

AND



« BRIEFING ON... »

CAR-T CELL TRIALS

(Data recorded from Jan 01st, 2018 to Dec 01st 2019)

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HIGHLIGHTS

- The overwhelming majority of indications are XXXXXXXXXXXX.
- The majority (>50%) of the clinical trials listed in this report are sponsored by XXXXXXXXXXXXXXX.
- XXXXXXXXXXX of the study have been recorded in Europe (sponsored by private companies).

- XXXXXXXXXXXX sponsors worldwide

CLINICAL STUDIES

Acute Lymphoblastic Leukemia (ALL)

Target: CD19 (XXXX studies listed)

CD19-targeted CAR-T Cell Therapy for Minimal Residual Disease in B-cell Malignancies After Autologous Stem Cell Transplantation ID:NCT03564977, QingdaoCH201805 Qingdao Central Hospital (CN)

Product : CD19-targeted CAR-T cells **Phase: NA** Status : recruiting Start/Planned completion : JUL 2018 / JUN 2020 Estimated Enrollment: 20 Collaboration : Yake Biotechnology Ltd (CN) Sites : Updated : JUN 2018 Contact : wldoctor@126.com

Related Informations / Publications

*Bone Marrow Transplant. 2019 Aug;54(8):1208-1217.

A retrospective comparison of allogenic and autologous chimeric antigen receptor T cell therapy targeting CD19 in patients with relapsed/refractory acute lymphoblastic leukemia. Hu Y et al. The First Affiliated Hospital, School of Medicine, Zhejiang University, Zhejiang, China (collab : YaKe Biotechnology Ltd, Shanghai) Link : <u>Abstract</u>

A Single Center, Open Label, Single Arm Exploratory Clinical Study of CD19-Directed Allogeneic Chimeric Antigen Receptor CART-cell Immunotherapy Cell Therapy in Pediatric Patients With Relapsed/Refractory B-Cell Acute Lymphoblastic Leukemia ID:NCT04173988, 2019-272

Children's Hospital of Fudan University (CN)

Product : CD19-Directed Allogeneic Chimeric Antigen Receptor T- cells **Phase: early phase I** Status : not yet recruiting Start/Planned completion : NOV 2019 / JUL 2022 Estimated Enrollment: 6 Sites : 1 (CN) Updated : NOV 2019 Contact : zhaixiaowendy@163.com, hongsheng@hotmail.com

The Clinical Study of CD19 UCAR-T Cells in Patients With B-cell Acute Lymphoblastic Leukemia (B-ALL)

ID:<u>NCT04166838</u>, V1.0

Shanghai Longyao Biotechnology Inc., Ltd. (CN)

Product : CD19 UCARTcells **Phase: early phase I** Status : recruiting Start/Planned completion : NOV 2019 / NOV 2019 Estimated Enrollment: 20 Sites : 1 (CN) Updated : NOV 2019 Contact : <u>nitengfeng@163.com</u>

CTA101 UCAR-T Cell Injection for Treatment of Relapsed or Refractory CD19+ B-cell Acute Lymphoblastic Leukemia ID:<u>NCT04154709</u>, XYFY2019-KL135-02 Nanjing Bioheng Biotech Co., Ltd (CN)

Product : CTA101 (CD19-directed CAR-T cells) **Phase: I** Status : recruiting Start/Planned completion : NOV 2019 / JUN 2022 Estimated Enrollment: 15 Sites : 1 (CN) Updated : NOV 2019 Contact : lizhenyumd@163.com, zimu05067@163.com

Related Informations / Publications (related to the three above mentioned studies)

*J Clin Invest. 2019 Dec 17. pii: 130144.

CD19-targeting CAR T cell immunotherapy outcomes correlate with genomic modification by vector integration. Nobles CL et al. University of Pennsylvania, Philadelphia, Pennsylvania, USA

Results / Comments : These data clarify how insertional mutagenesis can modulate cell proliferation in CART19 therapy and how data on integration-site distributions can be linked to treatment outcomes

Link : <u>Abstract</u> - <u>Full Text</u>

*J Clin Oncol. 2019 Dec 9:JCO1901892.

Optimizing Chimeric Antigen Receptor T-Cell Therapy for Adults With Acute Lymphoblastic Leukemia. Frey NV et al. University of Pennsylvania Perelman School of Medicine, Philadelphia, PA, USA

Results / Comments : Fractionated dosing of CTL019 with intrapatient dose modification optimizes safety without compromising efficacy in adults with r/r ALL Link : Abstract

*Front Immunol. 2019 Nov 12;10:2664.

Mechanisms of Relapse After CD19 CAR T-Cell Therapy for Acute Lymphoblastic Leukemia and Its Prevention and Treatment Strategies. Xu X et al. Zhujiang Hospital, Southern Medical University, Guangzhou, China

Link : Abstract - Full Text

**Sci Immunol*. 2019 Jul 12;4(37).

Engineering nanoparticles to locally activate T cells in the tumor microenvironment. Wang D et al. Shanghai Institute of Materia Medica, Chinese Academy of Sciences, Shanghai 201203, China

Results / Comments : The nanoplatform that uses the antibody nanoparticle alone both for immune stimulation and PDL1 inhibition could be readily adapted to other immune checkpoint inhibitors for improved ICB therapy

Link : Abstract

Colorectal Cancer

Target: XXXXXX

(XXX studies listed)

An Open-label, Phase I Study to Assess the Safety, Cell Kinetics and Clinical Activity of Multiple Doses of CYAD-101, Administered Concurrently With the FOLFOX Treatment in Patients With Unresectable Metastatic Colorectal Cancer ID: NCT03692429, CYAD-N2L-101

Celyad (BE)

Product: CYAD-101. This Phase I study will explore the hypothesis that targeting of NKG2D-ligands with an allogeneic CAR T-cells, CYAD-101

Phase: I

Status: recruiting Start/Planned completion: NOV 2018 / OCT 2033 Estimated Enrollment: 36 Collaboration : Iqvia Pty Ltd (WW) Sites: 5 (BE, UK) Updated: JUL 2019 Contact: Igavrilovic@celyad.com, aflament@celyad.com

Related Informations / Publications

-DEC 2019

Celyad Receives Additional €2.5 Million in Non-Dilutive Funding Link : Press Release

**Mol Ther.* 2019 Jun 5;27(6):1114-1125.

Adoptive Transfer of NKG2D CAR mRNA-Engineered Natural Killer Cells in Colorectal Cancer Patients. Xiao L et al. The Third Affiliated Hospital of Guangzhou Medical University, Guangzhou, Guangdong 510150, China

Results / Comments : The results highlight a promising therapeutic potential of using RNA CAR-modified NK cells to treat metastatic colorectal cancer

Link : Abstract

*Am J Cancer Res. 2019 May 1;9(5):945-958.

Antitumor activity of NKG2D CAR-T cells against human colorectal cancer cells in vitro and in vivo. Deng X et al. Hebei Medical University Shijiazhuang, Hebei, China Results / Comments : There were no severe pathological changes found in vital organs in any of the treatment groups. NKG2D CAR-T cells showed excellent killing effect and represented a promising immunotherapeutic strategy against human colorectal cancer Link : Abstract - Full Text

Multiple Myeloma

Target: XXX (XXX studies listed)

Phase 1 Study of CART-XXXXX as Consolidation of Standard First or Second-Line Therapy for High-Risk Multiple Myeloma ID:<u>NCT03XXXXX,</u> University of XXXXXXX (USA)

Product : XXXXXXXXXX Phase: I Status : recruiting

© OctopusyX BioConsulting, BioPharmAnalyses All Rights Reserved Start/Planned completion : MAY 2018 / MAY 2021 Estimated Enrollment: 39 Collaboration : XXXXXXXX Sites : 1 (US) Updated : APR 2019 Contact :

Related Informations / Publications

*Blood Adv. 2019 Oct 8;3(19):2812-2815.

T-cell phenotypes associated with effective CAR T-cell therapy in postinduction vs relapsed multiple myeloma. Garfall AL et al. Division of Hematology-Oncology, Department of Medicine, Abramson Cancer Center at the University of Pennsylvania, USA.

Link : Full Text

* Ther Adv Hematol. 2019 May 19.

Novel monoclonal antibody-based treatment strategies in adults with acute lymphoblastic leukemia. Guerra VA et al. University of Texas MD Anderson Cancer Center, Houston, TX, USA

Results / Comments : Researchers here review the role of monoclonal antibodies in adult ALL and summarize the current and future approaches in ALL, including novel combination therapies and the possibility of early incorporation of these agents into treatment regimens

Link : Abstract - Full Text

*J Hematol Oncol. 2019 Jun 10;12(1):57.

Haploidentical CD19/CD22 bispecific CAR-T cells induced MRD-negative remission in a patient with relapsed and refractory adult B-ALL after haploidentical hematopoietic stem cell transplantation. Jia H et al. Chinese PLA General Hospital, No. 28 Fuxing Road, Beijing, 100853, China

Results / Comments : CAR simultaneously targeting CD19 and CD22 has the potential of inducing long-term remission in patients with B-ALL

Link : <u>Abstract</u> - <u>Full Text</u>

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