

Tali-cel is a safe and effective therapy in patients with Relapsed/Refractory B-cell non-Hodgkin lymphoma that allows equitable access- a real-world experience from India.

Hasmukh Jain 1, Atharva Karulkar2, Devanshi Kalra 2, Smriti Ravikumar2, Anand Valbhav2, Shrestha Shah 2, Afrin Firfiray 2, Juber Pendhari2, Sameer Melinker3, Rahul Bhargava 4, Neeraj Siddharth 5, Dr Dinesh Bhaurao16, Jayachandran PK27, Esha Kudib, Prashant Mehta 9, Hari Menon 10, Bhassaleha Begal1, Kunal Goyal11, Prakash Shekhawat12, Pawan Kumar Royella 13, Rakesh Boya 14, Rami Abhinav 15, Rajat Ahmed 16, Anil Ariband17, Ashwin V Nair18, Chandran Nair18, Harish Palaparthi20, Lingaraj Nayak 1, Pawan Singh 21, Priyanshi Pachauri22, Rajat Bhattacharya 23, Rajiv Kumar24, Ranjit Sahoo 25, Sharat Damodar26, Vikram Mathews 27, Vasu Babu Gol28, Abhishek Charan 29, Ajay Gupta 30, Amul Kapoor24, Anupam Chakrapani31, Ashish Bakshi32, Bijay Prabhakaran Nair18, Bilal Kaz33, Debranjani Chattopadhyay34, Ganesh S. Jaishtwar35, Kaushal Kalra 36, Kishore Kumar37, Lekshmon K S 38, Madhav Dhanthala 39, Mallikarjun Kalashetty 40, Narendra Anukonda 41, Naveen Gupta 42, Nivedita Dhinra 43, Padmaja Lokureddy 44, Prasad Narayanan 45, Parasham Narayanan 46, Prasanth Ganesh 47, Pune Jain 48, Priyanka Sarin49, Ramaswamy N.V.50, Rajan Kapoor24, Shyam Aggarwal51, Roy J Paliaty 52, Sainath Blethanabhotla 53, Sachin Ahmed54, Santosh Devas 55, Sivakumaran Janakiraman 56, Sudheep V 57, Sreenaj Vasudevan 58, Sameer Tulgale 59, Soraj Chiraniya 60, Vijay Patil61, Sumita Chaudhry 35, T Raja 62, Sunu Cytac 63, Shishir Seth 64, Chezhian Subash 65, Varun Rajan 66, Alok Shetty 1, Vishwanath Sathyanarayanan 67, Mohammed Sadique Ansari2, Nishant Tiwari2, Shamil Darbar2, Supriya Chawkekar2, Sushmita Sahay 2, Manivasagam Sundharam2, Ashish Saroha 2, Mounita Basu 2, Anjali Jaiswal2, Yuktam Yadav 2, Sakshi Soni2, Jayashree Thorat2, Shalini Purwar2, Nirali Shah 68, Terry Fry 69, Nitin Jain 70, Sattva Neelapu 70, Manju Sengar1, Rahul Purwar71

1 Department of Medical Oncology, Tata Memorial Hospital, Homi Bhabha National Institute, Mumbai, India, 2 Immunosoptrive Cell Therapy Private Limited (ImmunoACT), Mumbai, India, 3 Deenanath Mangeshkar Hospital, Pune, India, 4 Fortis Hospital, Gurgaon, India, 5 Amrita Hospital, Kochi, India, 6 Ray Gandhi Cancer Institute & Research Centre, New Delhi, India, 7 Cancer Institute, Adyar, India, 8 Max Super Specialty Hospital, Varanasi, India, 9 Amrita Hospital, Faridkot, India, 10 St. John's Medical College Hospital, Bengaluru, India, 11 Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, New Mumbai, India, 12 Bhagwan Mahaveer Cancer Hospital and Research Centre, Jaipur, India, 13 Basavakaram Indo American Cancer Hospital & Research Institute, Hyderabad, India, 14 Apollo Cancer Centres, Vizag, India, 15 Koval Hospital, Coimbatore, India, 16 Max Super Specialty Hospital, Saket, Delhi, India, 17 Gandhi Hospital, Hyderabad, India, 18 KIMS Health Cancer Centre, Tiruvananthapuram, India, 19 Mahatma Cancer Centre, Thiruvananthapuram, India, 20 KIMS Health Cancer Centre, Secunderabad, India, 21 Yashwantrao Hospital, Noida, India, 22 Fortis Hospital, Noida, India, 23 Apollo Hospitals, Kolkata, India, 24 Army Hospital Research and Referral, Delhi, India, 25 All India Institute of Medical Sciences, Delhi, India, 26 Mazumdar Shaw Medical Centre, Bangalore, India, 27 Christian Medical College, Vellore, India, 28 Renova Century Hospital, Hyderabad, India, 29 Hcg cancer centre, Shiga Park, Shantinagar, Mandanvi, Jaipur, India, 30 Apollo Hospitals, Delhi, India, 31 Apollo Hospitals, Kolkata, India, 32 Dr. L.H. Hirani Hospital, Mumbai, India, 33 Saradha Cancer Institute, Thane, India, 34 TMC, Kolkata, India, 35 Yashoda Hospital Hi Tech City, Hyderabad, India, 36 VMCC & Safdarjung Hospital, Delhi, India, 37 MOI INTERNATIONAL, CHENNAI, India, 38 KIMS Health Cancer Centre, Thiruvananthapuram, India, 39 Yashoda Hospital, Somajiguda, India, 40 Manipal Hospital, Bangalore, India, 41 Star Hospital, Hyderabad, India, 42 MGMC, Jaipur, India, 43 Max Super Specialty Hospital, Patparganj, India, 44 Apollo Hospitals Jubilee Hills, Hyderabad, India, 45 Cytecure, Bangalore, India, 46 Cancer Institute (WV) Adyar, Chennai, India, 47 Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, India, 48 Apollo Hospital, New Mumbai, India, 49 SJM Hospital, Bhuvanagwri, India, 50 Line Hospital, Kochi, India, 51 Sri Ganga Ram Hospital, Delhi, India, 52 Regent Hospital, Kochi, India, 53 Star Hospital, Navarangwadi, Hyderabad, India, 54 Star Hospital, Hyderabad, India, 55 MS Ramaiah Hospital, Bangalore, India, 56 Koval Medical Centre and Hospitals, Coimbatore, India, 57 Aster MIMS Hospital, Calicut, India, 58 Anala Institute of Medical Sciences, Thrissur, India, 59 Kokilaben Dhirubhai Ambani Hospital, Mumbai, India, 60 L.H. Hirani Hospital, Mumbai, India, 61 P.D. Hinduja Hospital, Mumbai, India, 62 Apollo Hospitals, Chennai, India, 63 Anala Hospital, Thrissur, India, 64 Apollo Hospital, Indraprastha, India, 65 MOI Hospital, Chennai, India, 66 Medanta Trust Hospital, Kochi, India, 67 Apollo Hospitals, Bangalore, India, 68 Pediatric Oncology Branch, Center for Cancer Research, National Cancer Institute, National Institute of Health, Bethesda, United States, 69 University of Colorado Hospital, Colorado, United States, 70 The University of Texas MD Anderson Cancer Center, Texas, United States, 71 Indian Institute of Technology Bombay (IIT Bombay), Mumbai, India

BACKGROUND

- Talicabtagene autoleucel (Tali-cel) is India's first indigenous, affordable and humanized anti-CD19 CAR-T cell therapy received market authorization in October 2023.
- More than 400 patients with r/r B-cell leukemia and lymphoma have been treated in real world across 90 cancer centers in India

OBJECTIVES

- To assess real-world clinical outcomes (ORR, PFS, OS), safety, and treatment delivery feasibility of Tali-cel in patients with relapsed/refractory B-cell non-Hodgkin lymphoma

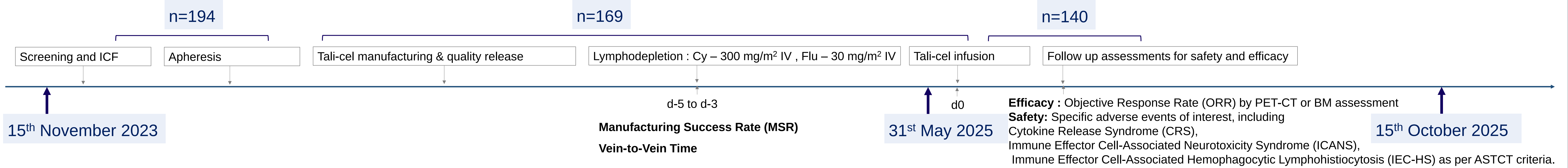
CONCLUSION

- Patients achieving CR demonstrated PFS of 84% and 64% at 6 months and 12 months, respectively with longest durable responses beyond 22 months.
- Tali-cel provided robust survival outcomes with Median Overall Survival (mOS) and Median Durability of Response (mDOR) not reached and a Median Progression-Free Survival (mPFS) of 10 months.
- Excellent safety profile of the humanized CAR-T cell was highlighted with minimal incidence of Grade III/IV CRS and ICANS.
- The first large multicenter study of Tali-cel in the Indian healthcare landscape, support its broader implementation across various levels of clinical practice.

METHODS

Multicenter , Non-interventional , retrospective study

- Cell therapy database was maintained as per regulatory guidance

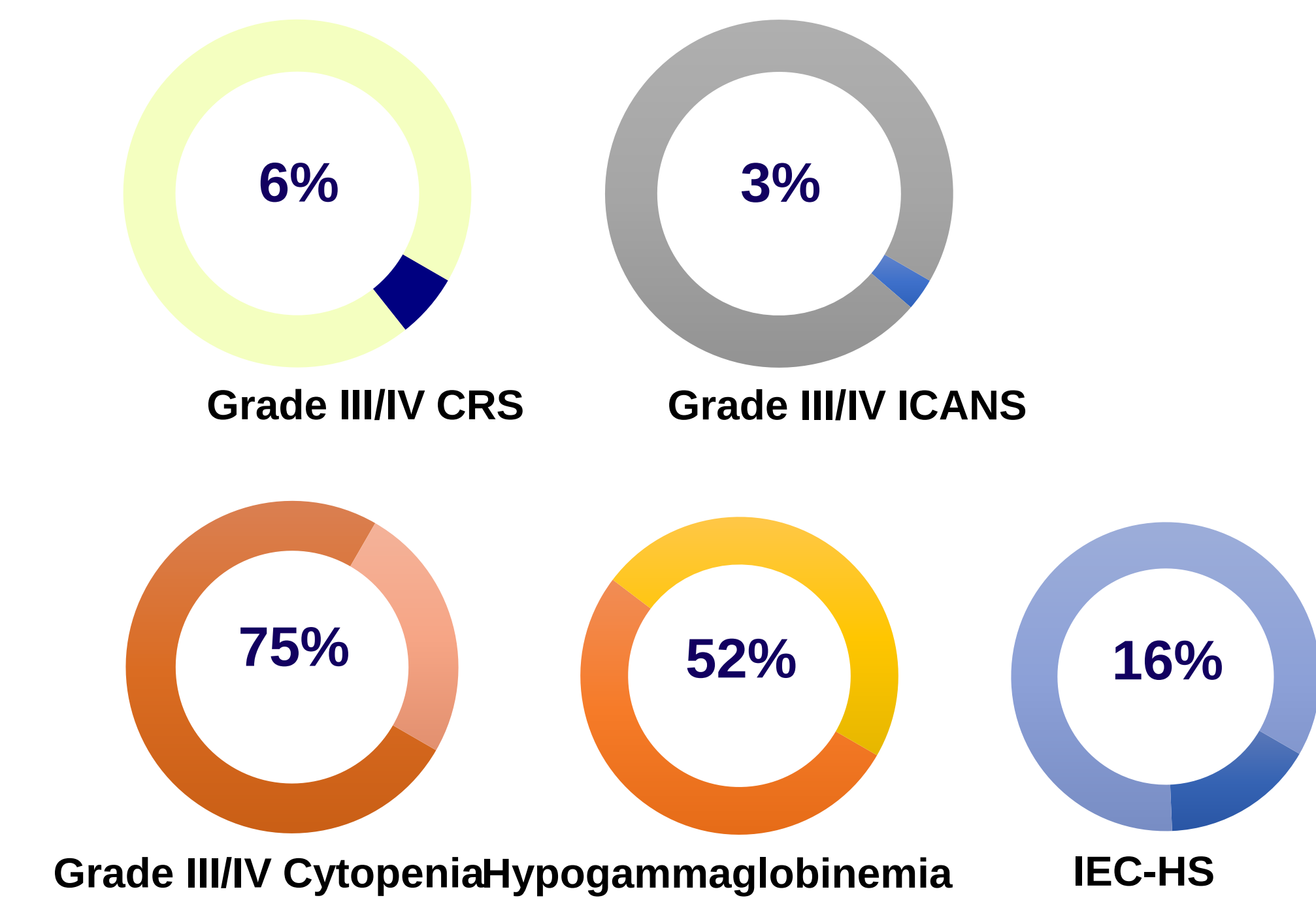


RESULTS

Patient baseline characteristics

Characteristics	All patients (n=194)
Age, years	
Median(range)	53 (17-83)
Sex, n(%)	
Male	124 (64%)
Female	70 (36%)
Prior Line of therapy, numbers	
Median (range)	3 (1-7)
1	31 (16%)
2	69 (36%)
≥3	94 (48%)
Prior transplant	16 (8%)
Disease histology, n(%)	
DLBCL	127 (65%)
HGNHL	41 (21%)
Others	26 (14%)
Disease burden, n(%)	
Bulky	44 (23%)
Non-bulky	145 (76%)
Unknown	5 (1%)
LDH prior infusion, n(%)	
Normal	46 (24%)
Elevated	81 (42%)
Unknown	67 (34%)
Primary refractory, n(%)	
Yes	73 (38%)
No	98 (51%)
Unknown	23 (11%)
Bridging therapy, n(%)	
Yes	156 (80%)
No	36 (19%)
Unknown	2 (1%)

Safety profile

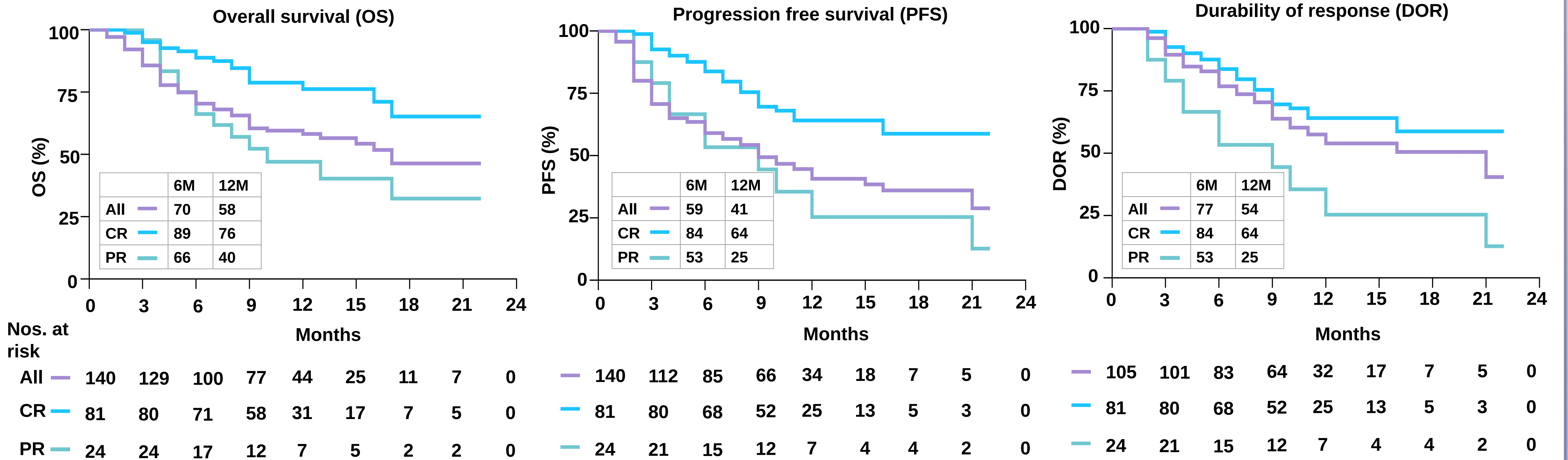


HCRU for toxicity management

Key Healthcare Resource Utilization (HCRU), n(%)	All patients (n=140)
ICU admissions	11 (7%)
Drugs for AEs management	
Tocilizumab	78 (48%)
Corticosteroids	33 (20%)
Anakinra	27 (17%)
Vasopressors	12 (7%)
IVIG	79 (48%)

Durability of response and survival outcomes

Median follow up : 09 months (range : 1-22)



Manufacturing Feasibility and Access

98% MANUFACTURING SUCCESS RATE

17 days Median manufacturing turn around time , range : 13-73

32 days Median vein-to-vein time , range : 20-124

References:

- Jain, Hasmukh, et al. The Lancet Haematology 12.4 (2025).
- Jain, Hasmukh, et al. Blood 144 (2024): 3755.
- Karulkar, Atharva, et al. Blood 142 (2023): 257.
- Jain, Hasmukh, et al. Blood 142 (2023): 4838.
- Karulkar, Atharva, et al. Blood 140 (2022): 4610-4611.
- Jain, Hasmukh, et al. Blood 140 (2022): 10332-10334.

Acknowledgements:

On behalf of all the authors, we would like to thank the patients, study investigators, and site personnel for their participation in this study.

Contact:

- Dr. Hasmukh Jain ; dr.hkjain@gmail.com
- Dr. Rahul Purwar ; rahul.purwar@immunoact.com
- Dr. Atharva Karulkar ; atharva.karulkar@immunoact.com

Abstract #6288

ASH 2025

Orlando, FL