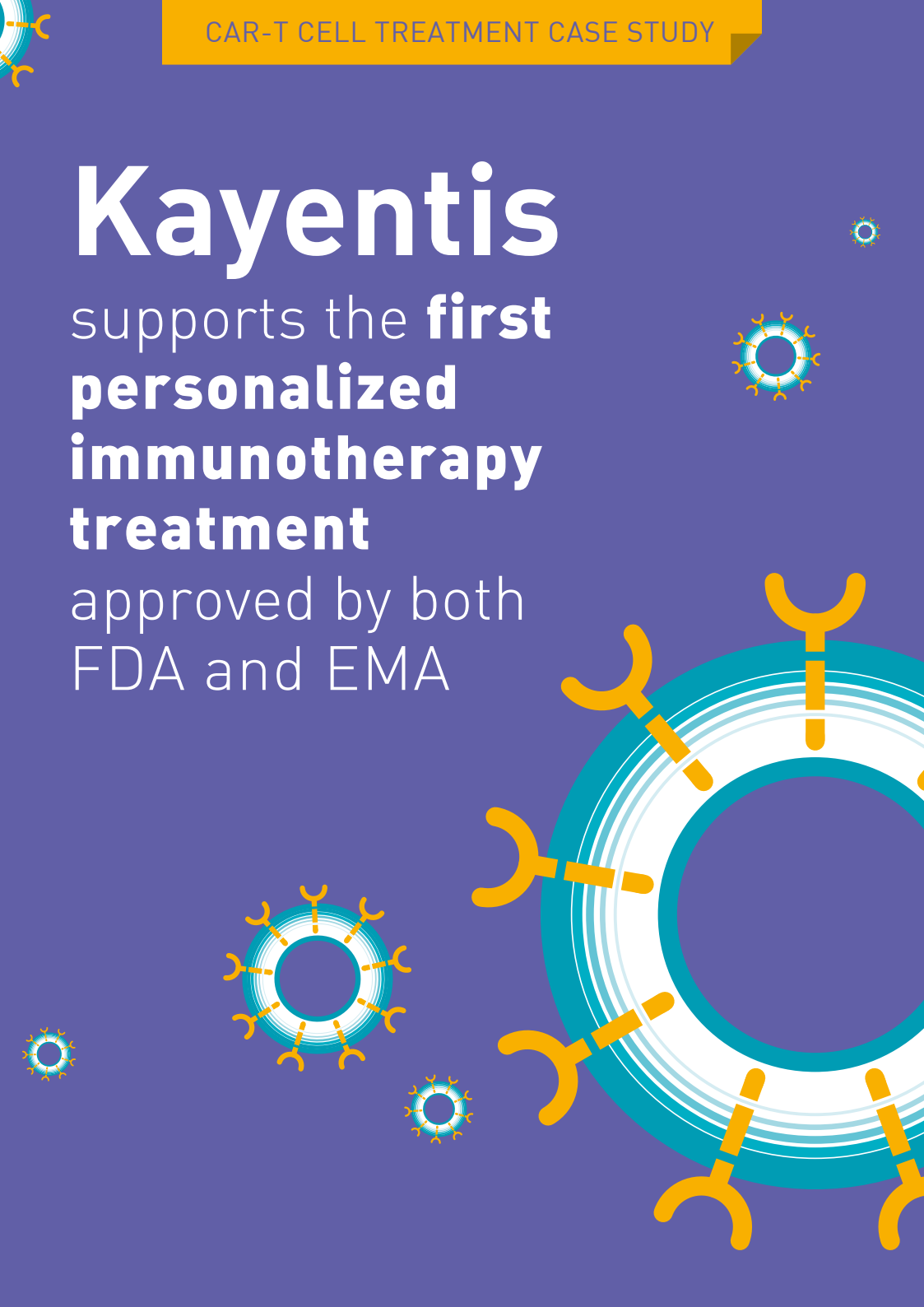


Kayentis

supports the **first
personalized
immunotherapy
treatment**

approved by both
FDA and EMA



Acute Lymphoblastic or Lymphoid Leukemia (ALL) is a cancer of the lymphocytes that can result in serious complications such as anemia, bleeding and severe infection. Some tumor cells may accumulate in the lymphatic system and can also invade other organs.

✓ **5,000** cases of ALL are diagnosed annually in the US¹.

✓ Children are particularly affected:

- **60%** of cases occur in patients **<20 years** of age¹
- Accounts for approximately **25%** of cancer diagnoses in children **<15 years** of age
- Is the most common childhood cancer in the US
- **80-90%** of adults with ALL will have complete remission **BUT ROUGHLY HALF OF THEM RELAPSE** - and the chance of survival in patients who relapse or fail to attain remission is **5-8%** in adults & **16-30%** in children.

Hence, there is a **desperate need of treatment options for refractory and relapse ALL patients for whom the prognosis is poor.**

➔ **CAR-T cell treatment is the first personalized immunotherapy treatment for refractory and relapse ALL patients approved by both FDA and EMA and has demonstrated effectiveness for approximately 450 patients in 2019 per recently published report. Its is estimated that 2,000 pts should be able to be administered this individualized therapy in the 5-10 years to come².**

¹National Cancer Institute. SEER Cancer Stat Facts: Acute Lymphocytic. Bethesda, MD, <http://seer.cancer.gov/statfacts/html/alyL.html>. Accessed May 2017.

²<https://www.statista.com/statistics/1098463/global-addressable-patient-population-car-t-cell-therapies-estimate/>

Kayentis partnership in CAR-T development program

Kayentis is supporting a key research program aimed at developing new generation immunotherapies to treat both children and adults.

THIS PROGRAM INVOLVES GLOBAL, MULTI-CENTER, RANDOMIZED CLINICAL TRIALS:

- ✓ Global phase II/III studies - 120 to 220 patients per study - in adult, pediatric and adolescent populations
- ✓ 10 to 20 countries in Europe, Middle East & North America, Asia Pacific including Japan.

QUALITY OF LIFE QUESTIONNAIRES USED FOR PATIENT REPORTED OUTCOMES & DISEASE ASSESSMENTS:

- ✓ European Organisation for Research and Treatment of Cancer (EORTC) validated questionnaires, such as EORTC-QLQ-C30 and FACIT-Fatigue questionnaires
- ✓ European Quality of Life group (EuroQoL) validated questionnaires (EQ-5D 3L / EQ5d Youth) & PedsQL Child, Young adult and Adolescent version.

Key challenges and success

- ✓ SUCCESSFUL SET-UP thanks to Kayentis' expertise with oncology and pediatric questionnaires.
- ✓ EFFICIENT MULTI-BRANCHING LOGIC according to patients age groups and questionnaire types.
- ✓ ANTICIPATED DEVICE OBSOLESCENCE MANAGEMENT PLAN for long term studies, securing permanent availability of the full solution until project completion.
- ✓ ADAPTED TRAINING for clinical site staff and patients, customized by age group and enriched by real time information as well as refreshers to manage long lasting studies.

Kayentis offers key eCOA expertise in oncology overall

✓ **15+** years of eCOA experience, innovation, and operational expertise in clinical trials.
25% of our experience is in Oncology - Hematology.

✓ **Device and instrument wide offer** to match the specificities of oncology and the variability of the patient populations. State-of-the-art technology and connectivity options adapted to global and local requirements; high interoperability and data integration capability.

✓ **Strong partnerships and established processes** with translation companies as well as automated tools to manage translations in an efficient and timely manner.

✓ **Global expertise:**

- 3 office locations (Europe, US, Japan)
- Familiarity with complex logistic and challenges of specific countries (e.g Russia, China)
- Knowledge of local management practices and solid practical eCOA expertise accross the world

✓ **Experience of eCOA/ePRO solutions** used for PROs & disease assessments including multiple myeloma, lymphoma, renal carcinoma, lung cancer, ALL, CML, and breast cancer.



www.kayentis.com

To learn more, please contact us at sales@kayentis.com