Eye Drops from Human Origin – First EDHO Workshop on Current Standards and Future Developments
organized by the ISBT Working Party Cellular Therapies
March 19-20, 2020 Vienna, Austria

Organizers
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Goals of the Meeting:
This Workshop will provide a forum for scientists, regulatory authorities, ophthalmologists and transfusion experts on the usage, quality, indication and manufacture of eye drops from human origin. Selected scientific lectures from well-known experts will be presented. Key discussions to find commonalities in production and quality issues include the latest scientific knowledge. The aim is to reach some consensus on classification, validation and standardization of these products. The active participation from various regulatory agencies will also be an important emphasis of this workshop. Ample time shall be provided for a highly stimulating discussion:

▪ To exchange knowledge between eye specialists, transfusion specialists and regulators.
▪ To enhance knowledge of eye physicians on properties of EDHO and its regulatory requirements
▪ To enhance knowledge of transfusion specialists on serum eye drops, the clinical need, patient’s needs and
▪ To develop a common ground for the regulation of EDHO

Sponsors:

Venue
Red Cross Transfusion Service of Vienna,
Wiedner Hauptstrasse 32, 1040, Vienna, Austria

Online Programme
https://www.isbtweb.org/working-parties/cellular-therapies/
Target groups:

- Regulatory authorities,
- Manufacturers of EDHO,
- Blood establishments,
- Transfusion medicine specialists,
- Ophthalmologists,
- Researchers,
- Vendors

Start of Meeting: Thursday March 19, 08.30 AM
End of Meeting: Friday March 20, 17.00 PM

Participation fee: € 500 for clinicians and scientists; special fees apply to (members of) companies - inquiries to: edho@gabriel.science
Registration form: please request by E-mail to: edho@gabriel.science
Participants: Limited to max. 30 persons

THURSDAY MARCH 19, 2020

Basics
Lacrimal gland, Meibomian glands, Corneal regeneration
Composition of tears, tear flow
Properties of serum, platelet lysate, extracellular vesicles
Discussion: physiological properties and what is comparable

Diseases of the eye
Dry eye syndrome, GVHD, rare diseases of the anterior eye,
Neurotrophic keratopathy, Sjögren’s Syndrome,
Post-surgery complications
Discussion: Where is the clinical need for EDHO?

Properties and Pharmacology of eye drops
Regulatory environment of pharmaceutical eye drops
Pharmaceutical eye drops for the treatment of dry eye disease

FRIDAY MARCH 20, 2020

Production of new EDHO
Eye drops from cord blood, human milk, platelet lysate, allogeneic and autologous
Discussion: production standards and differences to serum eye drops

Quality issues
Testing of growth factors, impurities, microbiology and general testing
Discussion: which tests for which products?

Clinical outcomes
Platelet lysate – clinical studies
Cord blood
Effects of EDHO on dry eye disease, Sjögren’s syndrome
Post LASIK and postoperative outcomes
Evidence based use of EDHO
Discussion: which products meet clinical requirements and which data support the use of EDHO

Regulatory requirements
Discussion: regulations overview and commonalities worldwide

Wrap up, final discussion and conclusions

New products and developments
Discussion: what is currently in use, how does it compare to EDHO?

Donation of EDHO and production of serum eye drops
Donor requirements of eye drops: Are all donors eligible for autologous donation?
How to produce autologous serum eye drops
How to produce allogeneic serum eye drops
Quality testing
Dilution, packaging, labelling, storage, patient’s perspective
Discussion: Key elements for serum eye drops-production, current requirements