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(Incorporated in the Cayman Islands with limited liability) (stock code: 2552)

## **VOLUNTARY ANNOUNCEMENT**

## BUSINESS UPDATE ON PRODUCT PIPELINE FOR DORZAGLIATIN

This announcement is made by Hua Medicine (the "Company", together with its subsidiaries, the "Group") on a voluntary basis to inform the shareholders of the Company and potential investors about the latest business updates of the Group.

The Company is pleased to announce its updated product pipeline for dorzagliatin which is set forth below:

	Trial	Products	Exploratory	NDA Enabling	Description/ Indication
	HMM0301	Dorzagliatin (HMS5552)		Phase III ongoing	Drug-naive T2D
	HMM0302	Dorzagliatin + Metformin		Phase III ongoing	Metformin tolerant T2D
New	HMM0303	Comparison study		Phase III initiation expected late 2019	Comparison against sulfonylurea and DPP-4 inhibitor
New	HMM0304	Comparison study		Phase III initiation expected 2020	comparison against a-glucosidase inhibitor
New	HMM0109	Dorzagliatin		Label expansion	Hepatic impaired T2D
New	HMM0110	Dorzagliatin		Label expansion	Renal impaired T2D
	HMM0111	Dorzagliatin + DPP-4 inhibitor	Phase I for combo		PK/PD study & DDI study
	HMM0112	Dorzagliatin + SGLT-2 inhibitor	Phase I for combo		PK/PD study & DDI study

	Trial	Products	Exploratory	NDA Enabling	Description/ Indication
New	HMM0113			Label expansion	PK/PD study & DDI
					study
New	HMM0114			Label expansion	PK/PD study & DDI
					study
New	HMM0115		Phase I for combo		PK/PD study & DDI
					study
New	HMM0116		Phase I for combo		PK/PD study & DDI
					study
	HMM0117	Dorzagliatin	Phase I for combo		PK/PD study & DDI
		+ GI P-1			study
New	HMM0119	Dorzagliatin	Phase I for combo		PK/PD study & DDI
		+ Pioglitazone			study/ NASH
	HMM1201	Dorzagliatin	Phase IIa		Basai insulin
		+ Insulin	preparation		tolerated
New	HMM1202	Dorzagliatin		Phase III preparation	Drug naive severe
		+ Insulin			T2D
		mGLUR5	Pre-clinical		PD-LID

As its two Phase 3 registration trials in China remain on track, and with over 600 patients having already completed the 24-week mark (for both trials together), the Company's preparation work for additional trials and studies to support its impending commercialization of dorzagliatin in China, and expansion of its future label continues in earnest. Working with leading key opinion leaders in both China and the United States, the Company will begin preparations and initiation of these studies now and through 2020.

The Company expects to initiate its head to head comparison trial (HMM0303) with both sulfonylurea (glimepiride) and the global blockbuster, DPP-4 inhibitor (sitagliptin) in the second half of 2019. Dr. Li Xiaoying, Vice President of the Chinese Diabetes Society and Director of Endocrinology at the Zhongshan Hospital will be leading this trial. As sulfonylurea as a class still commands over 8% of the total anti-diabetic pharmaceutical market in China in 2017 (according to Frost & Sullivan), and Januvia® and Janumet® combined generated over US\$5.9 billion in global sales in 2018, this trial has the potential to expand and accelerate the Company's commercialization plans for dorzagliatin. Shanghai Municipal Science & Technology Commission has provided a government grant subsidy in support of this important trial. For similar reasons, the Company is also beginning preparatory work for initiation of its head to head comparison trial (HMM0304) between dorzagliatin and α-glucosidase inhibitor, the leading China oral anti-diabetic drug with RMB 8.7 billion annual sales in 2017 in China (according to Frost & Sullivan).

The Company believes the Type 2 diabetes ('T2D") drug-naïve population in China provides a huge market opportunity due to the relatively low rate of diagnosis in

China (estimated at only 47.7% in 2017 by Frost & Sullivan), and coupled with the government's explicit announcement to invest in areas outside of Tier 3 cities to increase that rate. The Company has observed, though, that many such Chinese T2D drug-naïve patients have already advanced to a rather late stage of T2D (as measured by their diagnosed HbA1c levels) when finally diagnosed. It is this specific population that the Company believes its combination with insulin could provide a very strong therapy regimen as first-line therapy, and the Company initiate this trial (HMM1202) in 2020.

Within the next 12 months, the Company expects to announce top-line 24-week data for both of its Phase III trials in China, and also the results of its two Phase I combination drug-drug interaction trials in the United States. As of May 31, 2019, the Company has enrolled 630 patients into its combination with metformin Phase III trial (HMM0302) in China.

## **About Dorzagliatin**

Dorzagliatin is a first-in-class glucokinase activator, or GKA, designed to control the progressive degenerative nature of diabetes by restoring glucose homeostasis in Type 2 diabetics. By addressing the defect of the glucose sensor function of glucokinase, or GK, dorzagliatin has the potential to repair the impaired glucose homeostasis state of T2D and serve as a first-line standard of care therapy for the treatment of Type 2 diabetes, or as a cornerstone therapy when taken in combination with currently approved anti-diabetes drugs.

## Forward-Looking Statements

This announcement contains forward-looking statements including but not limited to statements regarding:

- the advancement of an anticipated clinical development, regulatory milestones and commercialization of products and drug candidates according to the latest updated product pipeline and
- the expected announcement of top-line data for some of the trials within the next 12 months.

Potential investors and shareholders should be informed that actual results and timing of completion or announcement may differ materially from those indicated in the forward-looking statements as a result of the following:

• any change of product pipeline and timetable could result in increased costs to the Company and delay or limit its ability to obtain regulatory approval;

- clinical drug development involves a lengthy and expensive process with an uncertain outcome, and failure can occur at any stage of clinical development;
- the Company's future success depends substantially on the success in China of its only clinical drug candidate, dozagliatin. The Company's ongoing Phase III clinical trials for dorzagliatin in China may not succeed, or it may not meet its goal of establishing dorzagliatin as a first-line standard of care in China, any of which could materially harm its business;
- if safety, efficacy, manufacturing or supply issues arise with any approved Type 2 diabetes drug that it uses in combination with dorzagliatin, the Company may be unable to market dorzagliatin or may experience regulatory delays and supply shortages, and its business could be materially harmed; and
- risks and uncertainties disclosed in the section entitled "Principal Risks and Uncertainties" in the Company's most recent annual report which may affect its results and business operations, some of which are inherent to it, some are inherent to the pharmaceutical sector, and some are from external sources.

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities of The Stock Exchange of Hong Kong Limited: The Company cannot guarantee that the Company will be able to develop, or ultimately market, dorzagliatin successfully. Potential investors and shareholders are advised not to place undue reliance on the aforesaid information and are advised to exercise caution in dealing in the securities of the Company.

By Order of the Board

Dr. Li Chen

Chief Executive Officer and

Executive Director

Shanghai, June 5, 2019

As of the date of this announcement, the Board of Directors comprises Dr. Li Chen and Mr. George Chien Cheng Lin as executive Directors; Mr. Robert Taylor Nelsen and Dr. Lian Yong Chen as non-executive Directors; and Mr. Walter Teh-ming Kwauk, Mr. William Robert Keller, Mr. Junling Liu and Mr. Yiu Wa Alec Tsui as independent non-executive Directors.