

生物医药投融资跟踪：海外呈现复苏态势，国内仍需等待 (Biomedical Investment and Financing Trends: Recovery Abroad, Domestic Market Awaits)

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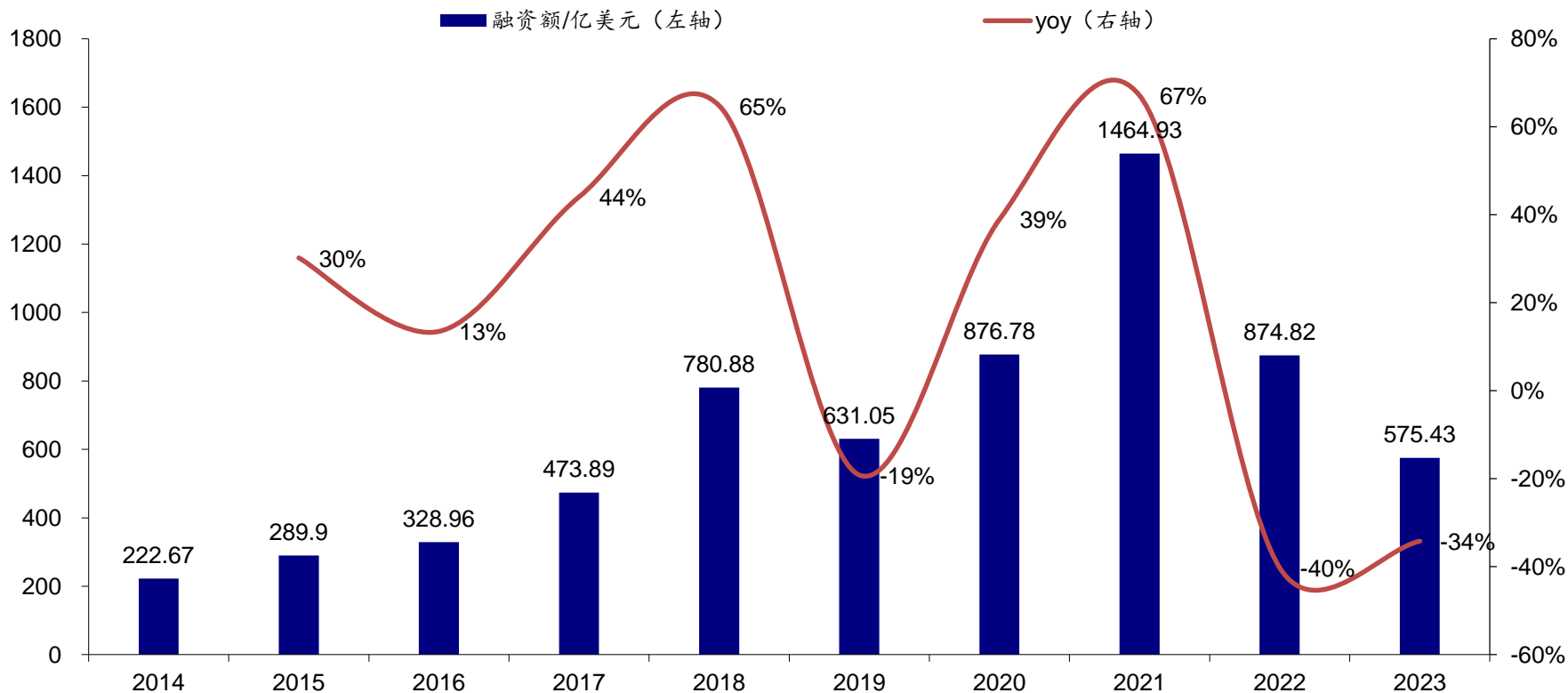
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1.1: 2014-2023年全球医疗健康融资回顾

- 全球医疗健康融资额2023年同比2022年仍有一定幅度下滑，基本接近2019年水平。2023年全球生物医药融资金额为575.43亿美元，同比2022年下滑34%，与2019年融资额631.05亿美元基本接近。

图：2014-2023年全球医疗健康融资金额



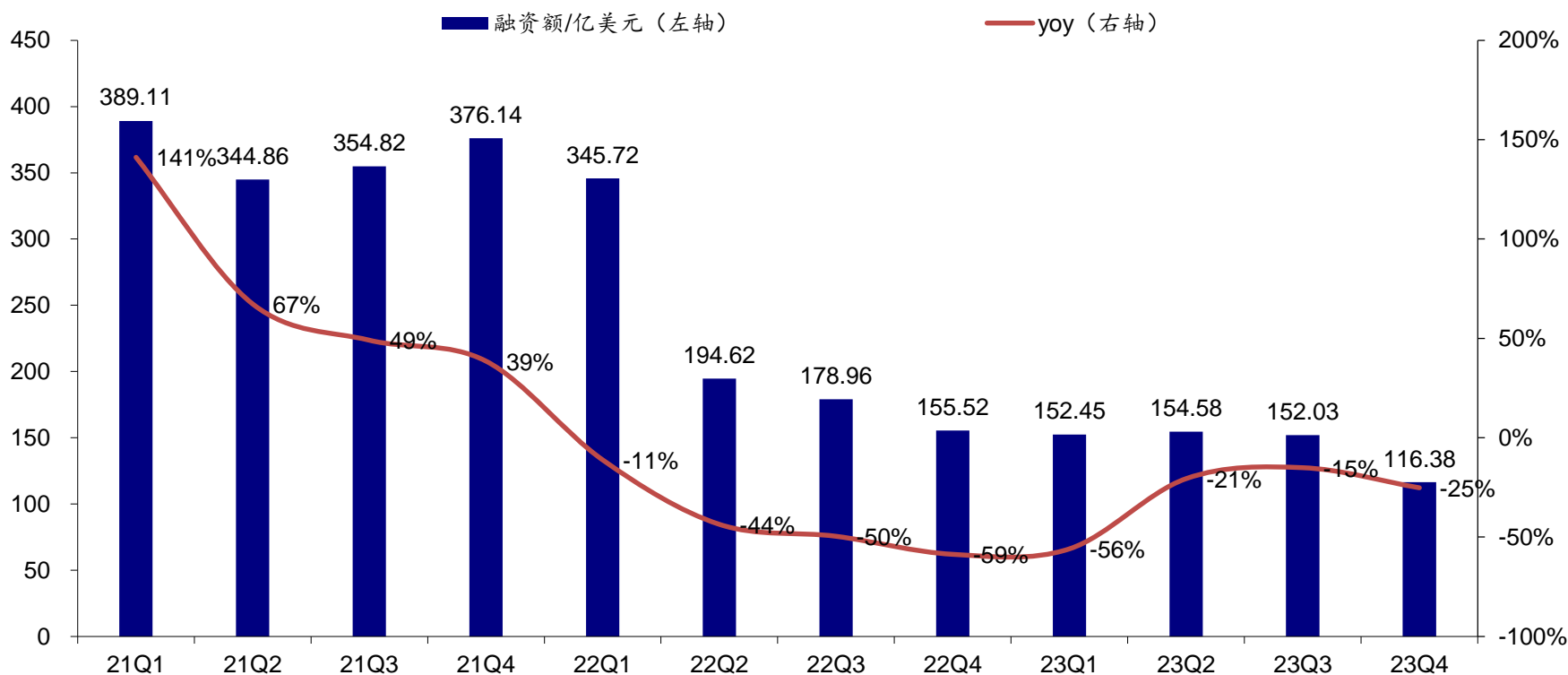
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1.2: 2021Q1-2023Q4全球医疗健康融资季度回顾

- 2023Q4融资金额小幅仍然下滑，2023Q1-2023Q3三个季度融资金额环比保持平稳。2022Q4-2023Q3全球医疗健康季度融资金额分别为155.52、152.45、154.58、152.03亿美元，季度间环比保持平稳。2023Q4季度融资金额为116.38亿美元，同比2022Q4季度融资金额下滑25%。

图：2021Q1-2023Q4全球医疗健康融资金额



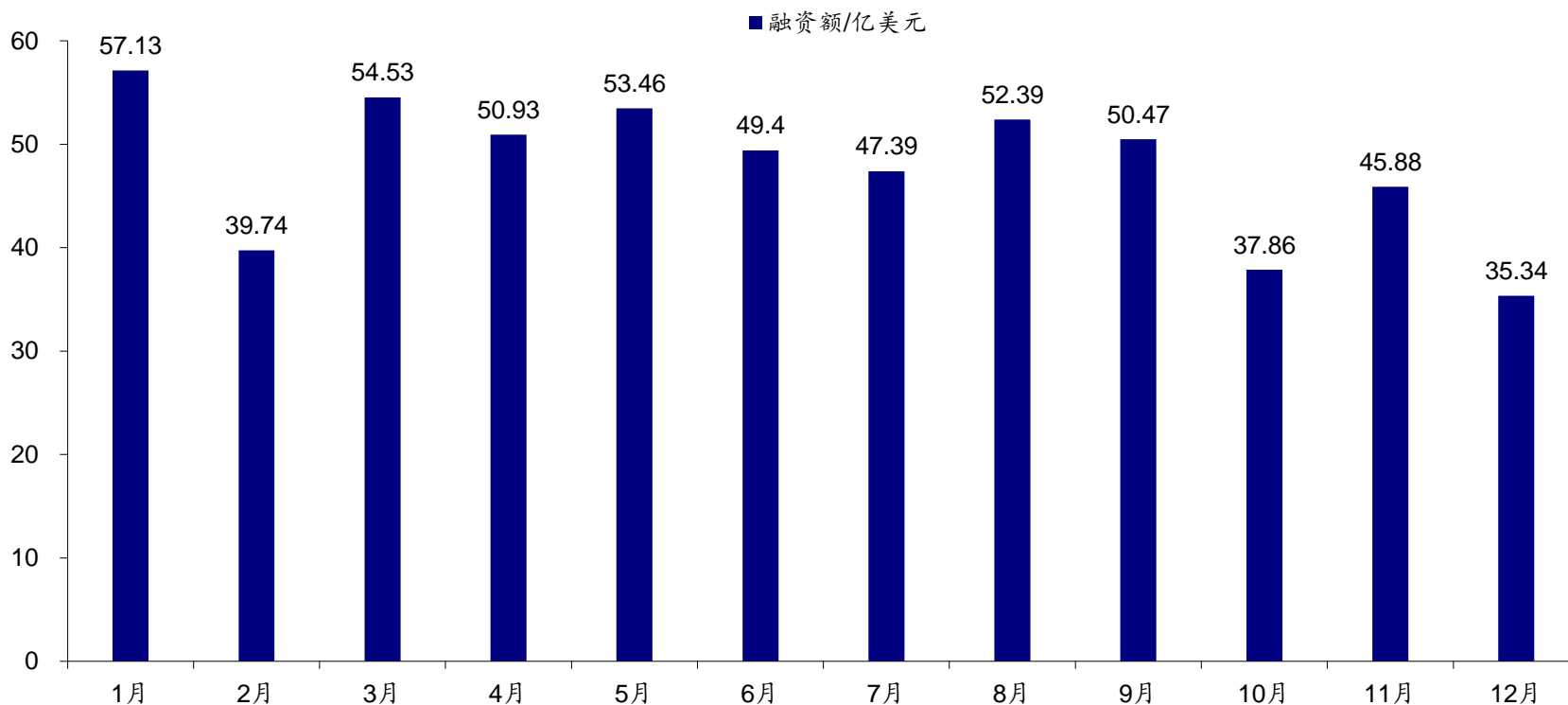
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1.3: 2023年全球医疗健康融资月度回顾

- 2023年12月全球医疗健康融资金额为35.34亿美元，环比2023年11月下滑23%。

图：2023年全球医疗健康融资金额月度回顾



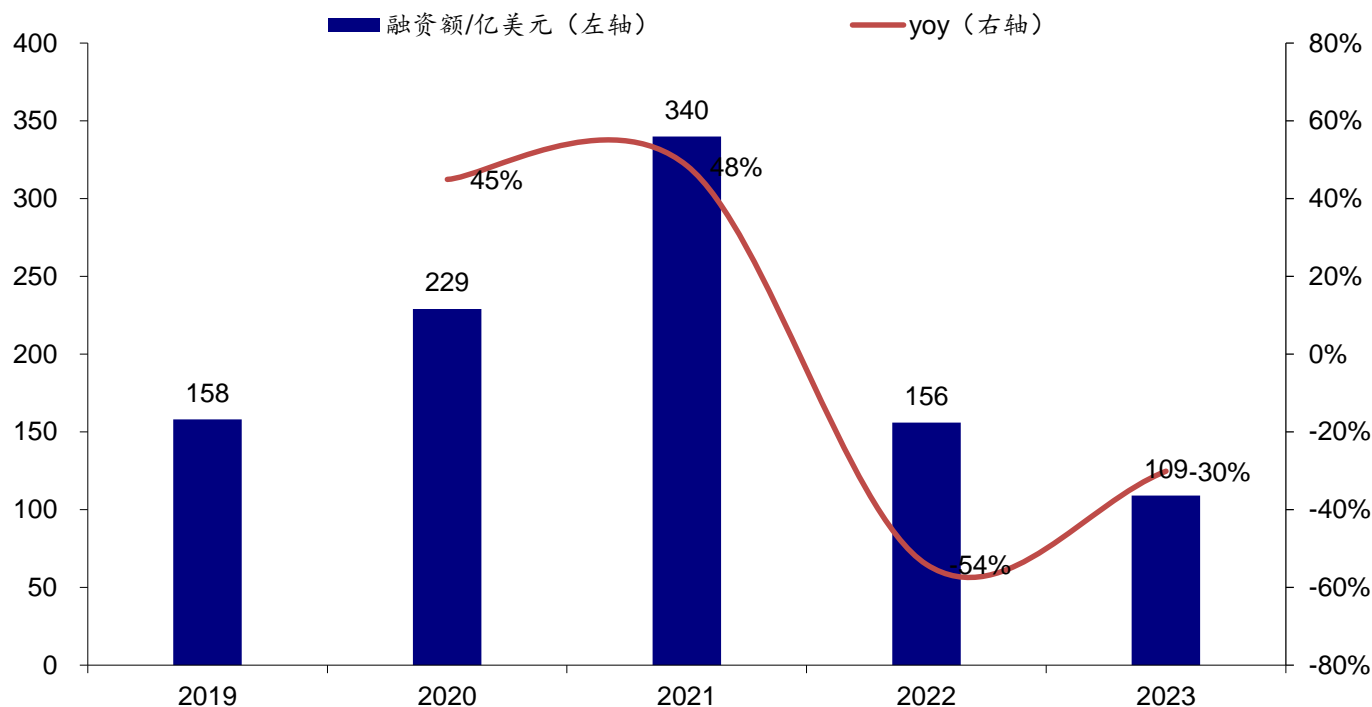
资料来源：动脉网，HTI

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2. 2019-2023年国内医疗健康融资回顾

- 国内医疗健康融资额2023年同比下滑30%。2023年国内医疗健康融资仍较为低迷，全年融资金额为109亿美元，在2022年同比大幅下滑54%的基础上，同比2022年下滑30%。

图：2019-2023年国内医疗健康融资金额回顾

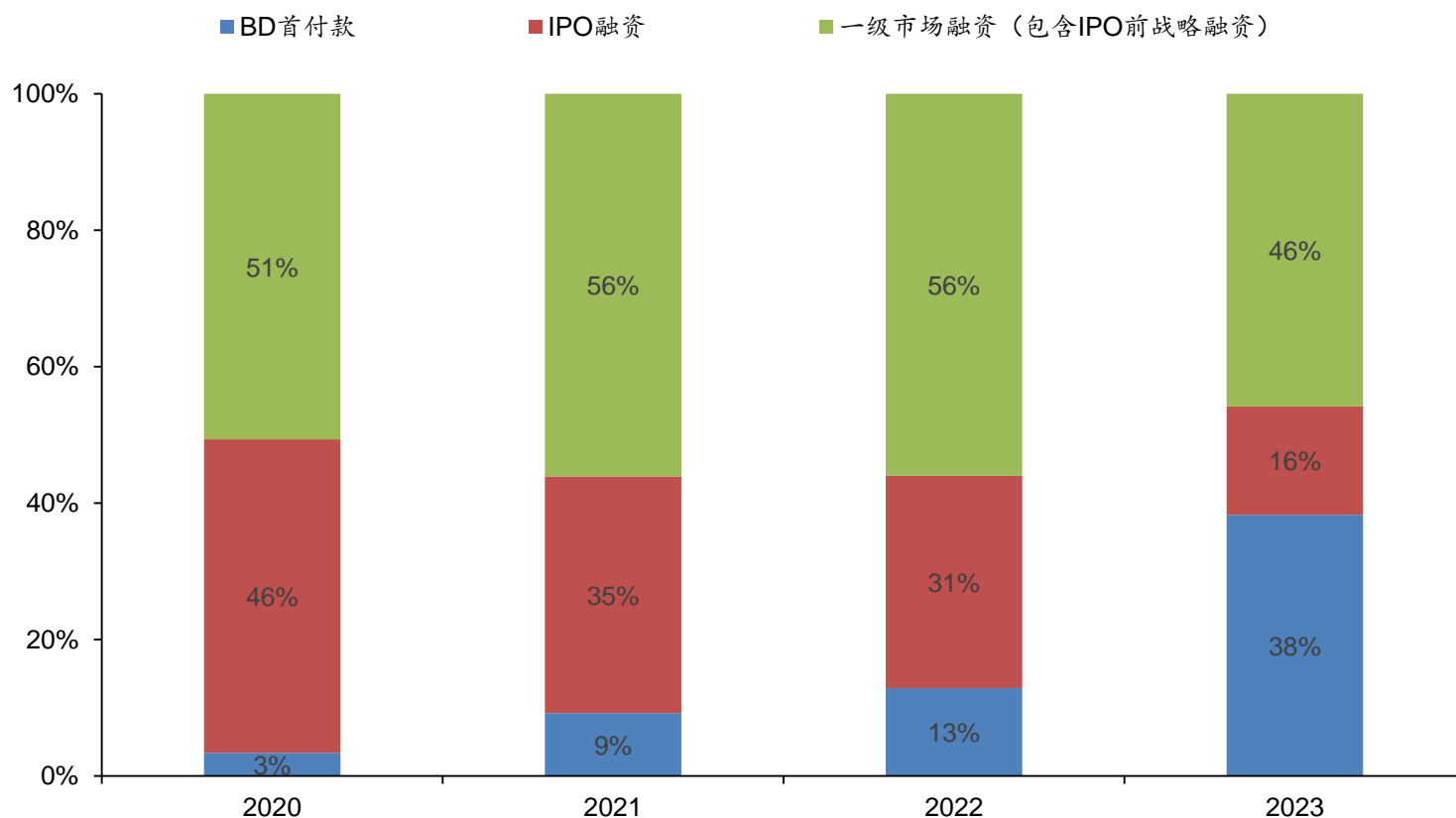


资料来源：动脉网，HTI

3. 2020-2023年中国创新药融资结构变化

- 中国创新药融资结构逐渐变化。2023年中国创新药企业通过项目BD获得的首付款总额到达210.21亿元，占比38%，首次超过IPO渠道募资总额。

图：2020-2023年中国创新药融资结构占比



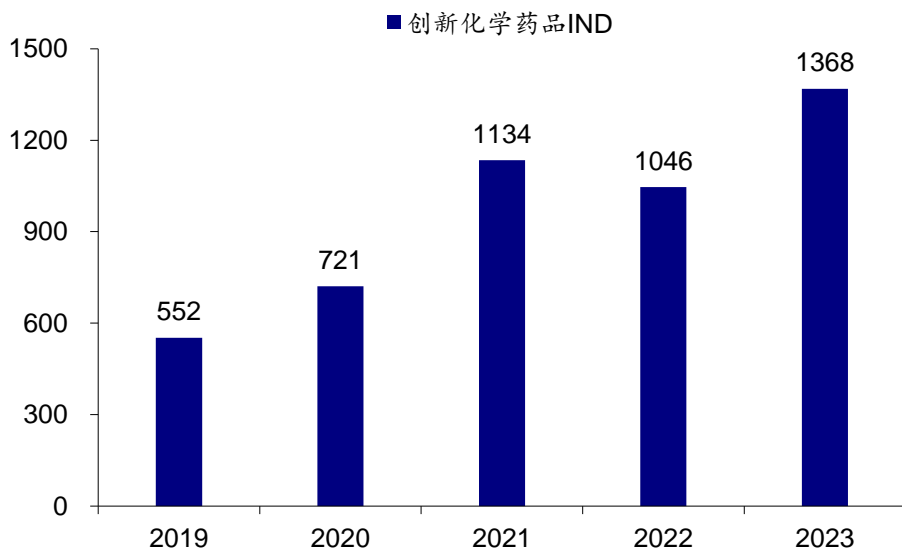
资料来源：医药魔方公众号，HTI

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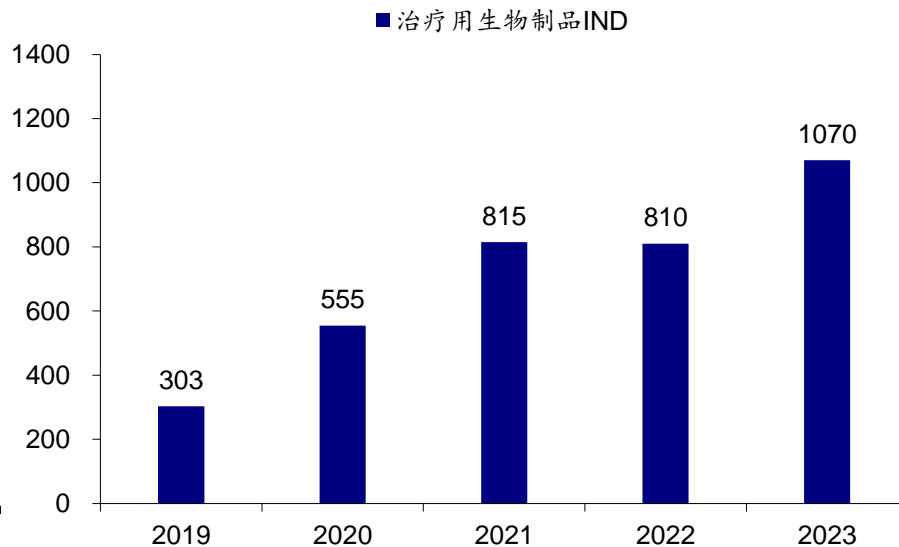
4. 2023年CDE创新药物IND审评情况

- 国内创新药物IND仍保持增长趋势。2023年国内创新化学药品IND数量为1368件，同比2022年增加31%；2023年国内治疗用生物制品IND数量为1070件，同比2022年增加32%。

图：2019-2023年国内创新化学药品IND数量（件）



图：2019-2023年国内治疗用生物制品IND数量（件）

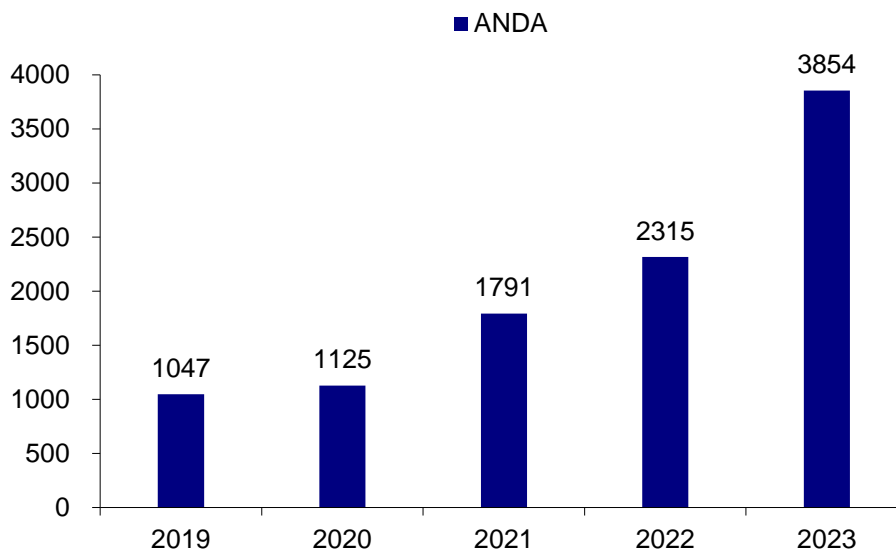


资料来源：CDE，HTI

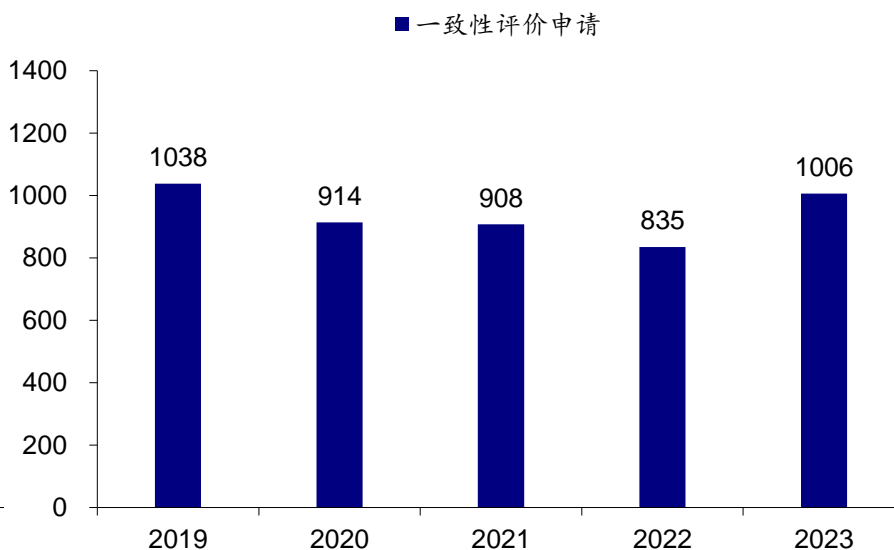
5. 2023年CDE仿制药物审评情况

- 国内仿制药注册申请数量仍保持增长趋势。2023年国内化学药品ANDA数量3854件，同比2022年增加66%；2023年国内化学药品一致性评价申请数量为1006件，同比2022年增加20%。

图：2019-2023年国内化学药品ANDA数量（件）



图：2019-2023年国内化学药品一致性评价申请数量（件）

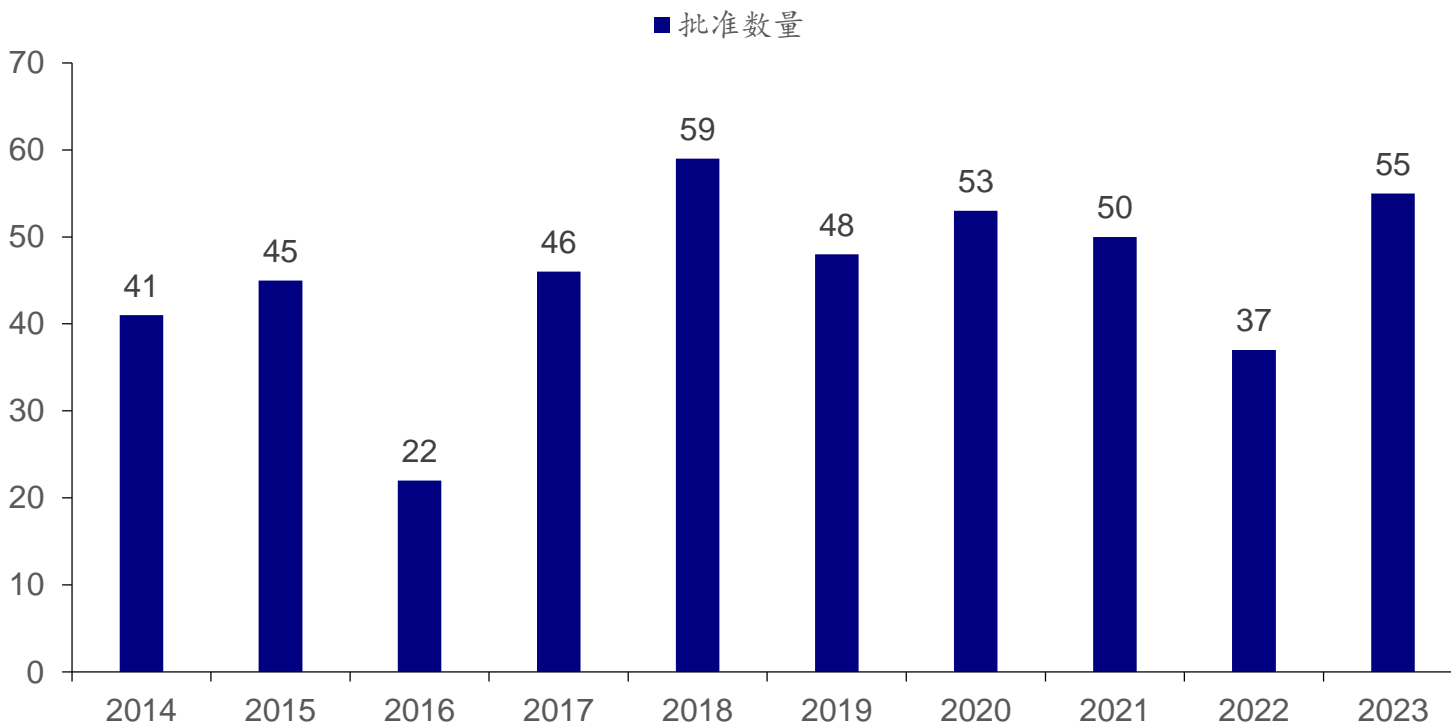


资料来源：CDE，HTI

6. 2023年FDA创新药物审评情况

- 2023年，CDER批准了55个新药。从2014年到2023年，CDER平均每年批准约46个新药。

图：2014-2023年FDA CDER批准的新药数量（件）



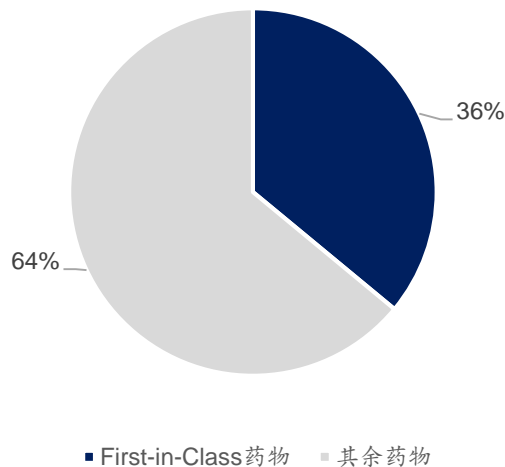
资料来源：FDA，HTI

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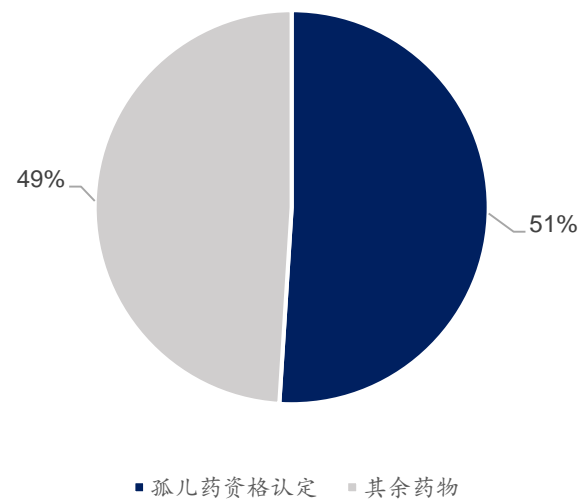
6. 2023年FDA创新药物审评情况

- 在2023年获批的55个新药中，CDER认定20个(36%)为First-in-Class药物。这些药物具有不同于现有疗法的作用机制。
- 在2023年获批的55个新药中，有28个(51%)获得了孤儿药认定，因为它们针对罕见病(在美国影响不到20万人的疾病)。罕见病患者通常很少或根本没有可用于治疗疾病的药物。

图：2023年CDER批准的First-in-Class药物占比



图：2023年CDER批准的药物中获得孤儿药资格认定的占比

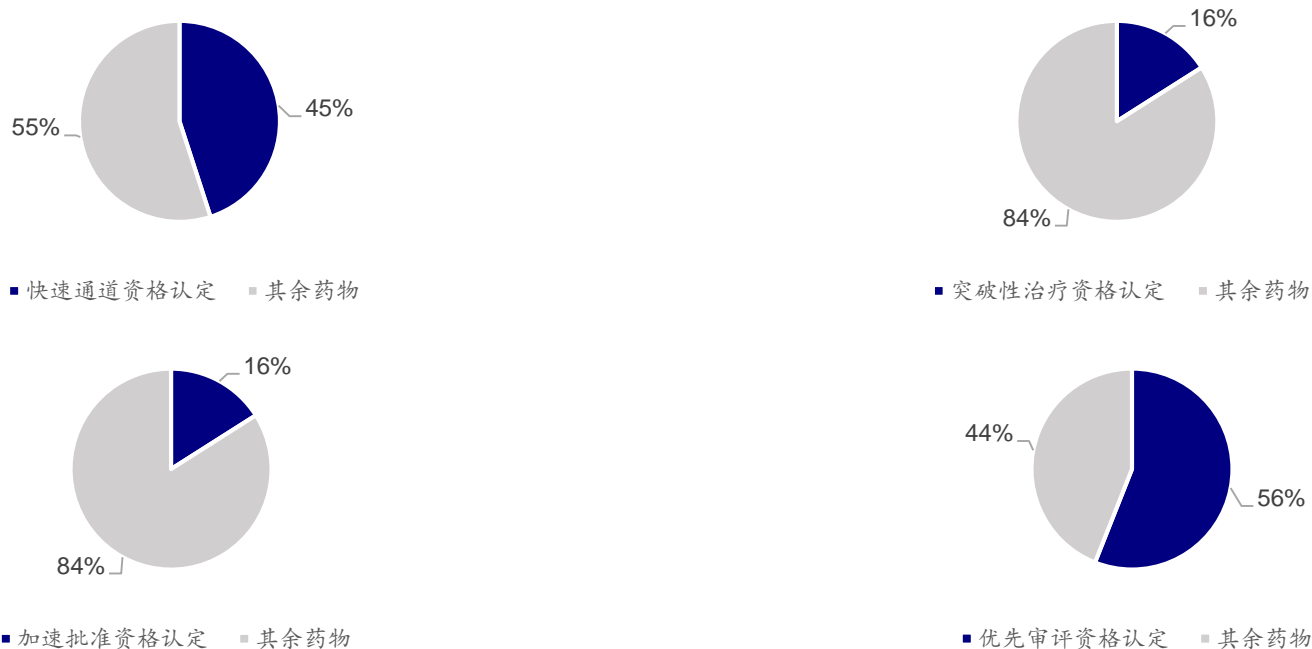


资料来源：FDA，HTI

6. 2023年FDA创新药物审评情况

- 在2023年获批的55个新药中：
 - 有25个(45%)授予快速通道。快速通道通过提高FDA与药物研发人员之间的沟通水平，并使CDER能够滚动审评药品申请的部分内容，加快了新药和生物制品的研发和审评。
 - 有9个(16%)被指定为突破性治疗。突破性治疗认定包括快速通道计划的所有特征，并在药物开发过程中提供强化的FDA指导，包括高级管理人员的参与。
 - 有31个(56%)被指定为优先审评。如果CDER确定一个药可治疗严重疾病，并且如果获得批准，将显著改善治疗诊断或预防严重疾病的安全性或有效性，则该药将接受优先审评。
 - 9个(16%)在加速审批途径下批准。该计划旨在将能够为未满足的医疗需求提供治疗的药物以比传统批准途径更快的时间表上市。

图：2023年CDER批准的药物中获得快速通道、突破性治疗、加速批准、优先审评资格认定的占比



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7. 风险提示

- 医药行业政策变化风险，中美贸易摩擦风险，创新药械研发进展风险，全球生物医药投融资增速下滑风险，医疗事故风险，公司收入利润增速不达预期风险

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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.

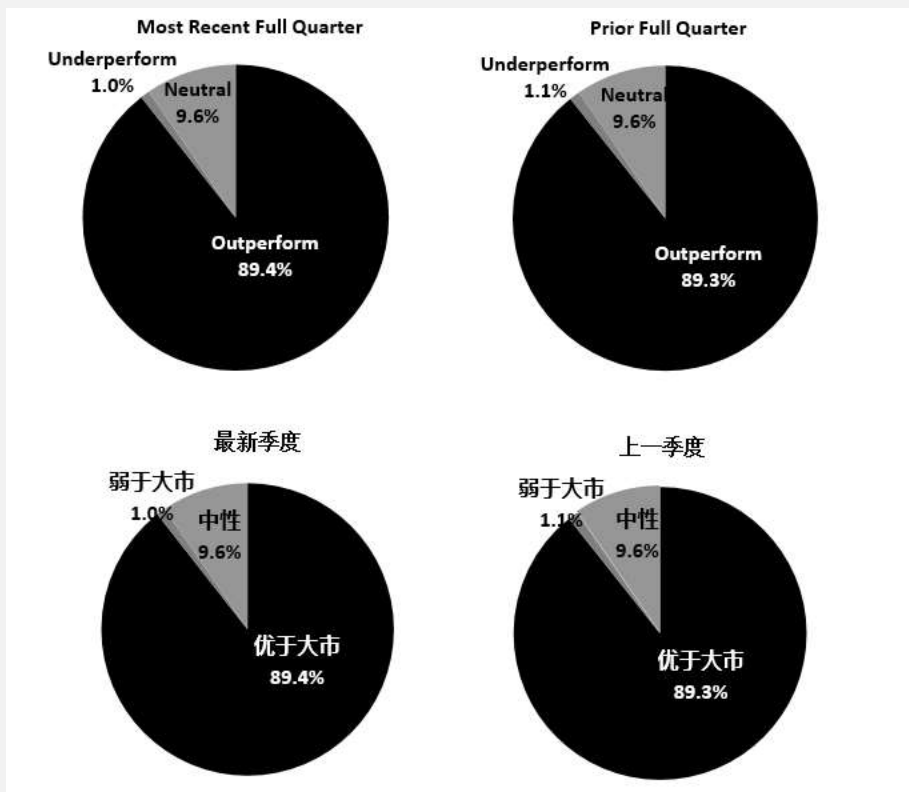
Neutral: The stock's total return over the next 12-18 months is expected to be in line with the return of its relevant broad market benchmark, as indicated below. For purposes only of FINRA/NYSE ratings distribution rules, our Neutral rating falls into a hold rating category.

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

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.

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评级分布 Rating Distribution



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截至2023年12月31日海通国际股票研究评级分布

	优于大市	中性 (持有)	弱于大市
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海通国际股票研究覆盖率	89.4%	9.6%	1.0%
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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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买入，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。

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

各地股票基准指数：日本–TOPIX, 韩国–KOSPI, 台湾–TAIEX, 印度–Nifty100; 其他所有中国概念股–MSCI China.

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	Outperform	Neutral (hold)	Underperform
HTI Equity Research Coverage	89.4%	9.6%	1.0%
IB clients*	3.9%	5.1%	5.6%

*Percentage of investment banking clients in each rating category.

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

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