Manufacturing Commercial Axicabtagene Ciloleucel (Axi-Cel) in Italy for patients with relapsed/refractory NHL: A 2-Year Retrospective Analysis

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Introduction

Axicabtagene Ciloleucel (Axi-Cel) is reimbursed in Italy for relapsed/refractory (R/R) large B-cell lymphoma after ≥2 previous treatments, for diffuse large B-cell lymphoma and high-grade B-cell lymphoma refractory to first-line chemoimmunotherapy (CIT) or relapsing ≤12 months after first-line CIT and for R/R follicular lymphoma after ≥3 previous treatments[1].

The experience of manufacturing and supplying commercial Axi-Cel LOTs in EU countries has been reported (van de Wiel L. EBMT2023. P198)[2].

The aim of this abstract is to describe the experience of manufacturing and supplying commercial Axi-Cel LOTs to patients treated in Italy.

Objective(s)

The aim of this abstract is to describe the experience of manufacturing and supplying commercial Axi-Cel LOTs to patients (pts) treated in Italy.

From 1 January 2022 to 31 December 2023, 415 pts were registered on Kite Konnect and underwent LK (Table 1).

Table 1 – Timeframe and source data extraction

Date range (from – to)	01.01.22 – 31.12.23
Unique patients registered on Kite Konnect and leukapheresed[a], n	415
Unique Patients LOTs evaluable for analysis, n	410

a Only patients from Italy are included in this analysis.

Method(s)

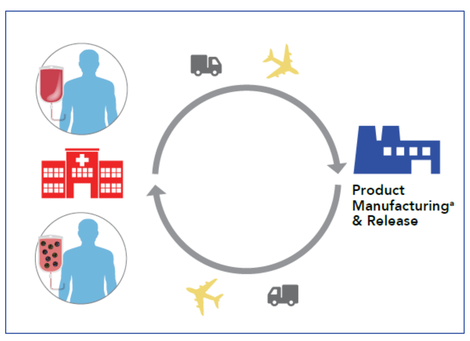
As shown in Figure 1, fresh leukapheresis (LK) material was collected from patients intended to receive commercial Axi-Cel at authorized treatment centres in Italy and shipped to the cell therapy manufacturing facility in the Netherlands for manufacturing.

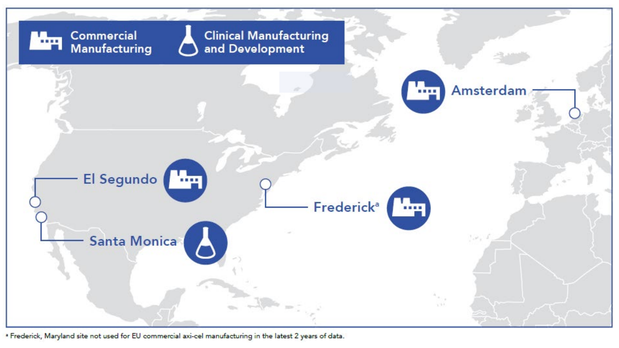
If additional LK was needed, the first LK was considered for each patient and was then referred to as that patient's LOT.

The LOT of the finished product remained at the manufacturing facility until it was released by the Qualified Person (QP) or the Physician and then sent to the hospital for administration.

Time needed for shipping from manufacturing facility (after the LOT release) to the treatment center is excluded from the turnaround time calculation.

Figure 1. Manufacturing Process and World Wide Kite's Commercial Manufacturing sites





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Result(s)

In total, 409 out of 410 LOTs were delivered to the treatment centres, resulting in a DSR of 99.8%. In addition, 397 LOTs were released by the QP or Physician out of 405 LOTs dispositioned, with a MSR of 98%.

The median Turnaround time (TAT) was 20 days (range, 17-30).

Manufacturing success rate (MSR) is defined as percentage of LOTs QP-released or Physician's released out of the total LOTs dispositioned in the time period of data extraction.

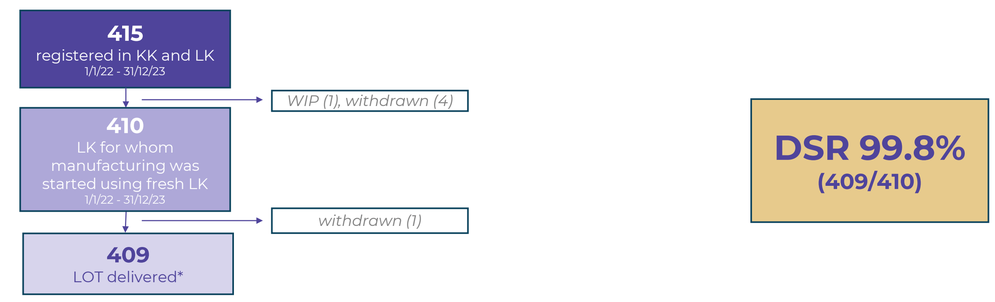
- PTS: patients; KK: KiteKonnect; LK: leukapheresed ; LOT: LOT; MSR: manufacturing success rate; QP: qualified persone

Glossary

LOT dispositioned definition includes:
- LOTs QP released, LOTs Physician released and Rejected LOTs
- LOTs dispositioned with a re-manufacturing (from a second apheresis or from excess of PBMC already available)
- Pts who have a LOT dispositioned in that timeframe, can underwent aph in 2021. Therefore, they are not included in those 415 pts

Manufacturing Success Rate definition includes:
- Products Out-of-Specification and Products In-Specification
- Products obtained from first-pass-manufacturing and products obtained from second-manufacturing (from a second apheresis or from excess of PBMC already available)

Delivery success rate (DSR) is defined as the percentage of patient LOTs shipped (dispositioned as Qualified Person–released or physician's release) out of the total number of pts leukapheresed in the time period (excluding those patient LOTs in process and patients withdrawn).



*Pts may have received the product in 2024
PTS: patients; KK: KiteKonnect; LK: leukapheresed ; LOT: LOTs; DSR: delvery success rate;WIP: work-in-progress

Glossary

Delivery Success Rate definition includes:
- Products Out-of-Specification and Products In-Specification
- Products obtained from first-pass-manufacturing and products obtained from second-manufacturing (from a second apheresis or from excess of PBMC already available)
- LOTs withdrawn and work in progress are excluded

Turnaround time (TAT) is defined as the time from date of LK to date of quality release of final product

Glossary

Turnaround time definition includes:
Time from first fresh leukapheresis* to only QP released (329 pz):
- Physician released product are *excluded* from this metric
- Re-manufacturing from second leukapheresi and excess of PBMCs are *excluded* from this metric
- If orders were canceled, rejected, or terminated before release, they did not complete a manufacturing cycle and were therefore not included in the turnaround times.

Time needed for shipping from manufacturing facility (after the LOT release) to the treatment center is *excluded* from the turnaround time calculation.

Conclusion(s)

The Italian experience of commercial Axi-Cel for R/R NHL demonstrates a high Delivery Success Rate and Manufacturing Success Rate with a short Turnaround time.

Real-world experiences show that patients outcome depend on fast and reliable manufacturing capability (Locke FL. ASH 2022. abs3345)[3].

Kite Manufacturing confirms to be rapid, reliable and predictable enabling Centers to plan for a timely product administration, also allowing an optimized Hospital Resources utilization.

Acknowledgements & Disclosures

Acknowledgements - The patients, families, friends, and caregivers . CAR T-cell centers and heath care professionals . The axi-cel European manufacturing sites . David Myers of Kite for data analysis and contributions to poster development srl - Noesis Group, funded by Kite, a Gilead Company . Louis van de Wiel of Kite for pictures and figures usage permission. Eleonora Ateri of Kite for poster development contribution.

Disclosures - Contributions to poster development and Medical writing support was provided by Aretré srl - Noesis Group, funded by Kite, a Gilead Company . This study was funded by Kite, a Gilead Company.
This poster is encore from 2024-SIE Congress, Milan September 2024

References

1. YESCARTA® (axicabtagene ciloleucel), SmPC (AIFA, July 2024)
2. Van de Wiel L et al., EBMT2023, Poster P198
3. Locke FL, et al. ASH 2022. Abstract 3345

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Ref. Poster Number #6679917