



Future Directions for Immune Cell Therapies

Ian Nisbet, PhD
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The Song of the Cell: An Exploration of Medicine and the New Human



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Cellular physiology is thus the basis for human physiology, and **cellular pathology** is the basis for **human pathology**....

The capacity to build new humans out of our building blocks – i.e., cells – lies very much within the reach of medicine today; **cellular reengineering can ameliorate, or even reverse, cellular pathology.** ”

Dr Siddhartha Mukherjee

Oncologist
Researcher
Entrepreneur
Pulitzer Prize winner

The Starting Point: Autologous CAR-T Cell Treatment Targeting CD19

April 2012: 7yo ALL patient, Emily Whitehead, treated with CD19 CAR-T cell product (now known as KYMRIA[®])



Source: Emily Whitehead Foundation (www.emilywhiteheadfoundation.org)

FDA-Approved CAR-T Products: Autologous CAR-T Cell Therapies for Rare Blood Cancers

Brand name	CAR Target	FDA Approval	Company	Indication(s)
<i>Kymriah</i>	CD19	Aug 2017	Novartis	B-cell ALL, DL and high-grade BCL, follicular lymphoma
<i>Yescarta</i>	CD19	Oct 2017	Gilead / Kite	BCL (including DLBCL), follicular lymphoma
<i>Tecartus</i>	CD19	Jul 2020	Gilead / Kite	MCL, B-cell precursor ALL
<i>Breyanzi</i>	CD19	May 2021	BMS	BCL, follicular lymphoma
<i>Carvykti</i>	BCMA	Feb 2022	Janssen/ Legend	Multiple myeloma
<i>Abecma</i>	BCMA	Apr 2024	BMS	Multiple myeloma
<i>Aucatzyl</i>	CD19	Nov 2024	Autolus	B-cell precursor ALL

Brand names are registered trademarks of the listed companies

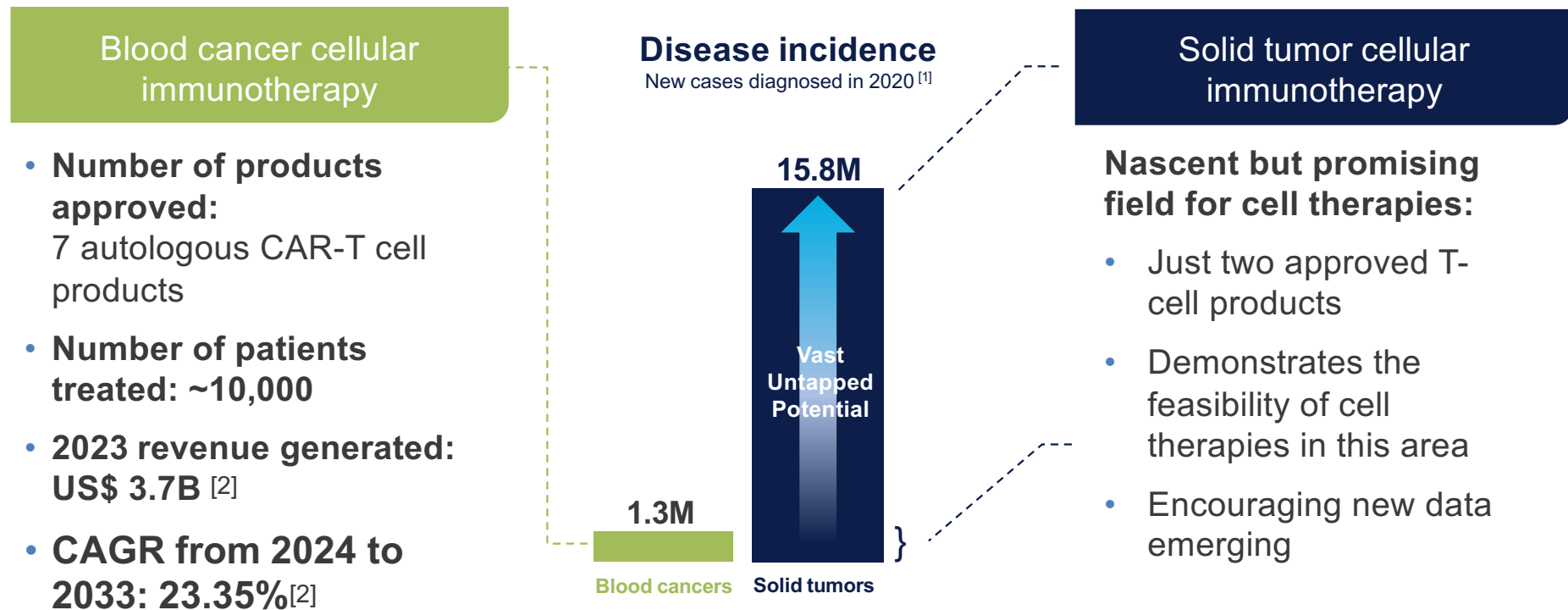
Issues with Autologous CAR-T Cell Products

Despite exceptional efficacy in approved indications, multiple challenges with autologous CAR-T cells limit their potential

Critical challenges for autologous CAR-T cells

- **Safety** – life threatening adverse events
- **Manufacturing** – logistics, COGS, batch failures
- **Cost** – patient-specific, extremely expensive
- **Logistics** – only available at specialised cancer centres
- **Efficacy** – limited to rare blood cancers (to date); tumor access and tumor microenvironment (TME)

Multi-Billion Dollar Solid Tumor Market



1 wcrf.org/cancer-trends/worldwide-cancer-data/

2 visionresearchreports.com/car-t-cell-therapy-market/40008

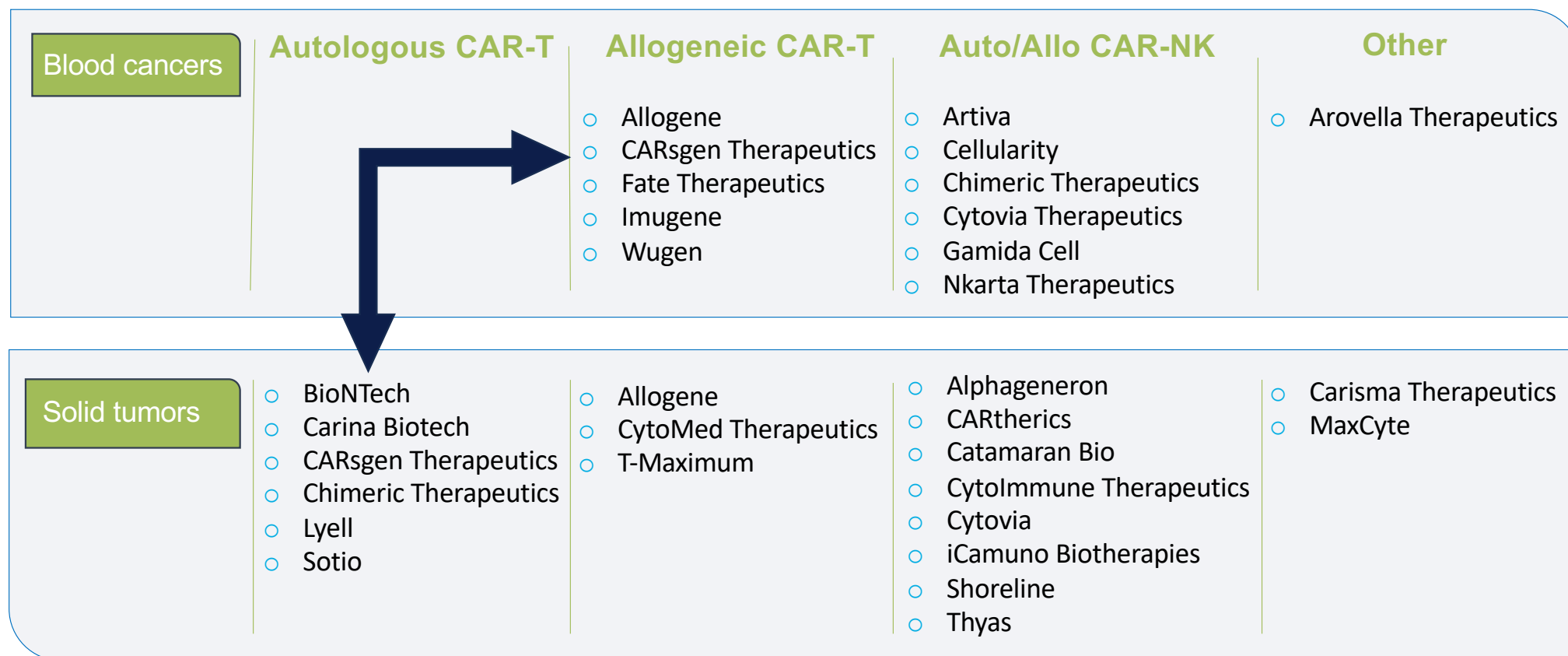
Addressing Issues with Autologous CAR-T Cell Products

Just as the challenges are multifactorial, so are the approaches to solving them

Approaches to solving the problems

- **Safety** – modified treatment protocols and patient monitoring; alternative cell types (e.g., NK cells)
- **Manufacturing** – improved protocols; allogeneic ("off-the-shelf") products
- **Cost** – improved manufacturing protocols; allogeneic products; alternative product modalities
- **Logistics** – alternative (safer) cell types; alternative product modalities
- **Efficacy** – gene modifications to overcome TME; tumor targeting; combination therapies

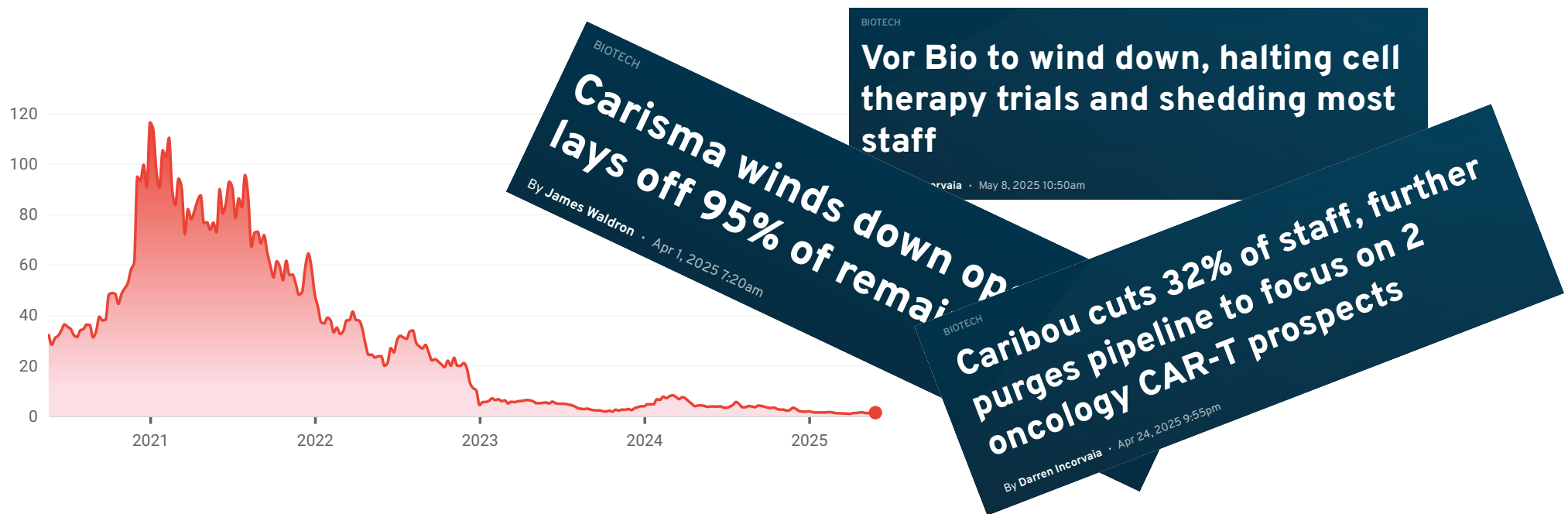
Expanding Beyond Autologous CAR-T Cells in Blood Cancers



Companies listed are representative examples of companies developing different types of products

Immune Cell Therapies: Not Flavor of the Month

Since 2021, immune cell therapies have fallen out of favor with investors and pharma



Sources: Google Finance, Fierce Biotech

Expanding Indications Beyond Cancer

Autoimmunity	Autologous CAR-T	Allogeneic CAR-T	Auto/Allo CAR-NK	Other
	○ BMS	○ Century Therapeutics ○ Fate Therapeutics	○ ONK Therapeutics ○ Therabest	
Other		○ Adicet Bio ○ Appia Bio	○ CARtherics ○ NKGen	○ Appia Bio ○ Carisma Therapeutics ○ GRI Bio ○ Resolution Therapeutics

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Emerging Modalities and Indications

New platforms open up alternative approaches to immune cell therapies; emerging safety profile will open up new indications

In vivo CAR-T cells

- Avoid cell manufacturing issues
- Drug therapy rather than a cell therapy
- Pharma friendly

- Abbvie
- AstraZeneca
- Gilead / Kite

Extracellular vesicles (EVs)

- Leverage manufacturing by-product
- More like a drug than a cell
- Unaffected by TME

- CARtherics
- INOVIQ

Earlier-stage cancer (adjuvant therapy)

- Establish safety profile then move to healthier patients
- Reduced tumor burden
- Reduced impact of TME

Poorly-treated chronic diseases

- Leverage safety profile for underserved, diseases such as:

- Endometriosis
- Fibrosis
- Cirrhosis
- Neurological diseases

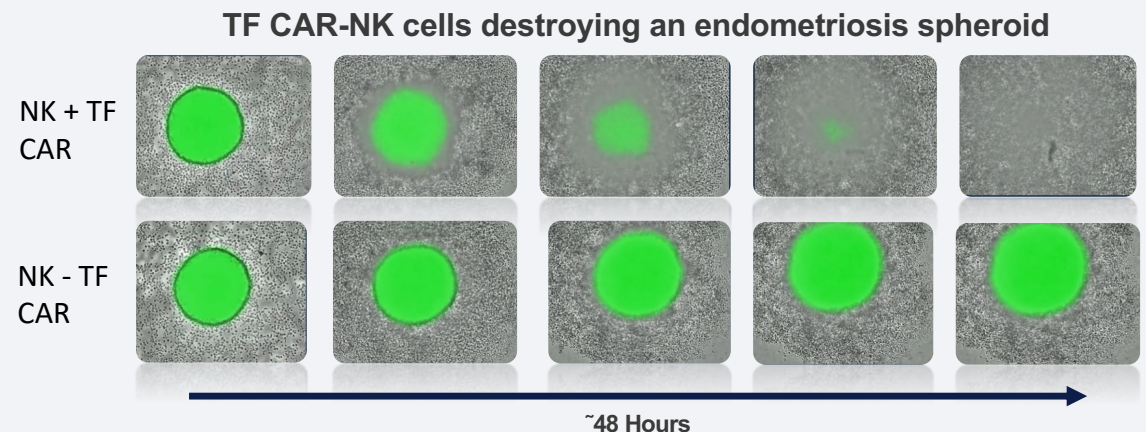
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Cartherics' Early *in vitro* Endometriosis Data

Tissue Factor (TF) CAR-NK cells kill endometriosis cells

Our Development Strategy:

1. Target markers that are common to cancer and endometriosis
2. Establish safety in cancer patients
3. Bridge to “healthy” but poorly served patients based on dose and safety from FIH cancer studies
4. Bridge to earlier stage patients



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We can name cells, and even systems of cells, but we are yet to learn the *songs* of cell biology.”

Dr Siddhartha Mukherjee

Oncologist
Researcher
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