巨子生物 Giant Biogene (2367 HK)

重组 I 型胶原蛋白械三证获批，成功切入医美注射赛道

Class III Approval for Recombinant Type I Collagen Marks Entry into Medical Aesthetics Injectables

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热点速评 Flash Analysis

(Please see APPENDIX 1 for English summary)

事件：陕西巨子生物技术有限公司旗下"重组 I 型 α1 亚型胶原蛋白冻干纤维"于 2024 年 10 月 21 日获得国家药品监督管理局（NMPA）批准第三类医疗器械注册证（国械注准 20253132049），用于面部真皮组织填充以纠正额部动力性皱纹。

巨子生物此次重组 I 型胶原蛋白冻干纤维获批，标志着公司正式切入医美注射赛道。值得注意的是，这是继锦波生物后国内第二张重组胶原蛋白械三证书，但巨子生物选择了一条差异化的技术路径——其获批的 I 型胶原蛋白在分子类型上与锦波已上市的 III 型胶原蛋白形成明确区分，这为产品后续的市场定位创造了独特空间。从技术细节来看，本次获批产品选用人天然 I 型 α1 单链氨基酸序列中的 305-1057 位（共 753 个氨基酸），注册证中明确标注"不具有三螺旋结构"。这一表述既体现了监管机构对重组胶原蛋白认知的科学深化，也反映了公司基于当前技术阶段的产品设计思路。在重组胶原蛋白行业普遍面临空间结构构建和规模化生产两大技术瓶颈的背景下，巨子生物此次获批彰显了其从实验室研发到商业化生产的综合实力，为后续产品矩阵的拓展奠定了重要基础。

从技术层面分析，重组胶原蛋白的功效取决于多重技术要素的组合。氨基酸序列的设计（长度、片段位置）、宿主细胞的选择（大肠杆菌/酵母/哺乳细胞）、后续修饰工艺及分级纯化水平共同决定了产品的生物活性和安全性。相较于同业企业，巨子生物采用长序列设计（753 个氨基酸），并通过高纯度（99.9%）生产工艺实现规模化量产，这对其技术路径和生产成本控制提出了极高要求。值得注意的是，公司已构建包含 50 多种重组胶原蛋白分子的专有分子库，为后续产品迭代提供了坚实的技术储备。

在产能布局方面，巨子生物已建立起显著的先发优势。值得关注的是，公司在重组胶原蛋白的规模化生产领域积累深厚——早在 2021 年就已建成符合医疗级标准的高纯度（99.9%）重组胶原蛋白生产线，展现出其在生产工艺和质量控制方面的领先能力。截至 2023 年，公司进一步完成发酵车间扩产，新增 2 条重组胶原蛋白生产线，目前已累计投产 6 条重组胶原蛋白生产线，形成超十吨级产能规模，远超同业水平，为产品快速商业化提供了坚实的供应链保障。同时，公司在西安高新区规划的活性天然产物制造产业化项目也在持续推进中，预计将进一步巩固其在规模化生产与成本控制方面的长期竞争力。

在行业格局层面，胶原蛋白注射剂作为三类医疗器械具有极高的审批壁垒。目前 NMPA 仅批准 7 家公司的 11 款胶原蛋白产品，其中重组胶原蛋白领域此前仅有锦波生物一家获批。值得强调的是，与传统的动物源胶原蛋白相比，重组胶原蛋白不仅具备更优的生物相容性、更低的免疫原性风险和更好的批次稳定性，还因其技术特性而能够实现规模化生产，显著降低了单位成本，在商业化和市场渗透方面具有明显优势。尽管创健医疗等企业的重组 III 型胶原蛋白产品已进入注册申报后期，但考虑到从获批到全面商业化通常需要 3 个月的生产准备期和约 1 年的渠道覆盖周期，巨子生物凭借其先发优势、完善的生产体系以及重组技术带来的规模化与成本优势，有望在 2025 年的市场竞争中占据有利位置。

本次获批也为公司后续产品申报铺平道路。目前公司另有两款医美产品处于审评阶段：针对面部皮肤的液体制剂正处于药械联合审评中，而针对颈纹的凝胶产品已于 2024 年 12 月进入优先审评通道。在积累首个产品审评经验后，后续产品的获批进程有望加速，从而形成完善的产品矩阵。

风险：行业监管政策变化风险；产品商业化进度不及预期风险；市场竞争加剧风险；技术迭代风险。

APPENDIX 1

Summary

Event: Giant Biogene's "Recombinant Type I α1 Collagen Lyophilized Fiber" was approved by the National Medical Products Administration (NMPA) on October 21, 2024, for a Class III Medical Device Registration Certificate (Registration No.: 20253132049). It is indicated for filling the facial dermal tissue to correct frontal dynamic wrinkles.

This approval marks Giant Biogene's official entry into the medical aesthetic injectables market. Notably, this is the second domestic recombinant collagen Class III certificate following Jinbo Bio, but Giant Biogene has chosen a differentiated technical path – its approved Type I collagen is molecularly distinct from Jinbo's already marketed Type III collagen, creating unique positioning potential for the product. Technically, the approved product uses amino acid residues 305-1057 (totaling 753 amino acids) from the human native Type I α1 chain sequence. The registration certificate explicitly states it "does not have a triple-helical structure." This phrasing reflects both the regulatory authority's deepening scientific understanding of recombinant collagen and the company's product design rationale based on the current technological stage. Amid industry-wide challenges in spatial structure construction and scalable production, this approval demonstrates Giant Biogene's comprehensive capabilities from R&D to commercial production, laying a crucial foundation for future product portfolio expansion.

Technically, the efficacy of recombinant collagen depends on a combination of factors: amino acid sequence design (length, fragment location), host cell selection (E. coli/yeast/mammalian cells), post-translational modification processes, and purification levels collectively determine the product's bioactivity and safety. Compared to peers, Giant Biogene employs a long-sequence design (753 amino acids) and achieves mass production with high purity (99.9%), placing extremely high demands on its technical pathway and cost control. It is noteworthy that the company has built a proprietary molecular library containing over 50 recombinant collagen molecules, providing a solid technical reserve for future product iterations.

Regarding production capacity, Giant Biogene has established a significant first-mover advantage. The company has deep experience in scalable production of recombinant collagen – as early as 2021, it had built a medical-grade, high-purity (99.9%) recombinant collagen production line, demonstrating leading capabilities in production processes and quality control. By 2023, the company further expanded its fermentation workshop, adding 2 new recombinant collagen production lines, bringing the total to 6 operational lines. This forms a production capacity exceeding ten tons annually, far surpassing industry peers and providing solid supply chain support for rapid commercialization. Concurrently, the company's planned Active Natural Products Manufacturing Industrialization Project in the Xi'an High-tech Zone is progressing, expected to further consolidate its long-term competitiveness in scaled production and cost control.

In terms of industry landscape, collagen injectables as Class III medical devices face high regulatory barriers. Currently, the NMPA has approved only 11 collagen products from 7 companies, with Jinbo Bio being the only previously approved player in the recombinant collagen segment. Importantly, compared to traditional animal-derived collagen, recombinant collagen offers superior biocompatibility, lower immunogenicity risks, better batch-to-batch consistency, and, due to its technical nature, enables scalable production, significantly reducing unit costs, thus holding clear advantages for commercialization and market penetration. Although recombinant Type III collagen products from companies like Chuangjian Medical are in late-stage registration, considering the typical 3-month production preparation period post-approval and an approximate 1-year channel coverage cycle, Giant Biogene, leveraging its first-mover advantage, established production system, and the scale/cost benefits of recombinant technology, is well-positioned to capture a favorable market position in 2025.

This approval also paves the way for the company's subsequent product applications. Currently, the company has two other medical aesthetic products under review: a liquid formulation for facial skin is undergoing combined drug-device evaluation, while a gel product for neck wrinkles entered the priority review channel in December 2024. With the experience gained from the first product's approval process, subsequent product approvals are expected to accelerate, forming a comprehensive product portfolio.

Risks: Changes in the external environment; Continued public opinion warfare; Lack of industry standards; Consumer confidence recovery not meeting expectations.

附录 APPENDIX

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