Autolus

# Autolus SLE/Autoimmune Disease Event

## Exploring CAR T Therapy for Refractory Systemic Lupus Erythematosus and the Broader Opportunity in Autoimmune Diseases

October 24, 2023

# Disclaimer

These slides contain forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to, statements regarding Autolus' development of the obe-cel program; the profile and potential application of obe-cel in additional disease settings; the future clinical development, efficacy, safety and therapeutic potential of the Company's product candidates, including progress, expectations as to the reporting of data, conduct and timing and potential future clinical activity and milestones; expectations regarding the initiation, design and reporting of data from clinical trials; expectations regarding the regulatory approval process for any product candidates; the Company's current and future manufacturing capabilities; and the Company's anticipated cash runway. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance, or events to differ materially from those expressed or implied in such statements. These risks and uncertainties include, but are not limited to, the risks that Autolus' preclinical or clinical programs do not advance or result in approved products on a timely or cost effective basis or at all; the results of early clinical trials are not always being predictive of future results; the cost, timing and results of clinical trials; that many product candidates do not become approved drugs on a timely or cost effective basis or at all; the ability to enroll patients in clinical trials; possible safety and efficacy concerns; and the impact of COVID-19 on Autolus' business. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Autolus' actual results to differ from those contained in the forward-looking statements, see the section titled "Risk Factors" in Autolus' Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 7, 2023, as well as discussions of potential risks, uncertainties, and other important factors in Autolus' subsequent filings with the Securities and Exchange Commission. All information in this presentation is as of the date of the release, and Autolus undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing the Company's views as of any date subsequent to the date of this presentation.


# Welcome and Introduction

Dr Christian Itin, Chief Executive Officer
Autolus

# SLE webcast

| Draft Agenda | |
|---|---|
| **Session 1: Welcome and Introduction**<br>Dr Christian Itin<br>Chief Executive Officer, Autolus<br>*8.30 am EST* | **Session 4: Autolus opportunity, advantage and next steps**<br>Dr Christian Itin<br>*8.55 am EST* |
| **Session 2: Current treatment landscape and unmet medical need**<br>Dr Maria Leandro, Consultant Rheumatologist/Associate Professor at UCL Hospitals and UCL, London, UK<br>*8.35 am EST* | **Session 5: Q&A and final remarks**<br>Dr Christian Itin/ Dr Edgar Braendle<br>*9.05 am EST* |
| **Session 3: Data review of Erlangen study and broader literature**<br>Dr Edgar Braendle, Chief Development Officer, Autolus<br>*8.45 am EST* | Event concludes<br>*9.30 am EST* |

# Welcome and introduction

## CAR T Therapy for Refractory Systemic Lupus Erythematosus (SLE) and broader opportunity in autoimmune disease

- The concept of addressing B cell mediated immune diseases by removing the B cell compartment reaches back into the 1990's and started to be clinically evaluated with first rituximab use in the early 2000's
- Making a broader and deeper cut using CD19 targeting was discussed in the late 1990's
- It was only in 2021 with the courageous clinical study conducted by Georg Schett and Andreas Mackensen at the Univ. of Erlangen using an academic CD19 CAR T product in refractory SLE patients that the transformative potential of a deep cut into the CD19+ B cell compartment became visible
- Autolus's potential advantages:
  - Potential best in class CAR T providing a deep cut into the B and plasma cell compartment with an outstanding tolerability profile
  - Accelerated development path to a potential commercial launch
    - Scope for a more limited and cost-effective registrational trial than previous SLE trials
    - Ability to leverage existing tolerability data from obe-cel in adult ALL
    - Established commercial manufacturing and product delivery
  - Strong economics with attractive cost of goods at launch and ability to leverage existing CAR T commercial infrastructure
- Brief outline of the clinical development plan & strategy

*Mackensen et al., Nature Medicine 2022

# Current treatment landscape and unmet medical need

Dr Maria Leandro, Consultant Rheumatologist/Associate Professor at UCL Hospitals and UCL, London, UK

# Summary

- Systemic Lupus Erythematosus (SLE) epidemiology, prognosis and survival
- Current SLE treatment strategies (EULAR guidelines 2023)
- SLE Pathogenesis (recent review)
  - B cells, plasma cells, autoantibodies
  - B cell lineage targeting drugs
- B cell depleting strategies

Reference: Dr. Maria Leandro, Consultant Rheumatologist at UCL Hospitals, SLE/Autoimmune event with Autolus, Oct 2023.

# Systemic Lupus Erythematosus

- Systemic autoimmune disease
- Can cause different symptoms in different people: arthritis, kidney inflammation, skin rashes, heart and lung inflammation, central nervous system abnormalities and blood disorders
- Renal (kidney) disease occurs in up to 40% of patients; can evolve to kidney failure requiring dialysis and is associated with higher risk of death
- Patients are prone to flares of their disease, and it results in long-term ill health and often poor mental health

Reference: Dr. Maria Leandro, Consultant Rheumatologist at UCL Hospitals, SLE/Autoimmune event with Autolus, Oct 2023.

# SLE Epidemiology

- Relatively uncommon disease
  - UK estimates (2012) approximately 1 in 1000 people
  - Meta-analysis (Europe and North America studies) overall mean prevalence of 24/100,000 population
  - Higher incidence and prevalence in Afro-Caribbeans, Asians and Hispanics
- Higher in females 9:1
- Peak incidence 20-30 (usually presents 15-40 yrs of age)

# SLE Prognosis and Mortality

- Survival improved substantially in the last 70 years but plateaued for some time
  - 5-yr survival from 50% 1955; 64-87% 1980s; around 95% now
  - Standardised Mortality Rate (SMR) 2-3 > general population (USA, Europe, Asia)
- Can be severe and associated with increased mortality from variety of causes
  - Disease activity (when vital organs and systems are involved)
  - Complications of treatment (e.g. infections)
  - Chronic comorbidities (e.g. cardiovascular disease)

Reference: Dr. Maria Leandro, Consultant Rheumatologist at UCL Hospitals, SLE/Autoimmune event with Autolus, Oct 2023.

# EULAR recommendations for the management of systemic lupus erythematosus: 2023 update

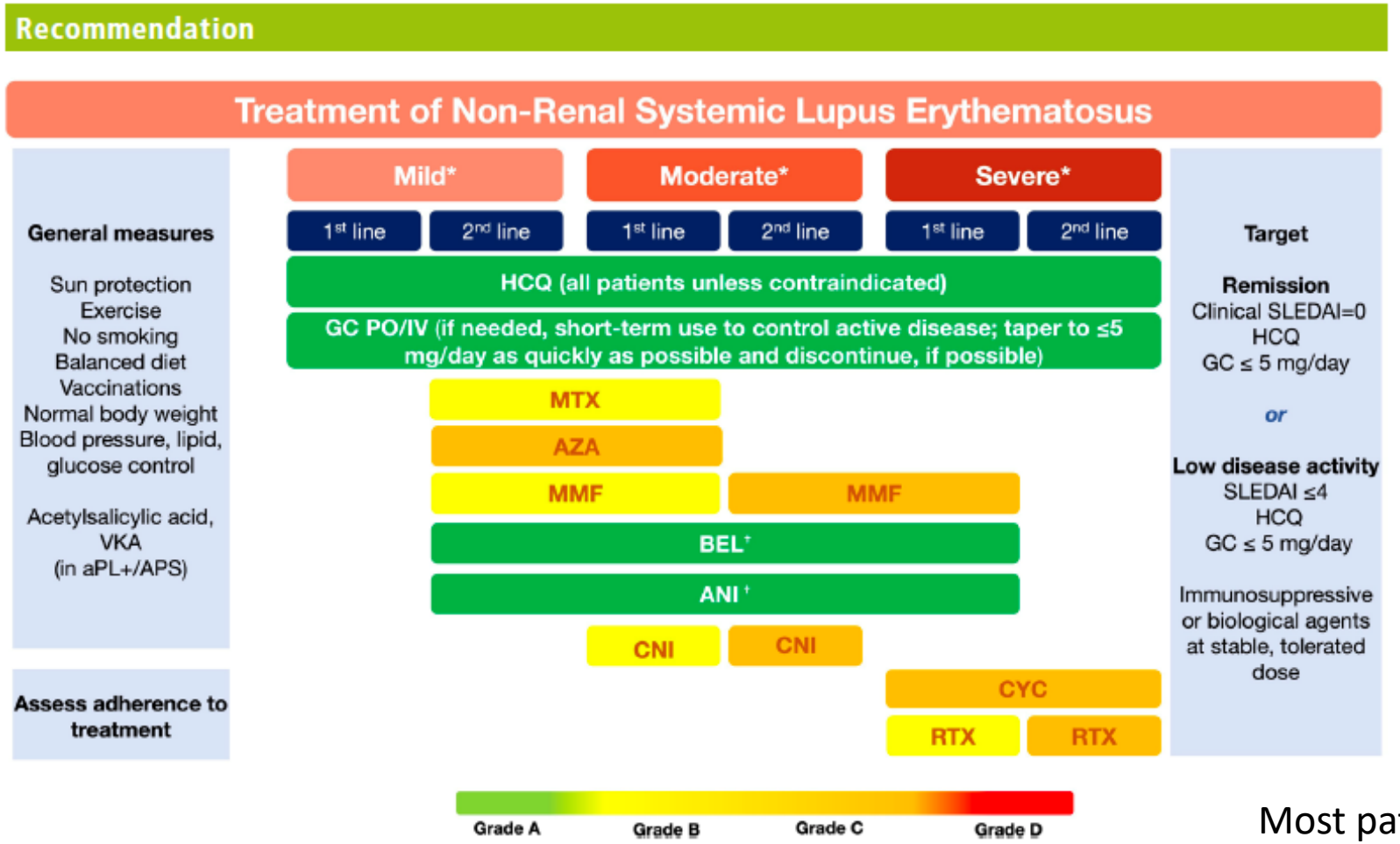
Glucocorticoids

Hydroxychloroquine

Methotrexate
Azathioprine
Mycophenolate

Cyclophosphamide

Calcineurin inhibitors




Belimumab

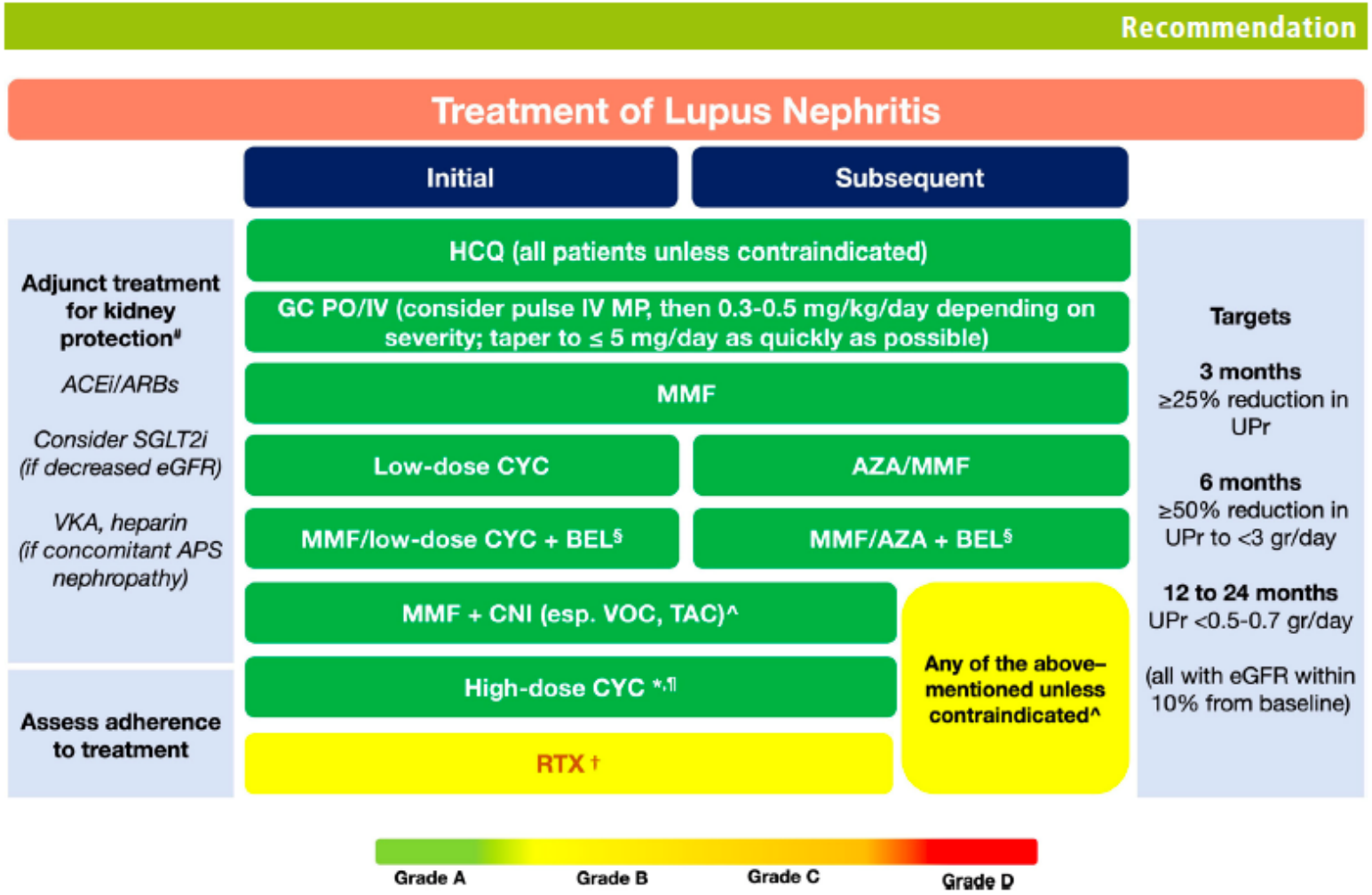
Anifrolumab

Rituximab

Most patients do not achieve sustained remission and need life-long treatment

Fanouriakis A, *et al*. *Ann Rheum Dis* 2023;**0**:1–15. doi:10.1136/ard-2023-224762

EULAR recommendations for the management of systemic lupus erythematosus: 2023 update




Fanouriakis A, *et al. Ann Rheum Dis* 2023;**0**:1–15. doi:10.1136/ard-2023-224762

Lupus nephritis

Up to 40% SLE patients

Risk of ESRD:
11-12% at 5 yrs
17-19% at 10 yrs
22-26% at 15 yrs

ESRD survival rates:
94% at 1 yr
69% at 5 yrs
40% at 10 yrs

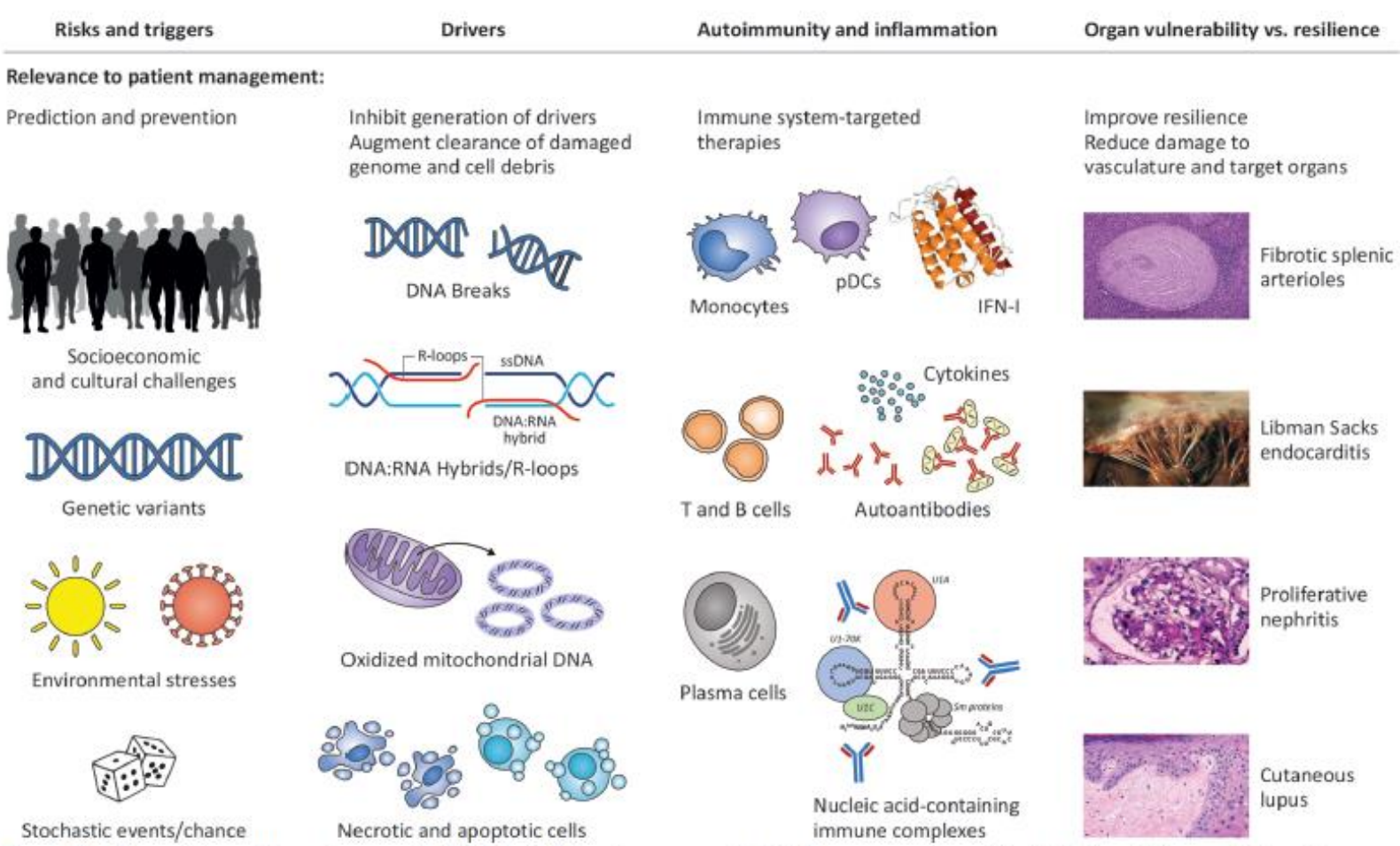



**Figure 1** A broad view of the pathogenesis of SLE. As SLE is an immune-mediated disease, research and identification of therapeutic targets have focused on elucidation of the relevant immune cells and mediators and the alterations in immune function that contribute to autoimmunity and inflammation in SLE. The scope of research with potential to favourably impact approaches to patient management should encompass studies of the societal, genetic and environmental risks that contribute to susceptibility of an individual to develop SLE. Additionally, identification and characterisation of the molecular drivers of immune system activation, particularly those that involve stimulatory nucleic acids, may lead to interventions that prevent autoimmunity or at least prevent progression to clinical disease. Finally, studies of the genetic, cellular and molecular mechanisms that contribute to target organ vulnerability to immune mediators, or alternatively, organ resistance to inflammation, may provide insights and management approaches that limit accumulation of damage. See text for discussion. IFN, interferon; pDC, plasmacytoid dendritic cell; SLE, systemic lupus erythematosus.

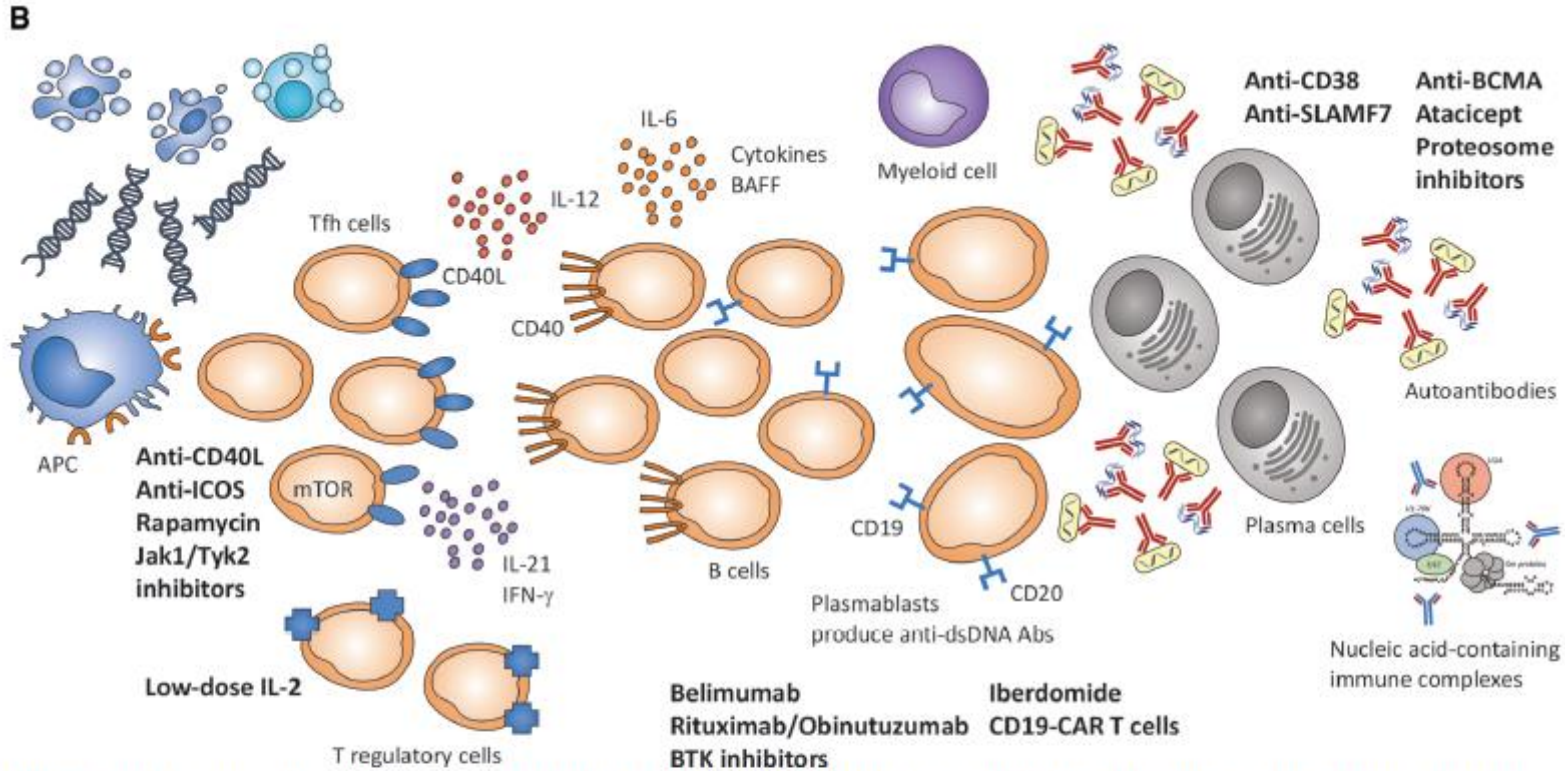



**Figure 5** Insights into pathogenic mechanisms identify therapeutic targets. (A) Inhibition of the IFN-I system is being addressed therapeutically, through approaches aimed at digesting stimulatory RNA-containing complexes, inhibiting or eliminating pDCs, inhibition of the TLR7 pathway signalling, blockade of IFNAR and inhibition of JAK1/TYK2 signalling. In addition, consideration should be given to therapeutic approaches that inhibit or eliminate long-lived plasma cells, as those cells are likely to produce the autoantibodies that form RNA-containing immune complexes and effectively deliver stimulatory RNA to endosomal TLR7. (B) Inhibition of components of the adaptive immune response represent rational therapeutic targets for treatment of patients with SLE. Inhibition of Th cell differentiation through inhibition of IL-12 signalling and expansion of Tregs might rebalance T-cell subsets to limit immune activation. Inhibition of ICOS or CD40L might reduce T cell-dependent B-cell activation and differentiation. Several approaches to direct (CD19 or CD20-directed therapies, BTK inhibition) or indirect (BAFF inhibitor) inhibition of B-cell differentiation can limit disease activity. Novel approaches such as CD19-CAR T cells that efficiently eliminate $CD19^+$ B cells may prove effective. Targeting long-lived plasma cells is challenging but is being pursued with targeted therapies such as anti-CD38 and anti-BCMA antibodies. Effective control of disease may require therapeutic inhibition of components of both innate and adaptive immune systems, as with iberdomide, an inhibitor of the Ikaros and Aiolos transcription factors, although such approaches are accompanied by challenging toxicities. Therapeutics are indicated in bold. BAFF, B-cell activating factor; IFN, interferon; IL, interleukin; pDC, plasmacytoid dendritic cell; SLE, systemic lupus erythematosus; TLR, toll-like receptor; Treg, T regulatory.

# CD19 Autologous CAR T-Cell Therapy in SLE

- Developed for the treatment of B-cell cancer – eliminate malignant clones including hard-to-reach, tissue-resident tumour cells
- Recent reports in SLE – generated a lot of interest
- Some trials under preparation/under way
- Also being explored in other autoimmune rheumatic diseases including Idiopathic Inflammatory Myopathies and Systemic Sclerosis

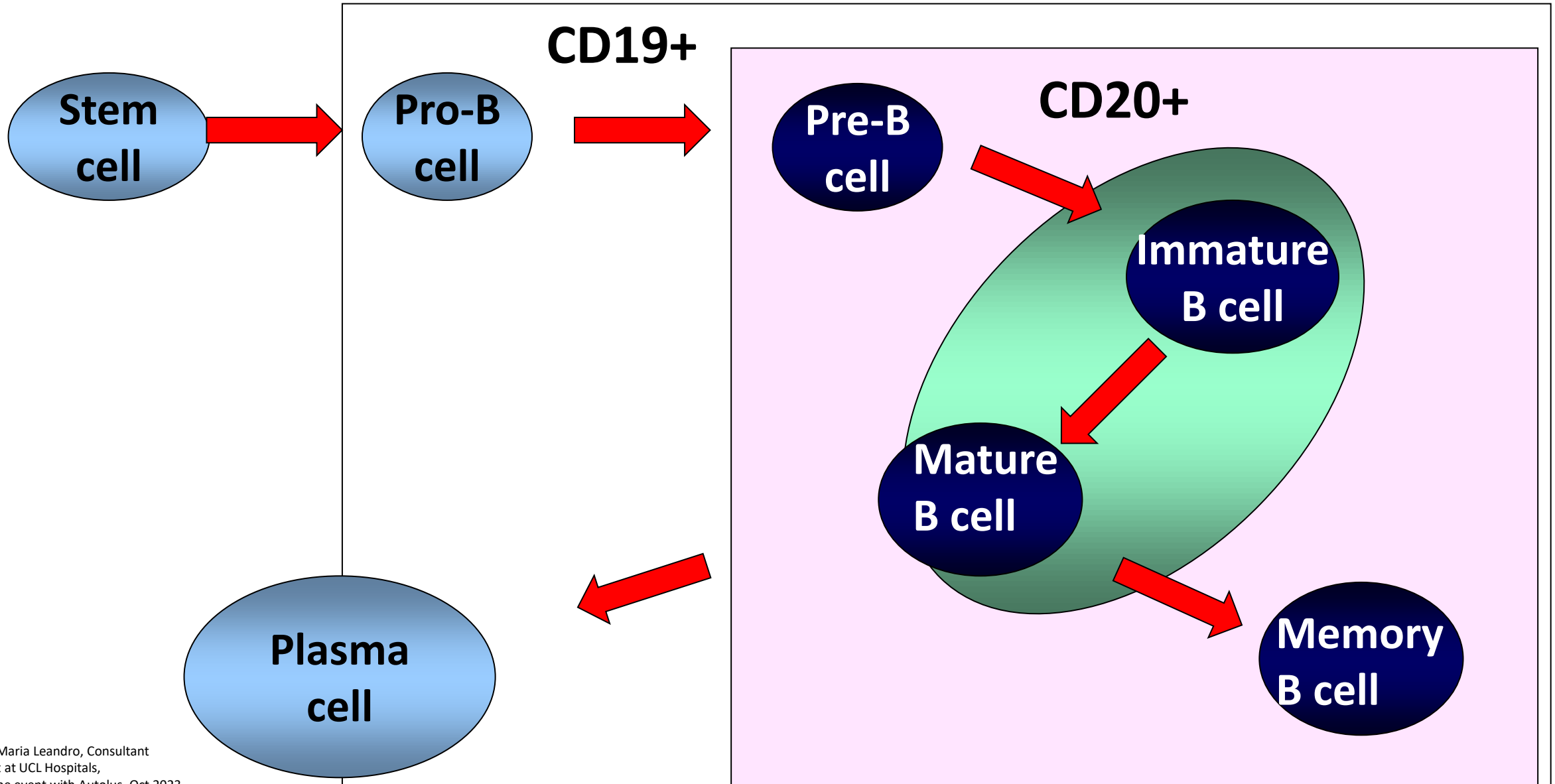
Reference: Dr. Maria Leandro, Consultant Rheumatologist at UCL Hospitals, SLE/Autoimmune event with Autolus, Oct 2023.

# B-cell depletion in SLE – CD19 CAR-T Cell Therapy

- Is a deeper B-cell depletion associated with better/more consistent responses?
- Targeting CD19 will include plasmablasts/plasma cells – how important is this?
- Could it be associated with a “resetting of the disease”?

Reference: Dr. Maria Leandro, Consultant Rheumatologist at UCL Hospitals, SLE/Autoimmune event with Autolus, Oct 2023.

# CD20 and CD19 Expression on B-Cell Lineage




Reference: Dr. Maria Leandro, Consultant Rheumatologist at UCL Hospitals, SLE/Autoimmune event with Autolus, Oct 2023.

# Challenges of CAR T-cell therapy in AID

- Are autologous T cells adequate to produce CAR T-cells – quantity and quality?
- Risk of side effects
- Long duration of B-cell aplasia – risk/benefit
- Risk of stopping immunosupressants and limiting steroid dose before leukapheresis
- Cost-effectiveness (disease ”resetting”?)

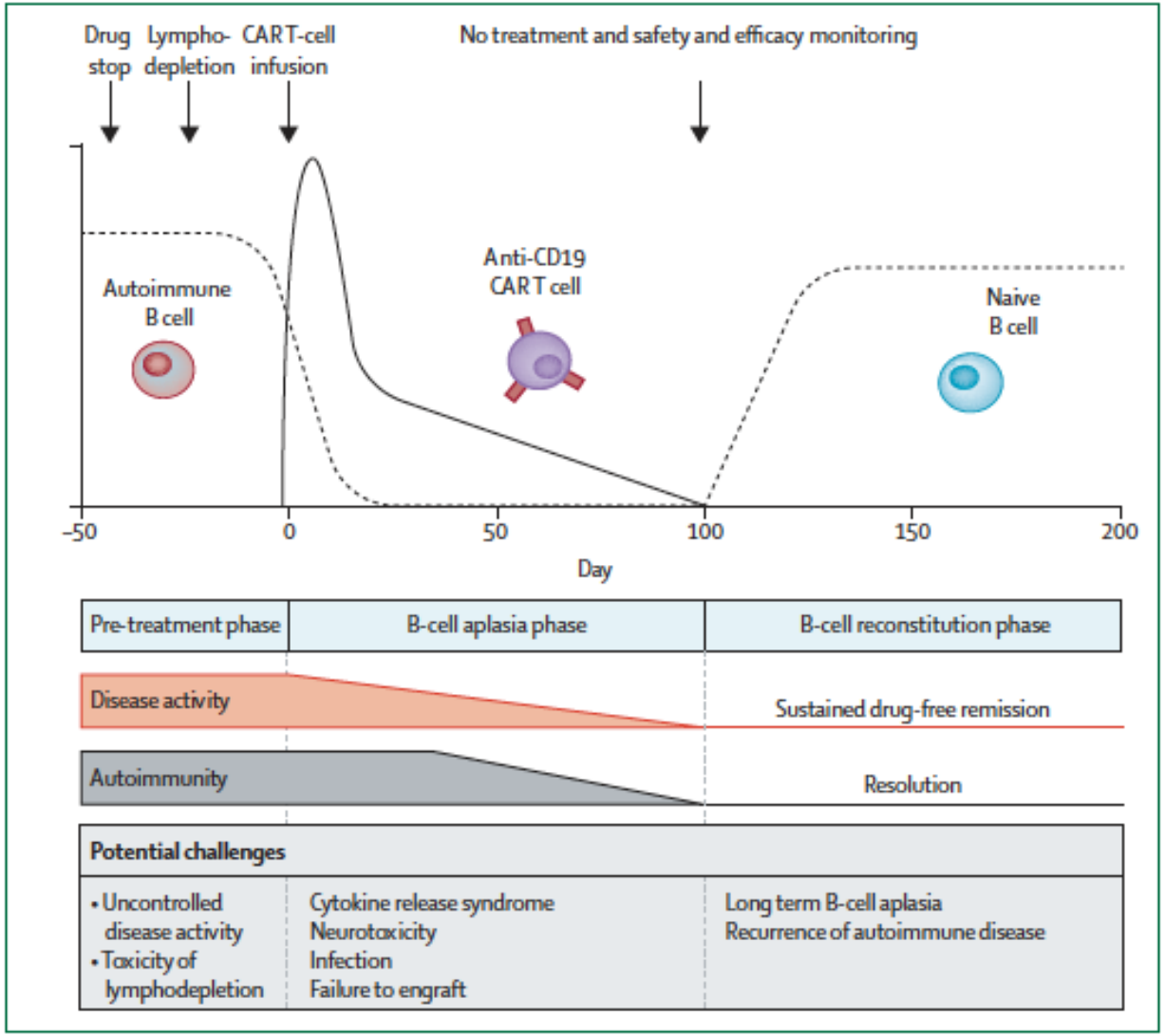



***Figure 4:*** **Phases and challenges of treatment with autologous CAR T cells in autoimmune diseases**
The pre-treatment phase consists of cessation of immunosuppressive treatment, leukapheresis, and lymphodepleting chemotherapy (conditioning), before CAR T cells are infused. This phase is followed by B-cell aplasia, which is characterised by expansion of CAR T cells. B cells then recur, and the B-cell pool is reconstituted. During aplasia disease activity (clinical, laboratory, and imaging signs of inflammation) decreases, autoimmunity (autoantibodies) resolves, and a phase of drug-free remission follows. The length of drug-free remission is unknown, but it is possible for some patients to be fully cured of their disease. Potential challenges of CAR T-cell therapy are summarised with respect to the different phases of treatment.

**CAR T-cell therapy in autoimmune diseases**

Georg Schett, Andreas Mackensen, Dimitrios Mougiakakos

www.thelancet.com Published online September 22, 2023

# Background: Data Review of Erlangen Study and Broader Literature

Dr Edgar Braendle, Chief Development Officer, Autolus

# What's next for CAR T-cell therapy?

## Obe-cel may have a competitive edge in autoimmune diseases

- CAR T-cell therapies have **established themselves in haematological indications**. There is an increasing body of evidence in their application to treat auto-antibody related **autoimmune diseases**
- Current therapies for autoimmune disease, including immunosuppressants, steroids and B-cell depleting or inhibiting biologics, aim to suppress the immune system. However, these therapies **require long-term administration, can have serious side effects and provide limited efficacy**
- Recent studies have shown that CAR T-cells targeting B-cell mediated autoimmune diseases, have the **potential to provide a powerful new therapeutic approach** with a "deep reset" of the immune system
- Obe-cel's **potential best in class response and tolerability, state of the art commercial manufacturing facility** and **commercial product delivery infrastructure** could enable an accelerated entry into the autoimmune space

# CD19 CAR T-cell therapy clinical proof of concept in SLE

## Erlangen group clinical proof of concept in SLE

- Georg Schett and Andreas Mackensen
- Initial clinical data published in Nature Medicine

## Manufacturing and dosing

- Academic manufactured autologous CD19 CAR T-cells
- Standard dosing regimen: flu/cy preconditioning followed by a single dose $1x10^6$ CAR T-cells/kg[1]

## Baseline characteristics

- Mostly female (4 of 5) and ages between 18-24
- All with advanced disease and multi-organ involvement
- All patients were heavily pretreated; refractory to current therapies

## Summary of topline results from the 5-patient study

- Potential transformational clinical benefit
- Complete remission in disease activity
- Maintained drug-free remission in follow-up
- Treatment was well tolerated

[1]Fludarabine (25 mg/m2/d i.v.) on days −5, −4 and −3 and cyclophosphamide (1,000 mg/m2/d i.v.) on day −3

Mackensen et al., Nature Medicine 2022

# Data support potential for transformational benefit as a standalone therapy

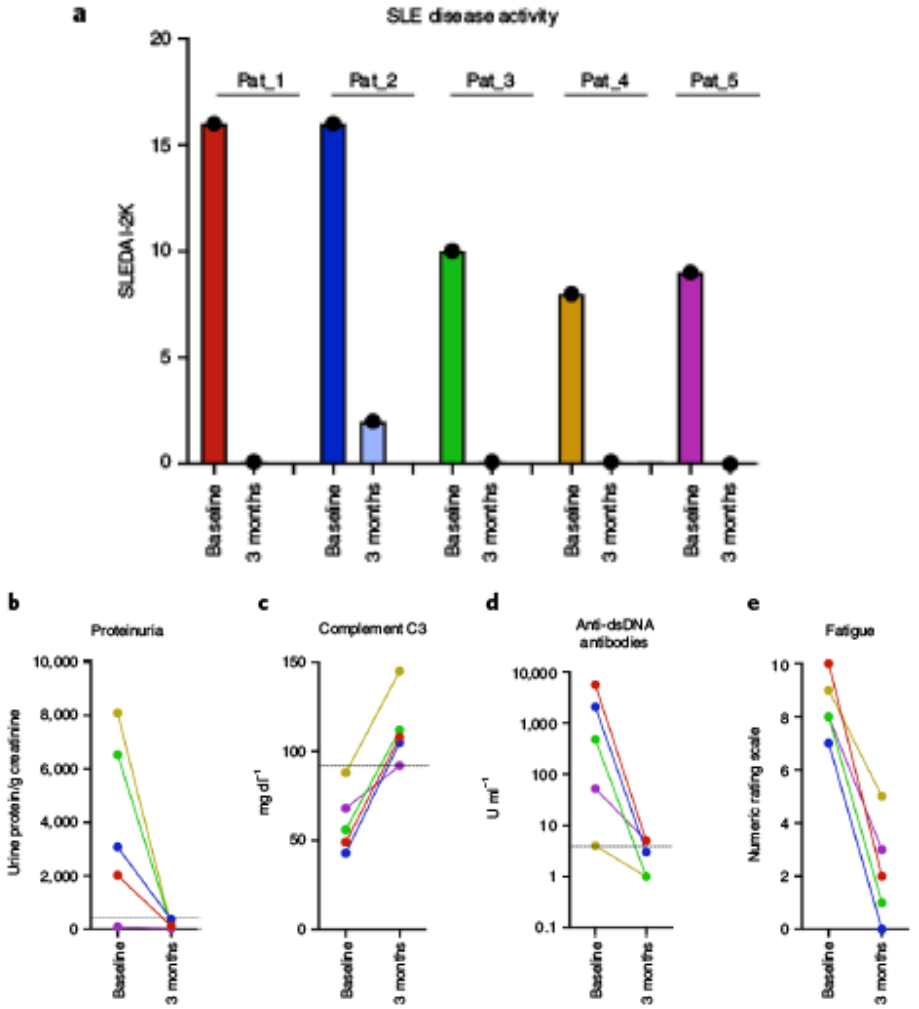
Andreas Mackensen and Georg Schett, University of Erlangen

**Favorable tolerability outcomes**

- Grade 1 CRS in 3 of 5 patients
- No ICANS observed in any patients

**Rapid and sustained disease remissions**

- Disease activity score (SLEDAI-2K) dropped from baseline (ranging 8 to 16) into complete remission within 3 months
- Rapid clearance of anti-dsDNA antibodies indicating rapid removal of autoreactive plasma cells
- Demonstrated improvement in proteinuria
- All patients in sustained remissions
  - Returning to full level of physical activity
  - Cessation of all SLE-specific medication, including steroids
  - Without reoccurrence of autoimmunity (1-2 years follow up)




CRS: Cytokine Release Syndrome
ICANS: Immune Cell-Associated Neurotoxicity Syndrome

Mackensen et al., Nature Medicine 2022

# Promising data in Myositis and Scleroderma

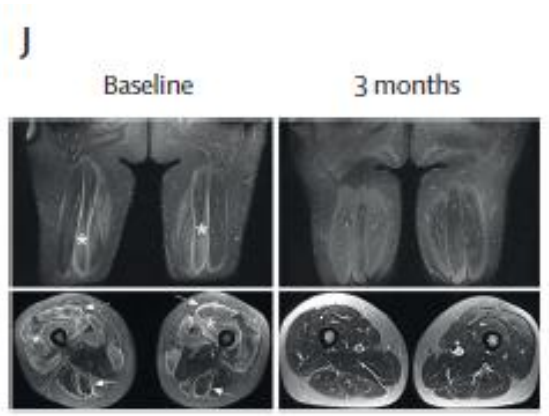
Andreas Mackensen and Georg Schett, University of Erlangen

- Approach applied to a patient with Myositis[1] and a patient with Scleroderma[2]
  - Same CAR T dose and preconditioning regimen
  - Both heavily pre-treated patients with highly refractory disease

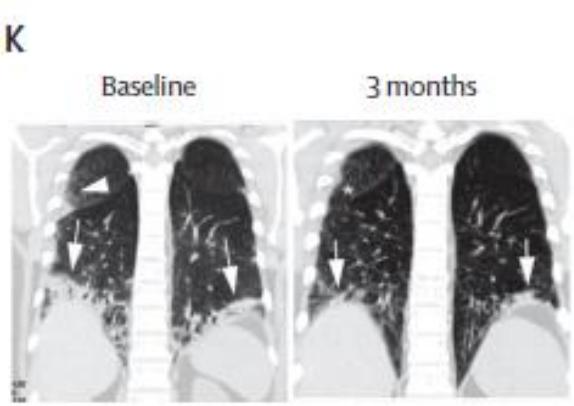
✓ **Outstanding Tolerability Profile:**
- Grade 1 CRS reported in both patients, easily resolved within 1-3days
- No cases of ICANS

✓ **Promising Response Profile:**
- Improvement or resolution of disease manifestations
- Auto-antibodies no longer detectable after treatment
- Short follow-up (up to 6 months)
- Durability of response needs to be evaluated further

**Myositis Patient**




Resolution of muscle lesions




Regression of alveolitis

1. Müller et al. Lancet, 2023
2. Bergmann et al. Annals of the Rheumatic Diseases, 2023

# CAR T therapy could be game-changing for autoimmune patients

Summary of clinical proof of concept data in SLE

- CD19 CAR T-cell therapy results in a deep cut into the CD19+ B and plasma cell compartment
- CD19 CAR T-cell therapy was well tolerated
- Autoreactive B plasma cells were CD19+ as rapid clearance of autoantibodies demonstrates
- Recovery of B cell aplasia leads to a reconstitution of B-cells without recurrence of autoreactive antibodies or relapse
- Patients achieved a complete reversal of their disease and required no further therapy with a follow-up period of 12-24 months
- The data suggests that CD19 CAR T therapy led to transformational outcomes in these refractory SLE patients

# Autolus Opportunity, Advantage and Next Steps

Dr Christian Itin, Chief Executive Officer
Autolus

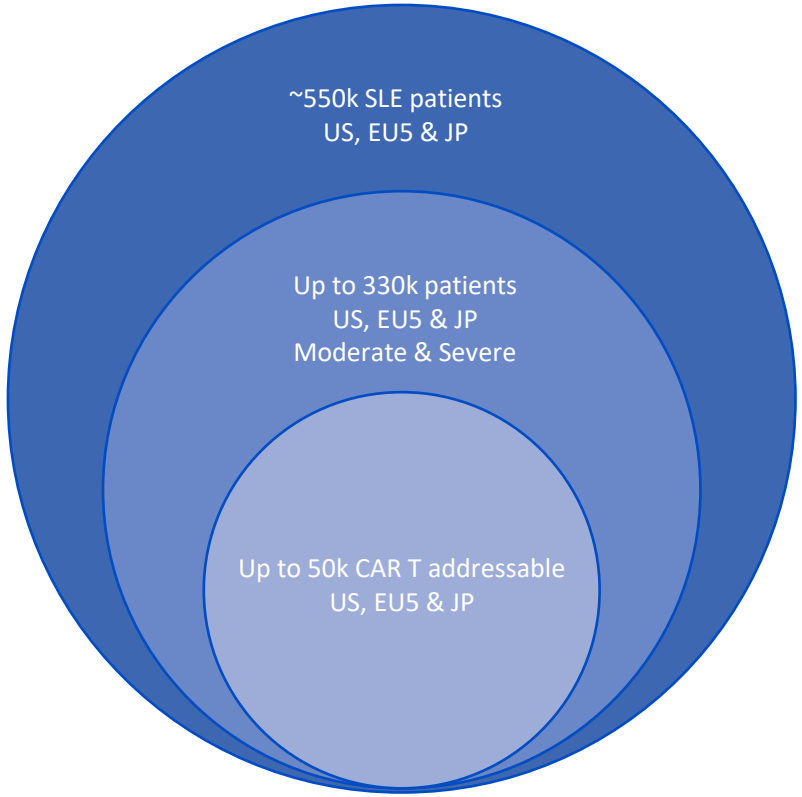
# Significantly underserved patient population with current therapies

## SLE market opportunity

- Drug fee remission is not possible based on the treatments currently available to patients
  - Recent therapy approvals only show a modest effect in controlled clinical studies
- The prevalent population of SLE patients in the US, EU5 and Japan is approximately 550,000 patients
  - Up to 330,000 patients with moderate to severe disease
  - Up to 50,000 patients potentially CAR T addressable[2]
- Opportunity to expand into additional autoimmune diseases

**Systemic Lupus Erythematosus**

*Patient Population*[1]




[1] *GlobalData 2023: SLE and LN: Seven Market Drug Forecast and Market Analysis to 2031*

[2] *Addressable patient population based on Autolus internal estimate in the range of 5-15%*

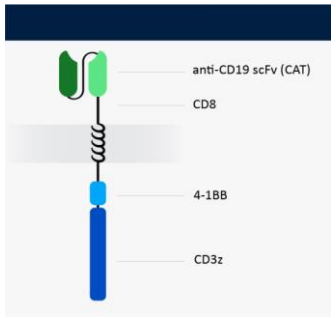
# Uniquely positioned to deliver CAR T therapy in autoimmune disease

| Obe-cel's potential advantages | Supporting evidence |
| --- | --- |
| Outstanding tolerability to drive physician and patient acceptability in rheumatology settings | ✓ Potential best-in-class risk/benefit profile in pivotal FELIX trial in adult ALL<br>✓ Low rates of high-grade CRS and ICANS across all patients |
| Deep cut into the CD19+ B and plasma cell compartment to remove all autoreactive clones | ✓ Demonstrated in B-ALL with very high rate of MRD negative complete remissions (97% of responders) |
| Development of robust, economical and scalable manufacturing and commercial infrastructure | ✓ Potential approved, commercial manufacturing facility in adult ALL with attractive cost of goods at launch for SLE<br>✓ Commercial systems and CAR T center services established with potential adult ALL launch |
| High treatment effect enables smaller clinical program and accelerated regulatory path to launch | ✓ Treatment effect demonstrated in Erlangen proof-of concept<br>✓ Clinical safety data from ALLCAR19 and FELIX as well as potential commercial patient data to supplement SLE pivotal study |

# Obe-cel has a unique mechanism of action

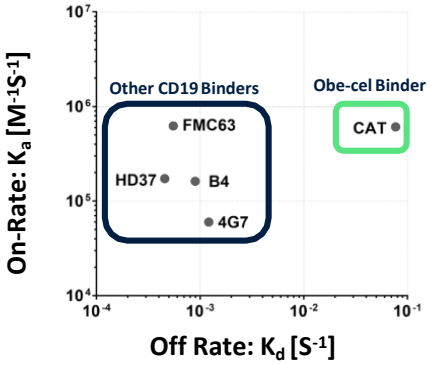
Designed for increased activity and reduced toxicity

## Differentiated CD19 binder




CD19 binder with fast off-rate

## Fast off-rate



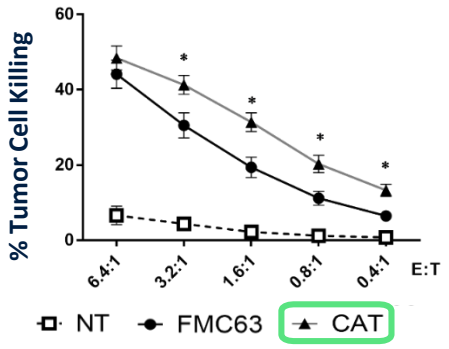

Shorter half-life of interaction compared to binders used in approved products

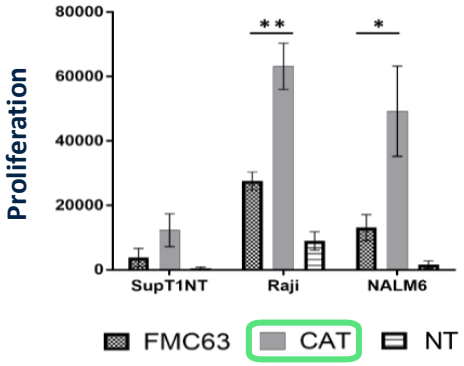
- obe-cel = 9.8 seconds
- Kymriah® = 21 minutes

## Potential for improved potency, reduced toxicity

- Avoids over-activation of CAR T cells → Reduced toxicities
- Increases CAR T peak expansion → Improved persistence
- Avoids exhaustion of CAR T-cells → Improved engraftment, Improved persistence

## Enhanced cytotoxicity and proliferation




Ghorashian et al. *Nature Medicine 2019*

# Obe-cel: Potential best-in-class profile supports autoimmune development

Felix study included subgroups of highly challenging ALL patients

FELIX 19

**Pivotal trial in adult ALL with sites in UK, Spain and US**

**Large adult B-ALL tolerability database available, which will be substantially expanded by time of launch in autoimmune with additional clinical study data and extensive data from commercial patients via REMS program**

## Obe-cel Path to Registration for adult r/r ALL

**BLA filing targeted by end 2023**

**MAA filing targeted in 1H 2024**

Key obe-cel regulatory designations

- FDA: RMAT
- EMA: PRIME
- MHRA: ILAP

# Potential best in class response and tolerability in challenging patients

## Summary of FELIX pivotal clinical trial data in r/r Adult ALL

### A very challenging patient population

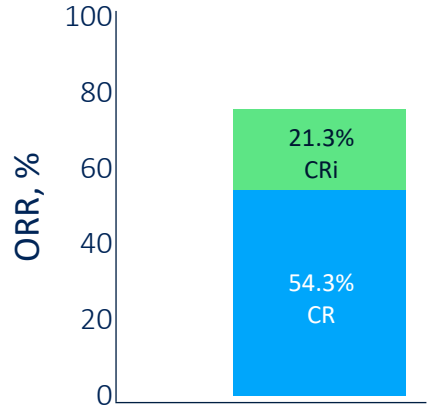
- Heavily pretreated and highly refractory patients
- Significant high disease burden and extra medullary disease

### High overall response rate with deep molecular responses

- 76% of infused patients achieved CR/CRi
- 97% of responders had MRD negative remissions

### Exceptional tolerability profile

- Very low rates of high-grade CRS and ICANS across all patients
- No high-grade events in low disease burden patients
- Believe low disease burden patients are most representative of potential autoimmune patient population




**ORR: 76%**
95% CI (66, 84)
p<0.0001*

**97% of responders were MRD negative at $10^{-4}$ level by flow cytometry**

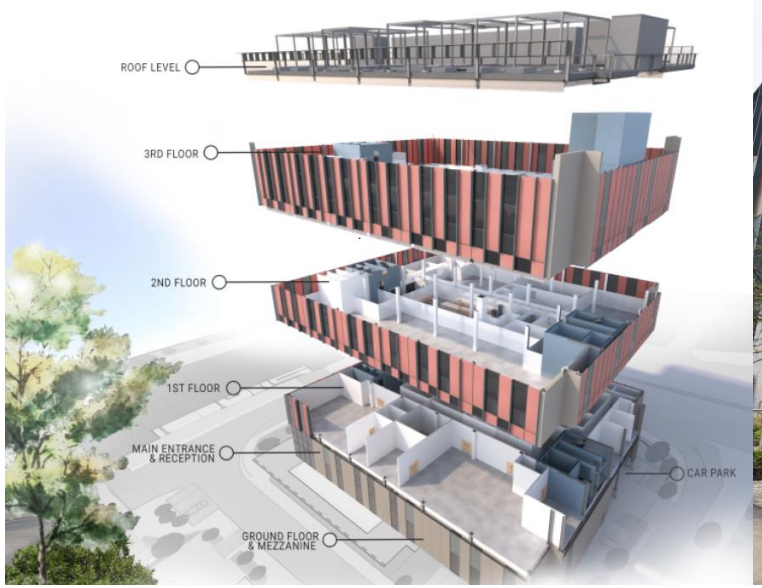
| FELIX | | ≥5% Blast (N=91) | <5% Blast (N=36) | All Patients (N=127) |
|---|---|---|---|---|
| **CRS** | | | | |
| | any grade | 70 (76.9%) | 17 (47.2%) | 87 (68.5%) |
| | Grade ≥ 3 | 3 (3.3%) | 0 | 3 (2.4%) |
| **ICANS** | | | | |
| | any grade | 26 (28.6%) | 3 (8.3) | 29 (22.8%) |
| | Grade ≥ 3 | 9 (9.9%) | 0 | 9 (7.1%) |

Roddie et al., ASCO 2023 Data Cutoff Date: 09-Jun-2023

# Established commercial manufacturing in the Nucleus

State of the art design and operations established

## Design




- ~70,000 sq ft  facility
- Modular build using PAMs
- 70% built off-site
- 60% reduced build time
- BREEAM Excellent rating for sustainability

## Build

- Groundbreaking on Nov. 8, 2021
- First clean room operational on Nov. 25, 2022
- Facility validation completed in 2nd half of 2023

## Operations

- First Prodigy operational on Dec. 14, 2022
- Capacity challenge in May 2023
- Designed for 2,000+ batches per year
- Target vein to delivery time 16 days at launch

# Highly reliable and consistent manufacturing quality and product delivery

Supported by data from the FELIX pivotal study

## Robust performance despite challenging B-ALL leukapheresates

- Fully enclosed semi-automated manufacturing (Miltenyi)
- Process optimized to manufacture for any patient
- Autoimmune patients will have normal leukapheresate
- Phase 1 study will use the same manufacturing process as FELIX with a fixed dose (50MM)

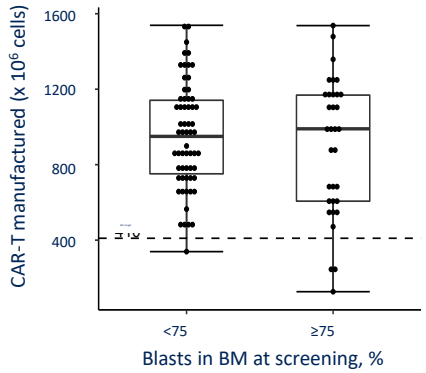
## Highly competitive product vein to release times

- Expected 16 days at launch for adult r/r ALL
- Higher quality leukapheresates and smaller dose in autoimmune patients enable shorter manufacturing and vein to release times

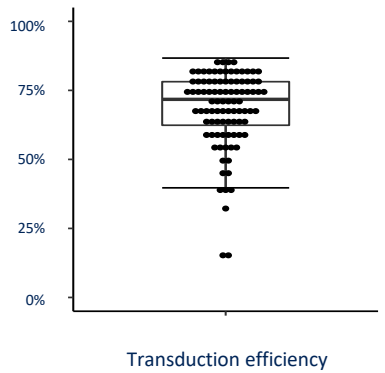
## Scalable autologous CAR T manufacturing at a low cost of goods

- Adult ALL manufacturing establishes attractive facility utilization and COGS ahead of launch in autoimmune indications

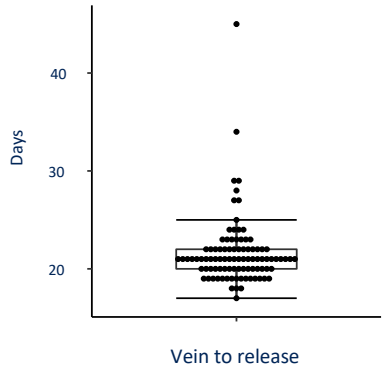
**96%** of products reached target dose



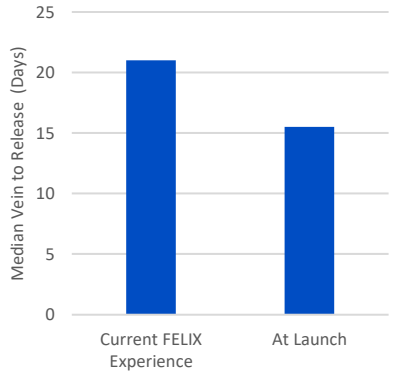

Median transduction efficiency of **72%**




Median **21 days** from vein to release

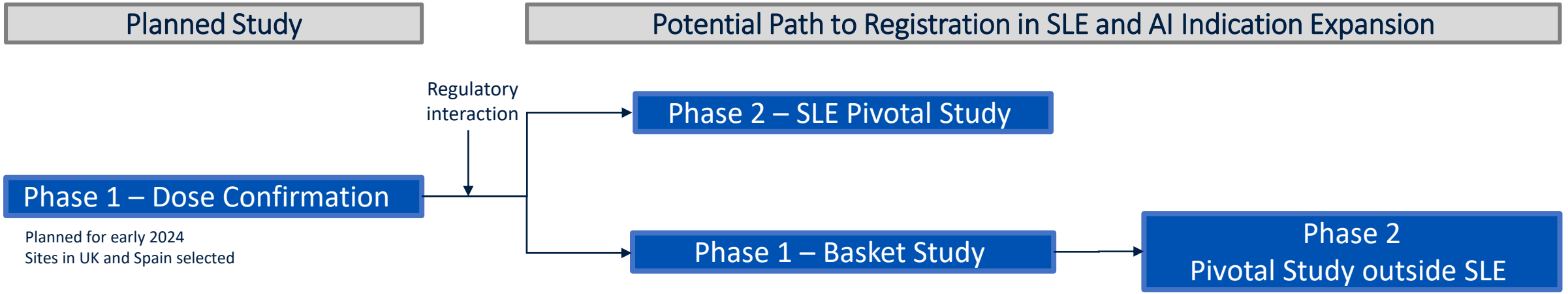



aALL vein to release time



# SLE Phase 1 study start planned for early 2024

Engagement with KOLs to guide study designs




| | |
|---|---|
| **SLE Indication**<br>1) Phase 1: Dose confirmation study<br>2) Phase 2: Pivotal study | • Single dose of obe-cel at 50m CAR T-cells<br>• Regulatory engagement sought ahead of pivotal (leverage FELIX tolerability data)<br>• Transformational treatment effect to support potential for a single arm pivotal study; significantly reducing development timelines and costs |
| **Other Autoimmune indications**<br>1) Phase 1: Basket study<br>2) Phase 2: Pivotal study (most promising indications) | • Basket study to explore opportunities for development in other indications<br>• Dose will be established from the SLE Phase 1 data and study initiated following the SLE regulatory interaction |

# Additional autoimmune indications

SLE provides gateway to exploring additional B-cell mediated autoimmune diseases

- SLE planned as the initial autoimmune disease, based on the scientific evidence generated by the Erlangen group, however, there are **other B-cell mediated autoimmune diseases that CAR T-cell therapy could successfully position**
- Indications under consideration include, Systemic Sclerosis/Scleroderma, Primary Membranous Nephropathy (PMN), Idiopathic Inflammatory Myositis (IIM), ANCA+ Vasculitis, Rheumatoid Arthritis
- The basket study would initiate following the Phase 1 SLE study, utilizing a similar dose. Provides an opportunity to rapidly develop in multiple indications in parallel prior to accelerating into a second pivotal autoimmune study
- The initial market opportunity for obe-cel in the additional indications of interest **are projected to be similar to SLE**

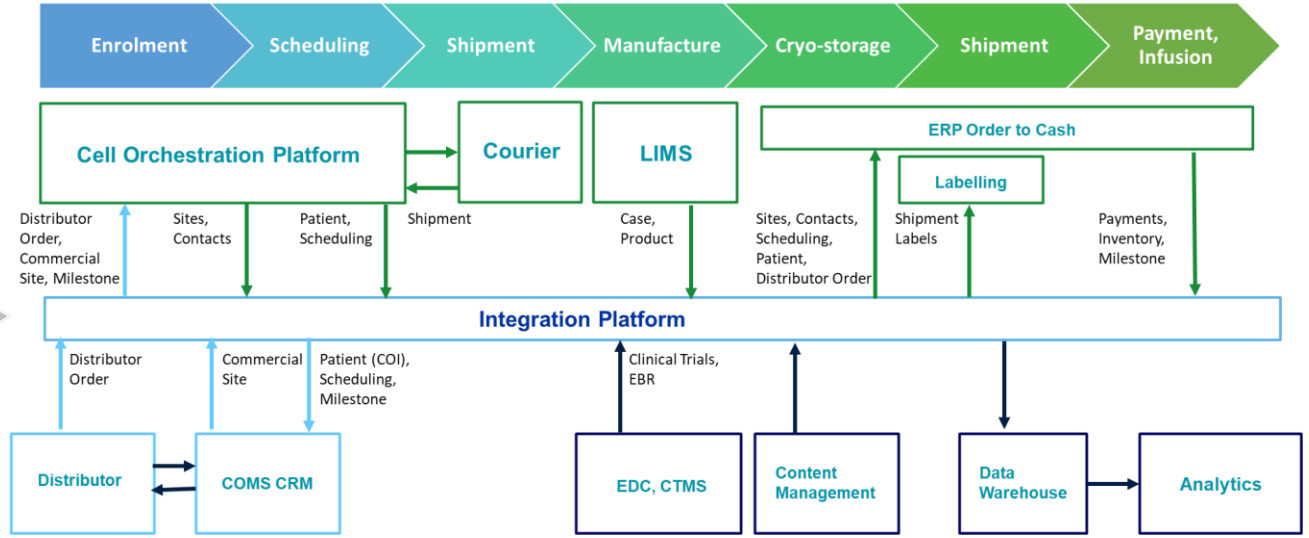
# Potential to leverage commercial infrastructure established in adult ALL

60+ centers in the US, 200+ globally for aALL potentially in place at time of commercial launch in SLE


Establishing CAR T Center Integrated Central Service and Support for aALL

Commercial Systems

- All GxP systems in place for BLA filing
- Establishing additional commercial systems for potential aALL launch



# Obe-cel ideally positioned as potential best in class and fastest to market

## Offers fastest and lowest risk cell therapy approach for B-cell mediated autoimmune diseases

| | Established Tolerability Profile | Established Clinical Profile | Manufacturing Infrastructure | Commercial Infrastructure | Comment |
|---|---|---|---|---|---|
| AUTOLUS (obe-cel) |  |  |  |  | Potential best-in-class risk/benefit ratio. Established manufacturing and product delivery. ALL commercial infrastructure in place for SLE. |
| BIOTECH: (new CAR T entrants) |  |  |  |  | Clinical profile not yet established. Likely use CDMO or local site for manufacturing with unfavorable cost implications. |
| PHARMA: (new CAR T products) |  |  |  |  | New products under development. Will need to re-establish efficacy & safety profile and commercial manufacturing for autoimmune. |
| ALLOGENEIC |  |  |  |  | Clinical profile not yet established. |

# Final remarks and Q&A

Dr Christian Itin

# Thank you