# 武田引进 ImmunoGen 的 FRα ADC 日本权益，多家国内药企布局 FRα ADC 赛道

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## 投资要点：

- **ImmunoGen 与武田就开发和商业化 ELAHERE 达成合作协议。**根据 ImmunoGen 官网，8 月 28 日， ADC 药物公司 ImmunoGen 宣布与武田制药达成独家合作，在日本开发和商业化叶酸受体 α（FRα）抗体偶联药物 ELAHERE。武田制药支付 3400 万美元的预付款及近期里程碑金额，并有资格获得潜在的监管和商业里程碑付款以及两位数的特许权使用费。

- **ELAHERE 已获 FDA 批准， III 期临床研究 MIRASOL 取得积极数据。**ELAHERE 为针对叶酸受体 α（FRα，一种在卵巢癌中高表达的细胞表面蛋白）靶点的全球首创（first-in-class）ADC 药物，由 FRα 结合抗体、可裂解的连接子和美登木素生物碱 DM4 组成。根据华东医药 2023 年一季报，2022 年 11 月，ImmunoGen 宣布 ELAHERE™获得美国 FDA 加速批准上市，是美国 FDA 批准的首个用于铂耐药卵巢癌的 ADC 药物，用于治疗叶酸受体 α（FRα）阳性且既往接受过 1-3 线全身治疗方案的铂耐药卵巢上皮性癌、输卵管癌或原发腹膜癌的成年患者。今年 5 月 ImmunoGen 公布Ⅲ期临床研究 MIRASOL 获得了积极的关键数据，于 FRα 阳性铂耐药卵巢癌患者中证明了总体生存获益。MIRASOL 试验一共招募了 453 名患者，最终数据结果显示：ELAHERE 治疗组相比于 IC 化疗组，中位 OS 从 12.75 个月延长到 16.46 个月，死亡风险降低 33%；中位 PFS 从 3.98 个月延长到 5.62 个月，疾病进展或死亡风险降低 35%。ELAHERE®组中研究者评估的 ORR 为 42.3%，包括 12 个完全缓解（CR），而 IC 化疗组为 15.9%，无 CR。安全性方面，与 IC 化疗相比，ELAHERE 不良事件发生率更低，没有发现新的不良安全信号。

- **华东医药拥有 ELAHERE 的中国权益，已被 CDE 纳入优先审评。**ELAHERE 的中国权益为华东医药所有，中国Ⅲ期单臂临床试验已达到研究预设的主要终点并于 2023 年 3 月递交了 pre-BLA，2023 年 7 月 3 日，CDE 同意将 ELAHERE 纳入优先审评审批程序。

- **中国多家药企布局 FRαADC 赛道，多数管线尚处早期。**除华东医药外，多家中国药企布局 FRαADC 赛道。其中同宜医药的 CBP-1008、CBP-1019 分别处于临床 II 期、I/II 期，阿斯利康制药的 AZD5335、普方生物的 PRO1184 均处于临床 I/II 期，普众发现的 AMT-151、百奥泰的 BAT8006、同宜医药的 CBP-1018 均处于临床 I 期。

- **风险提示。**新药研发风险、新药审批风险、新药上市风险、技术迭代风险等。

APPENDIX 1

Summary

Investment Points:

ImmunoGen partners with Takeda for ELAHERE development and commercialization. ImmunoGen paid Takeda $34 million upfront and near-term milestones, with potential regulatory and commercial milestone payments plus double-digit royalties.

ELAHERE, FDA approved with positive phase III data from MIRASOL study, is a first-in-class ADC drug targeting folate receptor α (FRα). In November 2022, it was FDA approved to treat platinum-resistant ovarian cancer. In May, positive data showed overall survival benefits in FRα positive platinum-resistant ovarian cancer patients.

Huadong Medicine owns ELAHERE rights in China, now under priority review by CDE. In China, phase III single-arm clinical trials met pre-set main endpoint in March 2023 and pre-BLA was submitted.

Several Chinese drug companies are joining FRα ADC race, mostly at early stages. Among them, Tongyi Medicine's CBP-1008, CBP-1019 are in phase II and I/II respectively, AstraZeneca's AZD5335, ProPharma's PRO1184 are in I/II phase, Puzhong Discovery's AMT-151, Bio-Thera's BAT8006, Tongyi Medicine's CBP-1018 are in phase I.

Risks involve new drug R&D, approval, market entry, and technical iteration.

## 附录 APPENDIX

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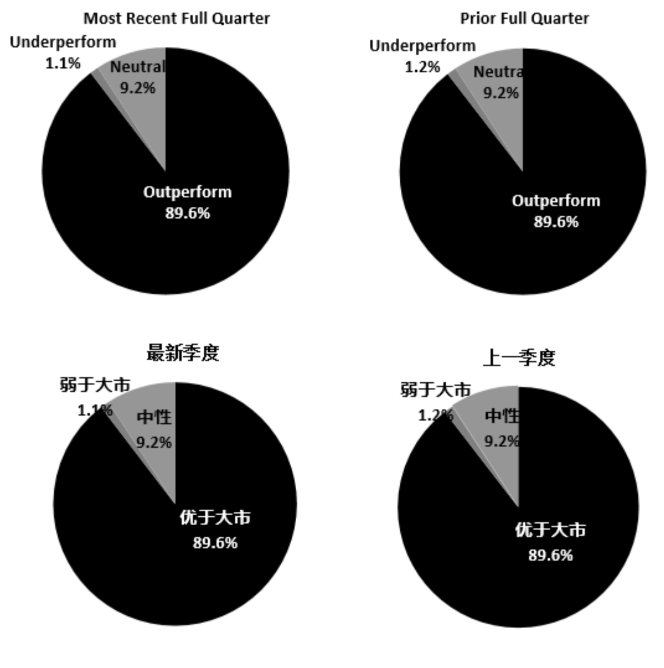

expected to exceed the return of its relevant broad market benchmark, as indicated below.

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卖出，未来 12-18 个月内预期相对基准指数跌幅在 10%以上，基准定义如下

各地股票基准指数：日本 – TOPIX, 韩国 – KOSPI, 台湾 – TAIEX, 印度 – Nifty100; 其他所有中国概念股 – MSCI China.

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|---|---|---|---|
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