



**American  
Red Cross**

Cell and Gene Therapy Solutions

**Partnering with Key Raw Material Providers to  
Ensure Timely Scale-Up in  
Support of Clinical Trials and Commercial Launch**

# Red Cross' Experience in Cell & Gene Therapy

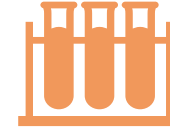
*Red Cross currently performs apheresis collections and processing/cryopreservation services in support of Cell & Gene Therapy*



## Autologous Activity

- Dendreon's primary provider of leukapheresis services since September 2009
- Perform collections in support of all FDA-approved T-cell therapies, as well as processing/cryopreservation if needed
- Multiple additional customers for autologous clinical trial collection services
- *Services performed at:*
  - 70 Red Cross fixed site locations
  - Multiple institutions (in-hospital collections)

*\* Red Cross has performed over 50,000 apheresis procedures in support of autologous cell therapies*



## Allogeneic Activity

- Currently perform healthy donor Leukopak collections at five Red Cross fixed sites
- Offer clinical-grade Leukopacks, lab services, and HLA testing
- Three cleanrooms on-site at ARC in Philadelphia PA for processing of Leukopak products

*\* Red Cross has produced over 300 Leukopaks for clinical use, and many more for RUO*

# Red Cross' Geographic Footprint – Cell & Gene Therapy Services



## Red Cross Infrastructure for CGT:

- 70 Autologous Collection Sites
- 5 Leukopak Collection Sites
- 5 Cellular Therapy Labs
- 5 HLA Labs

## Opportunities for Growth:

Hundreds of additional Red Cross facilities throughout the US provide for future expansion opportunities

# Cell & Gene Therapy Industry – Requests for Customization in Cell Sourcing are Common

- **Autologous** - Variations include:
  - Collection parameters
  - Packing procedure and materials
  - Electronic system (homegrown or third-party solution)
- **Allogeneic** - Customization requested across multiple areas, including:
  - Donors (e.g., request for specific donors, unique testing requirements, additional pre-screens)
  - Collection parameters
  - Processing parameters
  - Cleanroom vs. General Lab Space processing

# Cell & Gene Therapy Industry – Reliance on Small Number of Key Vendors

- Sole source or small number of vendors common in CGT, particularly for raw materials with a high degree of customization
  - Customization needs may require vendors to implement new equipment, facilities and/or processes unique to client needs
  - Investment required to implement customization can limit number of vendors
  - Quality audit requirements make instituting and maintaining multiple vendor relationships challenging
- Selection of key vendors typically takes into account those suppliers that can support clinical trial activity through commercial
  - Evaluations related to vendor's staying power in the market and ability to scale
  - Consistency of key raw materials throughout clinical and into commercial is desired

# Close Collaboration with Key Vendors Needed to Support Scale-up for Commercialization

*Cell & Gene Therapy industry is young, and even established vendors in the industry will likely need to add resources and/or capabilities to support your commercial launch*



Need for new collection sites and/or processing facilities (e.g., cleanrooms)



Recruitment, onboarding and training of new staff



Development of new/revised procedures/processes to support commercial



Planning for growth post-commercial launch

*Vendor's Change Management System is critical to capturing requirements, ensuring relevant stakeholders are engaged, and delivering capacity to support commercial launch and beyond on targeted timeframes.*

# How to Partner with Your Key Vendors

- **Ongoing communication is critical**
  - Sharing of forecasts is key
  - Don't let the perfect be the enemy of the good
- **Offset financial risk for vendors – options include:**
  - Start-up project fee
  - Minimum utilization guarantee
  - Minimum revenue guarantee
- **Understand your vendor's project plan for supporting your growth**

# Benefits of Partnering

- Early identification of any potential issues, which supports collaboration on resolution
- Better informed vendor can better meet your needs
- Vendor may be able to identify potential future improvements

***With the overall goal of ensuring that the raw materials needed to support ramp-up will be available as required so that these therapies are available to treat patients***



# Let's Discuss Your Needs

Contact us at **CellandGeneTherapy@redcross.org** or call **833-760-0625** to discuss your project and learn how we can partner with you to offer a customized cell sourcing solution for your allogeneic or autologous therapy