研究报告 Research Report
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石药集团 CSPC Pharmaceutical Group (1093 HK)

公司的口服 GLP-1RA 授权出海，总金额超 20 亿美元
The company's oral GLP-1RA is licensed out, with a total amount exceeding USD2bn

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热点速评 Flash Analysis

(Please see APPENDIX 1 for English summary)

事件

石药集团与 Madrigal Pharmaceuticals（Madrigal）就公司的口服小分子激活胰高血糖素样肽-1（GLP-1）受体激动剂 SYH2086 在全球的开发、生产及商业化订立独家授权协议，同意授予 Madrigal 在全球范围内开发、生产及商业化 SYH2086 的独家授权，同时保留公司在中国开发和销售其他口服小分子 GLP-1 受体激动剂产品的权益。石药集团将有权收取最高可达 20.75 亿美元的总金额，包括 1.2 亿美元的预付款、最高可达 19.55 亿美元的潜在开发、监管及商业里程碑付款，以及基于 SYH2086 年度净销售额的最高达双位数销售提成。

点评

SYH2086 目前处于临床前阶段，我们认为，当前代谢领域同靶点竞争已是红海，对于一款临床前的产品而言，本次交易的首付款和总包均超过我们预期。

本次合作伙伴 Madrigal 是美国代谢领域头部 Biotech，Madrigal 的核心药物 Rezdiffra（resmetirom）是一款口服的肝靶向 THR-β 激动剂日制剂，是 FDA 批准的全球首个也是唯一一个用于治疗中度至重度肝纤维化 MASH 的药物。我们认为本次合作，一方面是对石药口服 GLP-1 的高度认可，打开了减肥、糖尿病以及 MASH 市场的想象空间，另一方面也有望加速该资产在美国的临床开发。

此次交易不属于此前公司指引的 3 项总金额 50 亿美元对外授权合作的一部分，是额外增量，体现公司小分子平台价值。另外，全年 3 笔 50 亿美元交易有望落地，我们对公司 SYS6010（EGFR ADC）和 siRNA 平台的对外授权充满期待，是公司股价的重要催化。

1. 6 月石药的 AI 小分子平台已授权 AZ 多项资产，交易总额达 53 亿美元。
2. 石药的 EGFR ADC 临床 I 期数据显示，药效优于基于 MMAE 或 Dxd 等成熟毒素的 ADC 药物，≥3 级血液毒性发生率显著低于同类 ADC。目前国内已经获批三期临床，海外 EGFRm 3L/EGFRtw 2L 的三期临床有望开启。
3. 石药的小核酸平台已孵化 SYH2053（PCSK9）、SYH2062（AGT）、SYH2068（LP(a)）三条管线进入临床阶段，看好其潜在对外合作机会。

风险

新药研发风险，新药审批风险，药品商业化不及预期风险，竞争加剧风险，政策风险。

APPENDIX 1

Summary

What's news: The company's oral GLP-1RA is licensed out, with a total amount exceeding USD2bn

CSPC has entered into an exclusive licensing agreement with Madrigal Pharmaceuticals (Madrigal) for the global development, production, and commercialization of its oral small-molecule glucagon-like peptide-1 (GLP-1) receptor agonist, SYH2086. Under the agreement, Madrigal is granted exclusive rights to develop, manufacture, and commercialize SYH2086 worldwide, while SPC retains the rights to develop and sell other oral small-molecule GLP-1 receptor agonist products in China. CSPC is entitled to receive up to a total of USD2.075bn, including: USD120mn upfront payments, up to USD1.955bn in potential development, regulatory, and commercial milestone payments, and royalties on SYH2086's annual net sales, reaching up to double-digit percentages.

SYH2086 is currently in the preclinical stage. We believe that the metabolic disease field has become highly competitive for targets of this GLP-1 class, making the upfront payment and total deal value for a preclinical-stage product exceed our expectations.

The partner in this collaboration, Madrigal, is a leading U.S. biotech in the metabolic disease space. Madrigal's core drug, Rezdiffra (resmetirom), is an oral, liver-targeted THR-β agonist dosed once daily and is the first and only FDA-approved drug for treating moderate-to-severe liver fibrosis in MASH. We view this partnership as not only a strong validation of CSPC's oral GLP-1RA, opening up potential in the obesity, diabetes, and MASH markets, but also an accelerator for the asset's clinical development in the U.S.

This deal is not part of the company's previously guided three licensing deals each totaling USD5bn but represents an additional upside, highlighting the value of its small-molecule platform. Moreover, the three major deals worth USD5bn are expected to materialize this year. We remain optimistic about the potential out-licensing opportunities for SYS6010 (EGFR ADC) and the siRNA platform, which could serve as key catalysts for the company's stock price.

1. In June, CSPC licensed multiple assets from its AI-powered small-molecule platform to AstraZeneca, with the total deal value reaching USD5.3bn.

2. Phase I clinical data for CSPC's EGFR ADC demonstrated superior efficacy compared to ADC drugs based on conventional payloads like MMAE or Dxd, with significantly lower rates of Grade ≥3 hematologic toxicity. The drug has already been approved for Phase III trials in China, and global Phase III trials for EGFRm 3L/EGFRwt 2L indications are expected to commence.

3. CSPC's siRNA platform has advanced three candidates—SYH2053 (PCSK9), SYH2062 (AGT), and SYH2068 (Lp(a))—into clinical stages, and we anticipate potential out-licensing opportunities for these assets.

Risks

Risks in new drug R&D; risks in new drug approval by regulatory authorities; risks in underperformance in commercialization; risks in intensified competition; risks in policy.

附录 APPENDIX

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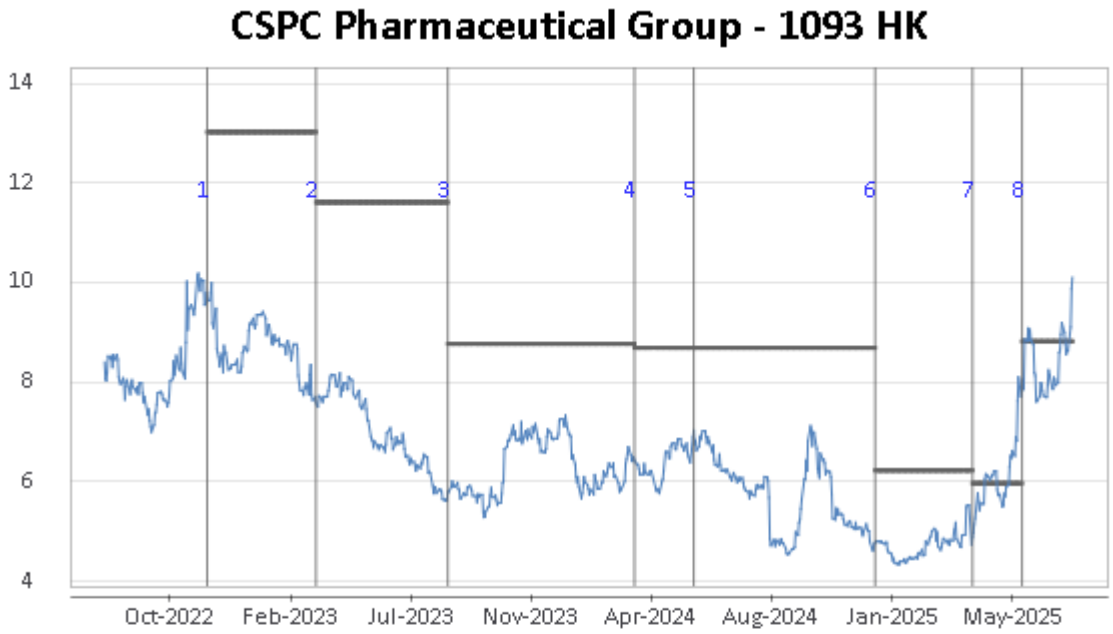

1. 25 Nov 2022 OUTPERFORM at 9.79 target 13.02.
2. 28 Mar 2023 OUTPERFORM at 7.64 target 11.61.
3. 24 Aug 2023 OUTPERFORM at 5.63 target 8.77.
4. 22 Mar 2024 OUTPERFORM at 6.49 target 8.69.
5. 28 May 2024 OUTPERFORM at 6.89 target 8.69.
6. 19 Dec 2024 OUTPERFORM at 4.80 target 6.23.
7. 8 Apr 2025 OUTPERFORM at 4.89 target 5.97.
8. 3 Jun 2025 OUTPERFORM at 7.83 target 8.82.