研究报告 Research Report

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康哲药业 China Medical System Holdings (867 HK)

重磅品种芦可替尼获批上市，未来增长可期

Blockbuster Drug Ruxolitinib Cream Approved for Market, Promising Sales Ramp-up Growth Ahead

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热点速评 Flash Analysis

(Please see APPENDIX 1 for English summary)

事件

1 月 30 日，康哲药业子公司德镁医药，获得中国国家药品监督管理局（NMPA）批准磷酸芦可替尼乳膏新药上市许可申请，用于治疗 12 岁及以上儿童和成人患者伴面部受累的非节段型白癜风。芦可替尼乳膏（Opzelura®）是 Incyte 开发的选择性 JAK1/JAK2 抑制剂芦可替尼制成的一种创新型乳膏。2022 年 12 月，德镁医药与 Incyte 就芦可替尼乳膏订立许可协议，获得在中国大陆、香港特别行政区、澳门特别行政区、台湾地区及东南亚十一国研发、注册及商业化产品的独家许可权利，以及生产产品的非独家许可权利。

白癜风是一种慢性自身免疫性疾病，其特征是皮肤色素脱失，其发病原因为产生色素的细胞即黑素细胞的缺失。中国约有 1030 万人患有白癜风，其中约 820 万人患有非节段型白癜风。

销售推广策略：在产品正式获得 NMPA 批准之前，受益于国家赋予海南“先行先试”、大湾区“港澳药械通”等政策，公司已启动芦可替尼乳膏的试点应用。2023 年 8 月至 2025 年 1 月期间，海南地区使用芦可替尼乳膏的白癜风初诊患者已经超 7700 人。管理层表示，“先行先试”期间已经完成医生的学术教育和前置性推广工作。管理层预计，芦可替尼乳膏正式挂网后，2026 年渠道建设将重点围绕 DTP 药房、线上电商平台（已经与京东健康、阿里健康达成协议），并积极主动参与 2026 年医保谈判，逐步进入医院和双通道药房渠道。

芦可替尼乳膏收入指引：管理层在投资者大会中预计，芦可替尼乳膏 2026 年收入不低于 5 亿元，2027 年收入实现翻倍，4-5 年时间实现快速达峰，峰值收入预期不低于 60 亿元（白癜风适应症大于 50 亿元，特异性皮炎适应症大于 10 亿元）。产品定价方面，管理层表示挂网价格低于此前海南“先行先试”试点价格 6800 元/支。

点评

白癜风适应症现有疗法，如外用糖皮质激素（TCS）及外用钙调神经磷酸酶抑制剂（TCIs）存在临床缺陷、超说明书用药、疗效有限或长期用药有不良反应等问题。我们认为，对于面部等暴露部位的白癜风患者，其治疗意愿强烈，并且愿意支付比较高的价格以获得更好的治疗效果和更低的不良反应，芦可替尼乳膏有望填补此前市场空缺。根据海南先行区芦可替尼乳膏在中国开展真实世界研究数据看，疗效积极，与境外关键临床研究结果一致，且未发现新的安全性事件，未发生导致停药或退出的不良事件，未发生研究药物相关的严重不良事件。我们看好芦可替尼乳膏进入医保后快速放量，成为德镁医药皮肤科产品组合中的重磅品种。

除白癜风适应症外，我们建议持续关注芦可替尼乳膏用于轻中度特异性皮炎适应症的进展。目前芦可替尼乳膏的特异性皮炎适应症已经纳入优先审评，我们预计公司会在近期递交上市申请，并有望于 2H26 获批上市。

风险

新药研发风险，集采风险，新药审评审批风险，新药商业化风险。

APPENDIX 1

Summary

On January 30th, Dermavon, a subsidiary of CMS Pharmaceutical, obtained approval from the Chinese National Medical Products Administration (NMPA) for the New Drug Application of ruxolitinib cream. This approval is for the treatment of non-segmental vitiligo with facial involvement in patients aged 12 and above, including both children and adults. Ruxolitinib cream (Opzelura®) is an innovative cream formulation of ruxolitinib, a selective JAK1/JAK2 inhibitor developed by Incyte. In December 2022, Dermavon entered into a licensing agreement with Incyte for ruxolitinib cream, securing exclusive rights for the development, registration, and commercialization of the product in Mainland China, Hong Kong SAR, Macao SAR, Taiwan region, and eleven Southeast Asian countries, along with non-exclusive rights for its production.

Vitiligo is a chronic autoimmune disease characterized by skin depigmentation, caused by the loss of pigment-producing cells known as melanocytes. In China, approximately 10.3 million people suffer from vitiligo, of which about 8.2 million have non-segmental vitiligo.

Sales and Promotion Strategy: Prior to the formal NMPA approval, benefiting from national policies such as Hainan's "Early and Pilot Implementation" and the Greater Bay Area's "Hong Kong and Macao Drug and Medical Device Access" policy, the company initiated pilot applications of ruxolitinib cream. Between August 2023 and January 2025, over 7,700 newly diagnosed vitiligo patients in Hainan used ruxolitinib cream. Management stated that during the "Early and Pilot Implementation" phase, academic education for doctors and pre-promotional work were completed. Management anticipates that after the official listing of ruxolitinib cream, channel development in 2026 will focus on DTP pharmacies and online e-commerce platforms (agreements have already been reached with JD Health and Ali Health), and the company will actively participate in the 2026 National Reimbursement Drug List (NRDL) negotiation, gradually entering hospital and dual-channel pharmacy channels.

Ruxolitinib cream sales guidance: Management projected during an investor conference that ruxolitinib cream revenue will be no less than CNY500mn in 2026, doubling in 2027, and reaching its peak rapidly within 4-5 years. The peak revenue is expected to be no less than CNY6bn (over CNY5bn for the vitiligo indication and over CNY1bn for the atopic dermatitis indication). Regarding pricing, management indicated that the listed price will be lower than the previous pilot price of CNY6,800 per tube under Hainan's "Early and Pilot Implementation" program.

Our takes

Existing therapies for vitiligo, such as topical corticosteroids (TCS) and topical calcineurin inhibitors (TCIs), have clinical limitations, including off-label use, limited efficacy, or adverse effects with long-term use. We believe that for vitiligo patients with affected areas such as the face, who have a strong desire for treatment and are willing to pay a higher price for better efficacy and lower adverse effects, ruxolitinib cream has the potential to fill a significant market gap. According to real-world study data from the Hainan pilot zone, the efficacy of ruxolitinib cream in China is positive, consistent with overseas key clinical study results. No new safety issues were identified, and no adverse events leading to treatment discontinuation or withdrawal or serious adverse events related to the study drug occurred. We are optimistic that ruxolitinib cream will experience rapid sales growth after inclusion in the NRDL, becoming a blockbuster product in Dermavon's dermatology portfolio.

In addition to the vitiligo indication, we recommend continued attention to the progress of ruxolitinib cream for mild-to-moderate atopic dermatitis (AD). Currently, the AD indication for ruxolitinib cream has been included in the priority review process. We expect the company to submit a marketing application in the near future, with potential approval anticipated in 2H26.

Risks

Risks associated with new drug research and development, risks related to centralized procurement policies, risks in new drug review and approval processes, and risks in new drug commercialization.

附录 APPENDIX

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1. 20 Mar 2023 OUTPERFORM at 12.34 target 17.75.
2. 5 Jun 2023 OUTPERFORM at 12.04 target 17.75.
3. 29 Aug 2023 OUTPERFORM at 11.34 target 17.57.
4. 24 Apr 2024 OUTPERFORM at 7.10 target 9.90.
5. 19 Aug 2024 OUTPERFORM at 7.23 target 9.96.
6. 7 Apr 2025 OUTPERFORM at 8.28 target 9.96.
7. 10 Sep 2025 OUTPERFORM at 14.54 target 18.38.