

PMDA-ATC Regenerative Medicinal Products Review Webinar 2023 for CDSCO, India

Date: June 28th, 2023

IST	JST	Sessions
12:30-12:35	16:00-16:05	Opening Ceremony Introduction announcement Remarks from PMDA (2 min)
12:35-13:15	16:05-16:45	1. Regulations for Regenerative Medicinal Products PMDA, Dr. NODA Shinichi, Deputy Review Director, Office of Cellular and Tissue-based Products (20 min.) Q&A: (20 min.)
13:15-13:55	16:45-17:25	2. Sharing Experiences of Regenerative Medicinal Products - Case1: (Carvykti: ciltacabtagene autoleucel) PMDA, Dr. NODA Shinichi, Deputy Review Director, Office of Cellular and Tissue-based Products (20 min.) Q&A: (20 min.)
13:55-14:15	17:25-17:45	Break
14:15-14:55	17:45-18:25	3. Sharing Experiences of Regenerative Medicinal Products (cont.) - Case2: (Stemirac: human (autologous) bonemarrow- derivedmesenchymal stem cells) PMDA, Dr. NODA Shinichi, Deputy Review Director, Office of Cellular and Tissue-based Products (20 min.) Q&A: (20 min.)
14:55-15:00	18:25-18:30	Closing Ceremony Remarks from CDSCO (2 min)

Review Reports: Regenerative Medical Products

<https://www.pmda.go.jp/english/review-services/reviews/approved-information/0004.html>