

Topic: 25. Gene therapy, cellular immunotherapy and vaccination - Clinical

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Varnimcabtogene autoleucel demonstrates significant, sustained improvements as a first-in-India patient-reported Quality of Life outcomes in relapsed / refractory B-cell malignancies (IMAGINE Study)

Type: Oral Presentation

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Background

Varnimcabtogene autoleucel (IMN-003A, varnim-cel), an autologous CD19-targeted chimeric antigen receptor T cell therapy with 4-1BB co-stimulatory domain and A3B1 murine scFv showed deep, durable responses in patients with relapsed/refractory B cell malignancies (RR BCM) in the phase 2 IMAGINE study in India (Efficacy and Safety of IMN-003A in Patients with RRBCM, CTRI/2022/03/041162). Varnim-cel is approved in India for RR B-cell Non-Hodgkin Lymphoma (B-NHL) above age 18 years.

Aims

As a first-in-India, to evaluate Quality of Life (QoL) outcomes in treated IMAGINE patients up to one year of follow-up.

Methods

The EuroQol 5-dimension (EQ-5D) instrument was administered at screening, day of varnim-cel infusion, then at days +28, +90, +180 and +365 post infusion. EQ-5D-Y (self or proxy version, as needed) was administered to patients aged 4 to 15 years. Mean changes from baseline and scheduled timepoints were evaluated for clinically meaningful changes. The proportions of patients experiencing clinically meaningful changes in EQ-5D were assessed using within-patient change thresholds.

Results

Of 24 treated patients, overall response rate was 92% (22/24) at D+28 (B-ALL 92%, MRDneg 91%; B-NHL 92%, CR 64%); 83% (20/24) at D+90 (B-ALL 83%, MRDneg 90%; B-NHL 83%, CR 70%); and 42% (B-NHL 50%, CR 83%) at D+365 (previously published) leading to regulatory marketing approval in India.

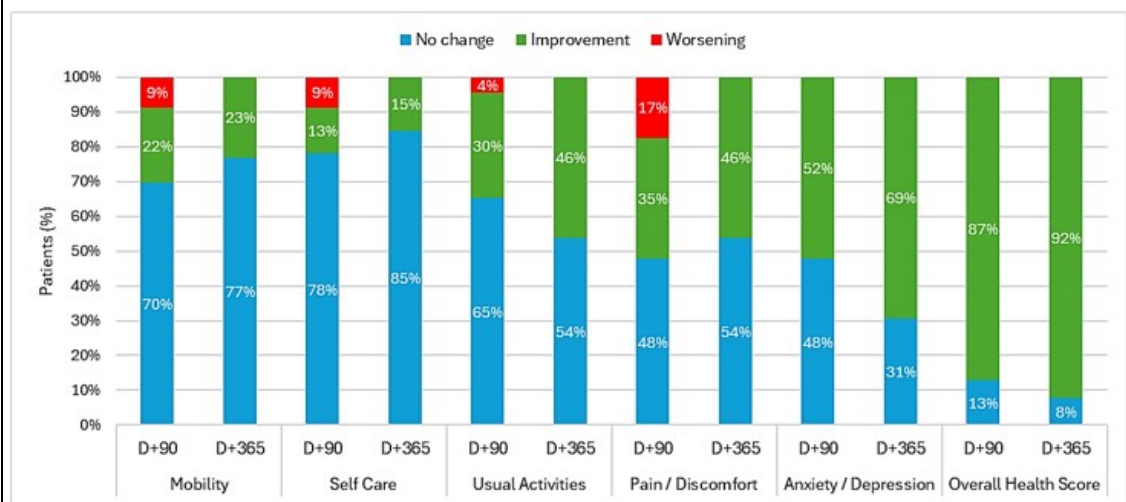
A total of 24 (100%) patients treated with varnim-cel were included in the QoL analysis. Significant and clinically meaningful improvements from baseline were observed for all 5 dimensions and overall health status (EQ VAS) at Day +90 [Mobility (22%), Self Care (13%), Usual Activities (30%), Pain / Discomfort (35%), Anxiety / Depression (52%), Overall Health Status (87%)] and at Day +365 [Mobility (23%), Self Care (15%), Usual Activities (46%), Pain / Discomfort (46%), Anxiety / Depression (69%), Overall Health Status (92%)].

Clinically meaningful improvements were seen in all 5 dimensions including overall health score and were sustained through 3 to 12 months after varnim-cel infusion. For patients with RRBCM with a poor prognosis and few treatment options, varnim-cel infusion provided early, sustained and significant improvements in EQ-5D parameters. The benefits in QoL outcomes were sustained across both age (paediatric and adult) and disease cohorts (B-ALL and B-NHL).

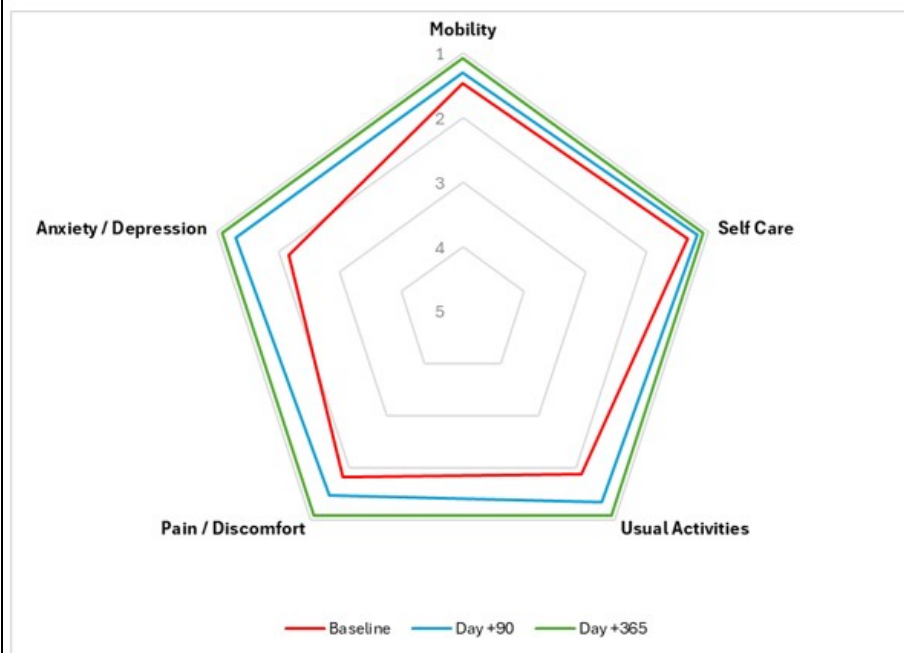
Summary/Conclusion

As a first QoL outcomes report from India for CAR-T cell therapy, these findings reveal QoL improvements complementary to the previously published positive survival and clinical response outcomes observed with varnim-cel infusion in the IMAGINE study. Early and sustained meaningful improvements in all dimensions including overall health score were commensurate with improved QoL over time indicating superior clinical and humanistic outcomes.

Figure 1:



(A) Primary QoL assessments comparing outcomes from baseline to Day +90 and Day +365 post varnim-cel infusion.



(B) Mean change in QoL parameters from baseline to D+365 post varnim-cel infusion (Spider plot).

Keyowrds: B cell lymphoma, Hematological malignancy, CAR-T, Quality of life