

**Novartis Oncology  
Cell & Gene Therapies**



# **International Supply Chain Expansion & Approvals During COVID-19 Cellicon Valley '21 Future of Cell and Gene Therapies, May 2021**

**Amir Hefni, PhD MBA  
Global Commercial Head, Cell & Gene, Novartis**



*“We’re making the immune system do things it never could ... it’s unlike anything the pharmaceutical industry has ever done.”*

**Carl H. June, MD**

**Richard W. Vague Professor of Immunotherapy at the Perelman School of Medicine and Director of the Center for Cellular Immunotherapies at the Abramson Cancer Center, University of Pennsylvania**

# Today...

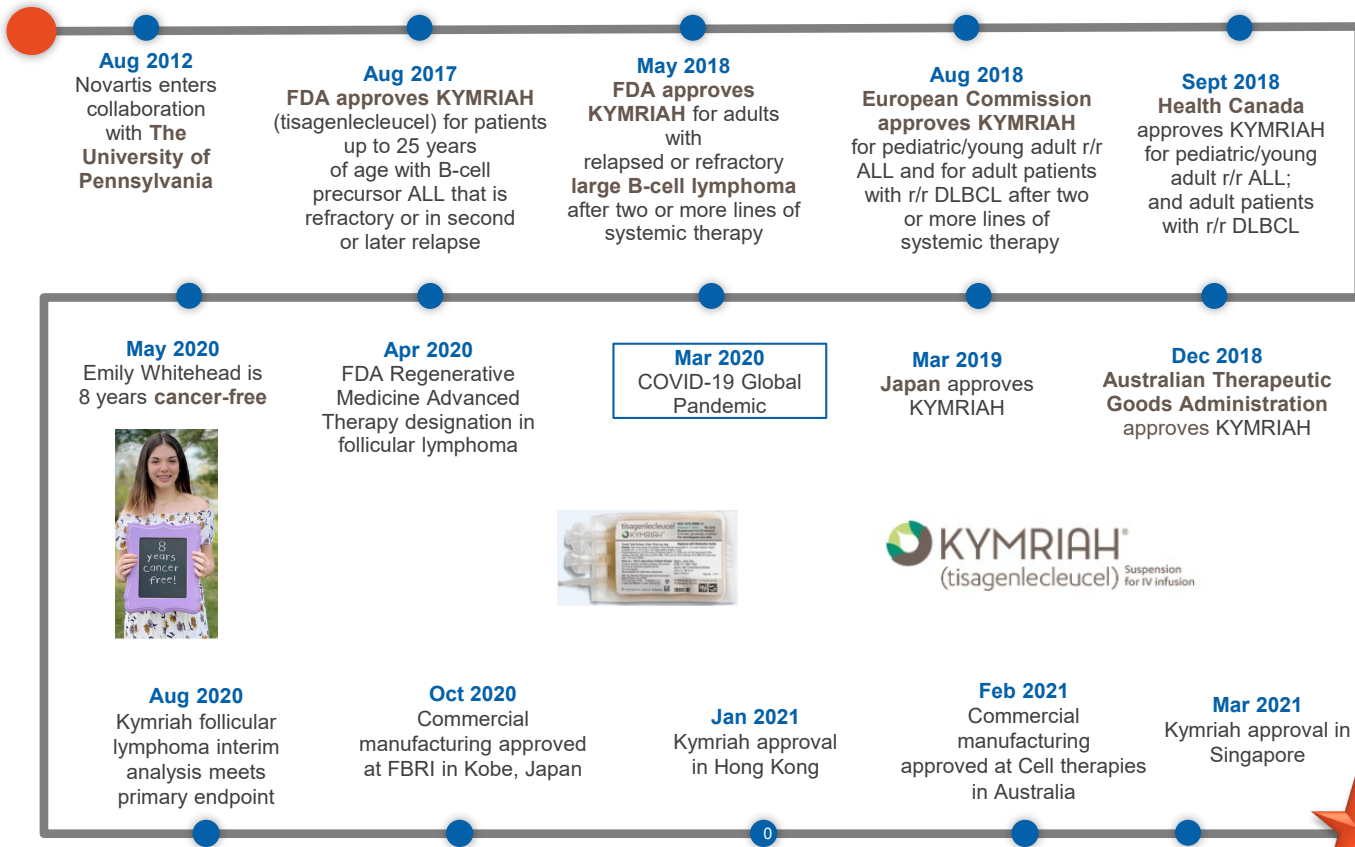
- **The Kymriah Journey: From FDA approval to today**
- **Our commitment to no queue & broader patient access**
- **Adapting to the COVID-19 pandemic**

# Novartis journey of bringing CAR-T cell therapy to patients



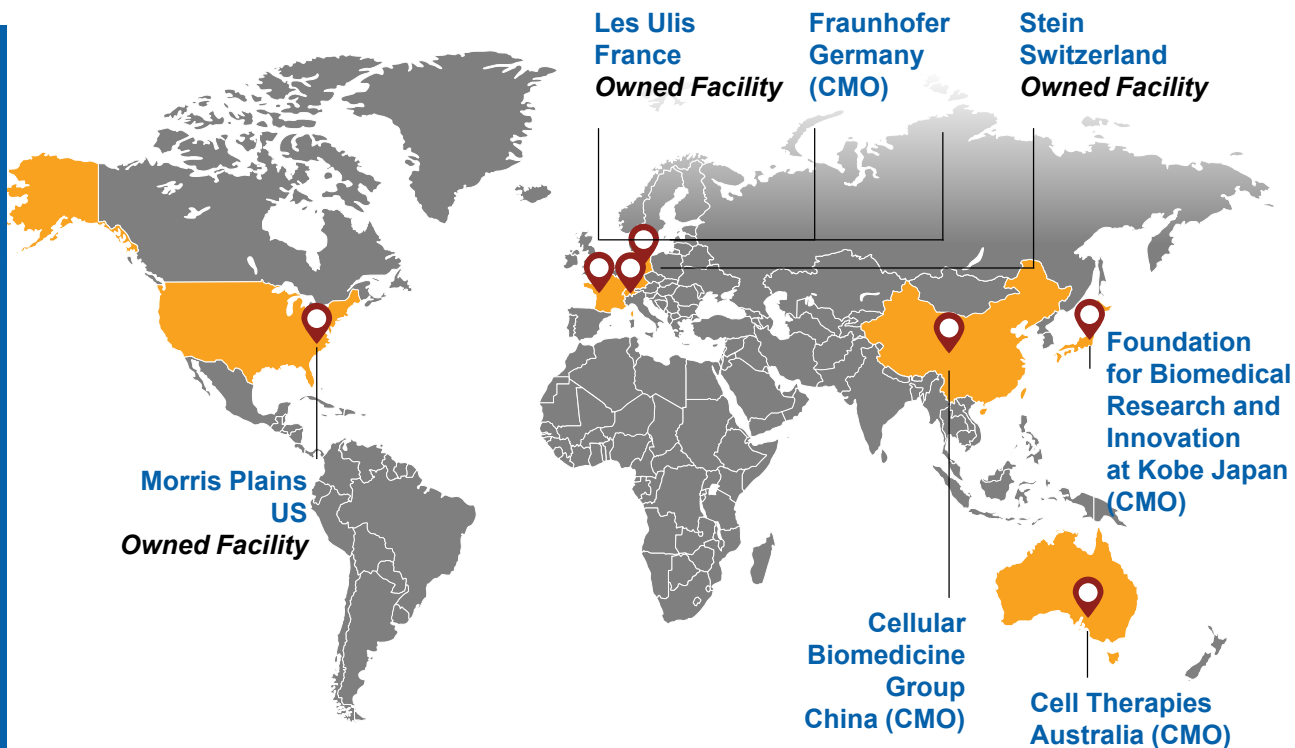
**Vas Narasimhan, MD**  
Chief Executive Officer  
of Novartis

*“Novartis is at the forefront of the science and development of immunocellular therapy as a potential new innovative approach to treating certain cancers where there are limited options.”*



# A truly global undertaking to successfully scale up and deliver Kymriah for patients in need

- 7 facilities across 4 continents
- Comprehensive, integrated footprint strengthens the flexibility, resilience and sustainability of the manufacturing and supply chain
- Strong capacity growth (+124% 2019 vs. 2021)
- Manufactured CAR-T cells for >4,500 patients worldwide



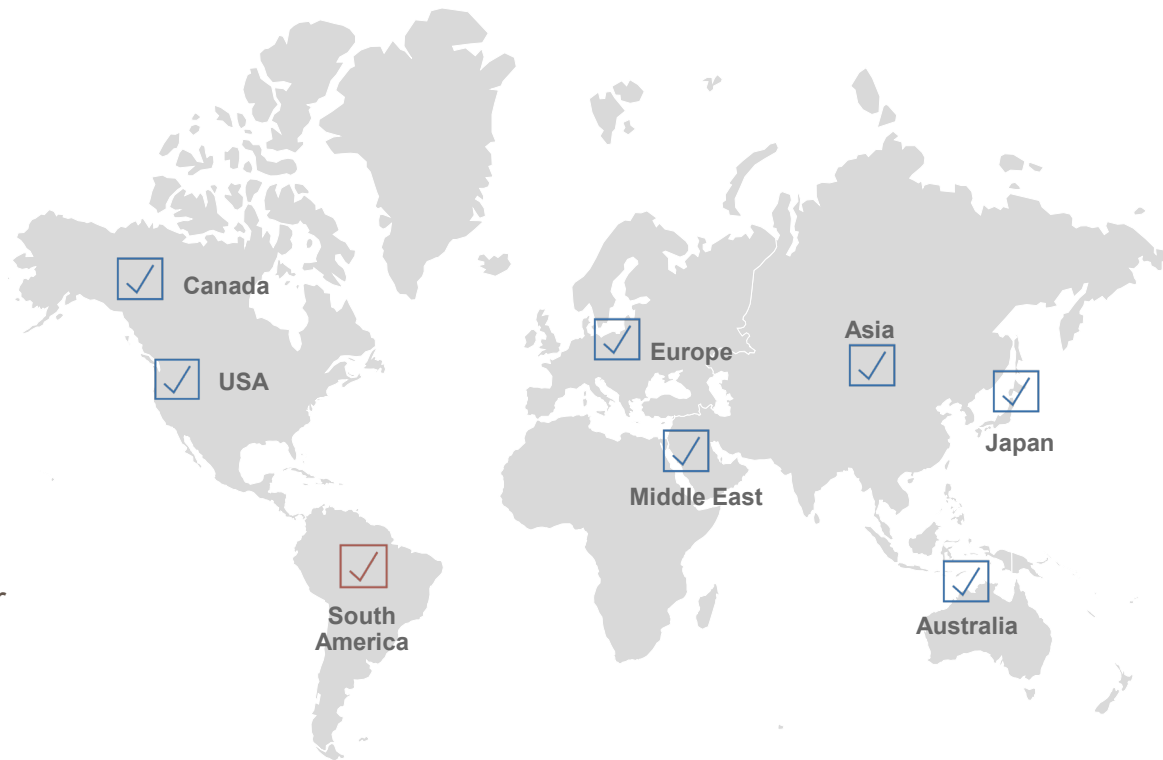
# Broad geographic footprint for worldwide access to Kymriah

Approved for r/r pALL and DLBCL in the US, EU, Switzerland, Canada, Australia, and Japan

- >300 qualified treatment centers
- Gradual expansion to ensure patient safety and supply

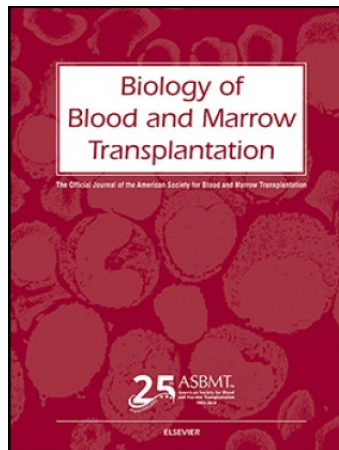
Reimbursement achieved in 28 countries

Additional markets being evaluated to provide greater patient access to Kymriah





# COVID-19: Can't Stop, Won't Stop



During COVID-19 Pandemic

## Increase Patient Access

- Regulatory approvals (Hong Kong, Singapore and Saudi Arabia)
- Three reimbursements (Romania, Hong Kong & Saudi Arabia)
- >90 global sites onboarded (25 US, 35 EU, 34 Intl)
- Benefits of outpatient use, supported by RWE

## Accelerate Capacity Building

- >10 FDA approved manufacturing updates (capacity, consistency & quality)
- Two new manufacturing sites (Japan & Australia)

## Commitment to Partnership

- Moving apheresis and infusion dates and sites to accommodate patient and site needs
- Virtual site onboarding
- Moving fully into e-signatures to avoid delays (including patient support)
- Travel assistance programs

*“Though these recommendations are fluid, at this time it is our opinion that the COVID-19 pandemic should not serve as reason to defer CAR T cell therapy for patients truly in need of a potentially curative therapy.”\**

\*Source: Biol Blood Marrow Transplant 26 (2020) 1239-1246

# Update on Kymriah manufacturing



Capacity- eliminating queue<sup>1-4</sup>



Continuous manufacturing improvements<sup>5</sup>



Final product viability<sup>6,7</sup>

[Click here](#) for full Prescribing Information for KYMRIA<sup>®</sup> (tisagenlecleucel) suspension for IV infusion, including Boxed WARNING, and Medication Guide.



# Relentless drive to address medical needs through reimagining medicine using our Cell & Gene Platform

Expand access to Kymriah across the globe

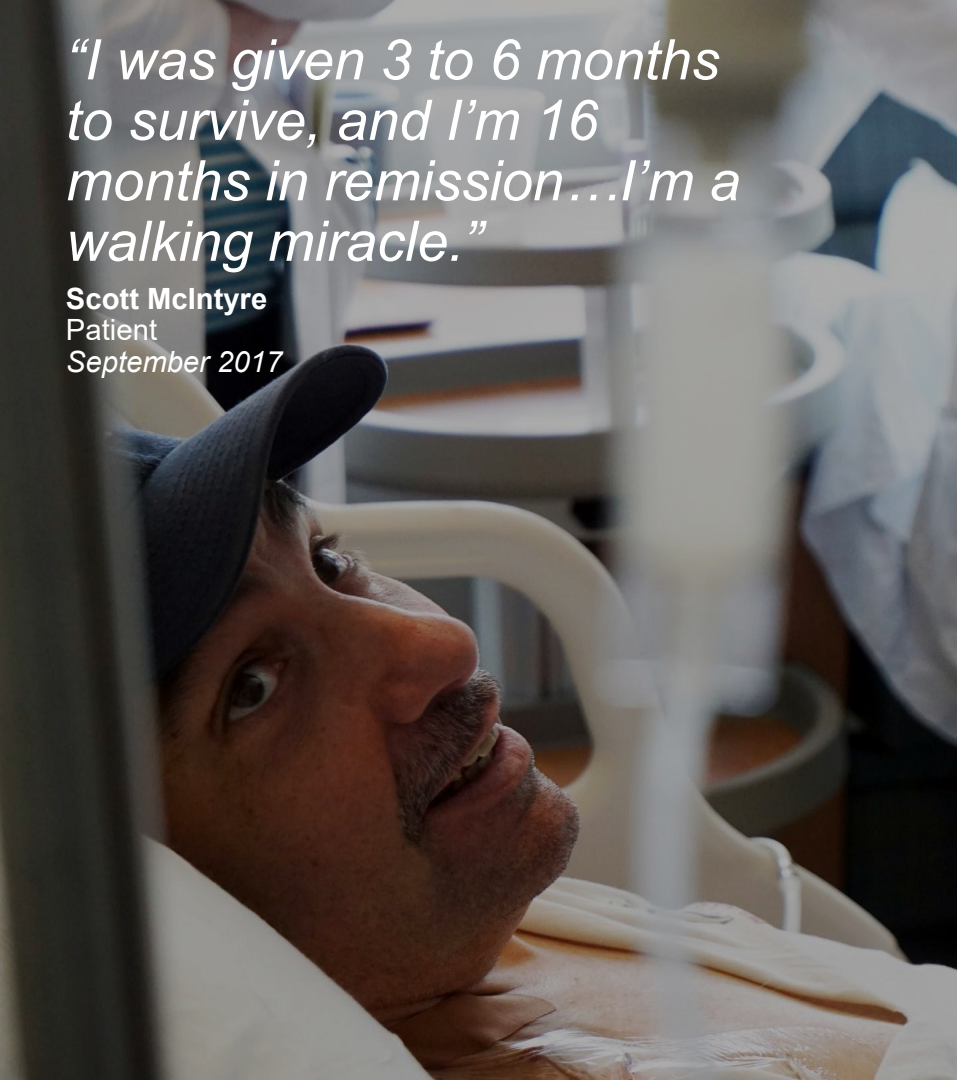


Internal pipeline to address new patients and targets




External collaborations to deliver Kymriah to patients



A man with a mustache and a dark baseball cap is lying in a hospital bed, looking upwards and to the right. The background is a blurred hospital room with white chairs and a table.

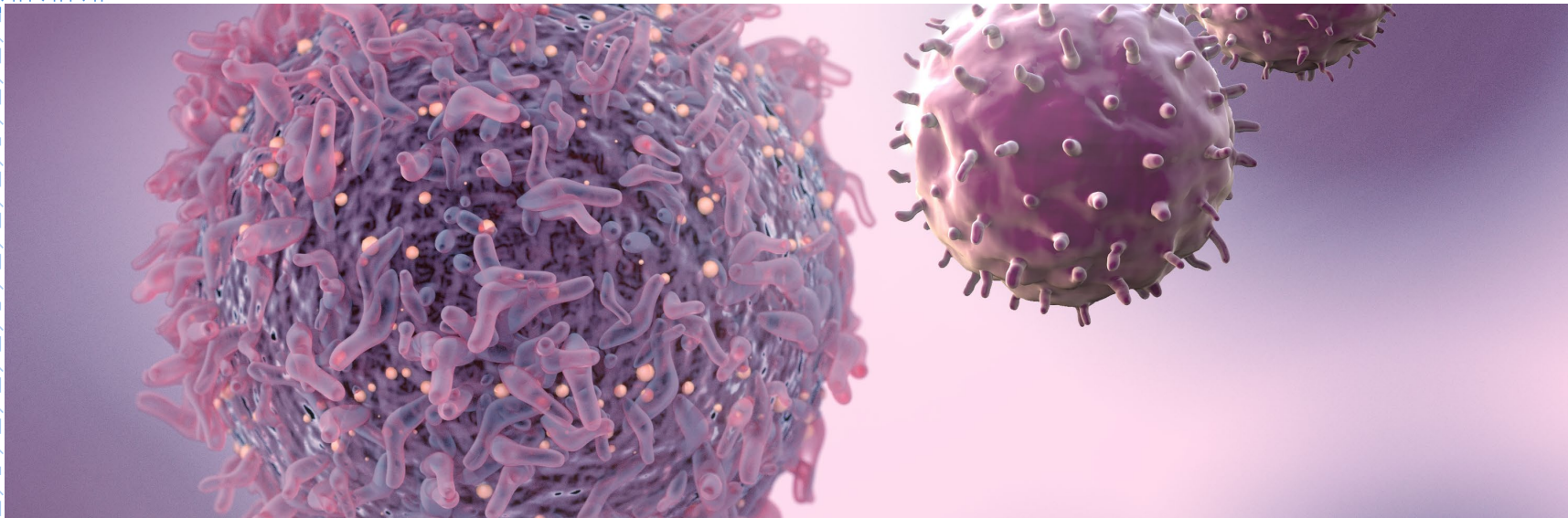
*“I was given 3 to 6 months to survive, and I’m 16 months in remission...I’m a walking miracle.”*

**Scott McIntyre**  
Patient  
September 2017

A man with a goatee and a dark suit is smiling, standing next to a young girl with brown hair and a purple top. She is resting her chin on his shoulder. They are in front of a brick wall.

*“Our daughter was going to die, and now she leads a normal life...she’s standing right beside me and it’s because of this treatment.”*

**Tom Whitehead**  
Father of Emily Whitehead



**Thank you**