Program

ATMP Sweden 2019

AstraZeneca, Mölndal - PGN conference entrance, Pepparedsleden 5

We are very excited to offer a full day schedule covering a diversity of topics within the ATMP field. We look forward to your participation and your feedback.

8:00	**Registration opens/Light refreshment**
8:30	**Welcome address** Shalini Andersson - Head of New Therapeutic Modalities, Early CVRM, AstraZeneca
8:35	**Opening address - Mikael Wiberg (CAMP)**
Session 1	**Translational ATMP projects** Chair: Alexandra Karström - chair of VOG CELL, Akademiska Sjukhuset Collaborations between academia, industry and specialist clinics create a powerful platform to move cutting edge technology to novel patient solutions. The ATMP field offers new treatments for patients where current standard care lacks sufficient improvements in survival or quality of life. This session presents the processes by which ATMP solutions are moving from the lab to patients.
8:40	KEYNOTE: Olle Korsgren - Uppsala University "Diabetes and cell therapy"
9:10	Helena Brisby - Gothenburg University "Cell therapy and disc degeneration"
9:25	Jonas Nilsson - Professor, Director of Sahlgrenska Cancer Center "CAR-T cell therapy for malignant melanoma of the skin and the eye"
9:40 **CAMP project**	Teresa Olsen Ekerhult - Sahlgrenska University Hospital, Dept. Urology, Gothenburg "ATMP for urethra reconstruction with de- and recellularization technique"
9:50 **CAMP project**	Moustafa Elmasry/Ahmed Elserafy - Linköping University "Development of Multilayered Tissue-Engineered Skin Construct"

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10:10	Karin Agerman, Chief Research and Development Officer, CombiGene "Turning research into clinical use - gene therapy for treatment resistant epilepsy"
10:25	**Coffee break**
Session 2	**Entering the clinical phase** Chair: Stephan Mielke Navigating the regulatory processes for entering into a clinical trial is a great challenge for those looking to move novel therapies to the clinic. Lessons from the pharmaceutical industry are combining with ATMP based regulations to drive forward cell and gene therapy products to the clinical phase. This session presents specific examples of navigation of this process and resources to expedite the process.
11:00 Swelife-ATMP project	Ann Novotny - Gothia Forum "Support functions - generic process guide, templates and checklist"
11:10	Steffen Thirstrup, MD, PhD. - Director, NDA Advisory Services "EMA perspective"
11:30	Anna Collén, PhD, Senior Project Director CVRM, IMED Biotech Unit, AstraZeneca "VEGF-A modified mRNA in Cardiovascular Disease"
11:45	Christoph Varenhorst - Pfizer "Opportunities with gene therapy in disease with high unmet need"
12:00	Karin Mellström - CellProtect Nordic Pharmaceuticals "Autologous ex vivo expanded NK-cells for treatment of multiple myeloma. "
12:20	**Lunch and networking**
Session 3	**Process development, production, infrastructure and logistics** Chair: Pontus Blomberg Good Manufacturing Practice within ATMP ensures production of functionally consistent, high quality products with special care to prevent harm to the end user. From raw material to patient delivery each reagent and process needs to be documented as safe, consistent and traceable. This session explores these processes and facilities generating platforms of expertise.

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13:15	**Keynote:** Karin Hoogendoorn, PharmD*, Scientist ATMPs, Leiden University Medical Center, the Netherlands "Process and product characterisation of cell based medicinal products- an introduction"
13:45 **CAMP project**	Matti Sällberg "Developing of a pre-GMP facility for vectors and genetically modified cells"
13:55	Evy Lundgren-Åkerlund - CEO, Xintela "Translating innovation to GMP production and clinical studies"
14:10	Margareta Tennander - GE Healthcare "Testa Center - authentic production test-bed"
14:25 **CAMP project**	Stefan Scheding, MD, Professor - Skåne University Hospital Lund, Sweden "Label-free acoustic separation of stroma cell products"
14:35 **CAMP project**	Jim Lund - Research Institutes of Sweden (RISE) "Establishing QC and logistics strategies for cell-based products for secure patient treatment"
14:45	Kristina Runeberg - Takara Bio Europe "GMP manufacturing and distribution of pluripotent stem cells"
15:00	**Coffee and fruit break**
Session 4	**Bringing ATMPs to the market and patient** Chair: Michael May (CCRM) Market approval and reimbursement are great challenges in the development of ATMPs. This session will cover 3 areas critical to the delivery of ATMPs to patients 1) Collection of sufficient data for market approval of an ATMP, 2) Accessing clinics and processes to deliver ATMPs within healthcare and 3) Efforts towards the development of business models and health economy models for public healthcare reimbursement.

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15:30	**Invited Keynote** Prof. Graziella Pellegrini - Centre for Regenerative Medicine S. Ferrari, University of Modena and Reggio Emilia "Translational medicine overcoming the challenges to restore vision"
16:00	Stephan Mielke - Karolinska University Hospital (CAST) and Institutet (Labmed) "CD19 CAR T cells: The stony road from pivotal phase II-based market authorization to real standard of care"
16:15	Maria Landgren - SKL-NT-rådet "Swedish challenges around implementation (patient related)/reimbursement"
16:30	Douglas Lundin - Chefsekonom TLV (Tandvårds- och läkemedelsförmånsverket) "Do we need to make a different kind of health technology assessment for ATMPs?"
16:45 Swelife-ATMP project	Anna Ridderstad-Wollberg - RISE "Health Economy and business models for ATMPs in Sweden"
16:55	**Panel - The path towards reimbursement in Sweden (Swedish)** **Moderator:** Johan Brun This panel continues from the last session to discuss specific examples and Swedish opportunities/challenges in public reimbursement of ATMPs. Topics also include health economy, payment models, budget systems to drive new healthcare options.
	Panel members: 1: Dag Larsson - Läkemedelsindustriföreningen – grundläggande HTA/HE perspektivet 2: Malin Lenre - Novartis - Industriperspektivet 3: Johan Hyllner – AstraZeneca - Industri/forskningsperspektivet 4: Jan Kilhamn – Västra Götalandsregionen - Akademi/sjukvårdsforskningsperspektivet 5: Douglas Lundin – TLV - pris/subvention myndighetsperspektivet 6: Maria Landgren – SKL/NT-rådet - sjukvårds/betalarperspektivet
17:40	**Closing address Johan Hyllner (AstraZeneca)**
17:45	**Concluding remarks Ebba Carbonnier (Swelife)**
18:00	**Bus to Airport via Mölndal Station**

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This event runs within WP3 of Swelife-ATMP (Contract no. 2017-02453).

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