



荣昌生物三季度业绩展示

2023 Third Quarter Presentation

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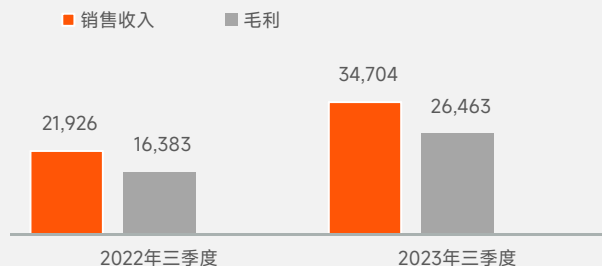
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财务数据

FINANCIAL
DATA

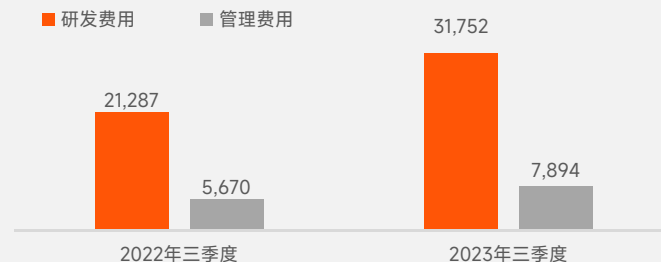
01

销售收入及毛利（人民币万元）



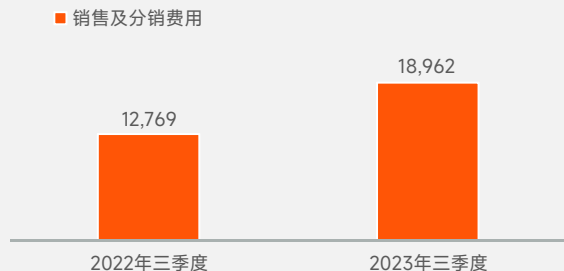
- 主要是由于注射用泰它西普和注射用维迪西妥单抗销量增加，销售收入增加。

研发费用及管理费用（人民币万元）



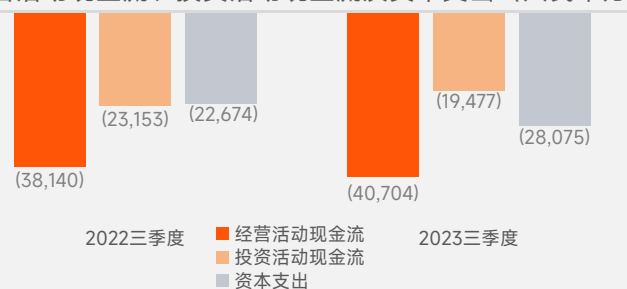
- 主要是由于本期新药研发管线增加、多个创新药物处于关键试验研究阶段导致临床试验费、材料费等费用增加；研发人员增加、员工工资水平上涨导致人员费用增加。
- 行政开支增加主要由于2023年三季度业务继续扩张

销售费用（人民币万元）



- 销售及分销费用增加主要由于2023年三季度上市产品市场营销的不断增长

经营活动现金流、投资活动现金流及资本支出（人民币万元）



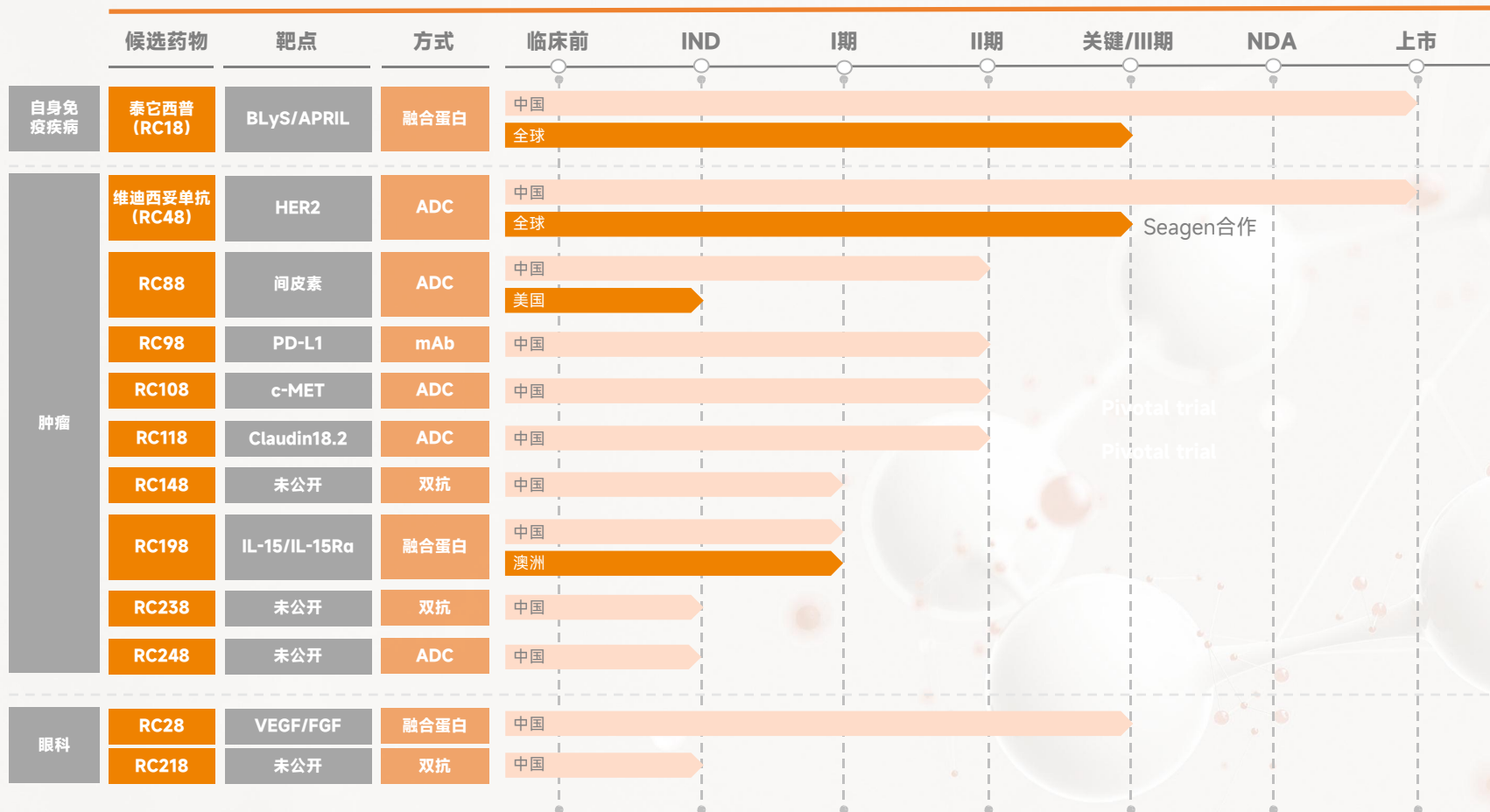
- 经营活动现金流为负主要归因于各期除税前净亏损
- 投资活动现金流主要为新生产设施建设
- 资本支出主要用于厂房建设和设备购买以及上海研发中心土地。

研发进展

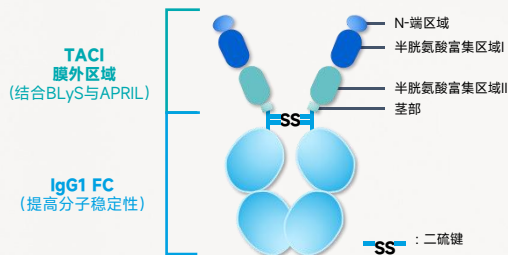
R&D DEVELOPMENT

02

状态 (状态栏显示临床试验地点)

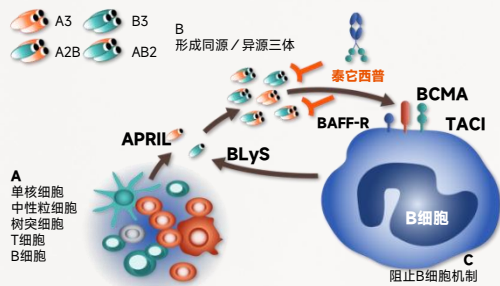


分子结构示意图



有望成为全球治疗系统性红斑狼疮 (SLE) 同类最佳治疗药物

双重靶向作用机制



有潜力用于治疗多种B-CELL介导的自身免疫疾病

状态 (状态栏显示临床试验地点)

适应症	临床前	IND	I期	II期	关键/III期	NDA	上市
系统性红斑狼疮	中国						
儿童系统性红斑狼疮	中国						
狼疮肾炎	中国						
视神经脊髓炎频谱系疾病	中国						
类风湿关节炎	中国						
IgA肾炎	中国						
干燥综合征	中国						
多发性硬化症	中国						
重症肌无力	中国						
IgG4-RD	中国						

RA (中国)

已于2023Q3递交BLA

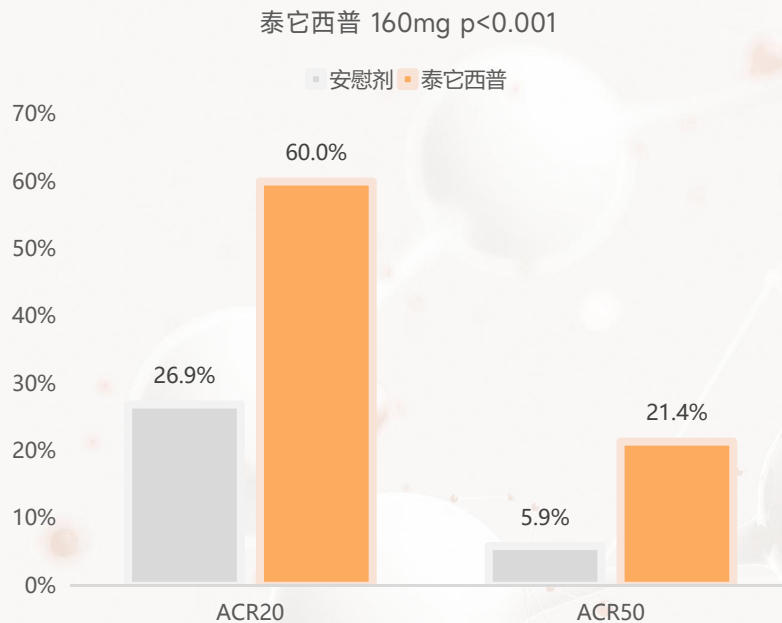
III期临床试验

入组**479例**受试者

- 360例患者使用泰它西普160mg
- 119例安慰剂对照

临床数据已向2023年ACR Meeting 投稿

III期临床试验第24周有效性数据



MG (中国)

III期临床已于2023Q2实现FPI

III期临床试验

计划招募**100例**受试者

1:1随机分配至240mg组或安慰剂组

CDE: 突破性治疗品种

II期临床试验有效性数据

QMG: -7.7

QMG: -9.6

160mg, n=14

240mg, n=15

PSS (中国)

III期临床已于2023Q2实现FPI

III期临床试验

计划招募**375例**受试者

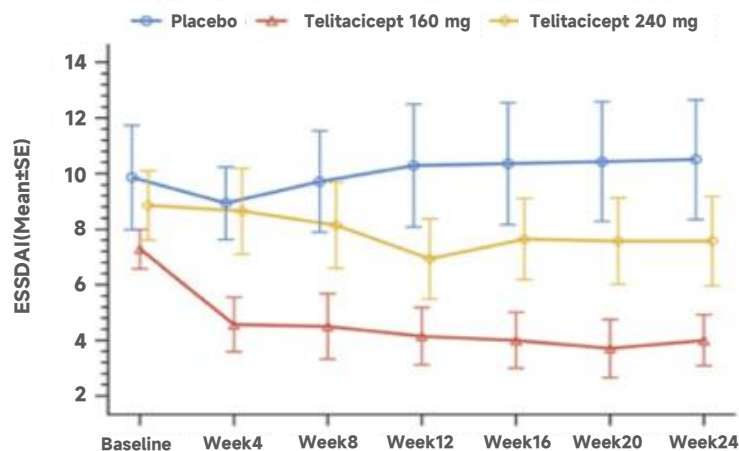
1: 1: 1随机分配至80mg组、160mg组、
或安慰剂组



British Society for
Rheumatology

RHEUMATOLOGY

II期临床试验有效性数据



IGAN (中国)

III期临床已于2023Q2实现FPI

III期临床试验

计划招募**308例**受试者

1:1 随机分配至240mg组或安慰剂组

KI REPORTS
KIReports.org

CLINICAL RESEARCH

Randomized Phase 2 Trial of Telitacicept
in Patients With IgA Nephropathy
With Persistent Proteinuria

 Check for updates

II期临床试验有效性数据

尿蛋白下降:
25%

尿蛋白下降:
49%

160mg, n=16

240mg, n=14

SLE

Global phase III study is ongoing, and we plan to further accelerate the process of this phase III study.

MG

Achieved orphan drug and fast-track designations. Also got the clinical approval of phase III study in US.

Telitacicept

Priority will be given to marketing MG in the US
To promote registered trials for other indications concurrently

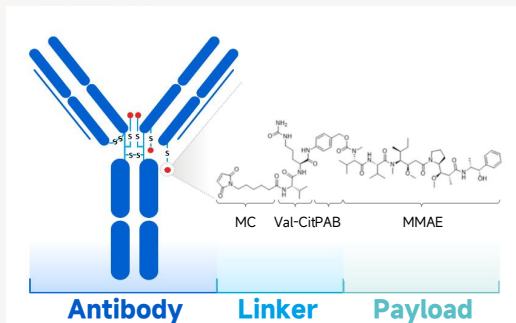
IGA Nephritis

Reached consensus with FDA for the phase III study

PSS

Reached consensus with FDA for the phase III study

Clinical Progress of Disitamab Vedotin (RC48)



UC

- RC48 has achieved considerable progress in the phase II study for neoadjuvant UC patients
- Maintain the leading position in the UC indication, and continue to promote earlier lines treatment for UC patients including first line treatment, neoadjuvant treatment and treatment for NMIBC

GC

To promote the earlier line treatment studies in the GC field

BC

To promote the earlier line treatment studies as well as HER2-low-expressing studies in the BC area

Status (Clinical Sites Indicated on Status Bar)

Indications	Pre-IND	IND	PhI	PhII	Pivotal/PhIII	NDA	Launched
HER2-expressing GC	China						
HER2-expressing UC	China						
Combined with PD-1 to treat HER2-expressing perioperative MIBC patients	China						
Combined with PD-1 to treat HER2-expressing first line UC patients	China						
Combined with Gemcitabine bladder instillation for NMIBC	China						
HER2-expressing UC	Global						Cooperation with Seagen
Combined with PD-1 to treat HER2-expressing first-line UC patients	Global						Cooperation with Seagen
HER2-low-expressing BC	China						
HER2 positive BC with liver metastasis	China						
HER2-low-to non-expressing UC	China						
HER2-expressing gynecology malignant tumor	China						
HER2-expressing melanoma	China						
Neoadjuvant therapy for HER2-expressing BC	China						
Combination treatment for HER2-expressing first-line GC patients	China						
Combined with PD-1 to treat cervical cancer	China						
Combined with radio therapy to treat HER2-expressing solid tumors	China						
Neoadjuvant therapy for HER2-expressing GC	China						
Second line HER2-expressing GC patients	China						
HER2-expressing prostatic cancer	China						
Combined with PD-1 to treat HER2-low-expressing first-line BC patients	China						

- The phase III study of RC48 combined with PD-1 to treat first-line UC patients is ongoing.
- With completion of enrollment and positive signal has been observed for the phase II study of RC48 combined with PD-1 to treat neoadjuvant MIBC patients, we plan to communicate with CDE for a confirmatory trial.
- The phase I/II IND of RC48 combined with Gemcitabine bladder instillation was approved in Jan, 2023, it further achieved FPI. Enrollment is ongoing.
- The paper of key clinical trial data of RC48 to treat second-line HER2-expressing UC patients has been accepted by JCO.

2023 ASCO[®]
ANNUAL MEETING

Journal of Clinical Oncology[®]
An American Society of Clinical Oncology Journal

GC

- The IND of RC48 combined with PD-1 and Herceptin to treat first-line HER2-expressing GC patients has been approved by CDE, and the trial is ongoing.
- We have further submitted IND application for RC48 combined with Cadonilimab to treat second-line GC patients, and we expect to get the approval within the year.

BC

- CDE has approved a phase II study of RC48 combined with PD-1 or Letrozole to treat neoadjuvant HR positive, HER2-low-expressing BC patients. We have already got FPI.
- CDE has approved a phase II study of RC48 combined with PD-1 or sequential chemotherapy to treat neoadjuvant HR negative, HER2-low-expressing BC patients. We have already got FPI.
- CDE has approved a phase II study of RC48 combined Pertuzumab with or without PD-1 to treat neoadjuvant HER2 positive BC patients. We have already got FPI.

Gynecological Oncology

- RC48 in combination with Zimberelimab to treat at least first-line platinum-containing standard PD-1/PD-L1 treated recurrent or metastatic cervical cancer with HER2-expressing has been approved by CDE.

Pivotal Study for Second-line UC Patients

Code	—	G001	Cohort 1	—	HER2 positive
Region	—	Global	Cohort 2	—	HER2-low-expressing
			Cohort 3	—	Combination with PD-1

Global:

Treatment for Second-line US Patients (Seagen)

Enrollment ongoing

Phase III Study of First-line UC Patients

Code	—	DV001	Control Group	—	Chemotherapy
Region	—	Global	Planned	—	700 patients
Combination	—				

Keytruda

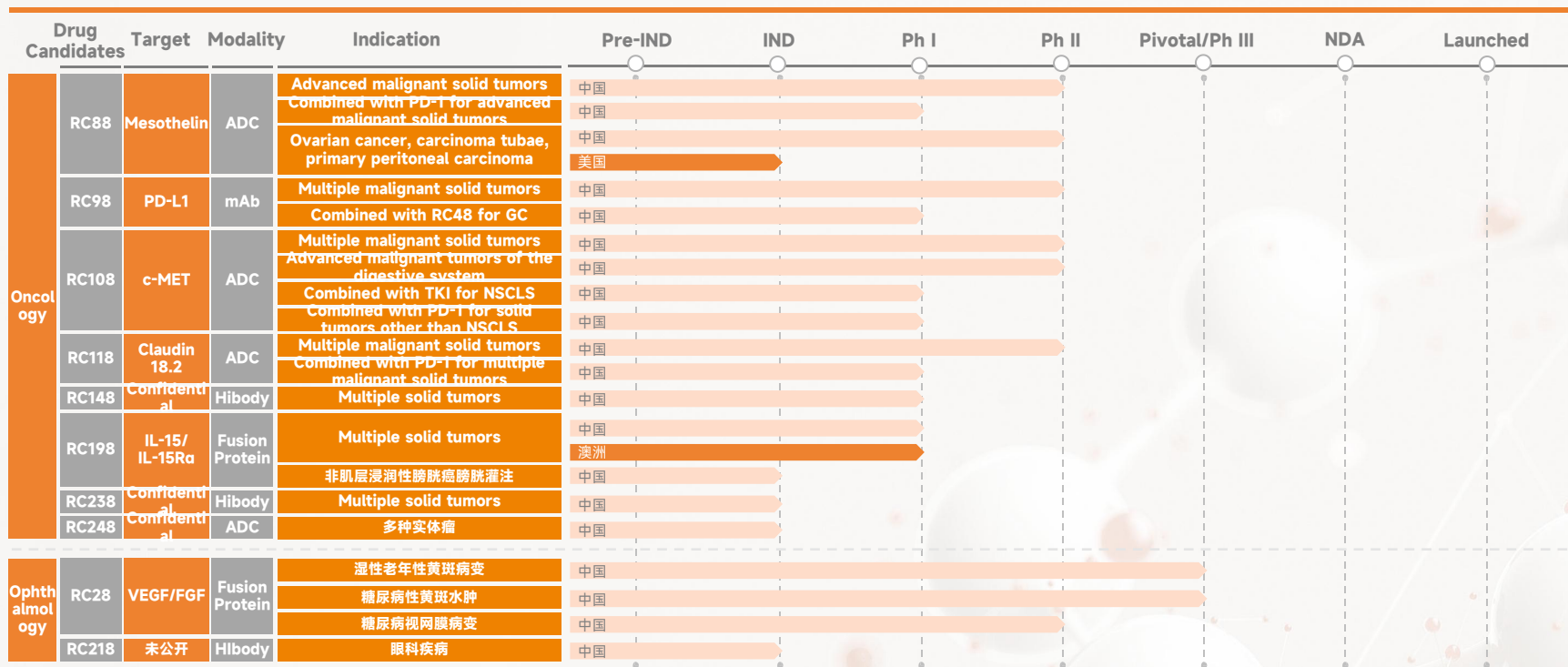
Global:

Combination with Keytruda for first-line UC Patients (Seagen)

Enrollment ongoing

Clinical Progress of Other Molecules

Status (Clinical Sites Indicated on Status Bar)



RC198 中国：I期临床试验已实现首例病人入组

RC28 中国：DMEIII期临床试验已实现首例病人入组

RC118 中国：完成I期的剂量爬坡阶段

RC148 中澳：I期临床试验均已实现首例病人入组

RC88 中国：已向CDE申报关键性临床研究方案

RC118 中国：联合PD1的I/IIa期临床试验，已完成首例入组

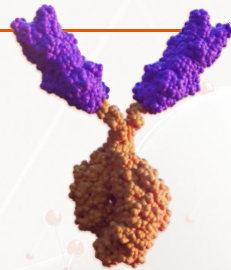
COMMERCIALIZATION 03

泰爱[®]

- 泰它西普成功纳入《国家医保药品目录（乙类）》
- 已组建超过700人的专业销售团队
- 已准入超过750家核心地级城市的三甲或综合医院
- 已覆盖超过2300家医院
- 已覆盖超过23000名目标医生
- 产品疗效获广泛认可，Q3单季度销售收入超过1.8亿元

全球首款、同类首创（first-in-class）的BLyS/APRIL双靶点新型重组TACI-Fc融合蛋白产品泰它西普，在系统性红斑狼疮取得了令人瞩目的疗效，有望成为全球SLE**同类最佳**治疗药物

对于其他B细胞介导自身免疫疾病（包括IGA肾炎、干燥综合征、重症肌无力）等疾病均有良好的疗效，有潜力成为治疗**多种B细胞介导自身免疫疾病的重磅药物**



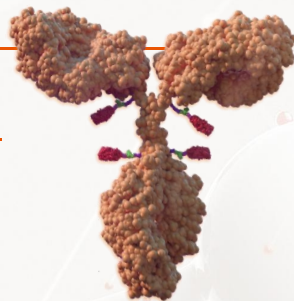
爱地希[®]

- 成功纳入《国家医保药品目录（乙类）》
- 已组建近600人的专业销售团队
- 已准入近650家核心地级城市的三甲或综合医院
- 已覆盖超过2000家医院
- 已覆盖超过24000名目标医生
- 已取得差异化竞争优势，Q3单季度销售收入超过1.5亿元

中国首款自主研发的ADC创新药、目前唯一一款同时获中国、美国**突破性疗法**认定的中国ADC产品

在**尿路上皮癌**领域具有显著的优势地位

在前线胃癌、HER2低表达乳腺癌等领域具有一定优势





RemeGen
荣昌生物

01

泰它西普推进多适应症全球开发，打造B淋巴细胞介导的自免药物领导者。

02

维迪西妥单抗加快国内临床，支持Seagen多适应症全球开发，构建差异化竞争优势。

03

提升ADC平台技术，开发新一代 FIC/BIC ADC 药物。

04

深耕国内销售，深化国际合作，实现商业化双轮驱动。



Remegen
荣昌生物