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CSPC PHARMACEUTICAL GROUP LIMITED

石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1093)

VOLUNTARY ANNOUNCEMENT

RESULTS OF PHASE III CLINICAL STUDY OF EFMEDAGLUTIDE ALFA INJECTION IN COMBINATION WITH METFORMIN IN CHINESE ADULT PATIENTS WITH TYPE 2 DIABETES MELLITUS PRESENTED IN A SHORT ORAL DISCUSSION AT THE 62ND ANNUAL MEETING OF THE EUROPEAN ASSOCIATION FOR THE STUDY OF DIABETES (EASD 2026)

The Board of Directors (the “**Board**”) of CSPC Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that the Group has presented the positive results of the Phase III clinical study (the “**Study**”) of the glucagon-like peptide-1 (“**GLP-1**”) receptor agonist Efmedaglutide Alfa Injection (the “**TG103 Injection**”) developed by the Group, in combination with metformin, for the treatment of Chinese adult patients with type 2 diabetes mellitus (“**T2DM**”) in a short oral discussion at the 62nd Annual Meeting of the European Association for the Study of Diabetes (EASD 2026). The results of the Study demonstrated that the TG103 Injection exhibited a favourable efficacy and safety profile in this population.

Study Design

The Study is a multicentre, randomised, open-label, dulaglutide-controlled Phase III clinical trial led by Professor Ji Linong of Peking University People’s Hospital, aimed at evaluating the efficacy and safety of different doses of the TG103 Injection in T2DM patients with inadequate glycaemic control on metformin monotherapy.

The Study enrolled T2DM patients aged 18 to 75 years who had received a stable dose ($\geq 1,500$ mg/day) of metformin monotherapy for at least 8 weeks prior to screening but still had inadequate glycaemic control, and whose glycated haemoglobin (“**HbA1c**”) levels were between 7.0% and 10.5% prior to randomisation.

A total of 632 patients were enrolled in the Study and randomly assigned to three treatment groups to receive once-weekly TG103 Injection 7.5 mg (n=210), TG103 Injection 15 mg (n=211; administered at 7.5 mg for the first 4 weeks, followed by escalation to 15 mg), and dulaglutide 1.5 mg (n=211), respectively, for 28 weeks of continuous administration. After Week 28, the dose for patients in the TG103 Injection 7.5 mg group was adjusted to 15 mg, while the treatment regimens for the TG103 Injection 15 mg group and the dulaglutide 1.5 mg group remained unchanged, with continuous administration up to Week 52 for all groups.

Study Results

At the meeting, the Group presented the positive results of the Study. The relevant efficacy and safety data are as follows:

- **Efficacy**

At Week 28, both the TG103 Injection 7.5 mg group and the TG103 Injection 15 mg group demonstrated a clinically meaningful reduction in HbA1c, with the HbA1c level in the TG103 Injection 15 mg group decreasing by 1.38% from baseline. Based on the treatment policy strategy analysis, which more closely reflects clinical practice scenarios, the reduction in HbA1c at Week 28 for each dose group of TG103 Injection was non-inferior to that in the dulaglutide 1.5 mg group.

During the treatment period, all dose groups of TG103 Injection showed a rapid onset of action, taking effect as early as Week 4 of treatment, with reductions in HbA1c of $\geq 1\%$ after 8 weeks of treatment. Notably, the reduction in the TG103 Injection 15 mg group was stably sustained without attenuation through Week 52. At Week 52, the numerical reduction in HbA1c in the TG103 Injection 15 mg group was higher than that in the dulaglutide 1.5 mg group (1.31% vs 1.25%), while the reduction in HbA1c in the TG103 Injection 7.5 mg group was comparable to that in the dulaglutide 1.5 mg group at Week 52.

In addition, at both Week 28 and Week 52, the proportion of patients achieving HbA1c $< 7.0\%$ in the TG103 Injection 15 mg group was higher than that in the dulaglutide 1.5 mg group (Week 28: 53.9% vs 52.2%; Week 52: 52.2% vs 46.8%).

- **Safety**

The safety profiles of the TG103 Injection 7.5 mg group, the TG103 Injection 15 mg group and the dulaglutide 1.5 mg group were generally similar. The primary adverse events were gastrointestinal events, with comparable incidence rates across the groups, indicating that TG103 Injection has a favourable safety and tolerability profile. The incidence of hypoglycaemia and the discontinuation rate due to adverse events in all dose groups of TG103 Injection were relatively low, and no severe hypoglycaemic events were reported.

Study Conclusions

TG103 Injection (7.5 mg and 15 mg) demonstrated a rapid onset of action and a stable, durable glycaemic improvement effect, with significant efficacy observed as early as Week 8. The glucose-lowering effect tended to stabilise by Week 12 and was maintained without attenuation up to Week 52. Concurrently, under a simple and rapid dose escalation regimen, TG103 Injection continued to exhibit a favourable safety and tolerability profile, with a relatively low incidence of gastrointestinal adverse events. The results of the Study indicate that, for T2DM patients with inadequate glycaemic control on metformin monotherapy, TG103 Injection represents a combination treatment option with promising clinical application prospects.

About TG103 Injection

TG103 Injection is a recombinant human glucagon-like peptide-1 (hGLP-1) Fc fusion protein injection administered once weekly. The product can selectively bind to and activate GLP-1 receptors, promoting insulin secretion and inhibiting glucagon release in a glucose concentration-dependent manner, thereby steadily lowering blood glucose levels. Additionally, TG103 Injection can suppress appetite, reduce food intake, and exert weight-regulating effects while also improving cardiovascular and metabolism-related indicators.

By Order of the Board
CSPC Pharmaceutical Group Limited
CAI Dong Chen
Chairman

Hong Kong, 30 September 2026

As at the date of this announcement, the Board comprises Mr. CAI Dong Chen, Dr. CAI Lei, Mr. WEI Qingjie, Mr. ZHANG Cuilong, Mr. WANG Zhenguo, Dr. LI Chunlei, Dr. YAO Bing, Mr. CAI Xin, Mr. CHEN Weiping, Mr. QU Zhiyong and Mr. ZHANG Yiwei as Executive Directors; and Mr. WANG Bo, Mr. CHEN Chuan, Prof. WANG Hongguang, Mr. AU Chun Kwok Alan, Mr. LAW Cheuk Kin Stephen and Ms. LI Quan as Independent Non-executive Directors.