Cell & Gene Supply Chain

OVERCOME CHALLENGES AND CREATING A SUSTAINABLE SUPPLY CHAIN
- Helicopter view C/G Landscape
- ATMP’s
- Figures
Janssen invests in European production site for cell therapy

Janssen will produce innovative therapies in Belgium. The Tech Lane Science Park in Ghent will be the location of Janssen’s first European state-of-the-art facilities for the production of CAR-T therapy. The facilities are being developed in cooperation with Legend Biotech to enable the future production of cell therapy products.

Roche To Buy Spark Therapeutics For $4.8B

Swiss drug maker Roche entered into a definitive agreement Monday to acquire Philadelphia gene therapy pioneer Spark Therapeutics in an all-cash deal valued at $4.8B.

Cell & Gene Therapy Investment Outlook In 2022:

By Steve Kessler and Adam Lohr, RSM

Cell and gene therapies are one of the most active areas of research and investment in the development of medicine. The appeal is understandable given the promise of novel drugs targeting poorly treated diseases; the recent success of several new gene and cell therapies; and substantial capital flowing in from private

CAR-T cell therapy specialist Kite Pharma, now part of Gilead Sciences, has expanded its cell therapy manufacturing footprint in Europe. A 117,000 square-foot facility in Hoofddorp, the Netherlands, will be operational by 2020.

Kite’s CD19-targeting CAR-T cell therapy axicabtagene ciloleucel, which received FDA approval in 2017, has become a cornerstone of its commercial efforts.

BMS to invest in new cell therapy manufacturing site in Europe

Novartis constructing $92m CAR-T plant as Kymriah arrives in EU

by Dan Stanton
Tuesday, August 28, 2018 12:00 pm

Up to 450 jobs will be created as Novartis commits to a production site for cell and gene therapies in Switzerland. The investment will support CAR-T drug Kymriah, which received European approval this week.

A year after the US Food and Drug Administration (FDA) approved Kymriah (tisagenlecleucel), the European Commission (EC) has granted the Novartis’ therapy approval to treat B-cell acute lymphoblastic leukemia (ALL).
- Enormous increase of number of transactions in C/G field since 2013
- Since 2020 reflecting back in a sales growth trend from 6.9 billion to 43.7 billion USD
- Helicopter view C/G Landscape
- ATMP’s
- Figures
- Deep dive: Cell & Gene Supply Chain
- Differences & Challenges
Deep dive: Cell & Gene Supply Chain

Differences between Cell Therapy and Traditional Biopharma Supply Chain

- Starting Material from Patient
# Deep dive: Cell & Gene Supply Chain

## Starting Material from Patient

<table>
<thead>
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<th>Apheresis</th>
<th>Infusion</th>
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[Diagram of the cell and gene supply chain process]

- **Apheresis**
  - Collect patient's white blood cells
  - Isolate and activate T cells
  - Engineer T cells with CAR or TCR gene

- **Infusion**
  - Grow and expand number of T cells
  - Infuse patient with engineered T cells
Deep dive: Cell & Gene Supply Chain

Differences between Cell Therapy and Traditional Biopharma Supply Chain

- Starting Material from Patient
- Few/single suppliers of raw materials
- Timing & scheduling are critical
- Each patient is a unique batch
- Requires Chain of Identity (COI) and Chain Of Custody (COC)
Deep dive: Cell & Gene Supply Chain

Requires Chain of Identity (COI) and Chain of Custody (COC)

Chain of Identity (COI) - tracks and links identifiers related to a donor and their cells/tissues for the entire product journey.

Chain of Custody (COC) - data stamps that capture the “who, what, when, and where” along each step of the journey.

COI - Assign unique #

COI Link to:
- MRN
- Patient ID

COI Link to:
- DIN/UDN (collection labels)

COI Link to:
- Air waybill
- Courier tracking #

COI Link to:
- Lot #
- WIP labels
- Drug product label w/ patient identifiers

COI Link to:
- Air waybill
- Courier tracking #

COI Link to:
- Delivery confirm
- MRN

ORDERING & SCHEDULING

COLLECTION

TRANSPORT

MANUFACTURING

TRANSPORT

INFUSION
- Starting Material from Patient
- Few/single suppliers of raw materials
- Timing & scheduling are critical
- Each patient is a unique batch
- Requires Chain of Identity (COI) and Chain Of Custody (COC)
- No (yet) product Inventory
Deep dive: Cell & Gene Supply Chain

C/G Supply Chain Challenges

- Planning & Forecasting
- Vendors
- Raw Materials
- Manufacturing, Packaging & Labeling
- Logistics
- Storage

- Demand, Capacity
- Sourcing Requirements
- Procurement, Tissue Collection
- Expertise, Regulations, Traceability, Internal, External
- Controls, Reliability, Delivery, Timelines, Conditions, Tracking
- Capacity, Conditions (Temperature), Time Period
- Helicopter view C/G Landscape
- ATMP’s
- Figures
- Deep dive: Cell & Gene Supply Chain
- Differences & Challenges
- Bringing it together: Appeal for orchestration to create a sustainable SC model
- Increase of supply/demand versus the current challenges
Bringing it together: Appeal for orchestration to create a sustainable SC model

- Standardisation
- Automation
- People
- Financials
Thanks a lot for your attention!

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