Supplementary

Table S1 Qualification of GMP-compatible iPSC cryo-banks

Attribute	Test	Method	Acceptance criteria	SCB	MCB	WCB
Identity	Cell morphology	Microscopy	Compact hESC-like colonies with distinct borders, high nucleus to cytoplasm ratio, and prominent nucleoli	•	•	•
	Surface markers	Flow Cytometry	SSEA4+>80%, Tra-1- 81+>80%	•	•	•
	Pluripotent markers	Immuno-cytochemistry	OCT4+>80%, NANOG+>80%	•	•	•
	STR	STR profiling	Identical to donor cells	•	•	•
Viability	Viability	Dye exclusion cell counting	>60%	•	•	•
	Doubling time	Serial passaging	Constant population doubling time.	•	•	•
Genetic stability	Karyotype	G-banding	Normal diploid	•	•	•
	Residual vector testing	PCR	Negative	•	•	0
	Cancer gene mutation	WGS/WES	Negative	0	• (WGS)	• (WES)
Potency	Pluripotency	Teratoma formation	Demonstration of tissues from all three germ layers	0	•	0
Microbiological safety	Bacteria	Culture	Negative	•	•	•
	Fungi	Culture	Negative	•	•	•
	Mycoplasma	PCR or pharmacopeial methods	Negative	•	•	•
	Virus	Pharmacopeial methods	Negative	0	•	0
	Endotoxin	Pharmacopeial methods	<0.5 EU/mL	•	•	•