研究报告 Research Report

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映恩生物 Duality Biologics (9606 HK)

核心产品 B7H3 ADC 前列腺癌数据披露，PFS 数据优异
B7H3 ADC CPRC Data Readout, with Excellent PFS Data

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热点速评 Flash Analysis

(Please see APPENDIX 1 for English summary)

事件

2026 年 ASCO 泌尿生殖系统会议上，映恩生物公布旗下 DB1311/BNT324（B7H3 ADC）针对后线去势抵抗性前列腺癌（CRPC）的最新疗效及安全性数据。本次披露的数据为 I/II 期临床（NCT05914116）的剂量优化阶段数据，包括 104 名接受治疗的患者（68 名患者接受 6 mg/kg Q3W 治疗，34 名患者接受 9 mg/kg Q3W 治疗），53%的患者为白人，整体患者中位治疗线数为 4 线。

数据显示：截至 2025 年 9 月 5 日，中位随访时间为 9.2 个月，仍有 52 名患者在接受治疗。58 名可评估患者 PSA50 缓解率为 35.4%，未经确认的 ORR 为 41.4%，确认的 ORR 为 34.5%，DCR 87.9%。生存获益上，中位 DOR 为 10.2 个月。在 82 名可评估疗效患者中，中位 rPFS 为 11.3 个月，6 个月/9 个月的 rPFS 率和 OS 率分别为 72%/63%和 92%/88%。整体安全性和此前报道一致，主要以 1-2 级不良反应为主。

接受过 lu177 治疗患者疗效同样优异：10 名可评估患者 PSA50 缓解率为 30.4%，确认的 ORR 为 30%，DCR 为 100%。23 名可评估疗效患者中，中位 rPFS 为 11.3 个月，9 个月 rPFS 率/OS 率分别为 61%/86%。

点评

生存数据历史最佳，展现了 BIC 潜力

2025 ASCO 公司披露的初步数据显示，在 38 名患者中 ORR 40%、DCR 95%，6 个月 rPFS 率 61%。本次样本量扩大、随访时间延长后，ORR/DCR 基本保持一致，rPFS 获益进一步延长（6 个月 rPFS 率 61%提升至 72%）。且该 rPFS 率横向对比优于其他药物（非头对头），如诺华的 lu177 在 PSMAVISION 研究中针对 3L+CRPC 患者 ORR 49%，rPFS 为 9.3 个月；强生 KLK2*CD3 TCE 针对 4L 患者 rPFS 为 7.9 个月；安进的 STEAP1*CD3 TCE 针对 3L 患者 ORR 29%，rPFS 为 7.8 个月。我们认为，DB1311 目前的生存数据展现出 BIC 潜力。

风险

新药研发风险，新药审批风险，新药商业化不及预期风险等。

APPENDIX 1

Summary

What's the news
At the 2026 ASCO Genitourinary Cancers Symposium, DualityBio presented the latest efficacy and safety data for its drug DB1311/BNT324 (B7H3 ADC) in the treatment of late-line castration-resistant prostate cancer (CRPC). The data disclosed this time is from the dose optimization phase of the Phase I/II clinical trial (NCT05914116), including 104 treated patients (68 patients received 6 mg/kg Q3W treatment, 34 patients received 9 mg/kg Q3W treatment). 53% of the patients were White, and the median number of prior lines of therapy for the overall patient population was 4.

Data showed: As of September 5, 2025, with a median follow-up of 9.2 months, 52 patients were still on treatment. Among 58 evaluable patients, the PSA50 response rate was 35.4%, the unconfirmed ORR was 41.4%, the confirmed ORR was 34.5%, and the DCR was 87.9%. Regarding survival benefits, the median DOR was 10.2 months. Among 82 efficacy-evaluable patients, the median rPFS was 11.3 months, with 6-month/9-month rPFS rates and OS rates of 72%/63% and 92%/88%, respectively. The overall safety profile was consistent with previous reports, primarily consisting of Grade 1-2 adverse events.

Efficacy was also excellent in patients who had received prior Lu177 treatment: Among 10 evaluable patients, the PSA50 response rate was 30.4%, the confirmed ORR was 30%, and the DCR was 100%. Among 23 efficacy-evaluable patients, the median rPFS was 11.3 months, with 9-month rPFS/OS rates of 61%/86%.

Our takes: best-in-class survival data demonstrates BIC potential
Preliminary data disclosed by the company at ASCO 2025 showed an ORR of 40%, DCR of 95%, and a 6-month rPFS rate of 61% in 38 patients. With the expanded sample size and extended follow-up in this release, the ORR/DCR remained largely consistent, while the rPFS benefit was further extended (6-month rPFS rate improved from 61% to 72%). This rPFS rate compares favorably (non-head-to-head) against other drugs, such as Novartis' Lu177 (ORR 49%, rPFS 9.3 months in 3L+ CRPC patients in the PSMAVISION study), Johnson & Johnson's KLK2*CD3 TCE (rPFS 7.9 months in 4L patients), and Amgen's STEAP1*CD3 TCE (ORR 29%, rPFS 7.8 months in 3L patients). We believe that the current survival data for DB1311 demonstrates Best-in-Class potential.

Risks
Risks associated with new drug research and development, new drug approval risks, risks of new drug commercialization falling short of expectations, etc.

附录 APPENDIX

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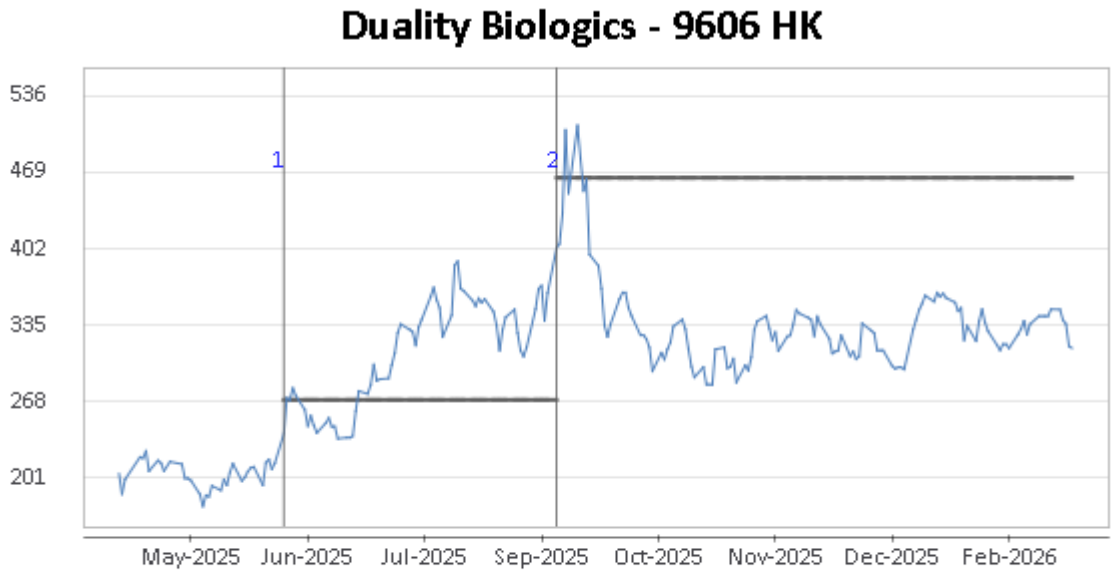

1. 9 Jun 2025 OUTPERFORM at 217.40 target 269.70.
2. 8 Sep 2025 OUTPERFORM at 363.20 target 464.20.

Source: Company data Bloomberg, HTI estimates