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信达生物临床数据更新

玛仕度肽高剂量9 mg减重临床II期（48周）

2023年10月30日

开发出老百姓用得起的高质量生物药

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1 玛仕度肽: 高剂量9mg 减重临床II期48周研究数据更新

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玛仕度肽高剂量9mg
减重临床II期48周研究数据更新

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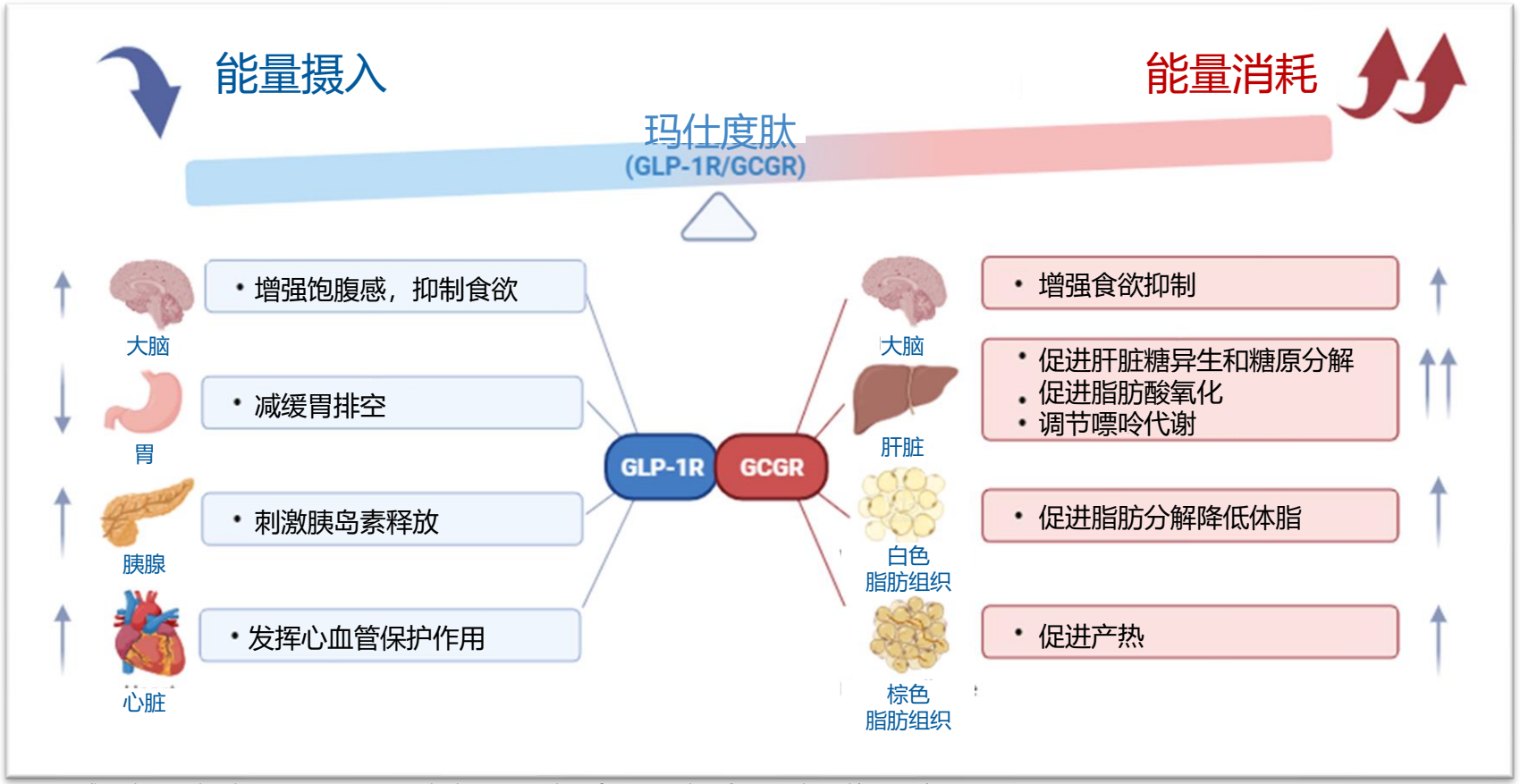
玛仕度肽GLP-1R/GCGR双靶激动剂的差异化机理

激动GCGR有望增强减重效力并改善代谢

同时激动胰高血糖素样肽-1受体(GLP-1R)和胰高血糖素受体（GCGR）相当于调节能量平衡等式的两端



GCGR激活有望增强减重效力并改善代谢

- 激活GCGR能够增加能量消耗和代谢速率从而达到持续减重的效应;
- GCGR在多个主要代谢器官/组织表达（包括肝脏，脂肪，脑等），尤其是在肝脏（人体最大的代谢器官）细胞上丰富表达，激活GCGR将提升肝脏脂肪消耗，并加速基础能量代谢。

1.Conceição-Furber E,et al. Is glucagon receptor activation the thermogenic solution for treating obesity? Front Endocrinol (Lausanne)2022;13:868037
2.Kleinert M, et al. Glucagon Regulation of Energy Expenditure. Int J Mol Sci. 2019 Oct 30;20(21):5407.
3. Jastreboff AM, et al. Retatrutide Phase 2 Obesity Trial Investigators. Triple-Hormone-Receptor Agonist Retatrutide for Obesity - A Phase 2 Trial. N Engl J Med. 2023 Aug 10;389(6):514-526.
4.Hope DCD, Vincent ML, Tan TMM. Striking the Balance: GLP-1/Glucagon Co-Agonism as a Treatment Strategy for Obesity. Front Endocrinol (Lausanne). 2021 Sep 8;12:735019.

玛仕度肽: 全球首个进入临床III期的GLP-1R/GCGR双靶激动剂

治疗肥胖和糖尿病的潜在最优候选药物，第四项临床III期即将启动

玛仕度肽适应症开发计划

- **2型糖尿病 (6mg)**：减重降糖双重获益，有望为糖尿病患者长期病程管理带来获益；
- **肥胖或超重 (6mg)**：满足广阔的肥胖或超重人群理想的减重目标；
- **肥胖 (9mg)**：媲美减重手术的疗效潜力，有望成为中重度肥胖患者更理想的减重方案；
- 未来将围绕更多治疗需求持续进行探索。

总览：玛仕度肽高剂量9mg减重临床II期48周研究

GLP1-1/GCGR双靶差异化优势凸显：展现出强劲减重疗效、优异安全性和多重差异化的代谢获益

双靶激活多重通路以提升减重疗效

玛仕度肽
(GLP-1R/GCGR)

平衡双靶配比达到良好安全性和依从性

减重疗效快速强劲，媲美代谢手术

- **全球前列、中国最高的减重效果：**治疗48周后，玛仕度肽9 mg组体重较基线的平均百分比变化与安慰剂组的治疗差值达**-18.6%**;
- 48周治疗下体重较基线下降至少15%和20%的受试者比例明显增加。

高剂量安全性和耐受性优异

- **48周治疗期间，未发生严重不良事件（SAE）**；
- 24周主要终点时，玛仕度肽组的心率**平均增幅与安慰剂组相近**，且在延长治疗期**未见**心率的进一步增加。整个治疗期间未见心血管风险增加的安全性信号。

多重、差异化的代谢获益，肝脂肪含量下降73.3%

- 在24周主要终点时，腰围、TG、TC、LDL-C、ALT和AST水平下降幅度显著优于安慰剂，且以上获益在延长治疗期继续维持，HDL-C水平在整个48周治疗期间维持稳定；
- **差异化优势凸显，肝脏脂肪含量大比例下降，血尿酸水平显著下降。**

依从性良好，给药方案简捷耐受

- **48周治疗期间，无受试者因不良事件提前终止研究药物治疗**;
- 二步法滴定给药即达到稳定维持剂量，简捷耐受。

**TG:甘油三酯（Triglycerols)，TC:总胆固醇 (Total cholesterol)，LDL-C:低密度脂蛋白胆固醇 (Low-density lipoprotein cholesterol)， ALT:谷丙转氨酶 (Alanine transaminase)，AST:谷草转氨酶 (Aspartate aminotransferase) ，HDL-C:高密度脂蛋白胆固醇 (High-density lipoprotein cholesterol)*

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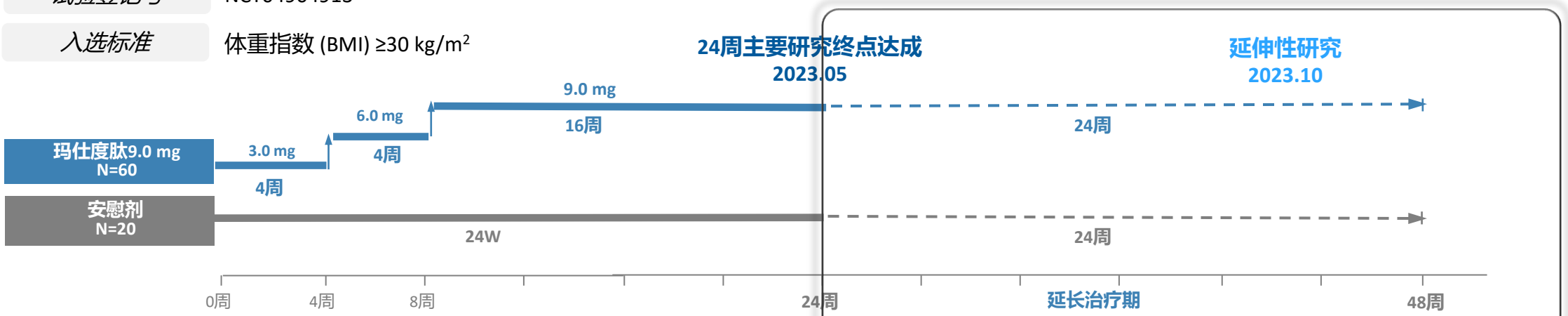
玛仕度肽高剂量9mg肥胖临床II期研究

24周主要研究终点达成，延伸性研究延长治疗期至48周

试验登记号	NCT04904913
入选标准	体重指数 (BMI) ≥30 kg/m²



基线特征	受试者人数	平均年龄	平均身高	平均体重	平均 BMI
	N=80	34岁	168.0 cm	96.9 kg	34.3 kg/m²
	N=59	34岁	168.4 cm	98.4 kg	34.7 kg/m²

- 本项II期临床研究共纳入80例受试者，按3：1的比例随机接受每周一次玛仕度肽9 mg或安慰剂治疗。
- 主要研究终点在2023年5月达成，为治疗24周后与安慰剂相比受试者体重相对基线的百分比变化。

- 作为一项延伸性研究，自愿继续接受治疗的受试者将延长治疗至48周。
- 59例受试者（玛仕度肽组43/60例，安慰剂组16/20例）自愿继续接受24周研究药物双盲延长期治疗。

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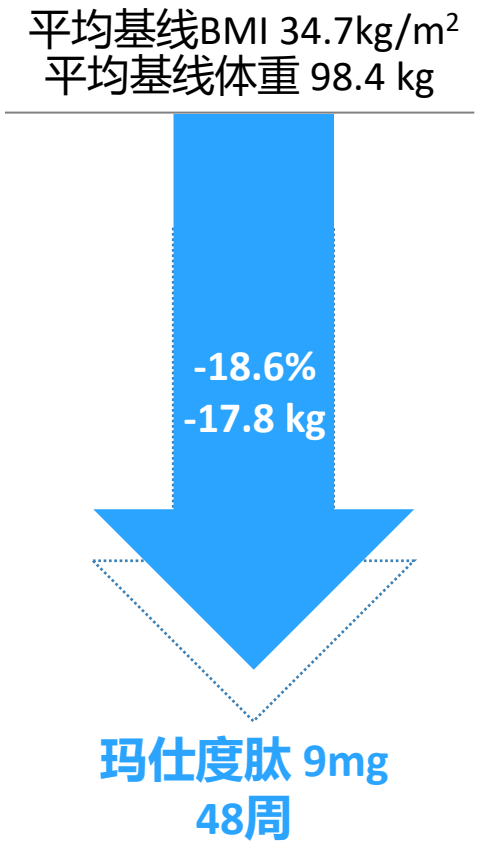
玛仕度肽高剂量9mg肥胖临床II期研究
减重疗效强劲：48周相较安慰剂体重降幅达18.6%

玛仕度肽 9mg 给药48周治疗与安慰剂相比受试者体重较基线的变化



强劲、持续的减重疗效

- 治疗48周后，玛仕度肽9 mg组体重较基线的平均百分比变化与安慰剂组的治疗差值达**–18.6%**，平均变化值与安慰剂组差值达**–17.8 kg**；
- **减重效果媲美代谢手术**，有望成为中重度肥胖人群长期体重管理**潜在更理想的治疗选择***。

**中国人BMI≥32.5 kg/m2 推荐接受代谢手术。*

减重起效快速、操作简捷

- **简捷耐受的两步滴定给药方案；**
- 展现出快速降低体重的特点。

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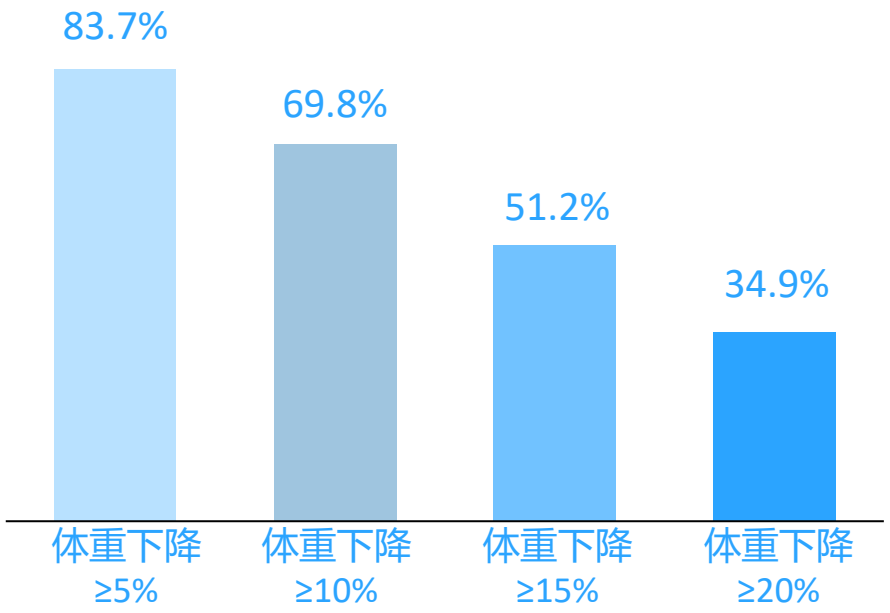
玛仕度肽高剂量9mg肥胖临床II期研究
体重下降超过15%和20%的受试者比例显著增加

玛仕度肽 9mg 给药48周治疗受试者体重达标率

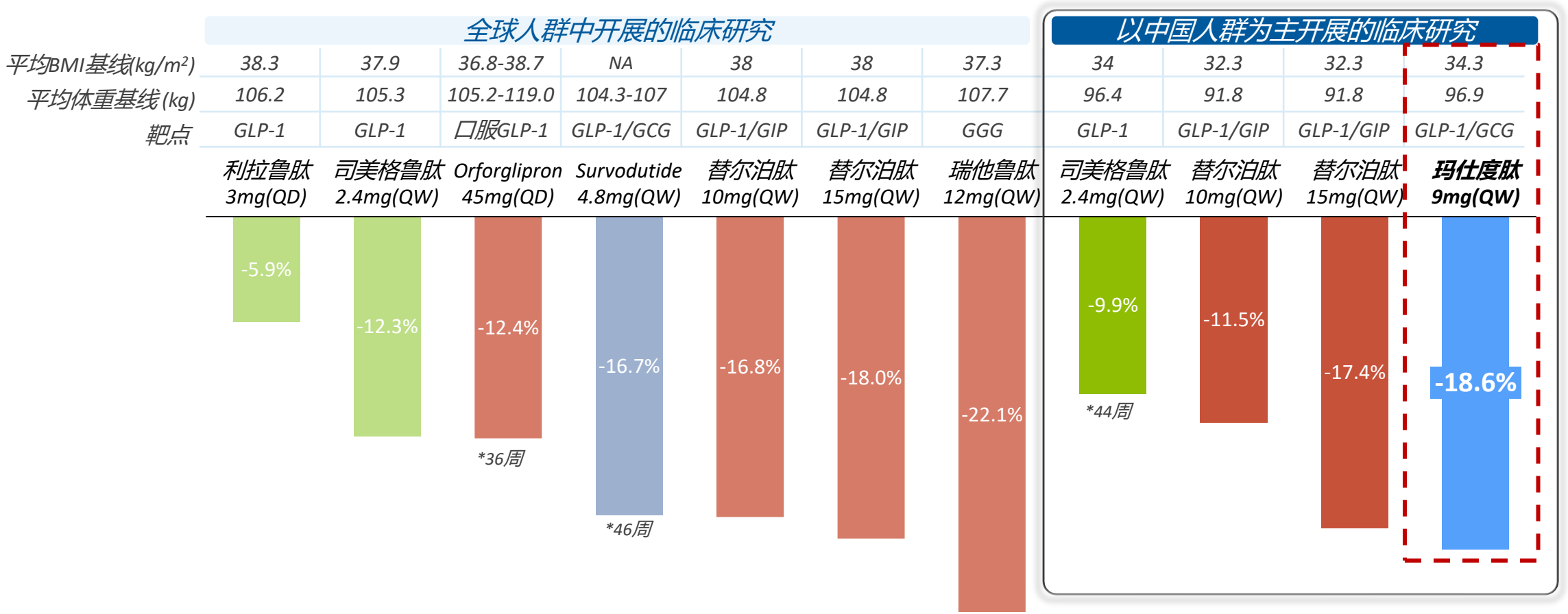


玛仕度肽 9mg 48周

- 治疗48周后，玛仕度肽 9 mg组有51.2%受试者体重较基线下降至少15%，34.9%的受试者体重较基线下降至少20%；
- **48周延长治疗期，体重下降超过15%和20%受试者比例较24周显著增加；**
- 安慰剂组无受试者体重降幅达到5%及以上。

主要GLP-1类创新药物48周减重疗效对比
玛仕度肽刷新GLP-1R/GCGR双靶激动剂减重疗效纪录

GLP-1类药物48周减重效果（间接对比，相较安慰剂）

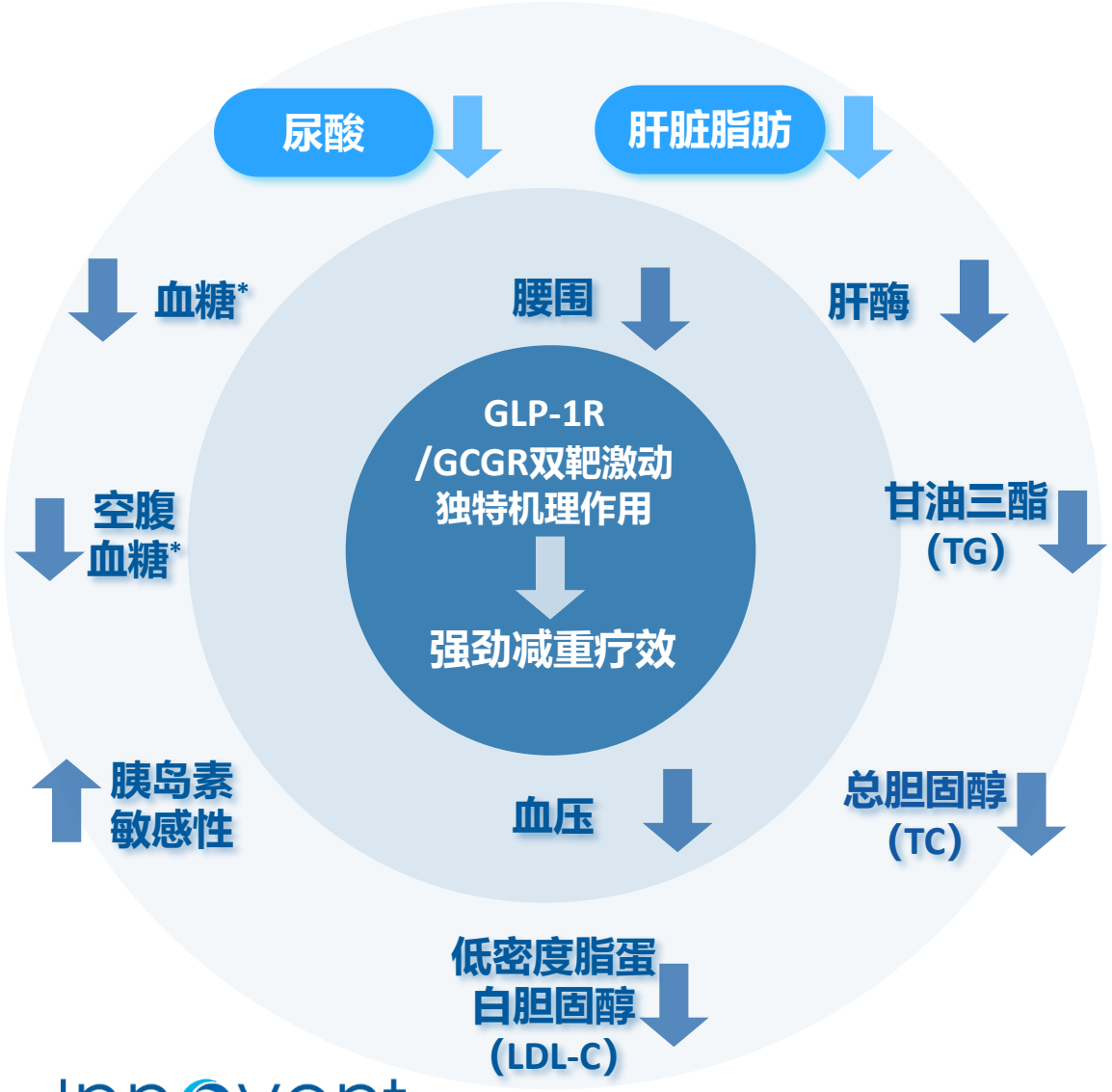


48-week weight loss data of liraglutide 3 mg, semaglutide 2.4 mg, tirzepatide 10/15 mg and retatrutide 12mg were estimated from published results of SCALE[1], STEP-1[2], SURMOUNT-1[3], SURMOUNT-CN[4] and a Phase II (NCT04881760)[5] studies, respectively; while <48-week weight loss data of orforglipron 45mg, survodutide 4.8mg and semaglutide 2.4mg(CN) were published results of a Phase II (NCT05051579)[6] , a Phase II (NCT04667377)[7] and STEP-7[8] studies, respectively.

[1]Pi-Sunyer X, et al. N Engl J Med. 2015. [2]Khoo TK, et al. N Engl J Med. 2021. [3]Jastreboff AM, et al. N Engl J Med. 2022. [4]Lin Zhao, et al. Presented at EASD 2023, October 2023. [5]Ania M, Jastreboff, et al. N Engl J Med. 2023. [6]Wharton S, et al. N Enal J Med. 2023. [7]Le Roux. C. Presented at the 2023 ADA. [8]Hansen MR. et al. Presented at the 30th ECO. May 2023

玛仕度肽的多重代谢获益（总结）

GLP-1R/GCGR双靶激动剂的独特作用机理带来多重、差异化的代谢获益



- 与体重变化相对应，治疗期间玛仕度肽组受试者的**平均腰围和血压**等指标均呈现持续下降并稳定保持。

- 在24周主要终点时，**甘油三酯（TG）、总胆固醇（TC）、低密度脂蛋白胆固醇（LDL-C）和肝酶（ALT/AST）**下降幅度显著优于安慰剂，且**胰岛素敏感性**改善，以上获益在延长治疗期得以维持；**高密度脂蛋白胆固醇（HDL-C）**水平在整个48周治疗期间维持稳定。

- 同时，玛仕度肽的GLP-1R/GCGR双靶激动的独特作用机理带来多重、差异化的代谢获益，包括脂肪肝受试者肝脏脂肪含量（LFC）大比例下降和显著降低血尿酸（sUA）水平。

*玛仕度肽在另一项二型糖尿病临床I期结果中展现出显著降低糖化血红蛋白（HbA1c）水平，空腹血糖水平，餐后血糖水平等获益

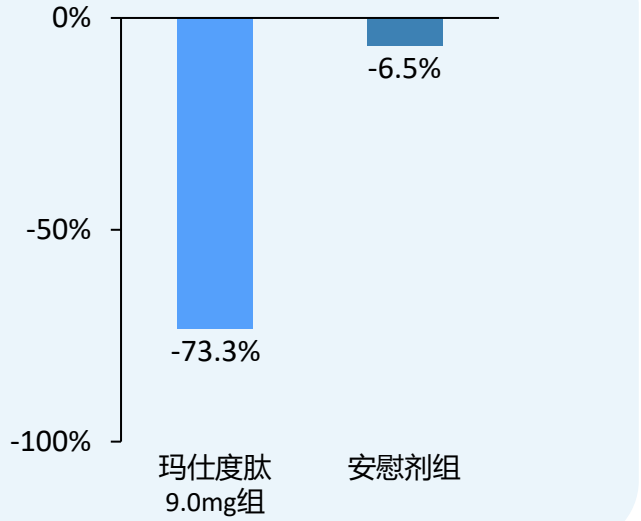
玛仕度肽的多重代谢获益（亮点）

显著降低肝脏脂肪含量、肝酶和尿酸

肝脏脂肪含量减少73%

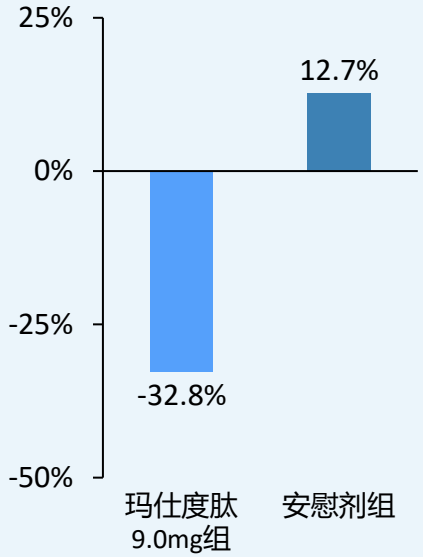
24周治疗下 MRI-PDFF测量*
平均肝脏脂肪含量较基线的百分比变化
(%)

***在基线肝脏脂肪含量水平≥5%受试者中*

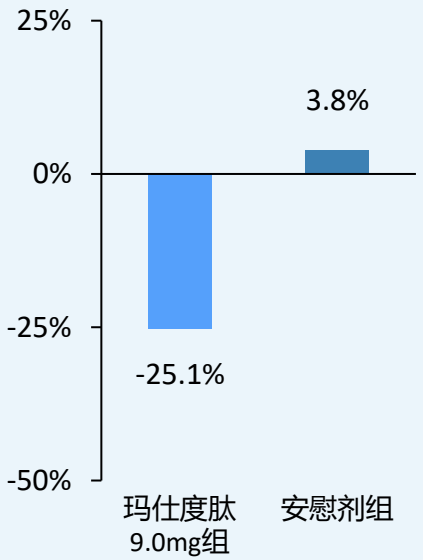


肝酶水平显著降低

*24周治疗下**
平均ALT水平较基线的百分比变化
(%)

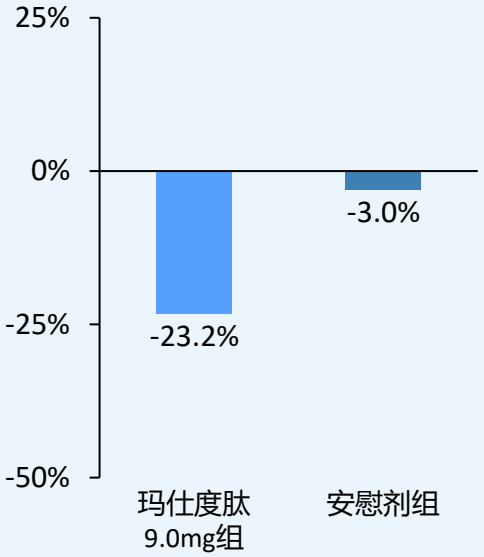


*24周治疗下**
平均AST水平较基线的百分比变化
(%)



尿酸水平显著降低

*24周治疗下**
平均 尿酸水平较基线的百分比变化
(%)



***肝脏脂肪含量水平≥ 5% 是识别肝细胞脂肪变的标准依据*

**注：以上获益在延长治疗期得以维持。*

*** Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, Abdelmalek MF, Caldwell S, Barb D, Kleiner DE, Loomba R. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. Hepatology. 2023 May 1;77(5):1797-1835.*

玛仕度肽的安全性特征（总结）

高剂量9mg 安全性和耐受性良好

整体安全性和耐受性良好

- 胃肠道不良反应（恶心、呕吐和腹泻）是最常发生的不良事件，绝大多数为**轻度或中度**。延长治疗期胃肠道不良反应的发生率**明显降低**，绝大多数为轻度。
- 48周治疗期间，整体安全谱与**GLP-1类药物**和玛仕度肽的既往研究中观察到的保持一致，且**未发现新的安全性信号。**

无受试者因不良事件终止治疗

- 48周治疗期间，**无受试者因不良事件提前终止研究药物治疗，未发生严重不良事件。**

未见心血管风险增加的安全性信号

- 24周主要终点时，**玛仕度肽9 mg组的心率平均增幅与安慰剂组相近**，且在延长治疗期未见心率的进一步增加。
- **整个治疗期间未见心血管风险增加的安全性信号。**

注：在所有受试者完成停药随访后，将对24周主要终点和48周延长治疗期的数据进行进一步分析，并在学术会议和学术期刊完整披露。

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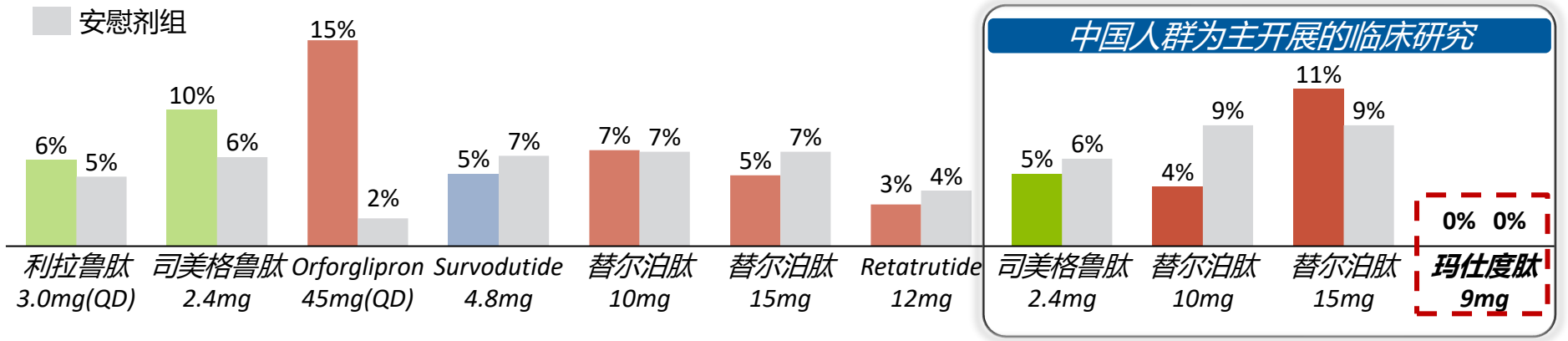
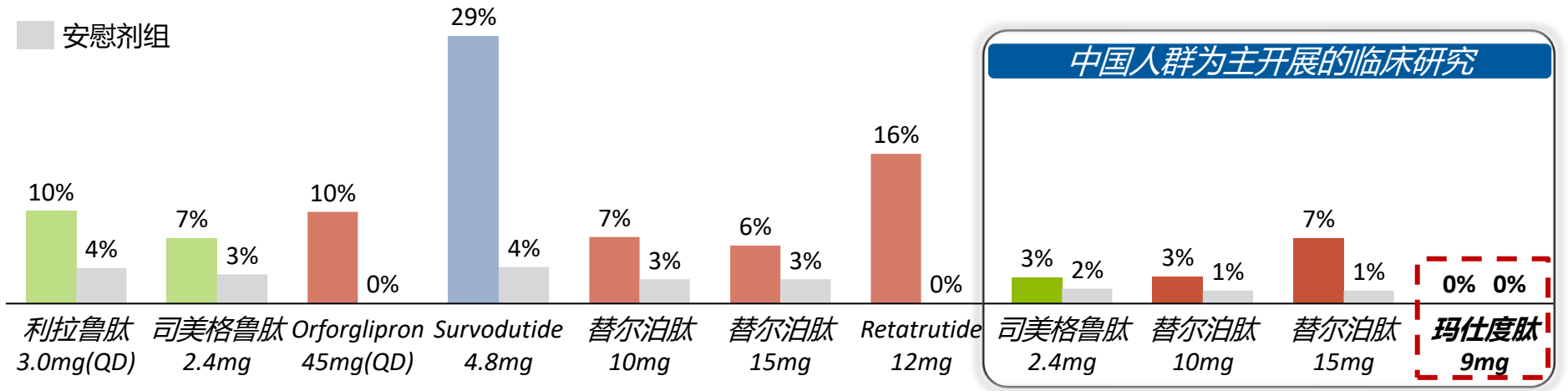
主要GLP-1类创新药物的安全性对比
玛仕度肽高剂量9mg安全性和耐受性良好

治疗期间严重不良事件发生率（%）（间接对比）



治疗期间因不良事件提前终止研究药物治疗发生率（%）（间接对比）

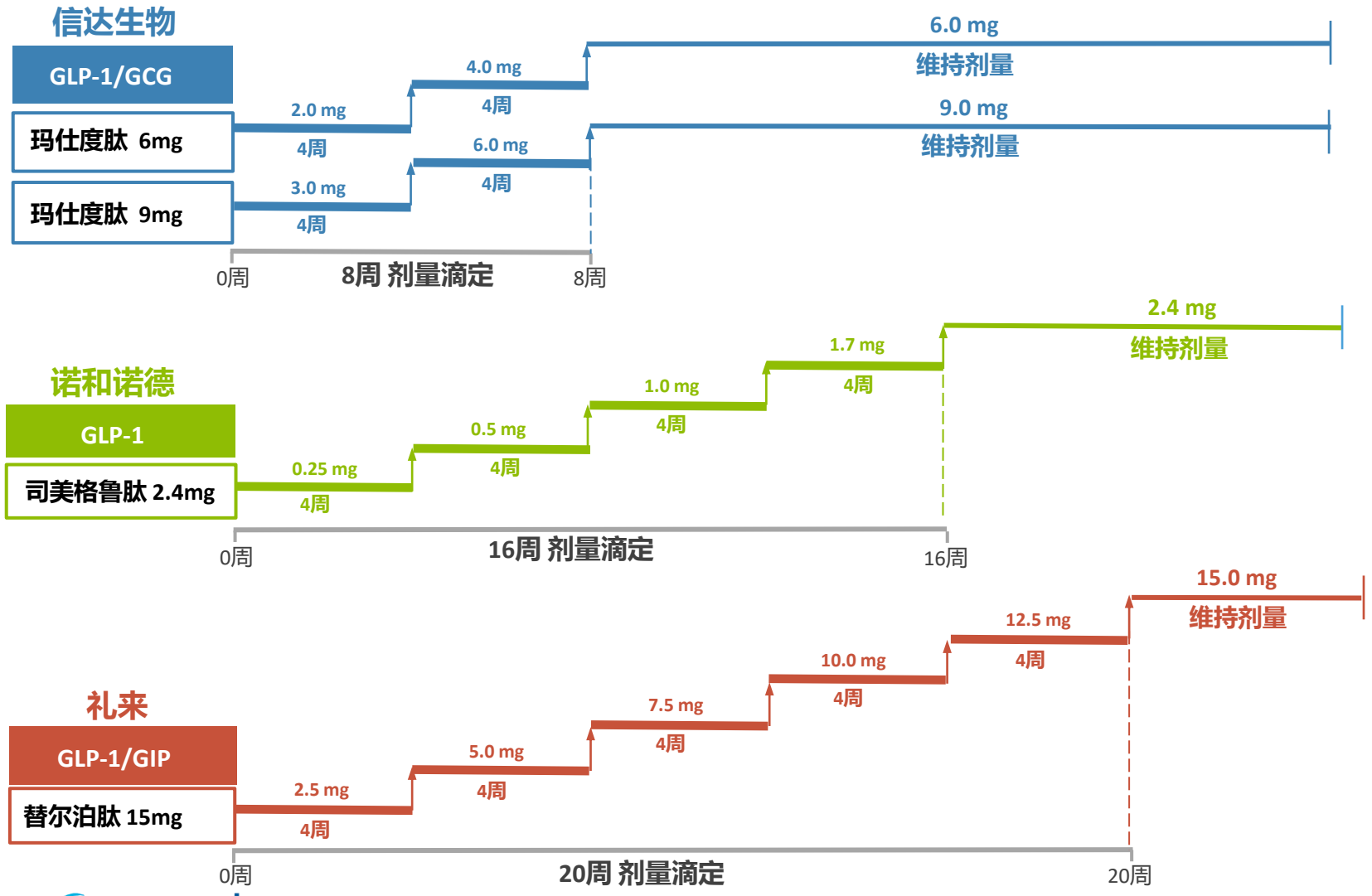


玛仕度肽在实现强劲减重疗效同时，展现了优异的安全性特征，并采用简捷耐受的两步滴定给药方案，优势凸显。

Safety data of liraglutide 3 mg, semaglutide 2.4 mg, tirzepatide 10/15 mg, retatrutide 12mg orforglipron 45mg, survodutide 4.8mg and semaglutide 2.4mg(CN) were from published results of SCALE[1], STEP-1[2], SURMOUNT-1[3], SURMOUNT-CN[4] and a Phase II (NCT04881760)[5] a Phase II (NCT05051579)[6], a Phase II (NCT04667377)[7] and STEP-7[8] studies, respectively.

[1]Pi-Sunyer X, et al. N Engl J Med. 2015. [2]Khoo TK, et al. N Engl J Med. 2021. [3]Jastreboff AM, et al. N Engl J Med. 2022. [4]Lin Zhao, et al. Presented at EASD 2023, October 2023. [5]Ania M, Jastreboff, et al. N Engl J Med. 2023. [6]Wharton S, et al. N Engl J Med. 2023. [7]Le Roux, C. Presented at the 2023 ADA, [8]Hansen MR, et al. Presented at the 30th ECO, May 2023

玛仕度肽更简捷耐受的给药方案
仅两步剂量滴定即达到稳定维持剂量



玛仕度肽 6mg/9mg
- **3** 种剂量(注射笔)
- **8**周剂量滴定

司美格鲁肽 2.4mg
- **5**种剂量(注射笔)
- **16周**剂量滴定

替尔泊肽 15mg
- **6**种剂量(注射笔)
- **20周**剂量滴定

玛仕度肽近期催化剂

肥胖或超重 (6mg)

- **2023年底至2024年初计划递交首个新药上市申请 (NDA)**
- 2023年底预计临床II期结果将全文发表于国际期刊

肥胖 (9mg)

- **2023年底启动临床III期研究**
- 计划未来临床II期结果全文发表于国际期刊/学术大会

2型糖尿病 (6mg)

- **2024年计划递交NDA**
- 2023年底至2024年初预计临床II期结果将全文发表于国际期刊

更多适应症计划中

- 更多治疗领域的潜力在评估和探索中

信达生物心血管及代谢（CVM）领域战略布局

打造品牌认知，持续推进下一代管线储备，为长期可持续发展提供差异化创新

下一代创新管线储备

- 口服CVM项目
- 其他创新药物形态
- 青少年及老年疾病

持续打造重磅高潜产品

获批产品

信必乐

信必乐® (托莱西单抗注射液)

中后期管线

玛仕度肽 (6mg)
- 临床III期– 超重或肥胖
- 临床III期 – 糖尿病

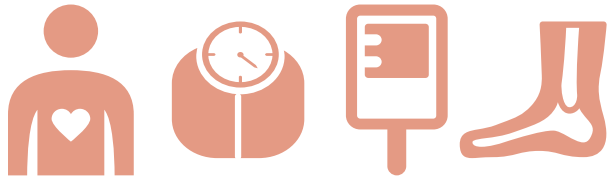
玛仕度肽 (9mg)
- 临床II期 – 中重度肥胖

IBI128 (Tigulixostat)
- 海外多中心临床Ph3 – 痛风 *(LG化学主导)*

IBI311
- 临床III期 – 甲状腺眼病

市场潜力巨大

~5亿
患者人群



~1000亿元
中国CVM市场规模

附录：中国超重及肥胖现状

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肥胖：日益严重的公共卫生问题

01 中国成年人超重/肥胖比例**超过50%**[1]

02 超重、肥胖是导致多种非传染性疾病（NCDs）的**危险因素**[2,3]

03 **显著未满足的临床需求**，亟需有效且安全的治疗手段达到理想的减重效果

04 肥胖作为一种复杂的慢性疾病需要**长期治疗管理**

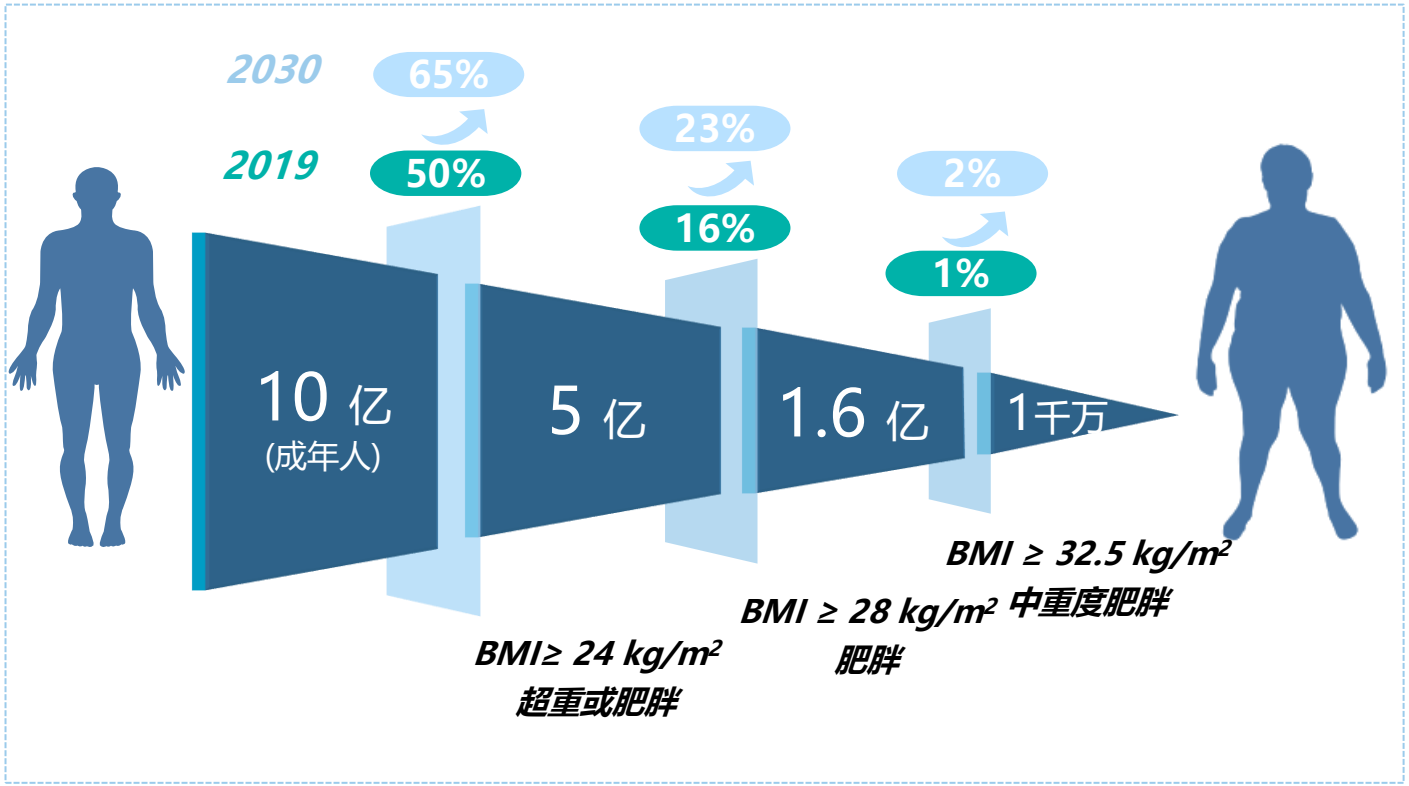
05 预计2030年中国超重及肥胖相关的医疗费用将达**4000亿人民币**[2]

1. Pan XF, Wang L, Pan A. Epidemiology and determinants of obesity in China. Lancet Diabetes Endocrinol. 2021 Jun;9(6):373-392. doi: 10.1016/S2213-8587(21)00045-0. Erratum in: Lancet Diabetes Endocrinol. 2021 Jul;9(7):e2. PMID: 34022156.
2. Wang Y, Zhao L, Gao L, Pan A, Xue H. Health policy and public health implications of obesity in China. Lancet Diabetes Endocrinol. 2021 Jul;9(7):446-461. doi: 10.1016/S2213-8587(21)00118-2. Epub 2021 Jun 4. PMID: 34097869.
3. Institute for Health Metrics and Evaluation. Global Health Data Exchange. GBD results tool. http://ghdx.healthdata.org/gbd-resultstool (accessed Jan 10, 2021).

中国已成为全球超重和肥胖人数最多的国家

中国有约5亿超重或肥胖的成年人, 全球排名第一[i,1].

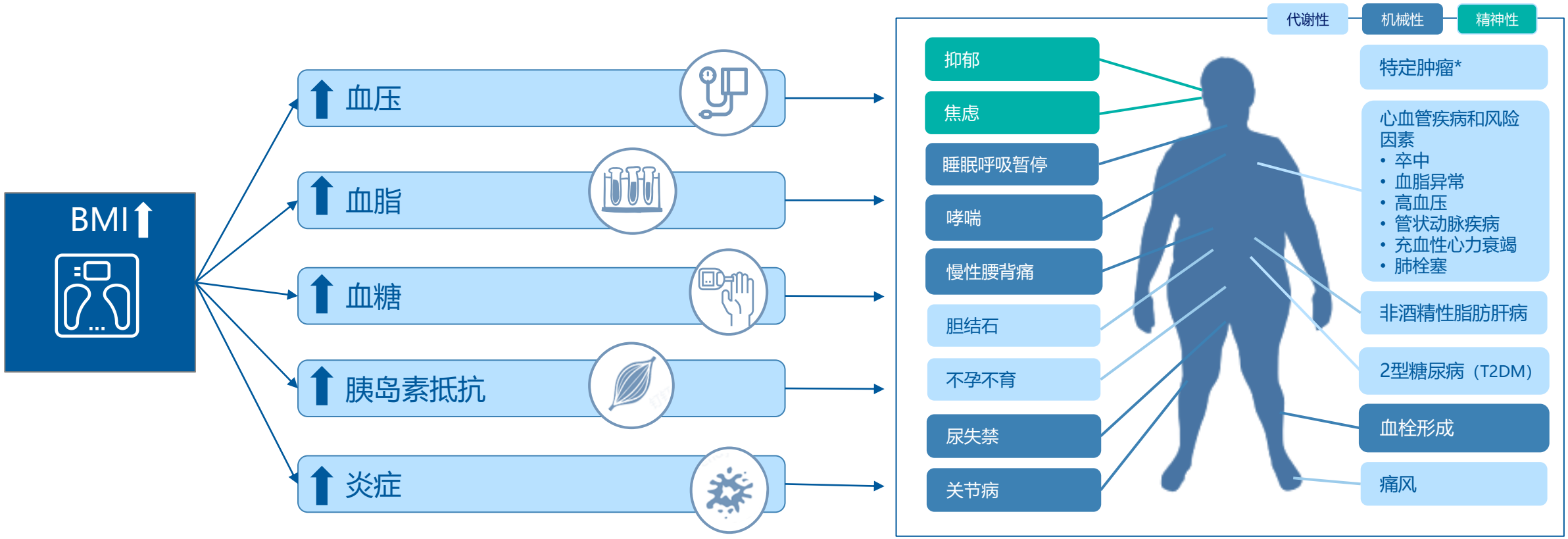
- 超重 (BMI 24-27.9kg/m^2): 3.4亿
- 肥胖 (BMI ≥ 28kg/m^2): 1.6亿
- 中重度肥胖 (BMI ≥ 32.5kg/m^2): 1000万



[i]: 根据WHO标准，成年人超重标准为BMI在25.0–29.9 kg/m² 之间，肥胖标准为BMI超过 30.0 kg/m². 根据中国大规模前瞻性研究证据表明中国人群相比白人在同等BMI水平下，体脂率和内脏脂肪含量更高，心血管风险和全因死亡率比例也更高。

1. Pan XF, Wang L, Pan A. Epidemiology and determinants of obesity in China. Lancet Diabetes Endocrinol. 2021 Jun;9(6):373-392. doi: 10.1016/S2213-8587(21)00045-0. Erratum in: Lancet Diabetes Endocrinol. 2021 Jul;9(7):e2. PMID: 34022156.
2. Wang Y, Zhao L, Gao L, Pan A, Xue H. Health policy and public health implications of obesity in China. Lancet Diabetes Endocrinol. 2021 Jul;9(7):446-461. doi: 10.1016/S2213-8587(21)00118-2. Epub 2021 Jun 4. PMID: 34097869.

肥胖会显著提高多种并发症风险，包含超过200种慢性疾病



*包括乳腺癌、结直肠癌、卵巢癌、宫颈癌、食管癌、肾癌、膀胱癌等.

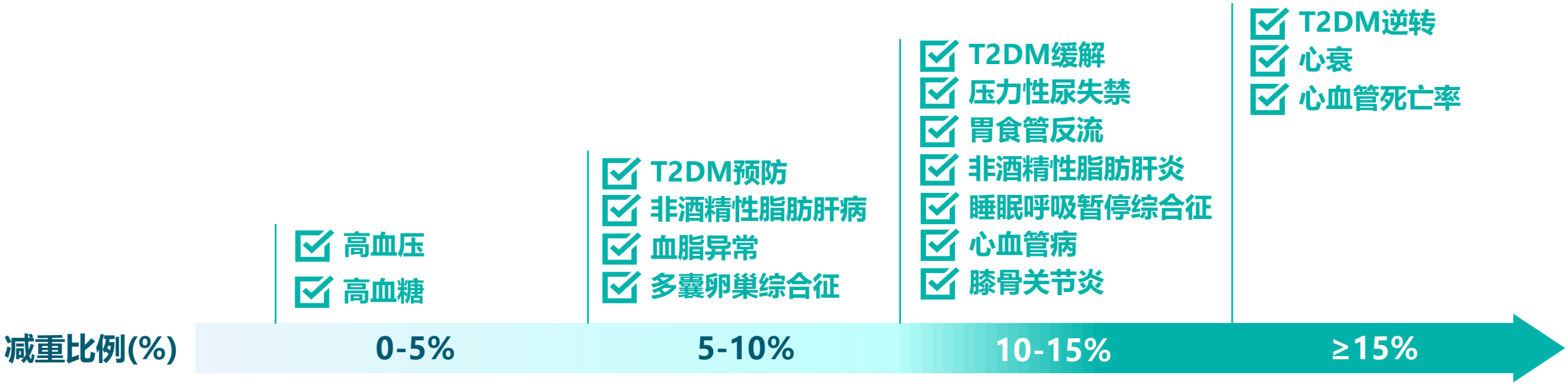
- 超重和肥胖导致的死亡占慢性非传染性疾病**相关死亡比例达11.1%**；
- 超重和肥胖影响人体几乎所有器官系统，与上述疾病**的发病率增加显著相关**。肥胖的并发症可大致分为代谢性、机械性和精神性三大类。

1. *Obes Rev. 2010;11:808-9;*
2. *BMC Public Health 2009;9:88;*
3. *Arch Gen Psychiatry 2010;67:220–9;*
4. *Arch Gen Psychiatry 2006;63:824–30;*
5. *Gastroenterology 2006;130:2023–30;*
6. *Prev Med 2010;51:18–23;*
7. *Prev Chronic Dis 2009;6:A48.*

体重管理可有效改善健康状况，逆转疾病进程

5%~15%

- 肥胖患者（或伴有并发症的超重患者）的初始体重控制目标是在起始的6个月内**减重5%-15%，且随着体重减轻百分比的增加，与肥胖相关的危险因素和合并症的改善获得提升。**



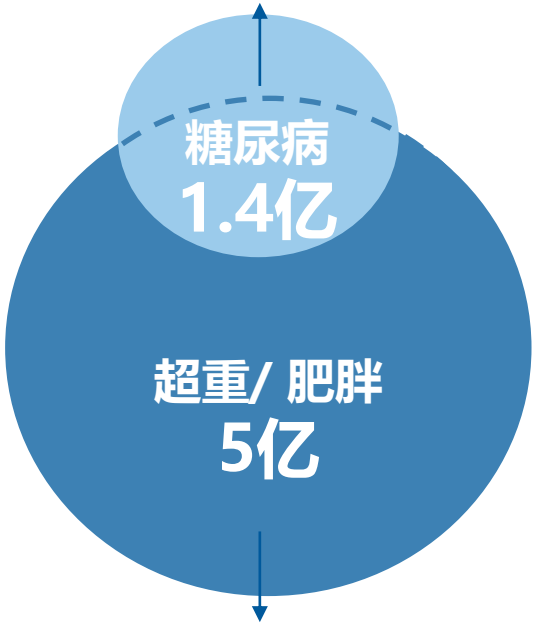
1. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY COMPREHENSIVE CLINICAL PRACTICE GUIDELINES FOR MEDICAL CARE OF PATIENTS WITH OBESITY; Endocr Pract. 2016 Jul;22 Suppl 3:1-203.

体重管理可有效预防、改善和缓解T2DM

超过10%的体重降幅有望带来T2DM的缓解

中国 ~50% 糖尿病患者

合并超重或肥胖



中国人群T2DM患病率:

- **BMI< 25人群：8.8%;**
- **25≤BMI<30 人群：13.8%;**
- **BMI≥30 人群: 20.1%.**

- **T2DM预防:** 在糖尿病前期，减重能**缓解症状，防止进展**至糖尿病。
- **T2DM治疗获益:** 对于超重或肥胖的2型糖尿病患者，适当和持续的(>5%) 的减重已被证明可以改善血糖控制，减少降血糖药物的使用，以及改善多重代谢指标，包括降低血压和血脂、改善胰岛素敏感性和β细胞功能。
- **T2DM潜在缓解:** 体重降幅从**10-15%起**可能会带来更大益处，如随着体重降幅增加，**T2DM缓解的几率增加**，使部分患者在较长时间内免于使用降糖药物。

1. JAMA. 2021 Dec 28;326(24):2498-2506. doi: 10.1001/jama.2021.22208.Prevalence and Treatment of Diabetes in China, 2013-2018
2. Chinese Diabetes Society, Guideline for the prevention and treatment of type 2 diabetes mellitus in China(2020 edition)
3. American Diabetes Association; 8. Obesity Management for the Treatment of Type 2 Diabetes: Standards of Medical Care in Diabetes—2021. Diabetes Care 1 January 2021; 44 (Supplement_1): S100–S110.
4. Hou X, Lu J, Weng J, Ji L, Shan Z, Liu J, et al. (2013) Impact of Waist Circumference and Body Mass Index on Risk of Cardiometabolic Disorder and Cardiovascular Disease in Chinese Adults: A National Diabetes and Metabolic Disorders Survey. PLoS ONE 8(3): e57319.
5. Ameera Meerasa, Satya Dash: Weighing in on Type 2 Diabetes Remission. Diabetes Care 5 January 2022; 45 (1): 28–30.

亟需突破性治疗手段以实现安全有效的减重效果

生活方式干预

低依从性

- 研究证据有限
- 时间投入大
- 难以标准化
- 减重效果不佳

目前中国尚缺乏公认的生活方式干预方案以广泛用于肥胖管理

药物治疗

<1% 治疗渗透率

- 现有药物减重疗效欠佳
- 现有药物响应不佳
- 现有药物的安全性和耐受性问题
- 合并用药限制

目前中国肥胖药物治疗种类单一，仅奥利司他获批用于肥胖治疗，不良反应限制了其广泛临床应用

手术治疗

~0.25% 治疗渗透率

- 心理抵触
- 高额费用
- 体重反弹
- 短期/长期并发症风险

减重手术的应用存在诸多障碍，诸如一系列术后并发症风险

1. Zeng Q, et al. Lancet Diabetes Endocrinol. 2021; 9(6): 393-405
2. Greater China Bariatric and Metabolic Surgery Database 2020 Annual Report[J]. Chinese Journal of Practical Surgery,2021,41(5):533-542.

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