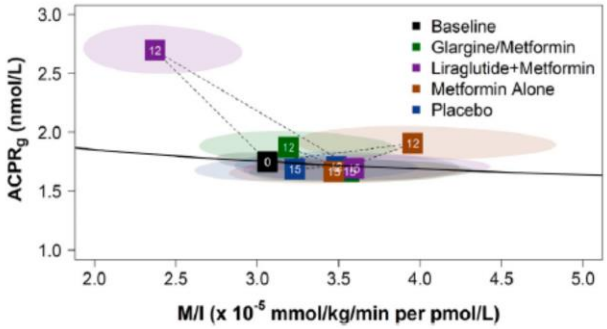
Source: Vivian Fonseca, Diabetes Care, 2009, Vol 32, S2; Source: J Merier, R Bonadonna Diabetes Care (2013) 36, S113
[1] Retrospective survey.

Current Diabetes Medicine Can Not Restore β-cell Function

Recent research indicates that we have not solved the fundamental cause of diabetes

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

https://doi.org/10.2337/dc19-0556

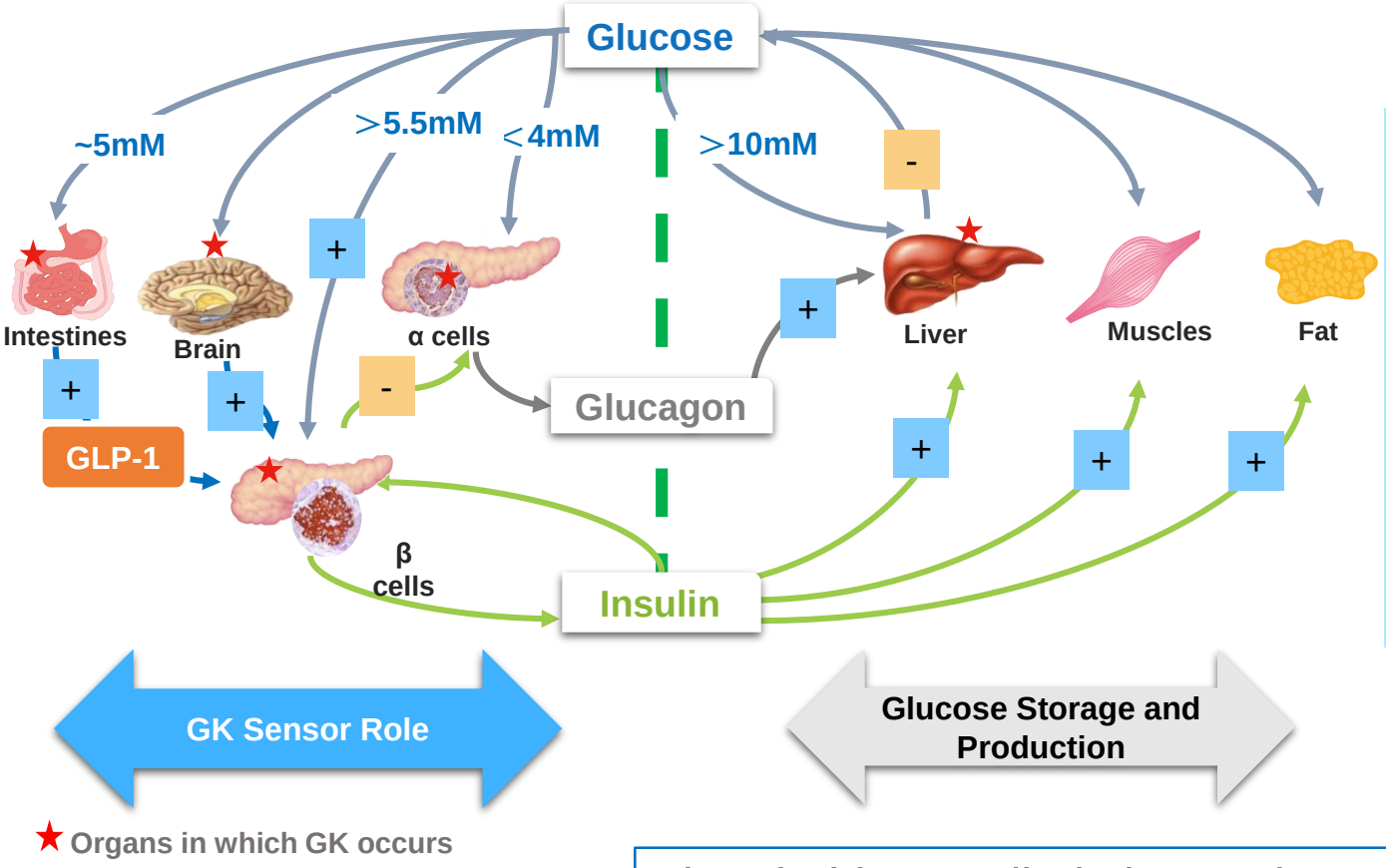


Restoration of glucose sensor function required

Treatment Group	• Impaired glucose tolerance (IGT) • Treatment-naïve type 2 diabetes (<12 months)
Treatment length	• 12-month treatment • Stop medication for 3 months • Measure β-cell function at 15 months
Treatment arms	• Metformin alone (12m) • Liraglutide (GLP-1) + metformin • Glargine (3m) + metformin (9m) • Placebo
Conclusion	• Interventions that improved β-cell function during active treatment **failed to produce persistent benefits after withdrawal** • Suggests continued intervention may be required to alter the progressive β-cell dysfunction

Glucose Controls Whole Body Glucose Homeostasis

Glucose is a ***hormone***
Glucokinase is a ***sensor***
Glucose Homeostasis is Controlled by Glucose via Glucose Sensor GK



Glucose Homeostasis

Glucose is controlled within a very narrow range:
4- 6.5mM

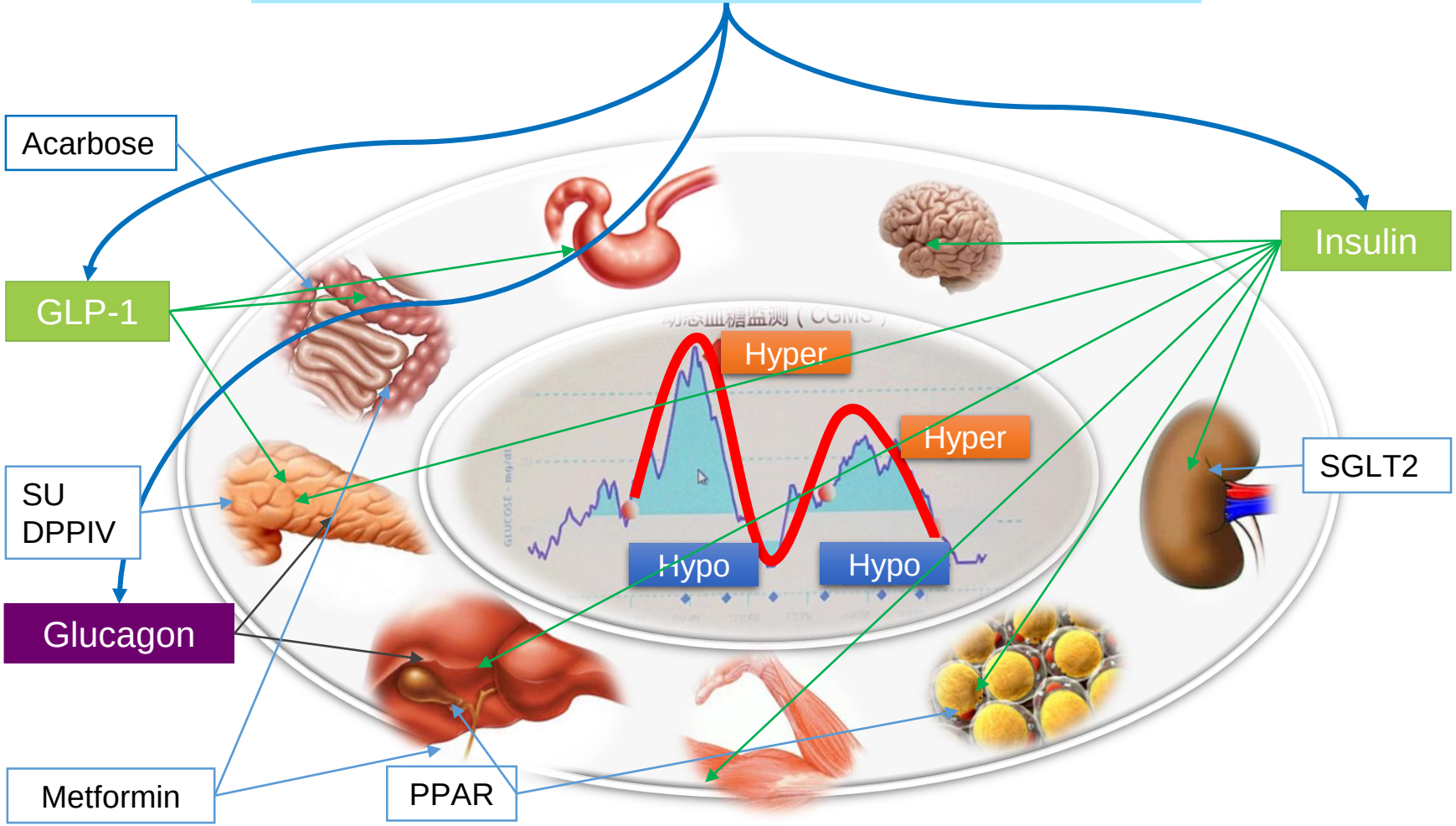
Set point:
5mM

Threshold controlled glucose homeostasis

Source: 陈力，2016《药物进展》

Fix the Sensor, Control Diabetes

Dorzagliatin
Cornerstone Control of Glucose Homeostasis



Glucokinase is a Glucose Sensor in Glucose Homeostasis

Thermostat in a Building

- Messenger: air temperature
- Set Point: 22^{o} Celsius
- Threshold: 21-23^{o} Celsius
- Controller: Thermo Sensor (thermostat)
- Effector: Electronic signal
- Operator: Heater, Cooler, Ventilator

Glucose Homeostasis in Human Body

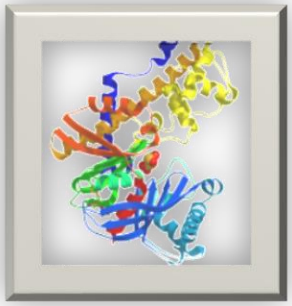
- Messenger: glucose level
- Set Point: 5 mmol/liter[1]
- Threshold: 4-6 mmol/liter[1]
- Controller: Glucokinase in the pancreas and small intestine-Glucose Sensor
- Effector: insulin, glucagon, GLP-1 (glucagon-like peptide 1)
- Operator: hexokinase 1-3[2], SGLT-2, GK_L (Liver GK)

Operation

Cooler

Heater

Ventilator



Operation

Insulin / GLP-1

Glucagon

Liver GK

When the sensor malfunctions or is impaired, automatic control is lost

Source: Franz Matschinsky, Mol. and Cell Biology of Type 2 Diabetes and Its Complications, 1998, vol 4, pp 14-29

[1] A common measure of blood glucose levels is hemoglobin A1c, or HbA1c, which measures average glycated blood glucose levels for the 3 months prior to testing. HbA1c levels for people without diabetes is between 4% and 5.6% (equivalent to 4-5.6 mmol/liter), for people with impaired glucose tolerance (IGT), or pre-diabetics, is between 5.74% and 6.4% (equivalent to 5.74 -6.4 mmol/liter) and for people with diabetes is 6.5% or higher (equivalent to 6.5 mmol/liter or higher).

[2] In addition to GK (also referred to as hexokinase type 4), Hexokinase types 1-3 play a role in the glucose homeostasis process. Unlike a properly functioning GK, which is only active at blood glucose levels over 5.5 mmol/liter, hexokinase types 1-3 are active in the presence of even small amounts of glucose in the bloodstream – providing as a bodily survival mechanism needed energy to the brain, muscles and other core bodily functions.

Key Recognitions of Glucokinase

- ✓ Discovered in the 1960s
- ✓ Published in Science Magazine in 2003 by Dr. Franz Matschinsky, “Godfather of Glucokinase”, in collaboration with Roche
- ✓ Partner with Hua Medicine in advancing GKA
- ✓ 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.”***

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

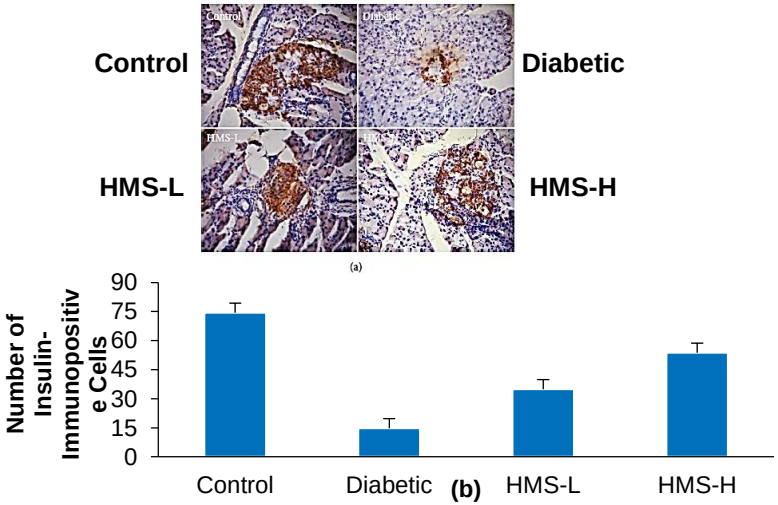
For the discovery that ***glucokinase (GK) is the sensor controlling glucose-stimulated insulin secretion*** *in the pancreatic β-cell and initiating GKA discovery*

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

Dorzagliatin Has the Potential to Repair the Glucokinase Glucose Sensor

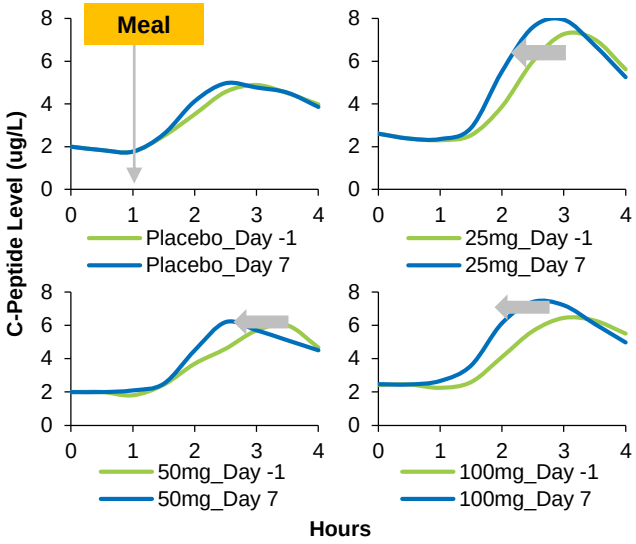
Type 2 Diabetes Rat Pancreas

Pre-clinical



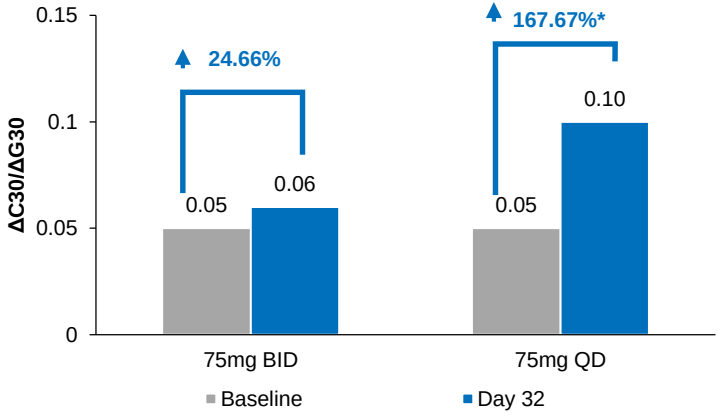
T2D Patient Early-stage insulin release

Phase Ib



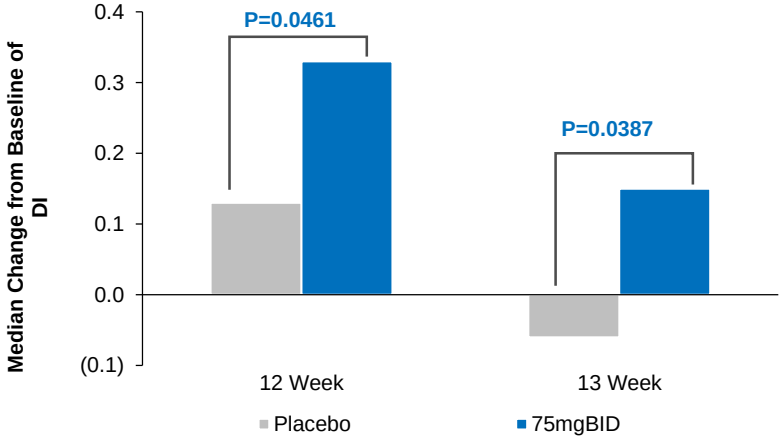
T2D Patient Early Insulinogenic index

Phase Ic



T2D Patients Disposition Index

Phase II



November 2019: HMM0301 Phase 3 Topline Results

HMM0301 Phase III 24-week topline results in Chinese drug-naïve patients with Type 2 Diabetes

First drug candidate focused on the underlying cause of type 2 diabetes, glucose sensing, to meet its primary efficacy endpoint over 24 week Phase III trial

- 1.07% HbA1c reduction from baseline of 8.35% in dorzagliatin treated group compared to 0.5% HbA1c reduction from baseline of 8.37% in placebo group (p-value < 0.0001)
- 45.4% of patients treated with dorzagliatin achieved target HbA1c level of 7.0% or less at 24-weeks compared to 21.5% of patients treated with placebo (p-value < 0.0001)
- Patients treated with dorzagliatin achieved homeostasis control rate of 45.0% compared with 21.5% in placebo group (p-value < 0.0001)

Dorzagliatin was well tolerated and had a good safety profile

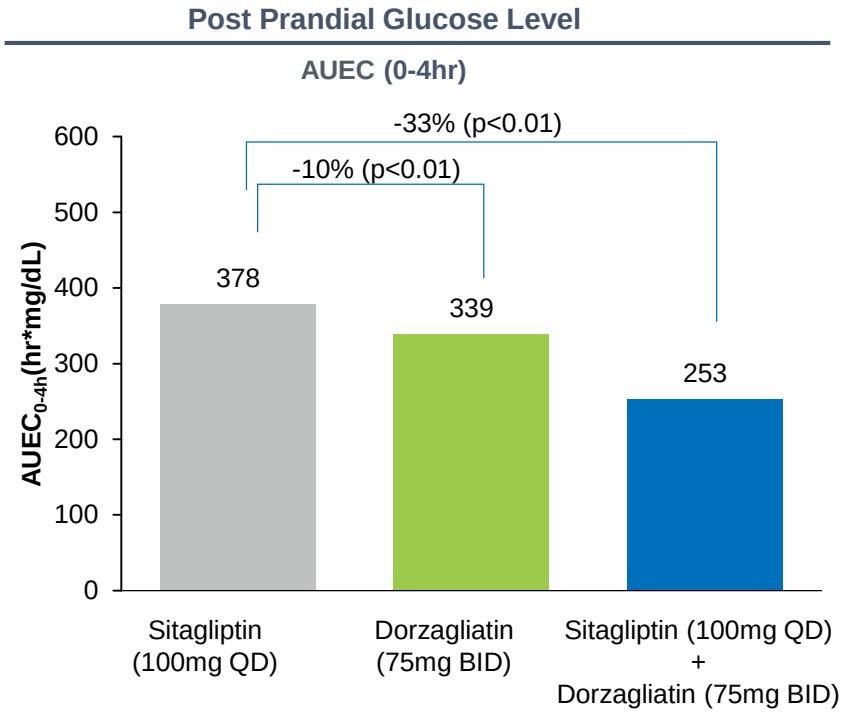
- No death, no drug-related serious adverse event over 24 week
- Less than 1% incidence of hypoglycemia over 24 week and no severe hypoglycemia

The 28 week open label safety outcome trial of HMM0301 is complete — Last patient out was March 2, 2020

January 2020: Positive Results of HMM0111 Validates the Synergy of DPP-4 and GKA

Phase I U.S. Drug-drug Interaction Trials

- Co-administration orally of dorzagliatin and sitagliptin at steady state demonstrated no impact on their PK properties
- OGTT showed synergy in glucose lowering effect over both monotherapies
- It has also demonstrated that dorzagliatin add-on to sitagliptin increases C-peptide secretion over dorzagliatin and sitagliptin alone, suggesting a synergistic effect of improved β-cell function.



- **Compared to sitagliptin, Dorzagliatin showed clear advantage on post-prandial glucose level (PPG) control in 0-4 hr in the Oral Glucose Tolerance Test (OGTT) study**
- **Dorzagliatin + sitagliptin gives the best effect on overall PPG reduction**
- **15 patients were included in the trial.**

Note: AUEC represents area under the effect curve

Jan 2020: Positive Results of HMM0110

Jan 2020: Positive Results of HMM0110 Supports the Potential of Dorzagliatin in T2D Patients with Moderate, Severe and End Stage Chronic Kidney Disease (i.e. stages 3-5 of CKD)

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:

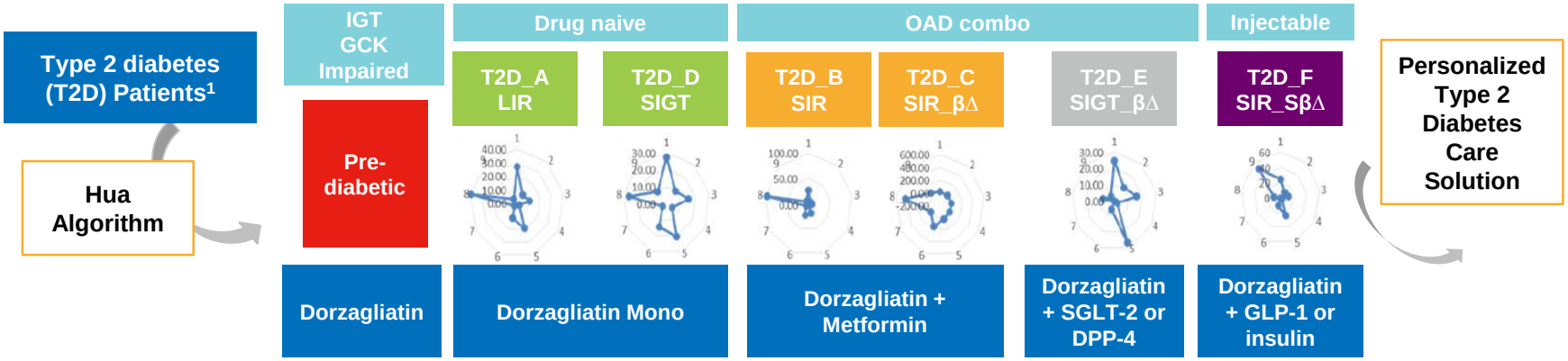
- In subjects with end stage renal disease and are not on dialysis, **the study indicated no significant impact on PK properties subjects exposed to dorzagliatin.**
- This result **supports dorzagliatin as a promising solution and potential supplementary option for T2D patients with moderate, severe 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**.
- Most of current oral antidiabetic drugs are not readily suitable for patients with renal impairment, especially at moderate, severe and end stages, as current oral treatments either require dose adjustment (e.g., metformin and the top-selling DPP-4 inhibitors) or are contraindicated (e.g., SGLT-2 inhibitors).
- Stage 3-5 CKD patients of T2D patients in China is about 21.9%

Potential as Cornerstone Therapy for Personalized Diabetes Care

Dorzagliatin has the potential to serve as the next generation cornerstone treatment of T2D
– Personalized diabetes care in progress with novel algorithm development

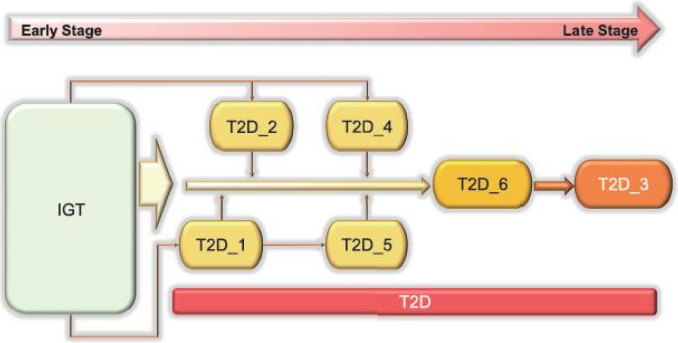
Personalized Type 2 Diabetes Medicine: A Comprehensive Solution for Diabetes Patients

A proprietary algorithm is developed at Hua Medicine based on clinically validated biomarkers



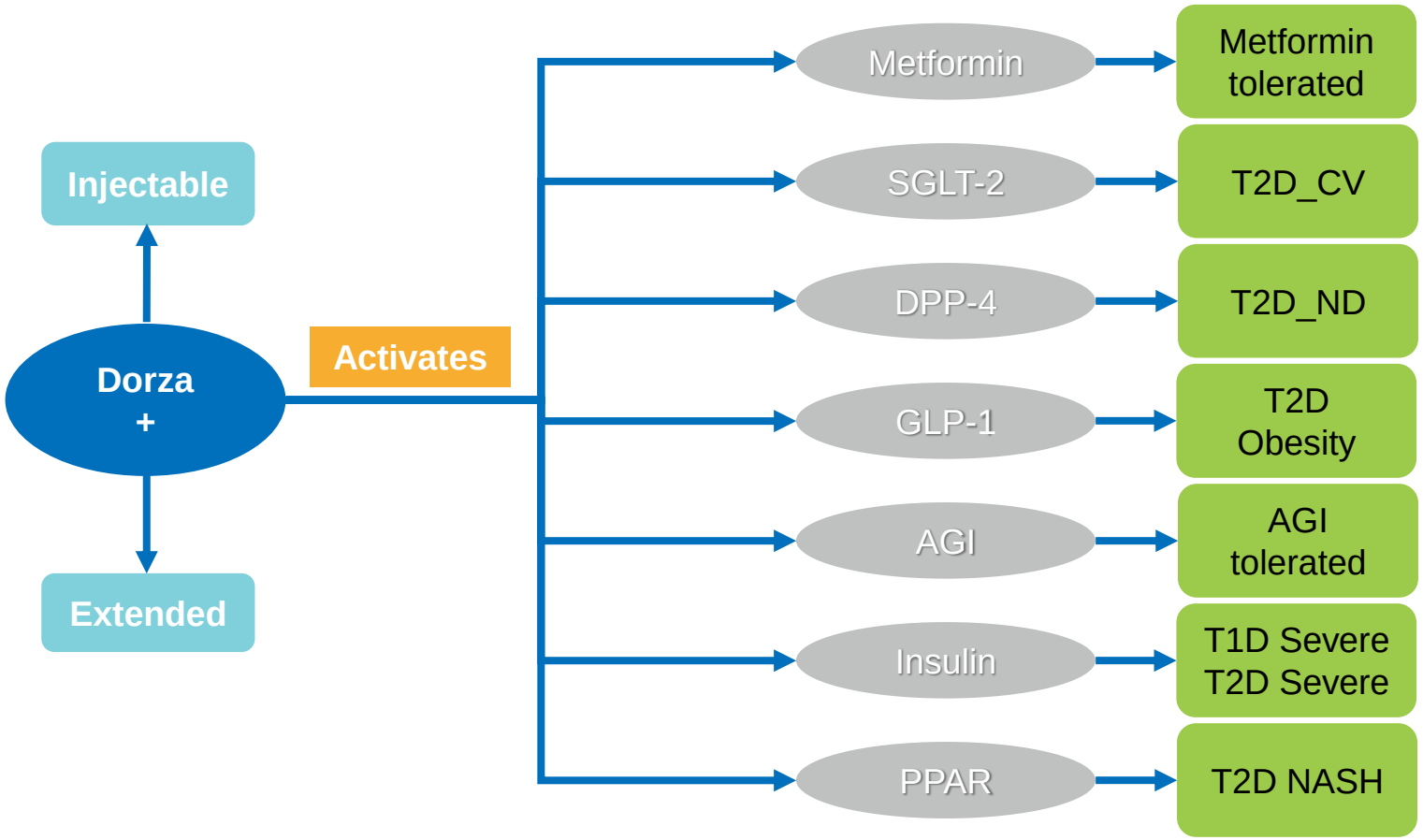
AI based machine learning results: providing a non-biased methodology to sub-classify T2D patients

Subtype	Predominate Influential Factor
T2D_1	Severe Impaired Glucose Tolerance
T2D_2	Impaired β-cell Function
T2D_3	Severe Impaired β-cell Function
T2D_4	Impaired Glucose Tolerance with aging
T2D_5	Severe Insulin Resistance with obesity
T2D_6	Impaired β-cell Function and Severe insulin resistance



[1] The Type 2 diabetes (T2D) patients are classified into 6 different subtypes: low insulin resistance (LIR), severe insulin resistance (SIR), SIR with diminished β-cell function (SIR_ βΔ), severe impaired glucose intolerance (SIGT), SIGT with diminished β -cell function (SIGT_ βΔ), and IR with severely diminished β -cell function (SIR_SβΔ)
Source: Poster 2019 ADA Scientific Sessions

Repair Sensor, Adopt Combo Therapy & Rebuild Homeostasis



Dorzagliatin profile

Priority attributes

- Restore glucose homeostasis——optimize time-in-range
- Protect β-cells and β-cell function
- HbA1c reduction with advanced glycemic control
- No/Limited hypoglycemia
- No GI side effect

Secondary attributes

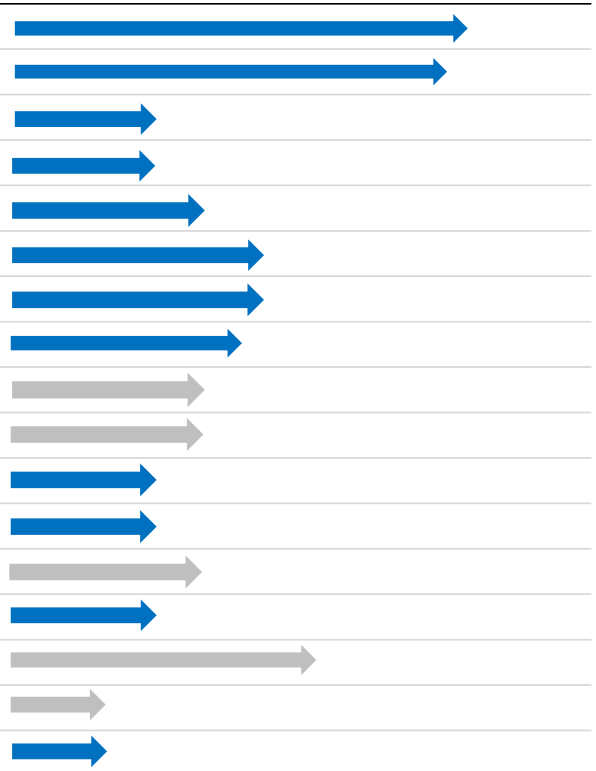
- T2D with diabetic kidney disease
- Sustained efficacy
- Limited side effects/no major adverse effects
- Neurodegeneration disease benefits

Key opportunity

- First-line in China for IGT driven T2D patients
- Combination therapy: FDC with 6 classes OAD covers major T2D patients
- Endogenous GLP-1 combo with DPP-4 inhibitors: additional indication in ND
- Combo with SGLT-2: T2D with metabolic syndrome
- Insulin sparing when add-on to late stage diabetes

Hua Medicine R&D Pipeline

Trial #	Drugs	Disease indication	Study type
HMM0301	Dorzagliatin	Drug naïve T2D	Registration trial
HMM0302	Dorzagliatin & metformin	Metformin tolerated T2D	Registration trial
HMM0311	Dorzagliatin +/vs OAD	To be determined	Label expansion
HMM0312	Dorzagliatin +/vs OAD	To be determined	Label expansion
HMM0109	Dorzagliatin	Hepatic impaired T2D	Label expansion
HMM0110	Dorzagliatin	Renal impaired T2D	Label expansion
HMM0111	Dorzagliatin + DPP-4	Obese T2D	PK/PD & DDI
HMM0112	Dorzagliatin + SGLT-2	Metabolic syndrome	PK/PD & DDI
HMM0113	Dorzagliatin + atorvastatin	Label expansion	PK/PD & DDI
HMM0114	Dorzagliatin + valsartan	Label expansion	PK/PD & DDI
HMM0115	Dorzagliatin + sulfonylurea	SU-tolerated T2D	PK/PD & DDI
HMM0116	Dorzagliatin + acarbose	Acarbose tolerated T2D	PK/PD & DDI
HMM0117	Dorzagliatin + liraglutide	GLP-1 tolerated T2D	PK/PD & DDI
HMM0119	Dorzagliatin + pioglitazone	NASH T2D	PK/PD & DDI
HMM1201	Dorzagliatin + insulin	Basal insulin tolerated T2D	Insulin sparing
HMM1202	Dorzagliatin + insulin	Drug naïve severe T2D	Pre-clinical
	mGLUR5	PD-LID	Pre-clinical



Currently Ongoing

Planned

Study Results Coming in the Next 12 Months

	Trial #	Trial description	Milestone	Announced
✓	HMM0301	Dorzagliatin monotherapy	Phase III 24-week top line data	(Nov. 2019)
✓	HMM0110	Dorzagliatin & renal impaired T2D	Phase I trial data	(Jan. 2020)
✓	HMM0111	Dorzagliatin & sitagliptin (DPP-4 inhibitor) combination	Phase I trial data	(Jan. 2020)
1	HMM0112	Dorzagliatin & empagliflozin (SGLT-2 inhibitor) combination	Phase I trial data	
2	HMM0109	Dorzagliatin & hepatic impaired T2D	Phase I trial data	
3	HMM0302	Dorzagliatin combination with metformin	Phase III 24-week top line data	
4	HMM0301	Dorzagliatin monotherapy	Phase III 52-week data	
5	HMM0302	Dorzagliatin combination with metformin	Phase III 52 week data	

Financial Review

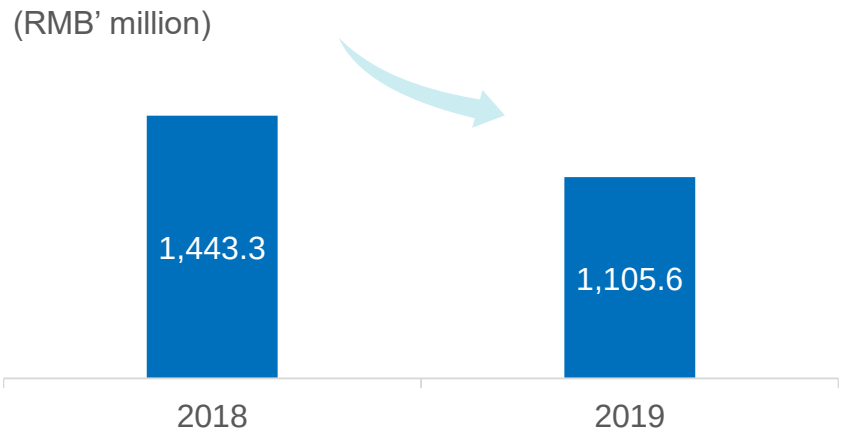
Financial Summary

Cash Balance: RMB1,105.6 million of cash at 12/31/2019 vs. 1,443.3 million at 12/31/2018.

Total cash decrease of RMB337.7million, consisted of

- Net cash used in operating activities was RMB342.1 million
- Net cash used in investing activities was RMB9.5 million
- Net cash used in financing activities was RMB1.2 million.
- Net effect of exchange rate changes was RMB15.1 million

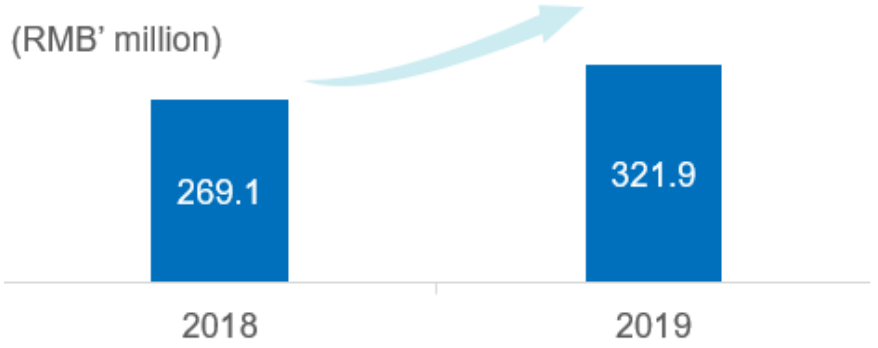
Net cash used in operation activities of RMB342.1 million mainly includes cash payment of RMB 238.3 million for the research and development activities and of RMB46.3 million for the administrative workforce employment.



Financial Summary- continued

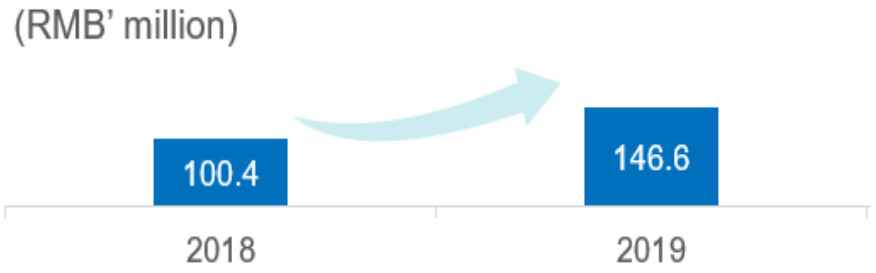
Research and development expenses of RMB321.9 million in 2019 vs. RMB269.1 million in 2018

- an increase of RMB25.3 million related to the progress of our Phase III clinical trials and additional Phase I clinical trials conducted in 2019
- an increase of RMB32.6 million associated with headcount increase and milestone bonus payments and share-based payments



Administrative expenses of RMB146.6 million in 2019 vs. RMB100.4 million in 2018

- increase related to the establishment of our finance and corporate development team and commercial strategy and marketing team,
- Increase in activities associated with market research and ongoing public listing costs in 2019



Financial Summary- continued

Other income of RMB29.6 million in 2019 vs. RMB10.4 million in 2018

- an increase of RMB13.1 million in government grants
- an increase of RMB6.1 million in bank interest income from short-term time deposits.

Other gains of RMB16.3 million in 2019 vs.RMB63.8 million in 2018

- Smaller appreciation of the U.S. dollar against the RMB in 2019

Loss before tax of RMB425.3 million in 2019, compared to RMB3,604.0million in 2018

- 2018 included RMB3,266 million of loss in fair value of convertible redeemable preferred shares before the listing date in 2018.

Adjusted net loss* of RMB350.9 million in 2019, compared to RMB279.3 million in 2018.

* Adjusted net loss was calculated by taking loss before tax for the year and adding back (a) share-based payments; and (b) loss on changes in fair value of financial liabilities at FVTPL.

Summary

Hua Medicine – A Global First-in-Class Biotech

Hua Medicine

Li Chen
CEO & CSO

Bob Nelsen
Chairman

Roche

Arch Ventures

JUNO THERAPEUTICS
DENALI THERAPEUTICS
GRAIL
UNITY BIOTECHNOLOGY
gossamerbio

Arch Ventures | Fidelity INVESTMENTS | venrock

SAIL | Ge Li | J Baldwin

Founding Investors

China-Based First-In-Class

- **Global rights** to dorzagliatin composition of matter, chemical process, formulation and multiple products in FDC with OADs
- **Met Primary Endpoint** in pivotal Phase III monotherapy trial, for China regulatory approval purposes
- **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 inhibitors
- Suitable for T2D patients with kidney disease
- Combination trials with metformin and SGLT2 are on going at various stages
- **Massive market opportunity** – global T2D population is 453 mm (120 mm in China alone)
- **RMB 1.1bn cash** as of December 31, 2019

Industry-wide Recognition

- In 2016, Hua obtained the **Annual R&D Achievement Award** of the 7th BayHelix Association Chinese Medicine Award
- In 2017, Hua was awarded the first China (Shanghai) Free Trade Zone System Pilot Program **Innovation Representative Enterprise**
- In 2018, Hua Medicine was awarded the 2017 **Innovation and Entrepreneurship Award** by the Pudong New Area People's Government
- In 2018, Dr. Li Chen was selected as one of the **40 Most Influential People in the Pharmaceutical Industry**, in celebration of the 40th Anniversary of Economic Reform and Opening Up
- In 2018, dorzagliatin's Phase II results were published in *The Lancet Diabetes and Endocrinology*, Dr. Dalong Zhu and Dr. Li Chen, etc., and were awarded the "**Most Influential Research Awards**" in the Chinese Diabetes Society's 2018 China Top 10 Diabetes Research
- In 2019, Dr. Li Chen was appointed as part-time researcher in the new drug industry of Shanghai Institute of Materia Medica, Chinese Academy of Sciences
- In 2019, Dr. Li Chen was appointed as a Director of the Biomedical Commission in the Shanghai Economic and Information Bureau of the 2nd Shanghai Youth and Intellectuals Association

HUA HM