研究报告 Research Report

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Healthcare

一周全球生物医药板块事件及分析（20220523-20220529）

Global Biopharmaceutical Sector Events and Analysis (20220523-20220529)

舒影岚 Linda Shu, PhD linda.yl.shu@htisec.com

Hao Huang h.huang@htisec.com

热点速评 Flash Analysis

(Please see APPENDIX 1 for English summary)

ADI-001 是一种针对 B 细胞抗原 CD20 的 FIC 同种异体 γ δ (γδ) CAR T 细胞疗法。ADI-001 还具有适应性和先天性细胞毒性效应功能，以补充 CAR 靶向，潜在地提高疗效并减少由于抗原丢失导致肿瘤逃逸的可能性。 ADI-001 表达独立于 MHC 的 γδ T 细胞受体，因此无需基因编辑即可降低移植物抗宿主病 (GvHD) 的风险。

ADI-001 的早期临床结果展现了很好的安全性和有效性。先前治疗的中位数为 3.5。在第 28 天， ORR 为 67%（4/6 患者），CR 率为 67%（4/6 患者）。治疗后随访≥3 个月的两名患者均保持 CR。安全性方面，大多数相关 AE (78%) 为 1/2 级。AESI 共有三个：两个 CRS（1 个 1 级和 2 个 2 级）和一个 1 级 ICANS，唯一相关的 SAE 是 2 级 CRS 和 1 级 ICANS。没有报告 GvHD，也没有 DLT 事件。Arcellx (11.550, 1.970, 20.56%)数据发布后，股价上涨 20.56%。

【点评】此前 CaribouBiosciences 亦披露了早期积极数据，异体 CART 治疗方案在早期临床中逐步验证。

p53 肿瘤抑制蛋白是一种转录因子，可在细胞应激反应中维持基因组稳定性。导致 p53 蛋白失活的 TP53 基因自发突变是所有人类癌症中最常见的突变事件，约一半肿瘤患者有 TP53 变异。P53 功能下降主要因为野生 P53 水平不足和变异，所以有多种治疗策略可以恢复 P53 功能。

PC14586 是一种新型的小分子结构校正子，可选择性地结合 p53 Y220C 突变蛋白并恢复 p53 野生型构象和转录活性，从而产生有效的临床前抗肿瘤活性。在临床 I 期数据 21 名患者中，5 名患者出现 PR：1 名小细胞肺和 1 名确诊为 PR (cPR) 的乳房，均在进行中； 1 例结直肠癌未确诊 PR (uPR)，2 例前列腺癌 uPR 且正在进行中。在 3 个最高剂量组（总日剂量 2000 至 3000 mg）中，10 名疗效可评估的患者中有 3 名 PR（2 名 uPR，1 名 cPR）和 7 名 SD。PC14586 安全性良好，仅出现 2 例三级以上 AE。

【点评】PC14586 在多个常见肿瘤都显示疗效。PMV 将继续推进更高剂量的招募，以增加样本量，推进关键 II 期临床研究。从全球范围来看 p53 Y220C 抑制剂尚无其他产品进入到临床阶段。除 p53 Y220C 外，p53 其他位点突变同样值得关注。

Innoviva 将以每股 2.20 美元的价格购买 Entasis 剩余股份，将 Entasis 私有化，对其生物技术及 III 期抗生素的估值为 1.13 亿美元。截至 22 年一季报显示，Entasis 只有 3350 万美元的现金和现金等价物，不足以支撑其明年的运营。

【点评】Entasis 拥有五款药物在研，durlobactam、durlobactam+sulbactam 和 zoliflodacin 均处在临床三期，durlobactam+sulbactam 具有治疗碳青霉烯类耐药不动杆菌的潜力。再鼎医药 (29.900, -0.100, -0.33%)拥有 durlobactam+sulbactam 和 durlobactam 在亚太地区权益。

CureVac 将强化其在肿瘤领域的研发，其目前有 3 个肿瘤产品在研。CureVac 与比利时的 myNEO 达成合作，myNEO 公司拥有一个新抗原发现和选择平台，以确定 mRNA 免疫疗法的新靶点。在传染病方面，该公司正在继续与 GSK 合作开发新的 mRNA 疫苗。其先前的候选药物（包括第二代 Covid shot CV2CoV）利用了非化学修饰的 mRNA，但 CureVac 预计将在 22 年开展基于修饰 mRNA 的流感和 Covid-19 临床计划。

【点评】肿瘤领域一直是 mRNA 产品研发的重点方向，22 年 AACR 上 BioNtech 公布了 Claudin 6 CART 和 mRNA 疫苗联用的积极早期临床结果，提示 mRNA 疫苗具有帮助 CART 持续起效的潜力。CureVac 作为 mRNA 领域三大巨头，在 mRNA 产品研发中屡受挫折，第一代新冠疫苗采用非化学修饰技术是其失败的原因之一。mRNA 疫苗在传染性疾病中，修饰 mRNA 是降低免疫原性的重要方式；在肿瘤疫苗领域，非修饰 mRNA 疫苗或是更好的选择。

红杉资本投资专注于放射性癌症疗法研发的 Full-Life Technologies。Full-Life Technologies 正在研究的潜在候选药物由杀死肿瘤细胞的放射性配体和优化的单域抗体或肽组成。

【点评】诺华 (91.460, 0.200, 0.22%)和拜耳是放射性治疗方案的领先企业。诺华的 177Lu-PSMA-617 于 22 年 3 月份获批治疗前列腺癌，预计 2026 年收入达 7.4 亿美金，放射性治疗方案是在肿瘤治疗和诊断领域具有巨大前景。放射性核素药物研发具备获取核素、运输、生产等高壁垒。国内远大医疗、东诚药业 (11.69, 0.41, 3.63%)、中国同福等在放射性核素药物均有布局。

APPENDIX 1

Summary

ADI-001 is a FIC allogeneic gamma δ (γδ) CAR T-cell therapy targeting the B-cell antigen CD20. ADI-001 also functions as an adaptive and innate cytotoxic effector to complement CAR targeting, potentially improving efficacy and reducing the likelihood of tumor escape due to antigen loss. ADI-001 expresses the MHC-independent γδ T-cell receptor, thus reducing the risk of graft-versus-host disease (GvHD) without the need for gene editing.

Early clinical results of ADI-001 demonstrated a good safety and efficacy profile. At day 28, the ORR was 67% (4/6 patients) and the CR rate was 67% (4/6 patients). Both patients with ≥3 months post-treatment follow-up maintained CR. for safety, the majority of relevant AEs (78%) were grade 1/2. there were three AESIs: two CRS (one grade 1 and two grade 2) and one grade 1 ICANS, and the only relevant SAE was a grade 2 CRS and a grade 1 ICANS. no GvHD was reported, and there were no DLT events. arcellx (11.550, 1.970, 20.56%) shares rose 20.56% after the data was released.

【Comment】Previously, CaribouBiosciences also disclosed early positive data, and the allogeneic CART regimen was progressively validated in early clinical settings.

The p53 tumor suppressor protein is a transcription factor that maintains genomic stability in response to cellular stress. Spontaneous mutations in the TP53 gene, which cause p53 protein inactivation, are the most common mutational event in all human cancers, and approximately half of tumor patients have TP53 variants. p53 function is reduced primarily due to insufficient levels and mutations of wild P53, so there are multiple therapeutic strategies to restore P53 function.

PC14586 is a novel small molecule structural corrector that selectively binds p53 Y220C mutant protein and restores p53 wild-type conformation and transcriptional activity, resulting in potent preclinical antitumor activity. Of the 21 patients in the clinical phase I data, 5 patients developed PR: 1 small cell lung and 1 breast with confirmed PR (cPR), both ongoing; 1 colorectal cancer with undiagnosed PR (uPR) and 2 prostate cancers with uPR and ongoing. In the 3 highest dose groups (total daily dose 2000 to 3000 mg), there were 3 PR (2 uPR, 1 cPR) and 7 SD in 10 patients with evaluable efficacy. PC14586 had a good safety profile with only 2 Grade III or higher AEs.

【Comment】PC14586 has shown efficacy in multiple common tumors. PMV will continue to advance enrollment at higher doses to increase sample size and advance to pivotal phase II clinical studies. Globally no other p53 Y220C inhibitors have reached the clinical stage. In addition to p53 Y220C, mutations at other p53 loci are also of interest.

Innoviva will purchase the remaining shares of Entasis for $2.20 per share, privatizing Entasis and valuing its biotechnology and Phase III antibiotics at $113 million. As of 1Q22, Entasis only had $33.5 million in cash and cash equivalents, which is not enough to support its operations next year.

【Comment】Entasis has five drugs in development, durlobactam, durlobactam+sulbactam and zoliflodacin are all in clinical phase III, and durlobactam+sulbactam has the potential to treat carbapenem-resistant immobilized bacilli.

CureVac will strengthen its R&D in oncology, where it currently has three oncology products in development. cureVac has entered into a collaboration with myNEO, a Belgian company with a neoantigen discovery and selection platform to identify new targets for mRNA immunotherapies. In infectious diseases, the company is continuing its collaboration with GSK to develop new mRNA vaccines. Its previous drug candidates (including second-generation Covid shot CV2CoV) utilized non-chemically modified mRNA, but CureVac expects to launch clinical programs for modified mRNA-based influenza and Covid-19 in FY22.

【Comment】 The oncology field has been the key direction for mRNA product development. 22 years at AACR, BioNtech announced positive early clinical results for the combination of Claudin 6 CART and mRNA vaccine, suggesting that mRNA vaccine has the potential to help CART continue to work. cureVac, as one of the three giants in the mRNA field, has suffered many setbacks in mRNA product development. CureVac, one of the top three players in the mRNA field, has suffered repeated setbacks in mRNA product development, with the use of non-chemical modification technology in the first generation of New Crown vaccines being one of the reasons for its failure. mRNA vaccines are an important way to reduce immunogenicity in infectious diseases; in the field of oncology vaccines, non-modified mRNA vaccines may be a better choice.

附录 APPENDIX

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优于大市，未来 12-18 个月内预期相对基准指数涨幅在 10%以上，基准定义如下

中性，未来 12-18 个月内预期相对基准指数变化不大，基准定义如下。根据 FINRA/NYSE 的评级分布规则，我们会将中性评级划入持有这一类别。

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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Outperform: The stock's total return over the next 12-18 months is expected to exceed the return of its relevant broad market benchmark, as indicated below.

Neutral: The stock's total return over the next 12-18 months is expected to be in line with the return of its relevant broad market benchmark, as indicated below. For purposes only of FINRA/NYSE ratings distribution rules, our Neutral rating falls into a hold rating category.

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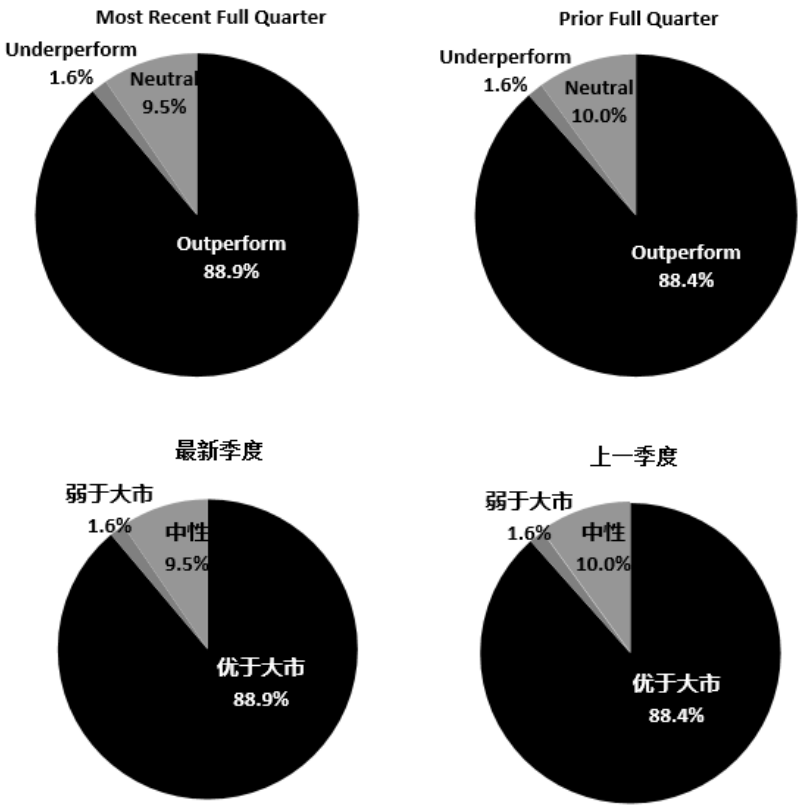
Benchmarks for each stock's listed region are as follows: Japan – TOPIX, Korea – KOSPI, Taiwan – TAIEX, India – Nifty100, US – SP500; for all other China-concept stocks – MSCI China.

评级分布 Rating Distribution



截至 2022 年 3 月 31 日海通国际股票研究评级分布

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海通国际股票研究覆盖率	88.9%	9.5%	1.6%
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*在每个评级类别里投资银行客户所占的百分比。

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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

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*Percentage of investment banking clients in each rating category.

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