

In- and exclusion criteria CARMAN study

Most relevant inclusion criteria:

- Histologically confirmed diagnosis of MCL according to WHO classification, with documentation of either overexpression of cyclin D1 or presence of t(11;14)
- **At least one High risk MCL feature**, defined as
 - i. MIPI-c high intermediate (HI) or high (H) risk (i.e. high-risk MIPI irrespective of Ki-67 or intermediate risk MIPI and Ki-67 \geq 30% (Ki-67 based on local pathology) and/or
 - ii. TP53 deletion and /or mutation and/or TP53 overexpression by immunohistochemistry (> 50% of lymphoma cells), sequencing (mutations and deletions) or FISH
- At least 1 measurable lesion according to the Lugano Response Criteria (>1.5 cm nodal lesion or > 1cm extranodal lesion); in case of bone marrow infiltration only, bone marrow aspiration and biopsy is mandatory for all staging evaluations.
- 18-75 jaar
- No evidence of CNS-disease
- Willingness not to drive a motor vehicle for 8 weeks post CAR T cell treatment

Most relevant exclusion criteria:

- Prior systemic treatment for MCL
- Serious concomitant disease interfering with a regular therapy according to the study protocol:
 - i. Clinically symptomatic cardiovascular disease such as arrhythmias, congestive heart failure, higher grade AV-block, unstable angina, myocardial infarction, cardiac angioplasty or stenting within 12 months of Screening, or any Class 3 (moderate) or Class 4 (severe) cardiac disease as defined by the New York Heart Association. Functional Classification or LVEF below 50%
 - ii. Baseline oxygen saturation \leq 92% on room air
 - iii. Endocrinological, e.g. severe, not sufficiently controlled diabetes mellitus
- History of or active malignancy other than MCL unless disease-free for at least 3 years, except non-melanoma skin cancer, carcinoma in situ (e.g., cervix, bladder, breast) or treated prostate cancer with PSA within normal range.