Scientific program

Thursday, September 26

9:00–10:30 Morning session 1

Biosimilar New Guideline for In Vivo Waivers
René Anour (AGES) 45 min.

Product-Specific Bioequivalence Guidance and Legal Basis for Complex Molecules
Parvinder Punia (Pharmexon) 45 min.

10:30–11:00 Coffee break

11:00–12:30 Morning session 2

NTIDs – Alpha Inflation
Paulo Paixão (University of Lisbon) 45 min.

Navigating the Science: Exploring the Development and Validation of Dosing Guidance Tools
Martin Wolfsegger (TAKEDA) 45 min.

12:30–13:45 Lunch

13:45–15:45 Afternoon session 1

Orally Inhaled Products – Guideline Update
Carolien Versantvoort (CBG-MEB) 45 min.

Requirements from Draft Nasal and Inhaled Products Example of Dissolution for Inhaled Products
Jean-Michel Cardot (SAS BORVO) 45 min.

OIP – Where We Are and Where We Go
Vít Perlík (Pharmacology, Faculty of Medicine, CU, CADORE) 30 min.

15:45–16:15 Coffee break

16:15–17:00 Afternoon session 1

Development of Lenacapavir (Sunlenca), the First-in-Class Long-Acting HIV Capsid Inhibitor Administered Twice-a-Year
Raju Subramanian (Gilead) 45 min.

Friday, September 27

9:00–10:30 Morning session 1

ICH M15 Model-Informed Drug Development General Principles Guideline
Pavel Farkaš (TEVA / PLIVA) 45 min.

M13A Final and Associated Q&A, Comments
Susana Almeida (International Generic and Biosimilar Medicines Association) 45 min.

10:30–11:00 Coffee break

11:00–12:30 Morning session 2

OTC Status for Products – National Specificities
Paolo Biffignandi (VI.REL Pharma) 45 min.

African Medicines Agency
Loice Kikwai (LCK Pharmaceutical Consulting) 45 min.

12:30–13:45 Lunch