

**5th ESTP International Expert Workshop
"Adversity of Lysosomal Accumulation"**

FRIDAY 23rd September 2016

13.00 - 13.30 **Sandwich lunch and coffee**

13.30 - 13.45 **Welcome and introduction**

13.45 - 14.00 *Xavier Palazzi* Adversity in toxicologic pathology - rules of the game
14.00 - 14.25 *Stefan Kustermann* Lysosomes - role in cellular uptake & degradation and cell health
14.25 - 14:40 *Jeff Engelhardt* Antisense oligonucleotide accumulation in lysosomes: an example of straight-forward adversity decision

14.40 - 15.00 **Coffee break**

15.00 - 15.30 *Agnes Schulte* Regulatory issues on the assessment of industrial chemicals-related accumulation in lysosomes
15.30 - 16.00 *Beatriz Silva Lima* *Regulatory issues on the assessment of pharmaceuticals causing accumulation in lysosomes
16.00 - 16.30 *Sabine Francke and James Willard* Communicating potentially adverse pathology findings in regulatory submissions pertaining to lysosomal accumulation: 2 phospholipidosis case examples
16.30 - 16.45 Questions from the audience
16.45 - 17.00 Wrap-up
17.00 - 18.00 **Expert discussion: basic requirements for adversity evaluation of lysosomal accumulation**

Saturday 24th September 2016

9.00 - 9.15 *James Willard* Phospholipidosis: overview
9.15 - 9.30 *Holger Fischer* Phospholipidosis induction by Cationic Amphiphilic Drugs - mechanistic insights
9.30 - 9.45 *Lindsay Tomlinson* *Phospholipidosis: case examples
9.45 - 10.00 *Takanori Harada* *Phospholipidosis: case examples
10.00 - 10.15 *Ryo Fukuda* *Phospholipidosis: case examples
10.15 - 10.30 *Thomas Nolte* *Phospholipidosis: case examples
10.30 - 10.45 Questions from the audience

10.45 - 11.00 **Coffee break**

11.00 - 11.30 **Expert discussion: Adversity considerations of phospholipidosis**
11.30 - 11.45 *Charles Wood* Regulatory aspects of lysosomal accumulation with chemicals
11.45 - 12.10 *Sibylle Gröters* Toxicity issues related to lysosomal accumulation of alpha2u-globulin
12.10 - 12.25 *Midori Yoshida* Alpha2u-globulin nephropathy: decision-making process of the Food Safety Commission in Japan
12.25 - 12.40 *Andreas Popp and Hans Harleman* Iron storage and compounds inducing iron accumulation in lysosomes

12.40 - 14.00 **Sandwich lunch and coffee**

14.00 - 14.20 *Annamaria Brändli-Baiocco and Annette Romeike* *Adversity considerations of lysosomal uptake of pegylated drugs
14.20 - 14.30 *Wolfgang Kaufmann* Case example: PEG-associated vacuolation of choroid plexus epithelium
14.30 - 15.30 **Expert discussion: Adversity considerations of lysosomal accumulation (except phospholipidosis)**

15.30 - 15.45 **Coffee break**

15.45 - 16.00 *Barbara Lenz* Summary: Adversity of lysosomal accumulation, viewpoint of toxicological pathologists
16.00 - 16.15 *Gabriele Pohlmeier-Esch* Summary: Aspects of lysosomal accumulation in regulatory submissions
16.15 - 16.30 Questions from the audience
16.30 - 17.45 **Expert discussion: conditions and step-wise approach of adversity decisions related to lysosomal accumulation**
17.45 - 18.00 *Wolfgang Kaufmann* Closing remarks