研究报告 Research Report

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信达生物 Innovent Biologics (1801 HK)

研发日点评：迈向国际一流的生物制药公司，驶向海水变蓝的未来

R&D Day Review: Striding Towards a World-Class Biopharmaceutical Company, Sailing Towards a Blue Ocean Future

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热点速评 Flash Analysis

(Please see APPENDIX 1 for English summary)

事件

2025 年 6 月 28 日，信达生物举办研发日活动。

点评

管理层发表 2030 年愿景为本次会议较大亮点。信达生物创始人俞总在演讲中重申愿景， 2030 年成为跻身国际一流的生物制药公司。其中，5 个产品管线进入全球多中心 3 期临床，2 个产品在海外上市，公司在产品、管线、市值层面都将在国际市场取得一席之地。

IBI363 的发展及 BD 预期

- IBI363（PD-1/IL-2α-bias 双抗）基于信达生物多年的积累和对分子的理解，临床策略清晰，I 期尽量暴露问题，提高对 MOA/用药理解，II 期选择有代表性的瘤肿进行 POC，奠定其它瘤肿开发，III 期对确定性高的适应症推进。一线适应症需针对剂量，人群和联合用药等因素做出判断。目前一线肠癌、胃癌、肺癌符合预期，预计在 2026 年读出一线 POC 数据。
- BD 层面上，管理层表示对合作伙伴主要有两点要求。①对方需有肿瘤管线及完善的美国注册和商业化能力，以便信达更多参与并提高自身能力；②对方需有精力和能力赋予产品更好的销售峰值。
- 不良反应总体可控，有望随着临床经验积累得到进一步改善。25ASCO 上公布的数据显示在 3mg/kgQ3W 组的三级以上不良反应率（TRAE）为 43.9%，其中关节痛和皮疹的发生率较高。管理层在交流中表示不良反应总体可控，临床团队有针对不良反应处理的经验。具体而言，关节痛和皮疹等都可以通过在症状发生早期进行干预以缓解不良反应。另外，3mg/kg 的高剂量组因其疗效较突出，用药时间较长，故而不良事件概率较高。未来 IBI363 推进到一线适应症时，考虑到一线患者耐受性相对较好，AE 管理经验加强，不良反应有望得到改善。

玛氏度肽有望快速推广放量

- 6 月 27 日，信达生物的玛仕度肽获批上市，适用于在控制饮食和增加体力活动基础上对成人患者的长期体重控制，初始体重指数（BMI）为：BMI≥28 kg/m²（肥胖）；或 BMI≥24 kg/m²（超重），并伴有至少一种体重相关的合并症（如高血糖、高血压、血脂异常、脂肪肝、阻塞性睡眠呼吸暂停综合征等）。
- 管理层表示，针对该产品将采取全渠道营销模式，包括院内（专家、品牌）及院边市场，私人诊所、医美机构、体检中心等院外渠道，以及零售、电商等新兴渠道全面铺开。我们建议关注该产品的放量，我们预计 2025-2026 年的销售额分别为 6 亿元和 18 亿元。

2030 年各领域展望

- 国内业务：玛氏度肽在 630 前获批上市，将显著带动非肿瘤业务收入的增长。另外，替妥尤单抗（IGF-1R，甲状腺眼病）获批、托莱西单抗（PCSK9，高胆固醇血症）进入医保、年底 IBI223（IL-23 p19，匹康奇拜单抗）有望获批等进展持续为非肿瘤业务带来增长动能，非肿瘤业务有望在 2027 年的 200 亿元的收入预期中与肿瘤业务并驾齐驱。
- 海外业务：肿瘤领域 IBI 363 和 IBI343（CLDN18.2 ADC）的研发进度处于前列，2027- 2030 年海外收入有望提升，前期将以肿瘤为主要动力，后期非肿瘤收入也将有所贡献。

风险：临床管线进展不及预期、新产品放量节奏不及预期、药价政策等风险。

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APPENDIX 1

Summary

On June 28, 2025, Innovent Biologics held its R&D Day event.

The announcement of the 2030 vision by the management was a major highlight of the meeting. Mr. Yu, the founder of Innovent Biologics, reiterated the vision of becoming a world-class biopharmaceutical company by 2030. Specifically, five product pipelines are expected to enter global multi-center Phase III clinical trials, and two products are planned to be launched overseas. The company aims to secure a foothold in the international market in terms of products, pipelines, and market value.

Development and BD Expectations of IBI363
- IBI363 (PD-1/IL-2α-bias bispecific antibody) is based on Innovent Biologics' years of accumulation and understanding of molecules. The clinical strategy is clear. Phase I trials aim to expose issues as much as possible to enhance the understanding of the mechanism of action (MOA) and dosing. Phase II will select representative tumor types for proof-of-concept (POC) studies to lay the foundation for the development of other tumor types. Phase III will advance the more certain indications. For first-line indications, judgments need to be made on factors such as dosage, patient population, and combination therapy. Currently, the first-line indications for colorectal cancer, gastric cancer, and lung cancer are meeting expectations, with POC data expected to be read out in 2026.
- On the business development (BD) front, the management has two main requirements for partners. First, the partner should have an oncology pipeline and complete capabilities for US registration and commercialization to allow Innovent Biologics to participate more and enhance its own capabilities. Second, the partner should have the energy and ability to give the product a better sales peak.
- Adverse reactions are generally controllable and are expected to improve further with the accumulation of clinical experience. Data presented at the 2025 ASCO showed that the rate of grade 3 or higher treatment-related adverse events (TRAEs) in the 3mg/kg Q3W group was 43.9%, with higher incidences of arthralgia and rash. The management indicated in communications that adverse reactions are generally controllable, and the clinical team has experience in handling adverse reactions. Specifically, arthralgia and rash can be alleviated by intervening early when symptoms occur. Additionally, the high-dose group of 3mg/kg has a higher probability of adverse events due to its more prominent efficacy and longer duration of use. In the future, as IBI363 advances to first-line indications, considering the relatively better tolerance of first-line patients and the strengthened AE management experience, adverse reactions are expected to improve.

Mazdumetor Expected to Expand Sales Rapidly
- On June 27, Innovent Biologics' Mazdumetor was approved for marketing, applicable for long-term weight control in adult patients on the basis of controlled diet and increased physical activity, with an initial body mass index (BMI) of BMI≥28 kg/m² (obesity); or BMI≥24 kg/m² (overweight), and with at least one weight-related comorbidity (such as hyperglycemia, hypertension, dyslipidemia, fatty liver, obstructive sleep apnea syndrome, etc.).
- The management stated that a full-channel marketing model will be adopted for this product, including in-hospital (experts, brands) and out-of-hospital channels such as private clinics, medical aesthetics institutions, health check-up centers, as well as emerging channels like retail and e-commerce. We suggest paying attention to the sales expansion of this product, and we estimate the sales for 2025 and 2026 to be 600 million yuan and 1.8 billion yuan, respectively.

Outlook for 2030 in Various Fields
- Domestic Business: The approval of Mazdumetor before June 30 will significantly drive the growth of non-oncology business revenue. Additionally, the approval of Titozumab (IGF-1R, thyroid eye disease), the inclusion of Toliximab (PCSK9, hypercholesterolemia) in the national health insurance, and the expected approval of IBI223 (IL-23 p19, Picancibumab) by the end of the year will continue to provide growth momentum for the non-oncology business. Non-oncology business is expected to match the oncology business in the 20 billion yuan revenue expectation by 2027.
- Overseas Business: In the oncology field, the R&D progress of IBI363 and IBI343 (CLDN18.2 ADC) is at the forefront. Overseas revenue is expected to increase from 2027 to 2030, with oncology as the main driver in the early stage and non-oncology revenue also contributing in the later stage.

Risk
- Clinical pipeline progress may not meet expectations.
- New product sales expansion may not be as fast as expected.
- Risks related to drug pricing policies.

附录 APPENDIX

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*Percentage of investment banking clients in each rating category.

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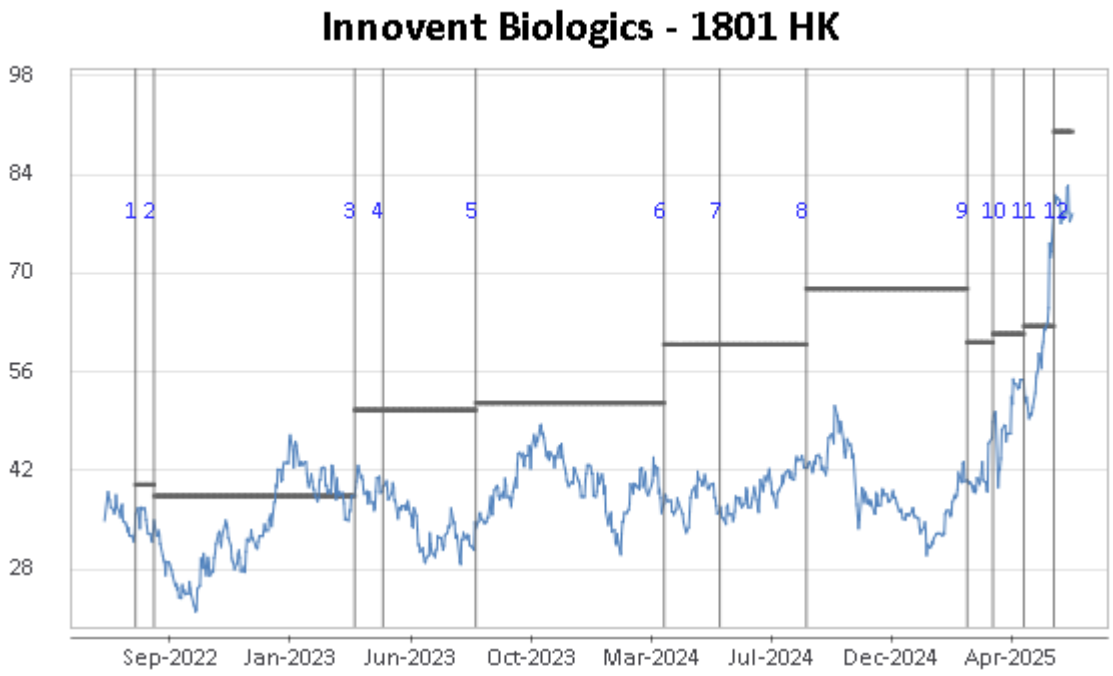
Recommendation Chart



1. 7 Aug 2022 OUTPERFORM at 35.80 target 40.00.
2. 26 Aug 2022 OUTPERFORM at 33.60 target 38.40.
3. 10 Apr 2023 OUTPERFORM at 38.35 target 50.60.
4. 12 May 2023 OUTPERFORM at 39.75 target 50.60.
5. 25 Aug 2023 OUTPERFORM at 34.65 target 51.60.
6. 25 Mar 2024 OUTPERFORM at 36.00 target 59.90.
7. 27 May 2024 OUTPERFORM at 35.90 target 59.90.
8. 2 Sep 2024 OUTPERFORM at 42.45 target 67.80.
9. 3 Mar 2025 OUTPERFORM at 43.20 target 60.20.
10. 1 Apr 2025 OUTPERFORM at 46.60 target 61.40.
11. 6 May 2025 OUTPERFORM at 54.30 target 62.50.
12. 9 Jun 2025 OUTPERFORM at 73.15 target 90.10.

Source: Company data Bloomberg, HTI estimates