

Agenda for the 6th APACRM

Date: Thursday, April 20th, 2023

Hybrid conference: Virtual and Nihonbashi Life Science Building, Tokyo

Time (JST)	Duration	Session	Chair/Speaker/Panelist
13:00-13:03	3 min	Opening remarks	Ken-ichiro Hata, FIRM
13:03-13:10	7 min	Introduction	Masayuki Nomura, FIRM
13:10-14:10	Update on Regenerative Medicine from each Participating Industrial Association		
	60 min	10-min presentations from each country/region (Pre-recorded)	Yoshitsugu Shitaka, FIRM (Japan)
			Eugene, J. WANG, CMBA (China)
			Bryan Choi, CARM & RMAF (Korea)
			Pawan Kumar Gupta, ABLE (India)
Chao-Sung Chang, BPIPO (Taiwan)			
14:10-15:30	Non-clinical data package - Working group 1 (WG1) activity		
	80 min	Advanced CAR-T: Presentation and Panel Discussion by 4 groups	Hiroshi Karasawa, Japan Chia-Ling Hsieh, Taiwan Ta Tung Yuan, Taiwan Karen Wen, Taiwan Sasikumar Muthusamy, India
15:30-15:40	10 min	Break	
15:40-16:40 (60 min)	Points to Consider for Regulations on Clinical Trials for AAV-based Gene Therapies in 6 Asia Countries - Working group 3 (WG3) activity		
	5 min	Opening Remarks	Bryan Choi, CARM & RMAF
	5 min	<ul style="list-style-type: none"> Marketing and Clinical Trends on AAV-based Gene Therapy Products in Asia Gap Analysis for Initiating Clinical Trials of in vivo Gene Therapy Products in Asia 	Hirokuni Mizoguchi, FIRM
	30 min	Summary of Regulatory Status for Clinical Trial Initiation of AAV Vector Products (Pre-recorded) <ul style="list-style-type: none"> China India Japan Korea Singapore Taiwan 	Alex Zhang Pawan Kumar Gupta Masato Komuro Bryan Choi Wong Kum Cheun Kevin Chiu
	20 min	Panel Discussion <ul style="list-style-type: none"> Differences and regulatory hurdle of regulation of each country/region Key points to facilitate the development of gene therapy products 	Chair: Prof. Bryan Choi Panelists: 6 countries/regions regulatory agencies and WG3 members
16:40-17:30	Regulations and Future Business Opportunities for Processed Cells, which are in different categories from Regenerative Medicinal Products aiming Official Regulatory Approval		
	50 min	Presentation and Discussion	Chair: Kunihiko Suzuki, FIRM Alex J. Zhang, CMBA (China) Pawan Kumar Gupta, ABLE (India) Sandy Chan, SAPI (Singapore) Wei-Kuang Chi, BPIPO (Taiwan)
17:30-17:55	Future activities		
	15 min	Introduction of other organizations	Keith Alm, ISSCR Zlatibor Velickovic, ISCT
	10 min	Discussion for Future activities	Chair: Yoshie Tsurumaki, FIRM
17:55-18:00	5 min	Closing	Setsuko Hashimoto, FIRM
18:30-20:00	<Reception> in-person only		

Abbreviations: ABLE, Association of Biotechnology Led Enterprises in India; BPIPO, Biotechnology and Pharmaceutical Industries Promotion Office in Taiwan; CARM, Council for Advanced Regenerative Medicine in Korea; CMBA, China Medical Biotech Association in China; RMAF, Regenerative Medicine Acceleration Foundation in Korea; SAPI, Singapore Association of Pharmaceuticals Industries in Singapore.