

公司/行业动态

金斯瑞生物科技 [1548.HK, 7.15港元, 未评级] - CAR-T会否带来额外60%的增长

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金斯瑞生物科技现有的CRO业务(占总收入超过80%)有望在2017年和2018年实现稳定的高双位数增长。随着FDA在2017年8月31日批准诺华公司的CAR-T(嵌合抗原受体T细胞疗法)药物Kymriah, CAR-T成为了市场焦点。金斯瑞作为领先的CAR-T临床研究公司(中国的其他CAR-T项目仍处于非常早期或未成熟阶段),其股价大幅飙升。我们认为公司的CAR-T治疗多发性骨髓瘤的潜力尚未完全反映。考虑到股价从高位下跌了25%,相信现在是重新关注该股份的好时机。根据彭博共识预测,公司的2017/18年市盈率为59/46倍。这估值仍远低于直接可比的CRO公司药明生物(2269.hk)(根据彭博共识预测,2017/18年市盈率为116/68倍)。

公司背景: 金斯瑞生物科技(金斯瑞)成立于2002年,是一家生命科学研究与应用服务及产品供货商,业务覆盖全球多个国家。在17年上半年,公司的收入有约83.6%来自生命科学研究服务(即是CRO,以合约方式向生物技术和医疗器械公司提供外包研究服务的组织)。其余5.5%、3.5%和7.4%的收入分别来自生命科学研究目录产品、临床前药物研发服务和工业合成生物产品。该公司于2015年在港交所上市。

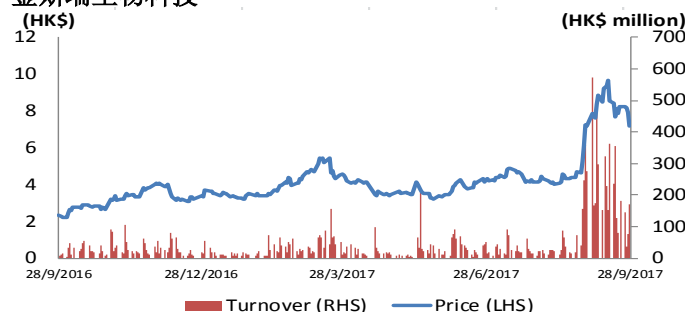
明星药物CAR-T: 2017年8月27日,吉利德科学公司斥资119亿美元收购Kite以取得旗下的CAR-T,预计这是继诺华公司的KYMRIAH(于17年8月31日获批)后第二个获得FDA批准的CAR-T。诺华公司的KYMRIAH用于B细胞急性淋巴细胞白血病(ALL),而金斯瑞的CAR-T则用于多发性骨髓瘤。

金斯瑞的CAR-T较竞争对手拥有优势: 金斯瑞的CAR-T结构涉及双链抗体靶点,对比竞争对手为单链靶点。金斯瑞已完全开发并拥有双链抗体靶点的专利,目前没有竞争对手拥有这技术知识。双链抗体靶点比单链靶点更能捕捉癌细胞。

金斯瑞的CAR-T研发和推出时间表: 目前公司的CAR-T临床研究(留意它们不是临床试验,因为公司尚未向CFDA提交资料,而在中国,CAR-T相关政策尚未出台)。目前,该公司的临床研究涉及70名患者,管理层预计将扩大到100名患者。根据我们的理解,我们认为约100名患者的数目仍远远不够(特别是未来的III期临床试验)。然而,在正面的发展方面,管理层的目标是2017年底前在美国提交IND申请,并预计在2018年第一季取得临床试验批准。如果进展顺利,我们预计公司需要2年完成美国临床试验,并在约2020年推出。

金斯瑞的CAR-T销售前景: 诺华的KYMRIAH价格为475,000美元,用于B细胞ALL。金斯瑞的CAR-T用于多发性骨髓瘤。多发性骨髓瘤在中国和美国的发病率约为~3-5 / 100,000人,即是中国和美国每年约有20,000 / 20,000名患者。由于预计多发性骨髓瘤患者的寿命约5年,中国和美国多

金斯瑞生物科技



市值: 15.79亿美元; 自由流通量: 40.18%

	2015A	2016A	2017E	2018E	2019E
收入 (百万美元)	114.7	138.5	138.5	168.5	232.0
EBIT (百万美元)	24.9	34.6	47.7	47.7	64.0
净利润 (百万美元)	26.2	28.1	36.2	36.2	44.4
同比变动	49.5%	7.2%	29.1%	22.7%	22.7%
净利润率	22.8%	20.3%	21.5%	21.5%	19.1%
经调整每股盈利 (美元)	0.0157	0.0155	0.0200	0.0200	0.0240
同比变动	9.8%	-1.3%	29.0%	20.0%	20.0%
股本回报率 (%)	16.0	15.4	18.3	18.3	20.1
股息收益率 (%)	0.2	0.1	0.1	0.1	0.1
市盈率(倍)	58.6	58.9	45.6	45.6	38.0
市净率(倍)	8.8	9.1	9.1	9.1	9.1

来源: 彭博

发性骨髓瘤的市场总规模可能达到20万人。如果金斯瑞将其CAR-T价格设于50万元人民币(约诺华KYMRIAH的1/6),再假设公司的价格优势使其取得5%市场份额(即医治约10,000名患者),则有可能产生约50亿元人民币的总收入。假设利润率为30%,有望在2022年前后为公司产生约15亿元人民币的利润,如果假设贴现率为10%,那么为2018年带来的利润现值为10亿元人民币。如果假设CAR-T的2018年市盈率为20倍,则金斯瑞的CAR-T的价值约为每股11.6港元,相当于60%的额外上升空间。

估值: 根据彭博共识预测,公司的2017/18年市盈率为59/46倍。这估值仍远低于直接可比的CRO公司药明生物(2269.hk)(根据彭博共识预测,2017/18年市盈率为116/68倍)。此外,考虑到公司CAR-T的潜力,再加上股价较高位回落超过25%,我们认为现时或是一个不错的进场时机。

催化剂: 有关于CAR-T项目的消息。

风险: 研发过程慢于预期;在多发性骨髓瘤的CAR-T项目方面,公司或面对国际大型企业的竞争(如Kite和Bluebird)。

COMPANY / INDUSTRY NEWS

Genscript Biotech Corporation [1548.HK, HK\$7.15, NOT RATED] – Another 60% upside from CAR-T?

Analyst: Harry He (harryhe@chinastock.com.hk; Tel: (852) 3698 6320;

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Genescript Biotech's (GS) existing CRO business (>80% revenue contribution) is expected to deliver stable high-teen growth in 2017 and 2018. With the FDA's recent approval on Novartis' KYMRIAH CAR-T (Chimeric Antigen Receptor T-cell immune therapy, 嵌合抗原受體T細胞療法) on Aug 31, 2017, CAR-T has become a market star. As a leading CAR-T clinical study Company (other CAR-T projects in China are at a very early/immature stage, Figures 1-6), its share price has surged sharply. We believe GS's CAR-T potential to cure Multiple myeloma (多發性骨髓瘤, MM) has not yet been fully revealed. With its share price down 25% from its peak, we believe it is good time to revisit the stock.

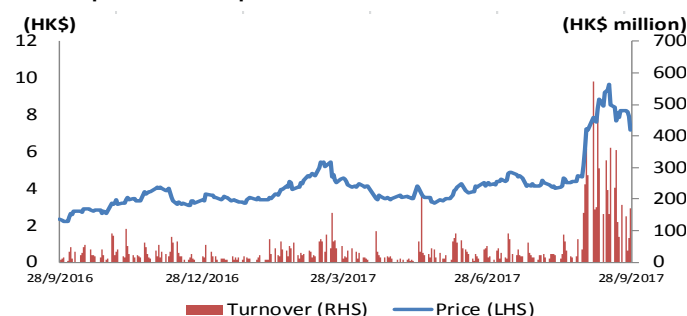
Background: Established in 2002, GS is a life sciences research and application service and product provider with comprehensive global portfolio coverage. In 1H2017, GS generated approximately 83.6% of its total revenue from life sciences research services (i.e. essentially CRO, which is an organization that provides support to pharmaceutical, biotechnology, and medical device companies in the form of outsourced research services on a contract basis). The remaining 5.5%, 3.5%, and 7.4% of its total revenue comes from life sciences research catalog products, preclinical drug development services, and industrial synthetic biology products, respectively. The Company was listed on the HKEx in 2015.

CAR-T, a market star: On August 27, 2017, Gilead Sciences paid US\$11.9bn to acquire Kite for its CAR-T, which is expected to be the second FDA-approved CAR-T after Novartis's KYMRIAH (approved on Aug 31, 2017). Novartis KYMRIAH is used for *B-cell Acute lymphoblastic leukemia* (B細胞急性淋巴細胞白血病, ALL), while GS's CAR-T is indicated for *MM*.

GS's CAR-T advantages over its competitors: The structure of GS's CAR-T involves two light-chain antibody targeting (雙鏈抗體靶點) vs. single targeting for its competitors (單鏈靶點). GS fully developed and owns the double antibody targeting patent, and currently no competitors have this technology know-how. Double chain antibody targeting is more efficient than single for capturing cancer cells.

GS's CAR-T R&D and launch schedule: Currently GS's CAR-T clinical studies (note that they are not clinical trials, as it has not submitted data to the CFDA yet, and in China, CAR-T-related policies have not yet been published). Currently, GS's clinical studies include 70 patients, and management expects to expand this to 100 patients. Based on our understanding, we think ~100 patients are far from enough (especially for the future Phase III clinical trial). However, one positive development is that management aims to file its IND application in the U.S. by end-2017 and expects to get clinical trial approval in Q1 2018. If things go smoothly, we expect it to take ~2 years to complete the U.S. clinical trials, followed by a launch in ~2020.

Genscript Biotech Corporation



Market Cap: US\$1579m; Free Float: 40.18%

	2015A	2016A	2017E	2018E	2019E
Revenue (USDm)	86.7	114.7	138.5	168.5	232.0
EBIT (USDm)	16.5	24.9	34.6	47.7	64.0
Net profit (USDm)	17.5	26.2	28.1	36.2	44.4
YoY %	182.3%	49.5%	7.2%	29.1%	22.7%
Net margin	20.2%	22.8%	20.3%	21.5%	19.1%
EPS Adj+ (USD)	0.0143	0.0157	0.0155	0.0200	0.0240
YoY %	n.a	9.8%	-1.3%	29.0%	20.0%
ROE (%)	16.6	16.0	15.4	18.3	20.1
Dividend yield (%)	0.0	0.2	0.1	0.1	0.1
PER (x)	64.0	58.6	58.9	45.6	38.0
PBR (x)	9.8	8.8	9.1	9.1	9.1

Source: Bloomberg

GS's CAR-T sales outlook: Novartis' KYMRIAH price is US\$475,000, indicated for B-cell ALL. GS's CAR-T is indicated for *MM*. *MM*'s incidence rate is ~3-5/100,000 in China and the U.S., i.e. ~20,000/20,000 patients each year in China and the U.S. With the expected life span of *MM* patients of ~5 years, the total market size of *MM* in China and U.S could be ~200,000 patients. If GS prices its CAR-T at RMB500,000 (or ~1/6 of Novartis' KYMRIAH), and if we assume it achieves a 5% market share due to its price advantage (i.e. treating ~10,000 patients), it could generate total revenue of about RMB5bn. Assuming a 30% profit margin, this would generate profit of about RMB1.5bn in ~2022, or ~RMB1bn in 2018 in terms of present value if we use a discount rate of 10%. If we give CAR-T a 20x PER for 2018, GS's CAR-T is worth ~HK\$11.6/share, i.e. another 60% upside.

Valuation: The Company is trading at 59/46x 2017/18E Bloomberg consensus PER (total two estimates). This valuation is still much lower than its direct comparable CRO company Wuxi Bio (2269.hk) (68x 2018E PER). Also, given its CAR-T potential, we believe the current share price level after a >25% correction from its peak may be a good entry point.

Catalysts: News flow on CAR-T.

Risk: Slower-than-expected R&D progress, competition from some major international players with CAR-T projects indicated for *MM*, such as Kite and Bluebird.

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Figure 1: CAR-T projects in China

ClinicalTrials.gov Search Results 09/27/2017

	Title	Recruitment	Study Results	Conditions	Interventions	Locations
1	CAR-T Cell Immunotherapy for HCC Targeting GPC3	Completed	No Results Available	•GPC3 Positive Hepatocellular Carcinoma •CAR-T Cell Immunotherapy	•Biological: CAR-T cell immunotherapy	•Central laboratory in Fuda cancer hospital, Guangzhou, Guangdong, China
2	CAR-T Cell Immunotherapy for EphA2 Positive Malignant Glioma Patients	Completed	No Results Available	•EphA2 Positive Malignant Glioma •CAR-T Cell Immunotherapy	•Biological: CAR-T cell immunotherapy	•Central laboratory in Fuda cancer hospital, Guangzhou, Guangdong, China
3	CAR-T Cell Immunotherapy for GD2 Positive Glioma Patients	Completed	No Results Available	•GD2 Positive Glioma •CAR-T Cell Immunotherapy	•Biological: CAR-T cell immunotherapy	•Central laboratory in Fuda cancer hospital, Guangzhou, Guangdong, China
4	CTLA-4 and PD-1 Antibodies Expressing MUC1-CAR-T Cells for MUC1 Positive Advanced Solid Tumor	Recruiting	No Results Available	•Advanced Solid Tumor	•Biological: Anti-CTLA-4/PD-1 expressing MUC1-CAR-T	•Ningbo No.5 Hospital (Ningbo Cancer Hospital), Ningbo, Zhejiang, China
5	Universal CD19-CART Treating ALL	Active, not recruiting	No Results Available	•Acute Leukemia	•Biological: universal CD19-CART	•Shanghai Biaray Inc., Shanghai, Shanghai, China
6	Safety and Efficacy Evaluation of IM19 CAR-T Cells	Recruiting	No Results Available	•Leukemia	•Biological: IM19 CAR-T	•Beijing hospital, Beijing, China
7	Humanized CAR-T Therapy for Treatment of B Cell Malignancy	Recruiting	No Results Available	•Leukemia, Lymphocytic, Chronic, B-Cell	•Biological: CAR-T	•Hualian First People's Hospital, Hualian, Jiangsu, China •Affiliated hospital of Xuzhou medical college, Xuzhou, Jiangsu, China
8	CD30-directed Chimeric Antigen Receptor T (CAR-T) Therapy in Relapsed and Refractory CD30 Positive Lymphomas	Recruiting	No Results Available	•Hodgkin's Lymphoma •Non-Hodgkin's Lymphoma	•Biological: CART30	•Chinese PLA General Hospital, Beijing, Beijing, China
9	PSCA/MUC1/PD-L1/CD80/86-CAR-T Cells Immunotherapy Against Cancers	Recruiting	No Results Available	•Lung Cancer •Cancer •Immunotherapy •CAR-T Cell	•Genetic: PSCA,MUC1,PD-L1,or CD80/86 targeting CAR-T cells	•The First Affiliated Hospital of Sun Yat-sen University, Guangzhou, Guangdong, China •The Second Affiliated Hospital of Guangzhou Medical University, Guangzhou, Guangdong, China
10	Study Evaluating the Efficacy and Safety With CAR-T for Relapsed or Refractory Neuroblastoma in Children	Recruiting	No Results Available	•Relapsed or Refractory Neuroblastoma	•Biological: GD2-targeted CAR-T cells	•Nanjing Children's Hospital, Nanjing, Jiangsu, China •Children's Hospital of Fudan University, Shanghai, Shanghai, China
11	CAR-T Therapy in Relapsed or Refractory Haematopoietic and Lymphoid Malignancies	Recruiting	No Results Available	•Leukemia •Lymphoma	•Biological: Autologous CAR-T	•Hematology Department, Hebei Medical University Fourth Hospital, Shijiazhuang, Hebei, China
12	The Sequential Therapy of CD19-targeted and CD20-targeted CAR-T Cell Therapy for Diffuse Large B Cell Lymphoma(DLBCL)	Active, not recruiting	No Results Available	•Lymphoma, Large B-Cell, Diffuse	•Biological: Anti-CD19 CAR-T cells and Anti-CD20 CAR-T cells	•Southwest Hospital of Third Military Medical University, Chongqing, Chongqing, China
13	Novel Autologous CAR-T Therapy for Relapsed/Refractory B Cell Lymphoma	Not yet recruiting	No Results Available	•B Cell Lymphoma	•Combination Product: CAR-T	
14	GPC3-T2-CAR-T Cells for Immunotherapy of Cancer With GPC3 Expression	Recruiting	No Results Available	•Hepatocellular Carcinoma •Immunotherapy •CAR •GPC3 Gene Inactivation •T Cell •Squamous Cell Lung Cancer	•Biological: GPC3 targeting CAR-T cells	•The First Affiliated Hospital of Sun Yat-sen University, Guangzhou, Guangdong, China •The Second Affiliated Hospital of Guangzhou Medical University, Guangzhou, Guangdong, China
15	A Clinical Research of Sequential CAR-T Bridging HSCT in the Treatment of Relapse/Refractory B-cell Malignancies	Active, not recruiting	No Results Available	•Lymphoma, Large B-Cell, Diffuse •Leukemia, Lymphocytic, Chronic, B-Cell •Lymphoma#Malignant	•Biological: CD19 or CD20 CAR T cells bridging HSCT	•Southwest Hospital of Third Military Medical University, Chongqing, Chongqing, China
16	A Study of GPC3 Redirected Autologous T Cells for Advanced HCC	Recruiting	No Results Available	•Carcinoma, Hepatocellular	•Drug: TAI-GPC3-CART cells	•Renji Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, Shanghai, China
17	A Clinical Research of CAR T Cells Targeting EpCAM Positive Cancer	Recruiting	No Results Available	•Colon Cancer •Esophageal Carcinoma •Pancreatic Cancer •Prostate Cancer •Gastric Cancer •Hepatic Carcinoma	•Biological: CAR-T cell immunotherapy	•IEC of Chengdu Medical College, Chendu, China

Source: FDA

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Figure 2: CAR-T projects in China

18	CAR-T for R/R B-NHL	Recruiting	No Results Available	*Relapsed Non Hodgkin Lymphoma *Refractory Non-Hodgkin Lymphoma *CAR - T CD19/CD20/CD22/CD30	*Biological: CAR-T	*the First Affiliated Hospital of Soochow University, Suzhou, Jiangsu, China
19	Phase I Study of CD19-CAR-T2 Cells for Patients With Chemotherapy Resistant or Refractory CD19+ Acute Leukemia	Recruiting	No Results Available	*Acute Leukemia	*Biological: CD19-CAR-T2 Cells	*Guangdong General Hospital, Guangzhou, Guangdong, China
20	Study Evaluating the Efficacy and Safety With CAR-T Immunotherapy for CD19 Positive Lymphoma	Not yet recruiting	No Results Available	*Lymphoma	*Biological: The Chimeric Antigen Receptor T Cell Immunotherapy (CAR-T)	*Jiangsu Cancer hospital, Nanjing, Jiangsu, China
21	Study Evaluating the Efficacy and Safety With CAR-T for Liver Cancer	Recruiting	No Results Available	*Liver Neoplasms	*Biological: EPCAM-targeted CAR-T cells	*Anhui No.2 Province People's Hospital, Hefei, Anhui, China
22	Study Evaluating the Efficacy and Safety With CAR-T for Stomach Cancer	Recruiting	No Results Available	*Stomach Neoplasms	*Biological: EPCAM-targeted CAR-T cells	*Anhui Provincial Cancer Hospital, Hefei, Anhui, China
23	CTLA-4 and PD-1 Antibodies Expressing EGFR-CAR-T Cells for EGFR Positive Advanced Solid Tumor	Recruiting	No Results Available	*Advanced Solid Tumor	*Biological: anti-CTLA-4/PD-1 expressing EGFR-CAR-T	*Ningbo No.5 Hospital (Ningbo Cancer Hospital), Ningbo, Zhejiang, China
24	CD22 Targeting CAR-T Therapy Against B Cell Hematological Malignancies	Recruiting	No Results Available	*Recurrent or Refractory B Cell Malignancy	*Biological: CD22 CAR-T	*Affiliated hospital of Xuzhou medical college, Xuzhou, Jiangsu, China
25	CAR-T Hepatic Artery Infusions for CEA-Expressing Liver Metastases	Recruiting	No Results Available	*Liver Metastases	*Biological: anti-CEA CAR-T cells	*University of Colorado Hospital, Aurora, Colorado, United States *Roger Williams Medical Center, Providence, Rhode Island, United States
26	Study Evaluating the Efficacy and Safety With CAR-T for Recurrent or Refractory Acute Non T Lymphocyte Leukemia	Recruiting	No Results Available	*Leukemia	*Biological: CD19-targeted CAR-T cells	*The Second Hospital of Anhui Medical University, Hefei, Anhui, China *No. 454 Hospital of People's Liberation Army, Nanjing, Jiangsu, China
27	Study Evaluating the Efficacy and Safety With CAR-T for Recurrent or Refractory Diffuse Large B Cell Lymphoma	Recruiting	No Results Available	*Lymphoma	*Biological: CD19-targeted CAR-T cells	*The First Affiliated Hospital of Anhui Medical University, Hefei, Anhui, China
28	The Effect of Chimeric Antigen Receptor (CAR)-T Cell Therapy on the Reconstitution of HIV-specific Immune Function	Not yet recruiting	No Results Available	*HIV/AIDS	*Biological: CAR-T cells	
29	A Clinical Research of CAR-T Cells Targeting HER2 Positive Cancer	Recruiting	No Results Available	*Breast Cancer *Ovarian Cancer *Lung Cancer *Gastric Cancer *Colorectal Cancer *Glioma *Pancreatic Cancer	*Biological: Anti-HER2 CAR-T	*Southwest Hospital of Third Military Medical University, Chongqing, Chongqing, China
30	A Clinical Research of BCMA-Targeted CAR-T in B Cell Malignancies	Recruiting	No Results Available	*Leukemia *Lymphoma *Multiple Myeloma	*Biological: Anti-BCMA-CAR-transduced T cells	*Southwest Hospital of Third Military Medical University, Chongqing, Chongqing, China
31	CAR-T Hepatic Artery Infusions and Sir-Spheres for Liver Metastases	Active, not recruiting	No Results Available	*Liver Metastases	*Biological: anti-CEA CAR-T cells *Device: Sir-Spheres	*Roger Williams Medical Center, Providence, Rhode Island, United States
32	A Clinical Research of CD30-Targeted CAR-T in Lymphocyte Malignancies	Recruiting	No Results Available	*Leukemia *Lymphoma	*Biological: Anti-CD30-CAR-transduced T cells	*Southwest Hospital of Third Military Medical University, Chongqing, Chongqing, China
33	Allogeneic CART-33 for Relapsed/Refractory CD33+ AML	Recruiting	No Results Available	*Relapsed and/or Refractory CD33+ AML	*Biological: allogeneic CART-33	*Affiliated Hospital of Academy of Military Medical Sciences, Beijing, Beijing, China *Chinese PLA General Hospital, Beijing, Beijing, China
34	CD19-targeting CAR-T Cells for B Cell Lymphoma	Completed	No Results Available	*B Cell Lymphoma	*Biological: CD19-targeting CAR T Cells infusion	*Central laboratory in Fuda cancer hospital, Guangzhou, Guangdong, China
35	A Clinical Research of CD20-Targeted CAR-T in B Cell Malignancies	Recruiting	No Results Available	*Leukemia *Lymphoma	*Biological: Anti-CD20-CAR-transduced T cells	*Southwest Hospital of Third Military Medical University, Chongqing, Chongqing, China
36	A Clinical Research of LeY-Targeted CAR-T in Myeloid Malignancies	Recruiting	No Results Available	*Myeloid Malignancies	*Biological: Anti-LeY-CAR-transduced T cells	*Southwest Hospital of Third Military Medical University, Chongqing, Chongqing, China

Source: FDA

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Figure 3: CAR-T projects in China

37	A Clinical Research of CD33-Targeted CAR-T in Myeloid Malignancies	Recruiting	No Results Available	*Myeloid Malignancies	*Biological: Anti-CD33-CAR-transduced T cells	*Southwest Hospital of Third Military Medical University, Chongqing, Chongqing, China
38	P-BCMA-101 Tscm CAR-T Cells in the Treatment of Patients With Multiple Myeloma (MM)	Recruiting	No Results Available	*Multiple Myeloma	*Biological: P-BCMA-101 CAR-T cells	*Sarah Cannon Research Institute, Nashville, Tennessee, United States *MD Anderson Cancer Center, Houston, Texas, United States
39	A Clinical Research of CD22-Targeted CAR-T in B Cell Malignancies	Recruiting	No Results Available	*Leukemia *Lymphoma	*Biological: Anti-CD22-CAR-transduced T cells	*Southwest Hospital of Third Military Medical University, Chongqing, Chongqing, China
40	A Clinical Research of CD123-Targeted CAR-T in Myeloid Malignancies	Recruiting	No Results Available	*Leukemia	*Biological: Anti-CD123-CAR-transduced T cells	*Southwest Hospital of Third Military Medical University, Chongqing, Chongqing, China
41	A Study of Mesothelin Redirected Autologous T Cells for Advanced Pancreatic Carcinoma	Recruiting	No Results Available	*Pancreatic Cancer	*Drug: TAI-meso-CART	*Renji Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, Shanghai, China
42	CD19 Chimeric Antigen Receptor (CAR)-Modified T Cell Therapy in Treating Patients With Acute Lymphocytic Leukemia	Recruiting	No Results Available	*Acute Lymphoblastic Leukemia	*Genetic: Second generation CAR-T cells	*Affiliated Union Hospital to Huazhong University of Science and Technology, Wuhan, Hubei, China
43	Allogeneic CART-19 for Elderly Relapsed/Refractory CD19+ ALL	Recruiting	No Results Available	*Leukemia	*Biological: allogeneic CART-19	*Affiliated Hospital of Academy of Military Medical Sciences, Beijing, Beijing, China *Chinese PLA General Hospital, Beijing, Beijing, China
44	CD19 CART Long Term Follow Up (LTU) Study	Recruiting	No Results Available	*Safety LTU, Pts Receiving CD19 Directed CAR T-Cell Therapy	*Genetic: Previously treated CART CD 19 patients	*Mayo Clinic Arizona Mayo Clinic Building, Phoenix, Arizona, United States *Childrens Hospital Los Angeles SC CTL019, Los Angeles, California, United States *University of California San Francisco SC-4, San Francisco, California, United States *Emory University School of Medicine/Winship Cancer Institute, Atlanta, Georgia, United States *Children's Healthcare of Atlanta SC CTL019, Atlanta, Georgia, United States *University of Chicago Medical Center, Hematology & Oncology, Chicago, Illinois, United States *University of Kansas Cancer Center SC, Westwood, Kansas, United States *University of Michigan Health System SC CTL019, Ann Arbor, Michigan, United States *University of Minnesota SC-4, Minneapolis, Minnesota, United States *Children's Mercy Hospital SC, Kansas City, Missouri, United States *and 24 more
45	Chimeric Antigen Receptor (CAR)-Modified T Cell Therapy in Treating Patients With Acute Lymphoblastic Leukemia	Recruiting	No Results Available	*Acute Lymphoblastic Leukemia	*Biological: Third generation CAR-T cells	*Department of Hematopoietic Stem Cell Transplantation, Beijing, China
46	CART19 in Patient With ALL	Recruiting	No Results Available	*Leukemia, Acute Lymphoblastic	*Biological: CART 19	*University of Pennsylvania, Philadelphia, Pennsylvania, United States
47	CD19 CAR-T Cells for Patients With Relapse and Refractory CD19+ B-ALL	Recruiting	No Results Available	*B-cell Acute Lymphocytic Leukemia	*Drug: Cyclophosphamide *Drug: Fludarabine *Biological: CD19 CAR-T	*The First Affiliated Hospital of Henan University of Science and Technology, Luoyang, Henan, China *Henan Cancer Hospital, Zhengzhou, Henan, China
48	CD19 CAR T Cells in Patients With Relapsed or Refractory CD19 Positive B-cell Lymphoma	Recruiting	No Results Available	*Lymphomas Non-Hodgkin's B-Cell *Relapse	*Biological: CD19 CAR T cells	*Institute of Hematology & Blood Diseases Hospital, Tianjin, China
49	CAR-T Cell Immunotherapy in MUC1 Positive Solid Tumor	Recruiting	No Results Available	*Malignant Glioma of Brain *Colorectal Carcinoma *Gastric Carcinoma	*Biological: anti-MUC1 CAR-T cells	*PersonGen Biomedicine (Suzhou) Co., Ltd., Suzhou, Jiangsu, China
50	Phase III/IIA Study of CART19 Cells for Patients With Chemotherapy Resistant or Refractory CD19+ Leukemia and Lymphoma	Active, not recruiting	No Results Available	*B Cell Leukemia *B Cell Lymphoma	*Biological: CART-19	*CHOP - http://www.chop.edu/service/oncology/pediatric-cancer-research/cart-19-trial.html , Philadelphia, Pennsylvania, United States

Source: FDA

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Figure 4: CAR-T projects in China

51	EpCAM CAR-T for Treatment of Nasopharyngeal Carcinoma and Breast Cancer	Recruiting	No Results Available	*Malignant Neoplasm of Nasopharynx TNM Staging Distant Metastasis (M) *Breast Cancer Recurrent	*Biological: CAR-T cells recognizing EpCAM	*West China Hospital, Sichuan University, Chengdu, Sichuan, China
52	Combination Transfer of #CD19-TCRα-41BB and #CD22-TCRα-41BB CAR-T Cells for B-cell Hematologic Malignancy	Recruiting	No Results Available	*Hematopoietic/Lymphoid Cancer	*Biological: Mixed CAR-T Transfer	*Xuzhou Medical University, Xuzhou, Jiangsu, China
53	CAR-T Therapy for Central Nervous System B-cell Acute Lymphocytic Leukemia	Recruiting	No Results Available	*B-cell Acute Lymphocytic Leukemia	*Biological: CD19 CAR-T cells	*The First Affiliated Hospital of Soochow University, Suzhou, China
54	CD19-CAR-T Treatment for ALL	Active, not recruiting	No Results Available	*Acute Leukemia	*Biological: CD19 CART	*Shanghai Bioray Inc., Shanghai, Shanghai, China
55	Anti-CD22 CAR-T Cell Therapy Targeting B Cell Malignancies	Active, not recruiting	No Results Available	*Leukemia *Lymphoma	*Biological: Anti-CD22-CAR-transduced T cells	*Fengtai District, Beijing, Beijing, China
56	CD19-targeting 3rd Generation CAR T Cells for Refractory B Cell Malignancy - a Phase IIIa Trial	Active, not recruiting	No Results Available	*B Cell Lymphoma *B Cell Leukemia	*Biological: Autologous 3rd generation CD19-targeting CAR T cells	*Uppsala University Hospital, Dept of Oncology, Uppsala, Sweden
57	A Study of CD19 Redirected Autologous T Cells for CD19 Positive Systemic Lupus Erythematosus (SLE)	Recruiting	No Results Available	*Systemic Lupus Erythematosus (SLE)	*Drug: cyclophosphamide *Drug: anti-CD19-CAR-T cells	*Shanghai Jiaotong University School of Medicine, Renji Hospital, Shanghai, China
58	A Study of GPC3-targeted T Cells by Intratumor Injection for Advanced HCC (GPC3-CART)	Recruiting	No Results Available	*Carcinoma, Hepatocellular	*Drug: GPC3-CART cells	*302 Military Hospital, Beijing, China
59	CAR-T-19 Cells For MRD Positive CD19+ ALL	Recruiting	No Results Available	*Acute Lymphoblastic Leukemia	*Biological: CART-19	*Fujian Medical University Union Hospital, Fuzhou, Fujian, China
60	Treatment of Relapsed and/or Chemotherapy Refractory CD33 Positive Acute Myeloid Leukemia by CART-33	Recruiting	No Results Available	*Relapsed Adult Myeloid Leukemia *Chemotherapy Refractory Adult Myeloid Leukemia	*Biological: CART33 cells *Biological: anti-CD33 CART *Biological: anti-CD33 CAR T cells	*Biotherapeutic Department and Pediatrics Department of Chinese PLA General Hospital, Hematological Department, Affiliated Hospital of Changzhi Medical College, Beijing, Beijing, China
61	A Study to Assess CD19-targeted Immunotherapy T Cells in Patients With Relapsed or Refractory CD19+ B Cell Leukemia	Recruiting	No Results Available	*Leukemia, B-Cell	*Drug: anti-CD19-CAR-T cells	*Shanghai Changhai Hospital#The Second Military Medical University, Shanghai, Shanghai, China
62	A Study of MGT Redirected Autologous T Cells for Advanced MGT Positive Liver Metastases(MGT-CART)	Recruiting	No Results Available	*Liver Metastases	*Biological: MGT-CART	*Xijing Hospital of Digestive Diseases, Xi'an, Shaanxi, China
63	CD19 CAR T Cells in Patients With Resistant or Refractory CD19+ Acute Lymphoblastic Leukemia	Recruiting	No Results Available	*Acute Lymphoblastic Leukemia, Adult B-Cell *Acute Lymphoblastic Leukemia Recurrent	*Biological: CD19 CAR T cells	*Institute of Hematology & Blood Diseases Hospital, Tianjin, China
64	Humanized CD19 CAR-T Cells With CRS Suppression Technology for r/r CD19+ Acute Lymphoblastic Leukemia	Not yet recruiting	No Results Available	*Acute Lymphoblastic Leukemia *CD19 Positive *Relapse *Refractory	*Biological: Humanized CD19 CAR-T cells *Biological: Humanized CD19 CAR-T cells with CRS suppression technology	
65	EGFR CART Cells for Patients With Metastatic Colorectal Cancer	Recruiting	No Results Available	*EGFR-positive Colorectal Cancer	*Biological: EGFR CART	*The Second People's Hospital of Shenzhen, Shenzhen, Guangdong, China
66	BCMA/CD38 CAR-T in the Treatment of Multiple Myeloma	Recruiting	No Results Available	*Multiple Myeloma	*Biological: BCMA/CD38 CAR T cells	*Shenzhen Geno-Immune Medical Institute, Shenzhen, Guangdong, China
67	Early cART and cART in Combination With Autologous HIV-1 Specific Cytotoxic T Lymphocyte (CTL) Infusion in The Treatment of Acute HIV-1 Infected Adults	Unknown status	No Results Available	*Acute HIV Infection	*Drug: cART(TDF/FTZ+3TC+LPV/r) *Procedure: CTL Infusion	*Beijing You'an Hospital, Capital Medical University, Beijing, Beijing, China *National Center for STD and AIDS Control and Prevention, Chinese Center for Disease Control and Prevention, Beijing, Beijing, China *The First Affiliated Hospital of Guangxi Medical University, Nanning, Guangxi, China *China Medical University, Shenyang, Liaoning, China *Department of Infectious Diseases, Tangdu Hospital, The Fourth Military Medical University, Xi'an, Shaanxi, China *Shandong Center for Disease Control and Prevention, Jinan, Shandong, China *Zhejiang University, Hangzhou, Zhejiang, China

Source: FDA

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Figure 5: CAR-T projects in China

68	CAR T Cells for Refractory B Cell Malignancy	Recruiting	No Results Available	*B-Cell Leukemia *B-Cell Lymphoma	*Biological: Autologous CD19-targeting CAR T cells	*No.2 Hospital of Hebei Medical University, Shijiazhuang, Hebei, China
69	CD30 CAR T Cells, Relapsed CD30 Expressing Lymphoma (RELY-30)	Recruiting	No Results Available	*Hodgkin's Lymphoma *Non-Hodgkin Lymphoma	*Genetic: CAR T Cells *Drug: Cyclophosphamide *Drug: Fludarabine	*Houston Methodist Hospital, Houston, Texas, United States *Texas Children's Hospital, Houston, Texas, United States
70	CD19-directed CAR T Cells Therapy in Relapsed/Refractory B Cell Malignancy	Recruiting	No Results Available	*Leukemia *Lymphoma	*Biological: CD19-directed CAR-T cells	*Shanghai Tongji Hospital, Tongji University School of Medicine, Shanghai, China
71	The Safety and Efficacy of CART-19 Cells in Relapse and Refractory Patients With CD19+ B-cell Lymphoma	Recruiting	No Results Available	*B Cell Lymphoma	*Drug: Cyclophosphamide *Drug: Fludarabine *Biological: CART-19	*Henan Cancer Hospital, Zhengzhou, Henan, China
72	Safety and Efficacy Evaluation of IM19 CAR-T Cells (IM19CAR-T)	Recruiting	No Results Available	*Leukemia	*Biological: IM19 CAR-T *Drug: fludarabine and cyclophosphamide	*Hebei Yanda Ludaopel Hospital, Beijing, China
73	Evaluate the Safety and Efficacy of CAR-T in the Treatment of Pancreatic Cancer	Recruiting	No Results Available	*Pancreatic Cancer *CAR	*Drug: Chimeric antigen receptor T cell	*Harbin Medical University, Harbin, Heilongjiang, China
74	CAR T Cells Targeting CD30 Positive Lymphomas (4SCAR30273)	Recruiting	No Results Available	*Lymphomas	*Genetic: Anti-CD30 CAR T cells	*University of Florida, Gainesville, Florida, United States *Peking University Cancer Hospital, Beijing, China
75	Treatment of Chemotherapy Refractory Multiple Myeloma by CART-138	Recruiting	No Results Available	*Multiple Myeloma	*Biological: CART-138 cells	*Chinese PLA General Hospital, Beijing, Beijing, China
76	Treatment of Chemotherapy Refractory EGFR(Epidermal Growth Factor Receptor) Positive Advanced Solid Tumors (CART-EGFR)	Recruiting	No Results Available	*Advanced EGFR-positive Solid Tumors	*Biological: CART-EGFR	*Chinese PLA General Hospital, Beijing, Beijing, China
77	Sequential Infusion of Anti-CD19 and Anti-CD20 CAR-T Cells Against Relapsed and Refractory B-cell Lymphoma	Recruiting	No Results Available	*Recurrent or Refractory B Cell Malignancy	*Biological: Mixed CD19/CD20 CAR-T Transfer	*Shanghai Longyao Biotechnology Inc., Ltd., Shanghai, jingan, China
78	Immunotherapy With Bispecific CAR-T Cells for B-Cell Lymphoma, ALL and CLL	Not yet recruiting	No Results Available	*Leukemia *Lymphoma	*Biological: anti-CD19 anti-CD20 Bispecific CAR-T	
79	The Safety and Efficacy of CART-19 Cells in B-cell Acute Lymphoblastic Leukemia (B-ALL)	Recruiting	No Results Available	*B-cell Acute Lymphoblastic Leukemia	*Drug: Cyclophosphamide *Drug: Fludarabine *Biological: CART-19 cells	*Henan Cancer Hospital, Zhengzhou, Henan, China
80	Memory-enriched CAR-T Cells Immunotherapy for B Cell Lymphoma	Recruiting	No Results Available	*Recurrent Adult Diffuse Large Cell Lymphoma *Recurrent Follicular Lymphoma *Recurrent Mantle Cell Lymphoma *Stage III Adult Diffuse Large Cell Lymphoma *Stage III Follicular Lymphoma *Stage III Mantle Cell Lymphoma *Stage IV Adult Diffuse Large Cell Lymphoma *Stage IV Follicular Lymphoma *Stage IV Mantle Cell Lymphoma	*Drug: CD19 CAR-T cells	*Department of Oncology, ChongQing, Chongqing, China
81	Evaluation of 4th Generation Safety-designed CAR T Cells Targeting High-risk and Refractory B Cell Lymphomas	Recruiting	No Results Available	*B-cell Lymphomas	*Genetic: Anti-CD19 CAR T cells	*Peking University Cancer Hospital, Beijing, Beijing, China
82	CD19-targeting, 3rd Generation CAR T Cells for Refractory B Cells Malignancy	Not yet recruiting	No Results Available	*B-cell Leukemia *B-Cell Lymphoma	*Biological: CAR T cells	*Uppsala University Hospital, Dept of Oncology, Uppsala, Sweden
83	CD19 CAR T Cells for Patients With Relapse and Refractory CD19+ B-cell Lymphoma	Recruiting	No Results Available	*B Cell Lymphoma	*Drug: Fludarabine *Drug: Cyclophosphamide *Biological: CD19 CAR T	*The Second People's Hospital of Shenzhen, Shenzhen, Guangdong, China
84	Pilot Study of T-APCs Following CAR T Cell Immunotherapy for CD19+ Leukemia	Recruiting	No Results Available	*CD 19+ Acute Leukemia	*Biological: T-cell Antigen Presenting Cells expressing truncated CD19 (T-APC)	*Seattle Children's Hospital, Seattle, Washington, United States
85	CAR T Cells in Treating Patients With Malignant Glioma Overexpressing EGFR	Unknown status	No Results Available	*Advanced Glioma	*Biological: anti-EGFR CAR T	*Shanghai Cancer Institute, Xuhui, Shanghai, China

Source: FDA

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Figure 6: CAR-T projects in China

86	CAR T in the Treatment of AML	Recruiting	No Results Available	*Acute Myeloid Leukemia	*Biological: Muc1/CD33/CD38/CD55/CD117/CD123-specific gene-engineered T cells	*Shenzhen Geno-Immune Medical Institute, Shenzhen, Guangdong, China
87	Efficacy of CART-19 Cell Therapy in B Cell Acute Lymphoblastic Leukemia	Recruiting	No Results Available	*Acute Lymphoblastic Leukemia	*Biological: CART-19	*First Affiliated Hospital of Henan University of Science and Technology, Luoyang, Henan, China
88	Combination CAR-T Cell Therapy Targeting Hematological Malignancies	Recruiting	No Results Available	*B-cell Malignancies	*Biological: 40CAR19 and 40CAR22 *Biological: 40CAR19 and 40CAR38 *Biological: 40CAR19 and 40CAR20 *Biological: 40CAR19 and 40CAR123	*Shenzhen Geno-Immune Medical Institute, Shenzhen, Guangdong, China
89	CART-meso Long-term Follow-up	Active, not recruiting	No Results Available	*Subjects Who Have Received Lentiviral-based CART-meso Therapy	*Biological: lentiviral-based CART meso therapy	*Abramson Cancer Center of the University of Pennsylvania, Philadelphia, Pennsylvania, United States
90	PD-1 Antibody Expressing CAR T Cells for Mesothelin Positive Advanced Malignancies	Recruiting	No Results Available	*Solid Tumor, Adult *Advanced Cancer	*Biological: PD-1 antibody expressing mesothelin specific CAR-T cells	*Ningbo No.5 Hospital (Ningbo Cancer Hospital), Ningbo, Zhejiang, China
91	Immunotherapy for High Risk/Relapsed CD19+ Acute Lymphoblastic Leukemia Using CAR T-cells to Target CD19	Not yet recruiting	No Results Available	*Leukemia, Lymphoblastic, Acute	*Biological: CD19CAR-41BBZ CAR T-cells	
92	Autologous CD19 CAR T Cells in Relapsed or Refractory B-cell Lymphoma	Recruiting	No Results Available	*B-cell Lymphoma	*Biological: autologous anti-CD19 CAR T cells	*Peking University Cancer Hospital, Beijing, China
93	A Cancer Research UK Trial of Anti-CD2 T-cells (1RG-CART)	Recruiting	No Results Available	*Relapsed or Refractory Neuroblastoma	*Genetic: 1RG-CARTim ^{v2} (Dose Level 1) *Genetic: 1RG-CARTim ^{v2} (Dose Level 2) *Genetic: 1RG-CARTim ^{v2} (Dose Level 3) *Genetic: 1RG-CARTim ^{v2} (Dose Level 4) *Drug: Cyclophosphamide *Drug: Fludarabine *Genetic: 1RG-CARTim ^{v2} (Dose Level 5)	*University College London (UCL), London, United Kingdom *Great Ormond Street Hospital for Children NHS Foundation Trust (GOSH), London, United Kingdom
94	A Study of Chimeric Antigen Receptor T Cells Combined With Interventional Therapy in Advanced Liver Malignancy	Recruiting	No Results Available	*Carcinoma, Hepatocellular *Pancreatic Cancer Metastatic *Colorectal Cancer Metastatic	*Drug: CAR-T cell	*Shanghai Tumor Hospital, Shanghai, Shanghai, China
95	Chimeric Antigen Receptor T Cells (CART) Therapy in Refractory/Relapsed B Cell Hematologic Malignancies	Recruiting	No Results Available	*Leukemia, B-Cell *Lymphoma, B-Cell	*Biological: CD19CAR	*Innovative Cellular Therapeutics CO., LTD., Shanghai, China
96	Chimeric Antigen Receptor-Modified T Cells for Breast Cancer	Completed	No Results Available	*Breast Cancer	*Biological: HER-2-targeting CAR T Cells infusion	*Central laboratory in Fuda cancer hospital, Guangzhou, Guangdong, China
97	CTLA-4 and PD-1 Antibodies Expressing Mesothelin-CAR-T Cells for Mesothelin Positive Advanced Solid Tumor	Recruiting	No Results Available	*Advanced Solid Tumor	*Biological: CTLA-4/PD-1 antibodies expressing mesoCAR-T	*Ningbo No.5 Hospital (Ningbo Cancer Hospital), Ningbo, Zhejiang, China
98	CAR-T Cell Immunotherapy in CD19 Positive Relapsed or Refractory Leukemia and Lymphoma	Recruiting	No Results Available	*Acute Lymphocytic Leukemia *Chronic Lymphocytic Leukemia *Follicular Lymphoma *Mantle Cell Lymphoma *B-cell Prolymphocytic Leukemia *Diffuse Large Cell Lymphoma	*Biological: PCAR-019 (anti-CD19 CAR-T cells)	*PersonGen BioTherapeutics (Suzhou) Co., Ltd., Suzhou, Jiangsu, China
99	Anti-mesothelin CAR T Cells for Patients With Recurrent or Metastatic Malignant Tumors	Recruiting	No Results Available	*Mesothelin Positive Tumors	*Biological: anti-mesothelin CAR T cells	*China Melan General Hospital, Beijing, China
100	Pilot Study of Autologous Anti-EGFRvIII CAR T Cells in Recurrent Glioblastoma Multiforme	Recruiting	No Results Available	*Glioblastoma Multiforme	*Biological: anti-EGFRvIII CAR T cells *Drug: cyclophosphamide *Drug: Fludarabine	*Sanbo Brain Hospital Capital Medical University, Beijing, China

Source: FDA

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