Sarah Cannon’s Approach to Offering CAR T Therapy in the Community Setting
Agenda

- Overview of HCA Healthcare
- Overview of Sarah Cannon Transplant and Cellular Therapy Network
- Our Experience with CAR T-cell Therapy
- Our Approach to offering CAR T-cell Therapy Safely
Who is HCA Healthcare

HCA Healthcare Statistics

- 280,000 colleagues
- 185 Hospitals
- 2,000+ sites of care
- 21 states and the United Kingdom
- 35 million patient encounters annually
- 2 million inpatient admissions annually
- 9.4 million outpatient & ASC visits annually
- 1.6+ million cancer patient encounters annually
Sarah Cannon Transplant & Cellular Therapy Network

- **Las Vegas, NV:** Sarah Cannon Transplant and Cellular Therapy Program at Mountain View Hospital (New Program under development)
- **Kansas City, KS:** Sarah Cannon Transplant and Cellular Therapy Program at Research Medical Center (Est. 2013)
- **Philadelphia, PA:** Thomas Jefferson University’s Sidney Kimmel Cancer Center
- **London, England:** HCA at UCH – London Bridge Hospital
- **Manchester, UK:** The Christie Clinic
- **Denver, CO:** Colorado Blood Cancer Institute at Presbyterian/St. Luke’s Medical Center (Est. 1991)
- **Dallas, TX:** Medical City Dallas Hospital (Est. 1994)
- **Austin, TX:** Sarah Cannon Transplant and Cellular Therapy Program at South Austin Medical Center (Est. 2014)
- **San Antonio, TX:** Sarah Cannon Transplant and Cellular Therapy Program at Methodist Hospital (Est. 1993)
- **Nashville, TN:** Sarah Cannon Transplant and Cellular Therapy Program at Centennial Medical Center (Est. 2007)
- **Philadelphia, PA:** Thomas Jefferson University’s Sidney Kimmel Cancer Center
- **Dallas, TX:** Medical City Dallas Hospital (Est. 1994)
- **Austin, TX:** Sarah Cannon Transplant and Cellular Therapy Program at South Austin Medical Center (Est. 2014)
- **San Antonio, TX:** Sarah Cannon Transplant and Cellular Therapy Program at Methodist Hospital (Est. 1993)
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Sarah Cannon Transplant & Cellular Therapy Network

The Largest Network Providing Transplant and Cellular Therapies

FACT/JACIE Accredited Hematopoietic Cell Transplant (HCT) Programs Across the U.S. and UK

HCTs performed since inception
15,000+

~1,200
HCTs performed each year

1 Comprehensive Network Approach for Patient Care:

• Quality Plan
• Patient Management Technology Platform
• HCT & IECT Patient Eligibility Criteria
• HCT & IECT MD & APP Practicing Privileges
• Standardized Nursing Education
• HCT Clinical Pathways
• HCT & IECT Policies and Procedures
• Corporate-level Vendor/Pharma contracting
• Centralized Payer contracting
• Network HCT/IECT Travel Nurse Program
Immune Effector Cell Therapy Experience

Studies open in:
• DLBCL
• Mantle Cell Lymphoma
• Indolent Non-Hodgkin Lymphoma
• Multiple Myeloma
• Sickle Cell Disease
• B-Cell Non-Hodgkin Lymphoma
• ALL
• CLL/SLL
• AML/MDS
• Sarcoma
• Melanoma
• Non-Small Cell Lung Cancer

Immune Effector Cell Therapy studies
Activated since Dec 2015

50+

300 +

patients who have received FDA-approved or research CAR T-Cell therapy to date

Immune Cell Therapy Committees
• Coordination and standardization of research processes across centers for both blood cancer and solid tumor indications
• Local committees comprised of site transplant, nursing, research staff and physicians meet monthly at each center
• Local committees report to Sarah Cannon Immune Effector Cell Therapy leadership monthly

Commercial CAR T-Cell Therapy
• SC executes Corporate-level Agreements with Pharma
• SC partners with Pharma to streamline the process across the Network

Products Available
• Novartis: DLBCL and P-ALL
• Kite: DLBCL, MCL & FL
• BMS: In process of offering DLBCL & MM
• J&J/Janseen: Working towards offering their MM product when it becomes FDA approved

Our Presence at ASH 2020
• 53 Abstracts and Presentations
• 21 Oral Presentations

Our Presence at TCT 2021
• 19 Abstracts and Presentations

Updated 4/16/2021
SCTCTN Requirements To Offer IECT

- Implementation of SCBCN SOPs to meet Immune Effector Cell Therapy FACT Standards
- Implementation of SCBCN Annual Competencies for MDs and APPs
- Implemented local IECT Committee Structure
- Participate on SCBCN Monthly IECT Committee
- Adoption of SCTCT Network’s CAR T-cell Patient Eligibility Criteria and Process
- Appropriate number of staff to handle the complexity of CAR T patients including IECT/HCT Physicians, IECT Coordinators, Research staff, BMT and ICU nursing staff, Oncology Pharm D.
- All physician specialties involved in the care of CAR T patients have been identified and appropriately trained
- Full adoption of all 3 modules of StafaCT software by Physicians and Staff
- Completion of IECT Readiness Assessment by members of the SCBCN team
Committee Goals
- Ensure safety, consistency and quality for our patients;
- Demonstrate Network capabilities and competency;
- Improve patient outcomes;
- Share lessons learned and develop best practices.

**IECT Subcommittee Members**
- Fred LeMaistre, MD
- Carlos Bachier, MD
- Peter McSweeney, MD
- Aravind Ramakrishnan, MD
- Paul Shaughnessy, MD
- Vikas Bhushan, MD
- Program Administrators
- SC Support Team
Expanded Access to IECT Is Needed

Patients receive CAR T treatment at SC’s five FACT-accredited IECT1 centers – 12 additional centers anticipated

SC employs a robust, structured process to qualify IECT centers for CAR T therapy administration

**IECT Center Site Requirements**
- Implement SOPs to meet Immune Effector Cell Therapy FACT Standards
- Implement SCBCN Annual Competencies for MDs and APPs
- Implement local IECT Committee Structure
- Participate in SCBCN IECT Committee
- Staff appropriate volume of HCPs and support (e.g., coordinators, nurses, oncologists, etc.) to support complexity of CAR T patients
- Administer appropriate training to all physician specialties involved in CAR T patient care
- Adopt all modules of StafaCT and provide necessary training to physicians and staff
- Ensure completion of the IECT Assessment across relevant staff

**Site Checklist**

1) IECT Centers – A Sarah Cannon / HCA facility with current or planned cellular therapy infusion and care capabilities
Barriers and Risks to Expansion

Maintain Patient Safety and Regulatory Compliance, While Increasing Timely Patient Access To Therapy

**Healthcare Delivery Infrastructure**
- IECT experienced Physician
- Resource-intensive process to become certified and maintain certification with Pharma. (REMS training)
- Committed consulting physicians, such as Neurologists
- Long-term patient monitoring/follow up
- Local Hospital with appropriate infrastructure to support patients
- Collection services
- Maintaining staff competencies

**Therapy Delivery Economics**
- Government Reimbursement Issues
- Managed Care single-case agreements can delay timelines
- Individualized authorization process
- Experienced individuals to manage CAR T-cell global case rates
- Lack of predictability of cost due to patient’s health condition and variability in cost of product

**Supply Chain Process**
- Coordination of manufacturing and patient treatment timelines
- Lengthy manufacturing time
- Product may not meet FDA specifications for release
Thank You