



# 中国医疗保健国际交流促进会

肝胆疾病委员会

## 无锡埃斯科普人工生物肝脏系统 专家论证报告

Expert Forum Report

On

### The Bio-artificial Liver System of Wuxi Excorp Co

中国医疗保健国际交流促进会肝胆疾病专业委员会接受无锡埃斯科普生物技术有限公司委托，于2009年11月1日组织相关专家，对其研发的人工生物肝脏系统进行评价论证，现将论证报告如下：

Entrusted by Wuxi Excorp Bio-tech Co., Ltd., the Liver and Gall Diseases Specialty Committee under China International Exchange and Promotion Association for Medical and Health Care (CPAM) organized relevant experts to conduct evaluation and verification on bio-artificial liver system of the Company on the 1<sup>st</sup> day of November 2009. The forum report is stated as below:

无锡埃斯科普生物技术有限公司人工生物肝脏系统是其与美国爱克思科医疗设备有限公司及以肝脏移植及生物组织工程闻名的美国匹兹堡大学器官移植研究所历时八年共同研发而成。目前，已完成美国食品与药物管理局（FDA）所规定的临床一、二阶段研究。根据该企业提供的相关资料，专家经过认真讨论，认为：

The bioartificial liver system is an 8-year lasting research result of Wuxi Excorp Biotech Co., Ltd., in collaboration with America based Excorp Medical Inc., and the Transplantation Institute at the University of Pittsburgh highly reputed for liver transplantation and biological tissue engineering. Presently, the project has wound up the Phase I/II clinical studies as mandated by USA Food and Drug Administration (FDA). Against the information provided by the Company, the experts believe after solemn discussions:

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1.该系统采用猪肝脏细胞通过人体新陈代谢，清除患者血液中各种毒素，其设计新颖，具有一定理论基础，并通过临床一、二阶段研究证实，临床应用的安全性、有效性得到肯定。2.该系统采用新鲜猪肝脏细胞，使用患者全血，具有血液流速快（200-300ml/min），供氧充分，以及操作简便且成本低廉等特点，在保证应用安全基础上，使患者症状、功能得到相应改善、恢复，对比非人工生物肝脏系统有明显优势和广阔的应用前景。3.建议企业依托专业学术机构，发挥专家优势，积极组织实施三期临床研究；并对新鲜猪肝脏细胞制备的保存、运输等方面制定切实可行方案，严格执行相关标准，在确保系统安全性、有效性前提下，扩大临床科研及应用，造福广大肝病患者的。

1. The bioartificial liver system uses porcine hepatocytes in providing metabolic assistance to human body to remove all kinds of toxins existing in the blood of patient. This system is uniquely devised, under certain theoretical basis, and is attested by Phase I/II clinical studies, whose safety and efficacy in clinical use are thus affirmed.

2. Adopting fresh porcine hepatocytes to filter whole blood of patient, the system is characterized by fast blood flow rate (200-300ml/min), sufficient oxygenating, simple operation as well as cost-effectiveness, etc., improves and rehabilitates signs and functions of patient while ensuring use safety, with marked advantages over non bioartificial liver systems, envisaging a vast market potential.

3. Recommend the Company to actively unveil the implementation of Phase III clinical studies, with backings from experts of specialty academic institutions; come up with practicable programs for preparation, conservation and transportation, etc., of fresh porcine hepatocytes, strictly implement relevant standards, as well as enlarge the clinical studies and applications on the premise that safety and efficacy of the liver system is guaranteed, so as to benefit the vast liver patients population.