

Healthcare

一周全球生物医药板块事件及分析

Weekly global biopharmaceutical sector events and analysis

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 热点速评 Flash Analysis

(Please see APPENDIX 1 for English summary)

一、罗氏的 TIGIT 单抗 Tiragolumab 在联合 PD-L1 单抗在一线治疗 NSCLC 研究中未能达到 mPFS 终点。

【点评】我们认为 tiragolumab 在 SCLC 和 NSCLC 临床试验中接连失利，并不代表 TIGIT 靶点失效，仍需观察不同设计、不同联用方案以及 OS 结果。默沙东、Arcus/Gilead、百济神州（ASCO 将发布 TIGIT/PD-1/贝伐珠治疗 HCC 数据）、信达生物、康方生物等均有相关产品在研。药明生物在 TIGIT 领域或有 2-3 款产品，我们预计远期在收入占比 1-2% 之间。

二、FDA 将 Amicus 的庞贝氏症产品上市申请 PDUFA date 推迟 90 天至到 22 年 8 月 29 日，以考虑新提交的信息，但并未要求提供新的临床数据，

【点评】药明生物是 Amicus 的庞贝病产品 CDMO，如果产品获批有望成为新的商业化品种，静待最终评审结果。

三、Caribou Biosciences 披露其领先的异体 CD19 CAR-T 数据，五名患有 r/r B-NHL 患者，ORR 100%，CR 80%。公司计划将在下个月的 EHA 会议发布 ANTLER 研究数据。

【点评】异体 CAR-T 概念的 POC 数据有望推动细胞治疗进入下一个阶段。

四、阿斯利康/赛诺菲就用于 RSV 预防 and 治疗的 Nirsevimab 单抗向 FDA 提交了新数据，该产品 III 期数据表明降低 74.5% 的 RSV 相关下呼吸道感染就医，但未达到降低住院率的次要终点，次要终点的结果或是受到新冠疫情影响。

【点评】RSV 感染在婴幼儿发病率高，缺乏有效的 RSV 疫苗及药物。除阿斯利康/赛诺菲外，GSK、辉瑞和 Moderna 等均有产品进入到后期临床。国内相关领域尚属蓝海，可持续关注。

五、FDA 疫苗负责人 Peter Marks 表示尽管成人疫苗必须达到 50% 的保护率，但针对年轻的儿童群体的疫苗不需要达到同样的标准。Moderna 和 Pfizer/BioNtech 的 mRNA 新冠疫苗针对 5 岁以下儿童的上市申请均审批中。

【点评】目前在美国获批的所有其他成人和儿童疫苗对 Omicron 效果均有下降，但它们在降低严重疾病、住院和死亡风险方面仍然有效。

APPENDIX 1**Summary**

1. Roche's TIGIT monoclonal antibody Tiragolumab failed to meet the mPFS endpoint in combination with PD-L1 monoclonal antibody in the first-line treatment of NSCLC study.

[Comment] We believe that the successive failure of tiragolumab in SCLC and NSCLC clinical trials does not mean that the TIGIT target has failed, and that different designs, different combination regimens and OS results still need to be observed. Merck Sharp & Dohme, Arcus/Gilead, Baxi Shenzhou (ASCO will release data on TIGIT/PD-1/Bevacizumab for HCC), Cinda Biologics, and Kangfang Biologics all have related products in the pipeline. WuXi Biologics may have 2-3 products in the TIGIT field, and we expect to be between 1-2% of revenue in the long term.

2. The FDA postponed Amicus' Pompe disease product marketing application PDUFA date by 90 days to August 29, 22 to consider the newly submitted information, but did not request new clinical data

[Comment] WuXi Biologics is the CDMO of Amicus' Pompe disease product, if the product is approved is expected to become a new commercial variety, pending the final review results.

3. Caribou Biosciences disclosed its leading allogeneic CD19 CAR-T data, five patients with r/r B-NHL, ORR 100%, CR 80%. The company plans to release data from the ANTLER study at next month's EHA meeting.

[Comment] The POC data from the allogeneic CAR-T concept is expected to drive cell therapy to the next stage.

4. AstraZeneca/Sanofi submitted new data to the FDA on Nirsevimab monoclonal antibody for RSV prophylaxis and treatment. Phase III data for the product showed a 74.5% reduction in RSV-associated lower respiratory tract infection visits, but did not meet the secondary endpoint of reducing hospitalization rates, and the results for the secondary endpoint were either affected by the COVID-19 outbreak.

[Comment] RSV infections are highly prevalent in infants and children, and there is a lack of effective RSV vaccines and drugs. In addition to AstraZeneca/Sanofi, GSK, Pfizer and Moderna have products that have entered into late stage clinical. The related domestic field is still a blue ocean and can be continuously focused.

5. Peter Marks, head of FDA vaccines, said that while adult vaccines must achieve 50% protection, vaccines for young children do not need to meet the same standard. mRNA-COVID-19 vaccines from Moderna and Pfizer/BioNtech for children under 5 years old are both under approval.

[Comment] All other adult and pediatric vaccines currently approved in the U.S. are less effective against Omicron, but they remain effective in reducing the risk of serious illness, hospitalization and death.

附录 APPENDIX

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弱于大市, 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

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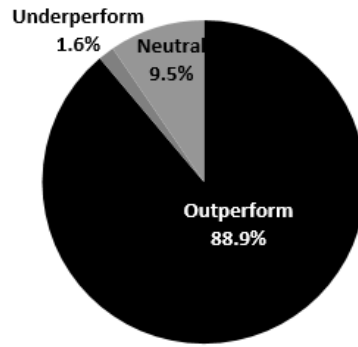
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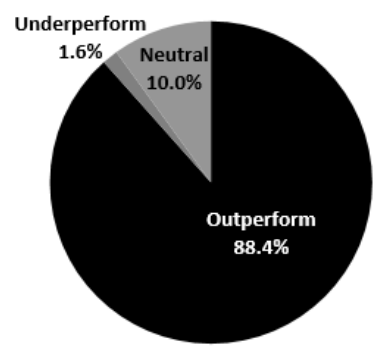
Benchmarks for each stock's listed region are as follows: Japan – TOPIX, Korea – KOSPI, Taiwan – TAIEX, India – Nifty100, US – SP500; for all other China-concept stocks – MSCI China.

评级分布 Rating Distribution

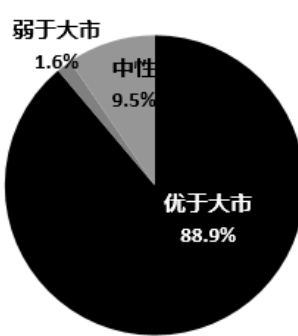
Most Recent Full Quarter



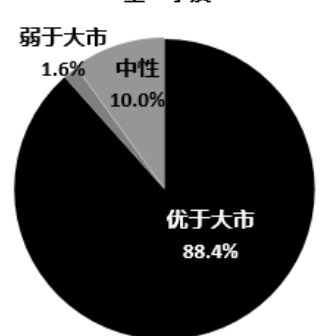
Prior Full Quarter



最新季度



上一季度



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