研究报告 Research Report

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信达生物 Innovent Biologics (1801 HK)

与武田制药达成 114 亿美元交易，合作商业化值得期待
USD11.4bn Deal with Takeda: Commercialization Collaboration Holds Promise

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热点速评 Flash Analysis

(Please see APPENDIX 1 for English summary)

事件

信达生物与武田制药达成全球战略合作（链接），包括两款后期在研疗法 IBI363（PD-1/IL-2α-bias）、IBI343（CLDN18.2 ADC），以及一款早期研发项目 IBI3001（EGFR/B7H3 ADC）的选择权。信达生物将获得 12 亿美元的首付款（其中包含 1 亿美元的战略股权投资），合计最高可达 102 亿美元的潜在里程碑付款，以及潜在销售分成（除 IBI363 在美国市场双方将采用利润损失共担模式）。具体来看：

1. IBI363（PD-1/IL-2α-bias）：双方在全球范围内共同开发，并在美国市场共同商业化；此外，武田制药获得其在大中华区和美国以外地区的独家商业化权益。根据协议，IBI363 的开发成本和美国市场的利润或损失，按 40/60 比例（信达生物/武田制药）分配。此外，武田制药需就大中华区以外市场向信达生物支付潜在的研发、销售里程碑，以及最高中高双位数的梯度销售分成（大中华区及美国以外市场）。
2. IBI343（CLDN18.2 ADC）：武田制药获得其在大中华区以外的独家权益。武田制药将就 IBI343 的许可支付潜在里程碑及最高中高双位数的梯度销售分成。
3. IBI3001（EGFR/B7H3 ADC）：武田制药获得其在大中华区以外权益的独家选择权。如果行权，武田制药将支付行权费、潜在里程碑款项，以及最高中双位数梯度销售分成。

点评

我们看好 IBI363 作为下一代肿瘤基石疗法的潜力，其有望持续拓展治疗边界，未来市场空间巨大。全球 IO 响应人群约 150 万，对应 500 亿美元热肿瘤市场。若拓展至 IO 耐药人群（约 100 万）及冷肿瘤人群（约 140 万），其市场空间有望扩大至 1500–2000 亿美元。作为“升级版“PD-1，IBI363 通过其双重激活与 α bias 减毒机制，有望突破 IL-2 剂量瓶颈。

IBI363 目前已积累的超过 1200 例患者的临床数据，信达生物和武田制药计划将率先推进 IBI363 于非小细胞肺癌（NSCLC）与结直肠癌（CRC）的全球开发，包括拓展至一线 NSCLC 和一线 CRC 适应症；此外，双方近期计划拓展 IBI363 至更多适应症的临床开发。

目前 IBI363 的首个全球 3 期临床研究（MarsLight-11）的 IND 获 FDA 批准，用于治疗 IO 耐药的鳞状非小细胞肺癌（sqNSCLC）患者。该研究将评估 IBI363 3mg/kg 剂量单药治疗相较多西他赛，在治疗经铂类化疗及抗 PD-1/PD-L1 免疫治疗进展后的 sqNSCLC 患者中的疗效和安全性。该研究的主要终点为 OS。

共同开发与商业化的模式，将助力信达生物积累搭建全球临床与商业化团队的经验。我们认为本次合作将充分利用信达生物在中国国内的开发效率和武田制药的国际化开发能力。武田制药每年研发投入约 50 亿美金，拥有 4500 人的临床团队，在肿瘤、免疫治疗领域具备丰富的临床、商业化经验。本次合作将有助于信达生物拓展全球布局，逐步在国际核心市场建立研发与商业化平台能力，并最大化可持续发展的长期价值。

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APPENDIX 1

Summary

What' the news

Innovent Biologics has entered into a global strategic collaboration with Takeda Pharmaceutical (link), which includes two late-stage investigational therapies—IBI363 (PD-1/IL-2α-bias) and IBI343 (CLDN18.2 ADC)—as well as an option for an early-stage R&D project, IBI3001 (EGFR/B7H3 ADC). Innovent will receive an upfront payment of USD1.2bn (including a USD100mn strategic equity investment), with total potential milestone payments of up to USD10.2bn, in addition to potential sales royalties (except for IBI363, which will adopt a profit and loss sharing model in the U.S. market). Specifically:

1. IBI363 (PD-1/IL-2α-bias): The two parties will co-develop it globally and co-commercialize it in the U.S. market. Additionally, Takeda Pharmaceutical has obtained exclusive commercialization rights for the therapy outside Greater China and the United States. According to the agreement, the development costs and profits or losses in the U.S. market will be shared in a 40/60 ratio (Innovent/Takeda). Furthermore, Takeda will pay Innovent potential R&D and sales milestones for markets outside Greater China, as well as tiered royalties of up to the mid-to-high double-digit percentage (for markets outside Greater China and the United States).

2. IBI343 (CLDN18.2 ADC): Takeda has secured exclusive rights for the therapy outside Greater China. Takeda will pay potential milestones for the licensing of IBI343, along with tiered royalties of up to the mid-to-high double-digit percentage.

3. IBI3001 (EGFR/B7H3 ADC): Takeda has obtained an exclusive option for rights to the therapy outside Greater China. If the option is exercised, Takeda will pay an exercise fee, potential milestone payments, and tiered royalties of up to the mid-double-digit percentage.

We are optimistic about the potential of IBI363 as a next-generation cornerstone therapy in oncology. It is expected to continuously expand treatment boundaries, with immense future market potential. The global immuno-oncology (IO) responsive population is approximately 1.5 million, corresponding to a USD50bn hot tumor market. If extended to the IO-resistant population (approximately 1 million) and the cold tumor population (approximately 1.4 million), its market potential could expand to USD150–200bn. As an "upgraded version" of PD-1, IBI363, through its dual activation and α-bias attenuation mechanism, is expected to overcome the dosage limitations of IL-2.

To date, IBI363 has accumulated clinical data from over 1,200 patients. Innovent Biologics and Takeda Pharmaceutical plan to prioritize the global development of IBI363 in non-small cell lung cancer (NSCLC) and colorectal cancer (CRC), including expanding into first-line NSCLC and first-line CRC indications. Additionally, the two parties have near-term plans to extend the clinical development of IBI363 to more indications.

The first global Phase 3 clinical trial of IBI363 (MarsLight-11) has received IND approval from the FDA for the treatment of IO-resistant squamous non-small cell lung cancer (sqNSCLC) patients. This study will evaluate the efficacy and safety of IBI363 at a 3 mg/kg dose as a monotherapy compared to docetaxel in sqNSCLC patients who have progressed after platinum-based chemotherapy and anti-PD-1/PD-L1 immunotherapy. The primary endpoint of the study is overall survival (OS).

The co-development and co-commercialization model will help Innovent Biologics accumulate experience in building a global clinical and commercial team. We believe this collaboration will fully leverage Innovent Biologics' development efficiency in China and Takeda Pharmaceutical's international development capabilities. Takeda Pharmaceutical invests approximately USD5bn annually in R&D and has a clinical team of 4,500 people, with extensive experience in clinical development and commercialization in the fields of oncology and immunotherapy. This collaboration will assist Innovent Biologics in expanding its global footprint, gradually establishing R&D and commercial platform capabilities in key international markets, and maximizing long-term sustainable development value.

Risks: new drug R&D risks, new drug approval risks, and new drug commercialization is weaker than expected.

附录 APPENDIX

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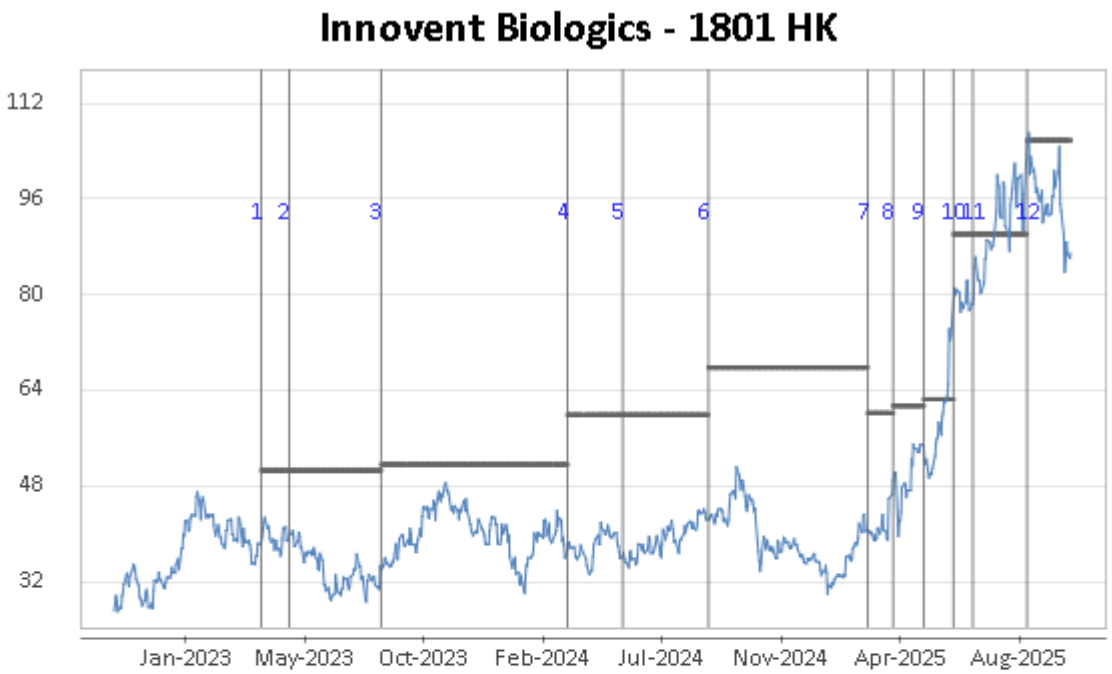

1. 10 Apr 2023 OUTPERFORM at 38.35 target 50.60.
2. 12 May 2023 OUTPERFORM at 39.75 target 50.60.
3. 25 Aug 2023 OUTPERFORM at 34.65 target 51.60.
4. 25 Mar 2024 OUTPERFORM at 36.00 target 59.90.
5. 27 May 2024 OUTPERFORM at 35.90 target 59.90.
6. 2 Sep 2024 OUTPERFORM at 42.45 target 67.80.
7. 3 Mar 2025 OUTPERFORM at 43.20 target 60.20.
8. 1 Apr 2025 OUTPERFORM at 46.60 target 61.40.
9. 6 May 2025 OUTPERFORM at 54.30 target 62.50.
10. 9 Jun 2025 OUTPERFORM at 73.15 target 90.10.
11. 1 Jul 2025 OUTPERFORM at 78.40 target 90.10.
12. 1 Sep 2025 OUTPERFORM at 96.85 target 105.80.