Cell & Gene Therapy: Opportunities in India

Murali Ramachandra, CEO, Aurigene Oncology

Agenda

Current Cancer Status in India

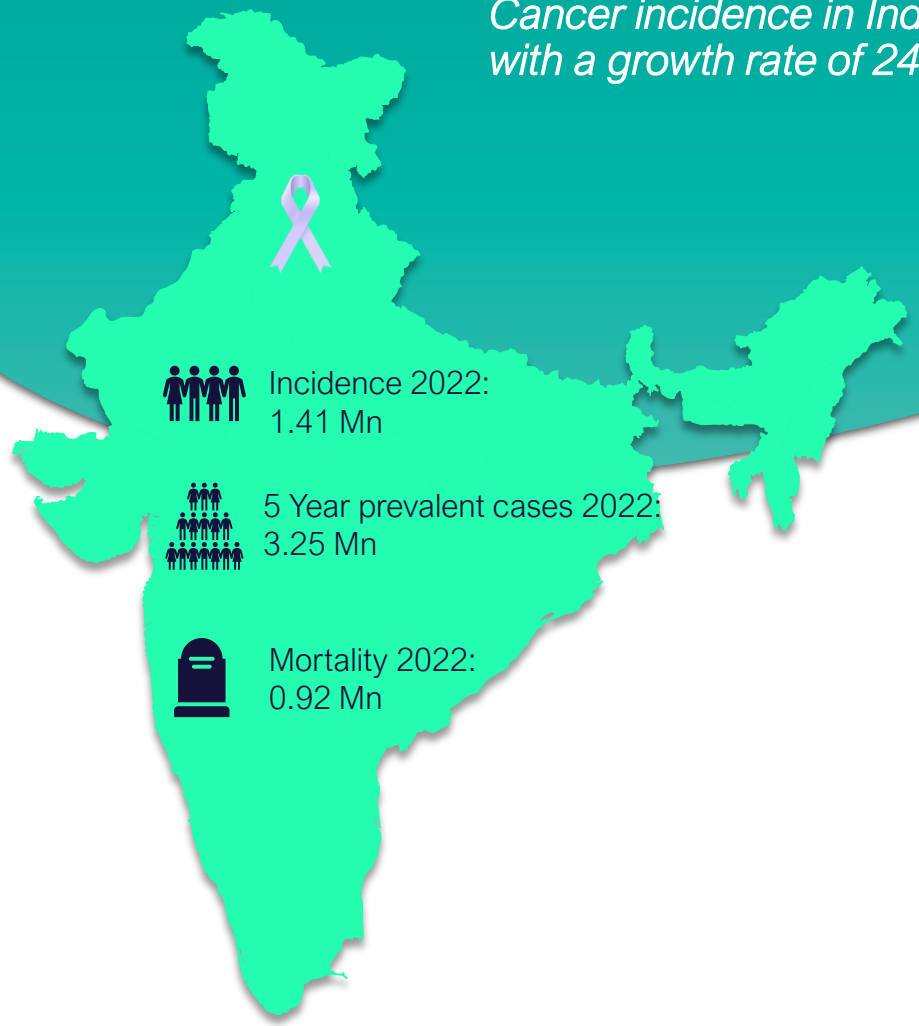
Opportunities in CART

India’s Readiness in CAR-T Therapy

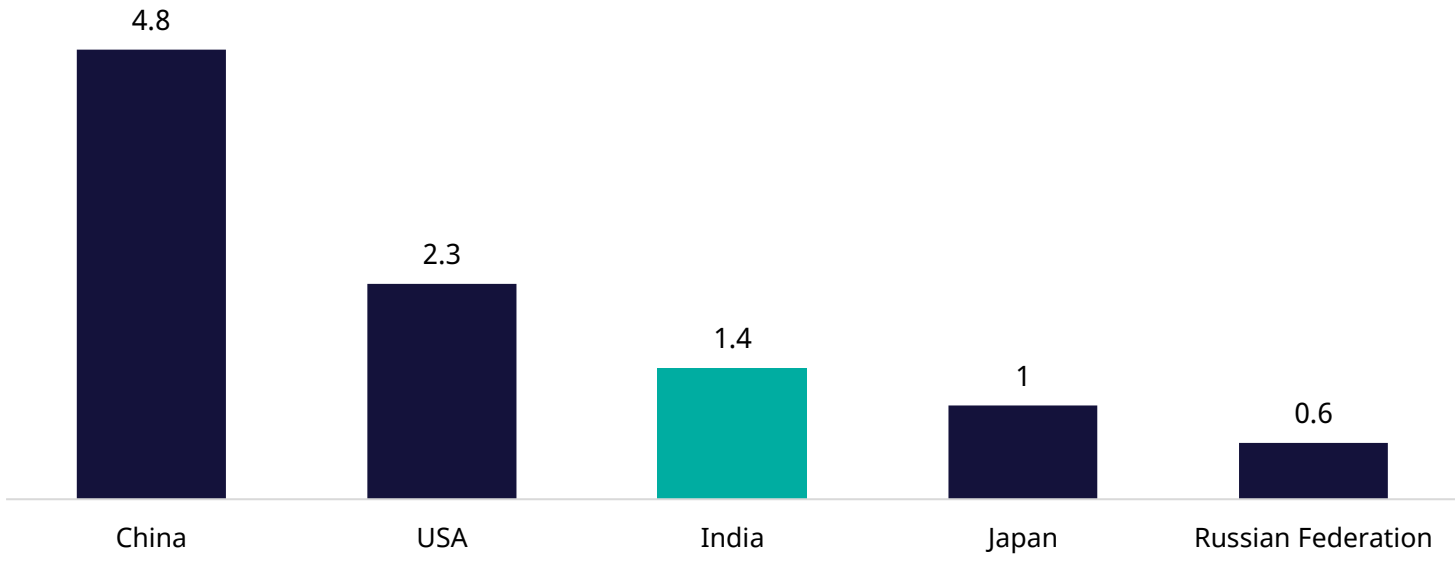
Recommendations to make INDIA CAR-T Ready

Globally, India holds 3rd position in terms of cancer incidence

Cancer incidence in India is expected to reach 1.51 Mn by 2025 and 1.73 Mn by 2030 with a growth rate of 24%



Top 5 countries by Cancer Incidence 2022 (Mn)



Source: Globocan

But India lacks universal access to transformational therapies

Majority of recent blockbuster medicines in oncology are not considered high priority by oncologists in India as they offer:

- ***Small incremental gains***
- ***High cost of therapy***
- ***Many are effective in only small subgroups of patients***

Cancer care in India is associated with significant financial toxicity:

80-85%

Population across all quintiles is not covered by health insurance

Government sponsored insurance scheme is the main type of health insurance for the population who are covered by health insurance.

~65%

Patients with cancer in India receive care in private health care facilities hence face significant OOP expenditure

Source: JCO Global Oncology (2022); Ministry of Health & Family Welfare (2022)

CAR-T therapy has been widely praised as a revolutionary cell immunotherapy

FDA has approved (including accelerated approval) cell therapies for cancer, diabetes and nasolabial folds

CAR T-cell therapy has shown outstanding success in patients

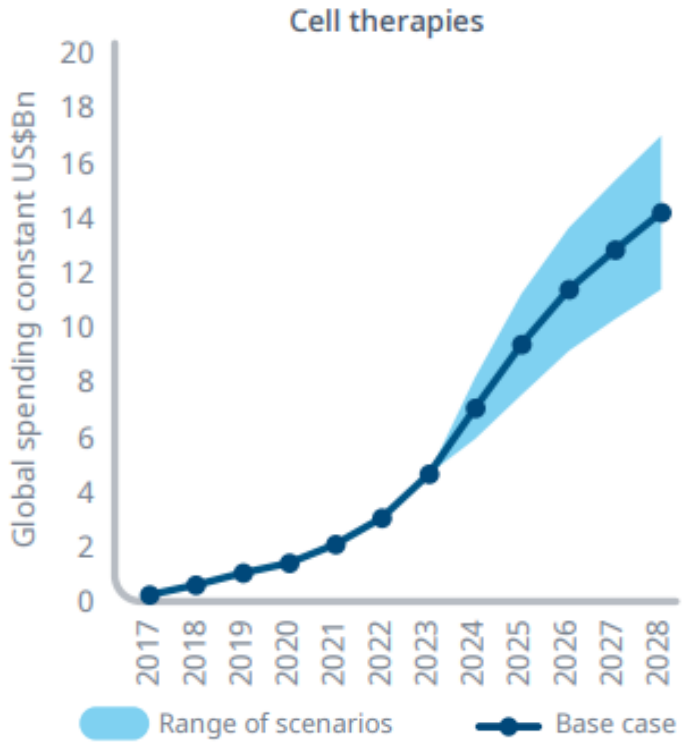
(e.g., CRR between 70% and 94% across distinct trials have been reported in B-ALL)

The therapy costs*

~ ₹4 crore to ₹ 5 crore
abroad

As per IQVIA, the global spending# for cell therapies is estimated to reach

~ $ 14 Bn by 2028



Source: FDA, IQVIA (2024), International Journal of Molecular Sciences (2023), Indian Express

*Price to patient; # Invoice based price

However, cell therapy is characterized by its high cost of manufacturing

- ***Long Process- Takes week/s to complete***
- ***Involves multiple steps***
- ***Being autologous, difficult to manufacture at scale***

High manufacturing costs

Aim is to make these therapies:

01.

Scalable

02.

Less Time Consuming

03.

Cost Effective

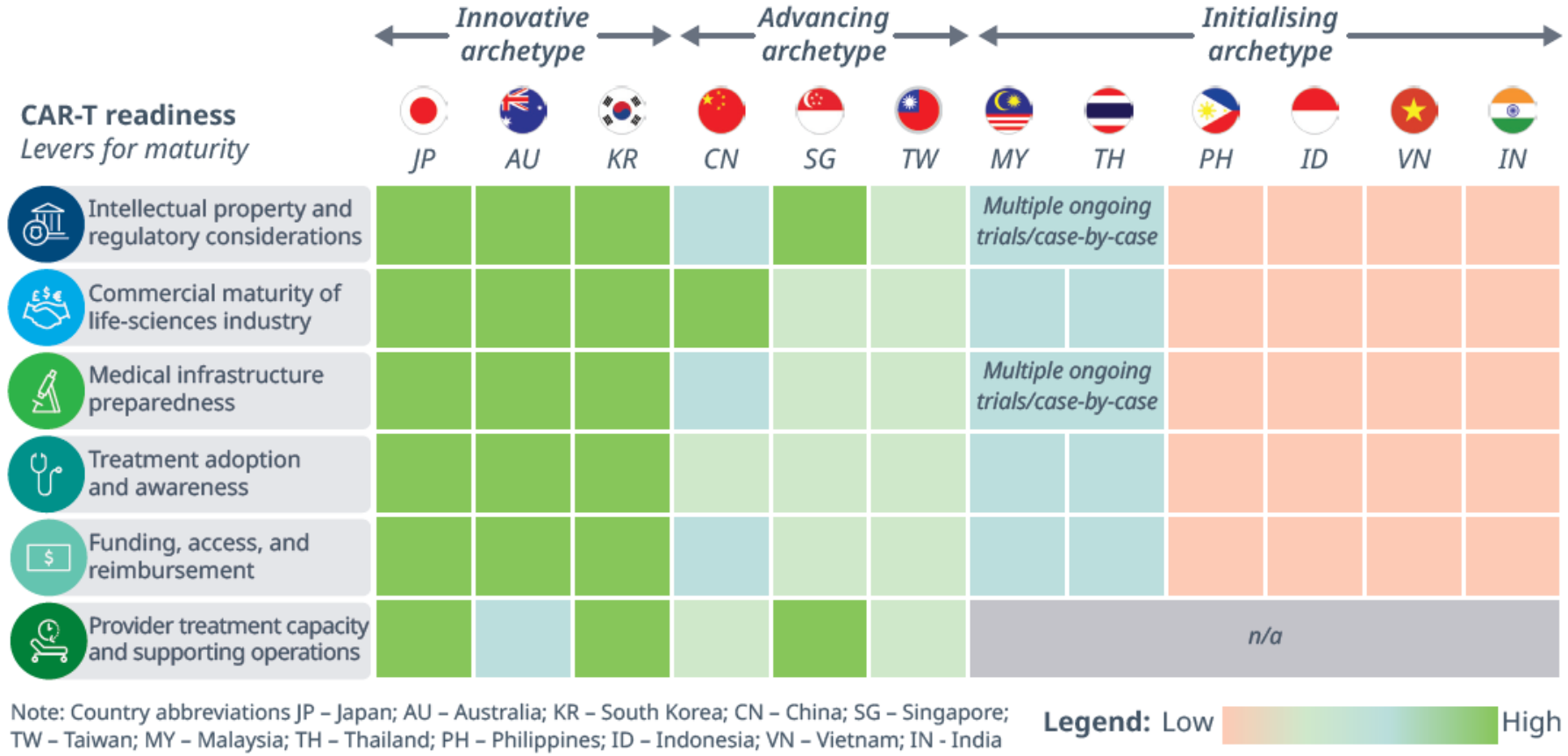
Further, India has limited preparedness for CAR T-cell therapy across regulatory access, delivery capability, & healthcare funding

Innovative archetype: strong state of readiness across multiple dimensions.

Advancing archetype: Relatively lower levels but still reasonable regulatory readiness or commercial maturity.

Initialising archetype: Reveal significant gaps in their preparedness for CAR T-cell therapy

Figure 2: APAC market maturity and CAR-T readiness: innovative, advancing and initialising archetypes



One of the biggest obstacles to expanding access is the cost of CAR-T therapy

Source: IQVIA (2024)

We urgently need strategies to ensure that all patients in India can access affordable and high-quality cancer care

Considering the commercial product early in the process can mitigate risks associated with cell therapy development

Commercial Viability

Helps attract and de-risk potential investors with the likely returns

- Implement proven demand forecasting and planning approaches
- Determine speed to market penetration
- Evaluate economies of scale
- Knowledge of regulatory process to know what to avoid during development

Manufacturing

Key concern: process involves manual labor

- Understand biology at a small scale, and then **scale to manufacture**
- Knowledge ramp up & standardization
- 'Make in India' raw materials and consumables
- Flexible modular manufacturing GMP-in-a-box solutions

Next Gen- CAR-T

- Viral vector alternatives for gene insertion
- Use of **allogenic therapy-** simplified supply chain & economies of scale
- CAR-T generation in vivo
- Rapid CAR-T systems and **automation**

Commercial Efficiency

Innovations in commercial models

- International partnership to foster **medical tourism** to attract patients from large economies to India
- Demonstrate value to Payer models of large economies to support **international reimbursements**
- Move toward **outpatient treatment** to lower costs and increase capacity

Source: Internal assessment and PwC (2023)

Preparation and evaluation of Indian ecosystem across 6 major domains are crucial

1 POLICY & PLANNING
National long-term strategy
Centre of Excellence for Cell Therapy
Incentivizing companies for raw materials & manufacturing
Tax benefits

2 REGULATIONS
Guidelines for Approvals
Dedicated Regulatory Pathways
Expedited Approvals
Standards to address clinical uncertainty- *endpoints, optimal dose*

3 REIMBURSEMENTS
Special reimbursement models
Dedicated budget for CGT
Patient associations to collaborate with member companies

4 GUIDANCE & PATHWAYS
Updated treatment guidelines
Screening Programs and referral pathways to enrol patients for CAR- T therapies

5 INFRASTRUCTURE & ACCESS
Specialist patient treatment centres
Training for healthcare staff
University programs that offer diplomas in CGT

6 MONITORING & EVALUATION
Patient registries for CGTs
Electronic Health Records

Thank you

MURALI RAMACHANDRA

CEO, Aurigene Oncology Limited

murali_r@aurigene.com

+91 80 7102 5444