10 October 2018

Agenda

"Advancing the delivery of ATMPs to patients"

The seventh annual regulatory conference organised by EBE

4 December 2018, HILTON London Canary Wharf, South Quay, Marsh Wall, E14 9SH London, UK

Time	Agenda item
9.30 – 10.00	**Registration**
10.00-10.10h	**Welcome & Introduction** - François Martelet, EBE Vice-President, CEO NetScientific
10.10-11.30h	**Session 1: Efficient approaches to evidence generation for regulatory approval and health technology assessment of ATMPs** True patient access to ATMPs requires granting of a marketing authorisation following a positive evaluation by regulatory authorities as well as a successful outcome in health technology assessment and reimbursement negotiations. This session aims to explore how collaborative efforts between regulators, HTA bodies and other stakeholders are trying to foster more efficient approaches toward development of ATMPs to meet evidence requirements for patient access. • Industry experience Presenter: Ken Genenz, TiGenix-Takeda (15 min) • EMA experience on joint scientific advice EMA/HTA with ATMPs Presenter: Anna Tavridou, EMA (15 min) • HTA body experience on joint scientific advice EMA/HTA with ATMPs Presenter: Chantal Belorgey, HAS (15 min) • Patients perspective Presenter: Simone Boselli, EURORDIS (15 min) • Panel discussion (20 min) Moderator: Marìa Pascual, TiGenix-Takeda Panellists: All presenters + Pierluigi Navarra, Medical School of Catholic University of Roma + Cristina Avendano, Spanish Society of Clinical Pharmacology +Nick Crabb, NICE
11.30-11.45h	Coffee break
11.45-12.45h	**Session 2: Meeting requirements for long-term follow-up of ATMPs in the post-authorisation phase** Continued long-term safety and efficacy durability monitoring in the post-marketing phase is particularly relevant for ATMPs to consolidate science-based evidence cumulated in the pre-marketing phase. Adapted approaches for ATMP post-authorisation follow-up of efficacy and safety, and risk-management are advised. This session will focus on recommended tools and methodologies, in particular patient registries, for long-term follow-up of ATMPs. • Update on the revision of the guideline on safety and efficacy follow-up – Risk management of ATMPs Presenter: Caroline Voltz, EMA (10 min) • Industry perspective on registries Presenter: Laurence Adegeest, Celgene (10 min) • HTA's body perspective on registries Presenter: Anja Schiel, NOMA (10 min) • Registry holder perspective Presenter: Eoin McGrath, EBMT (10 min) • Panel discussion (20 min) Moderator: Jacquelyn Awigena Cook, Celgene Panellists: All presenters
12.45-14.00h	Lunch

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14.00-15.00h	**Session 3: Complexity of innovative manufacturing and the associated challenges for comparability** ATMP complexity can lead to frequent manufacturing process changes both during development and after approval, requiring the conduct of comparability exercise. Comparability is identified as one of the main challenges in ATMP quality development. This session will highlight some of the common difficulties to perform the comparability exercise with ATMP products and how they may be addressed. • Industry perspective on comparability challenges Presenter: Agnes Yeboah, Celgene (10 min) • Comparability challenges for allogeneic cell therapy products Presenter: Angel Herrero, TiGenix-Takeda (10 min) • Comparability for ATMPs: Challenges and solutions Presenter: Simon Briggs, Novartis (10 min) • European regulators views Presenter: Margarida Menezes-Ferreira, CAT (10 min) • Panel discussion (20 min) Moderator: Florence Salmon, Novartis Panellists: All presenters + Margit Jeschke, Novartis
15.00-15.20h	Coffee break
15.20-16.30h	**Session 4: Stakeholder perspectives on optimizing delivery of ATMPs in the healthcare systems.** ATMPs can have characteristics that involve specialised hospital procedures for their use by medical staff and patients as compared to traditional medicines. Practical adoption of such innovative technologies at hospital required an integrated approach from multiple stakeholders. This session aims to hear the views from different users (health care professionals, patients, payers) on current challenges and opportunities for improvements to streamline access to ATMPs. • Viewpoint from a healthcare professional Presenter: Prof. Dr. Med Mohamed Abou-El-Enein, Charité Universitätsmedizin Berlin (10 min) • Viewpoint from a patient organisation Presenter: Mariette Driessens, EGAN (10 min) • Viewpoint from a Centre of Excellence Presenter: Patrick Ginty, Catapult (10 min) • Viewpoint from a payer Presenter: Evert Jan van Lente, AOK (10 min) • Panel discussion (30 min) Moderator: Esther Choi, BMS Panellists: All presenters
16.30–16.45h	**Closing remarks** - François Martelet, EBE Vice-President, CEO NetScientific