



Flash Note: CSPC Pharmaceutical Group (01093 HK)

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The First Generic Drug of Paclitaxel for Injection (albumin-bound) has been Granted Drug Registration Approval by the CFDA

紫杉醇（白蛋白结合型）首仿药获CFDA批准注册

- What happened:** CSPC Pharma (the "Company") announced that the paclitaxel for injection (albumin-bound) (the "Product") developed by the Company has been granted drug registration approval by the China Food and Drug Administration of the People's Republic of China. Paclitaxel for injection (albumin-bound) is an anti-microtubule agent indicated for the treatment of metastatic breast cancer after failure of combination chemotherapy or breast cancer relapse within 6 months of adjuvant chemotherapy. Other indications approved overseas include treatment of advanced or metastatic non-small cell lung cancer in combination with carboplatin, metastatic pancreatic cancer in combination with gemcitabine and metastatic gastric cancer.
- Comments and Views:** Currently the imported original drug, Abraxane, is the only paclitaxel for injection (albumin-bound) available in China, with estimated annual sales of over RMB250 million in China. Competition for the development of its generic drugs is so fierce that multiple companies have already applied for ANDAs. The first launch of the Product by the Company will be able to break the monopoly on the imported drug. As generics commonly have price advantages over original drugs, we believe that the Product will rapidly replace the original drug, Abraxane. Considering that paclitaxel for injection (albumin-bound) is a more efficient drug and contains less allergens than paclitaxel for injection of the conventional formulation, we also expect the penetration rate of paclitaxel for injection (albumin-bound) will step up along with a lower drug price.
- Investment suggestions:** We estimate that the Product will have peak sales of over RMB500 million considering that the paclitaxel for injection (albumin-bound) is expected to deliver peak sales of more than RMB2 billion and that no less than three companies are expected to launch generic drugs by 2020. We expect that paclitaxel for injection (albumin-bound) will bring about RMB100 million-RMB200 million in revenue to the Company in 2018. However, with consideration to weaker-than-expected Vitamin C API price, we consider maintaining a target price of HKD17.07 per share (9.3% upside potential) and an investment rating of "Accumulate".
- 事件描述:** 石药集团（“公司”）公告公司开发的注射用紫杉醇（白蛋白结合型）已获中华人民共和国国家食品药品监督管理总局颁发药品注册批件。注射用紫杉醇（白蛋白结合型）为一种抗微管药物,用于治疗联合化疗失败的转移性乳腺癌或辅助化疗后6个月内复发的乳腺癌。国外批准的其它适应症还包括: 与卡铂联用治疗晚期或转移性非小细胞肺癌、与吉西他滨联用治疗转移性胰腺癌及治疗转移性胃癌。
- 观点评论:** 注射用紫杉醇（白蛋白结合型）目前在中国仅有进口的原研药 Abraxane, 其中国市场年销售额估算超过 2.5 亿人民币。国内目前已有多家企业就该产品进行了仿制药申报, 竞争较为激烈。公司产品率先获批上市, 将打破进口产品垄断的局面。由于仿药一般较原研药更具价格优势, 我们认为公司的产品将会快速替代原研药 Abraxane。虑到紫杉醇（白蛋白结合型）相较普通紫杉醇疗效更好且过敏反应更少, 我们亦认为随着药品价格的降低, 注射用紫杉醇（白蛋白结合型）的渗透率将会进一步提高。
- 投资建议:** 我们预计该产品的销售峰值可达到 5 亿人民币以上, 考虑到紫杉醇（白蛋白结合型）的整体市场峰值预计将达到 20 亿元人民币以上而在 2020 前预计将有不少于三个仿药上市。我们预计紫杉醇（白蛋白结合型）将在 2018 年为公司带来 1-2 亿元人民币的营业收入。但考虑到维生素 C 原料药价格弱于预期, 我们考虑维持公司 17.07 港元的目标价(约 9.3% 的上升空间), 以及“收集”的投资评级。

Company Rating Definition

The Benchmark: Hong Kong Hang Seng Index

Time Horizon: 6 to 18 months

Rating		Definition
Buy	买入	Relative Performance > 15%; or the fundamental outlook of the company or sector is favorable.
Accumulate	收集	Relative Performance is 5% to 15%; or the fundamental outlook of the company or sector is favorable.
Neutral	中性	Relative Performance is -5% to 5%; or the fundamental outlook of the company or sector is neutral.
Reduce	减持	Relative Performance is -5% to -15%; or the fundamental outlook of the company or sector is unfavorable.
Sell	卖出	Relative Performance < -15%; or the fundamental outlook of the company or sector is unfavorable.

Sector Rating Definition

The Benchmark: Hong Kong Hang Seng Index

Time Horizon: 6 to 18 months

Rating		Definition
Outperform	跑赢大市	Relative Performance > 5%; or the fundamental outlook of the sector is favorable.
Neutral	中性	Relative Performance is -5% to 5%; or the fundamental outlook of the sector is neutral.
Underperform	跑输大市	Relative Performance < -5%; Or the fundamental outlook of the sector is unfavorable.

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