



ECHO7UM

ECHO-7 Oncolytic virotherapy for UVEAL MELANOMA

Solution for unmet medical need

UVEAL Melanoma is rare cancer type in the eye, but in fact 85% - of all ocular cancer cases

ECHO7UM is RIGVIR holding spin-off

- ECHO7UM will be corporate spin-off from company Latima ltd. subsidiary of RIGVIR holding
- Latima ltd. is the manufacturer (GMP) of a commercialised ECHO-7 virus that has been clinically used more than 14 years with trademark RIGVIR®
 - RIGVIR® is registered for cutaneous melanoma treatment in Latvia (since 2004), Georgia (2015), Armenia (2016), Uzbekistan (2018)
- As per EMA/CHMP Scientific Advice ECHO-7 (RIGVIR®) the available data are sufficient to enter any clinical trial phase II (e.g. a proof-of-concept study)
- Medicine with same active substance for rare disease can have different trademark
- ECO7UM will build foundation to execute clinical trials and register new medicine for rare disease uveal melanoma

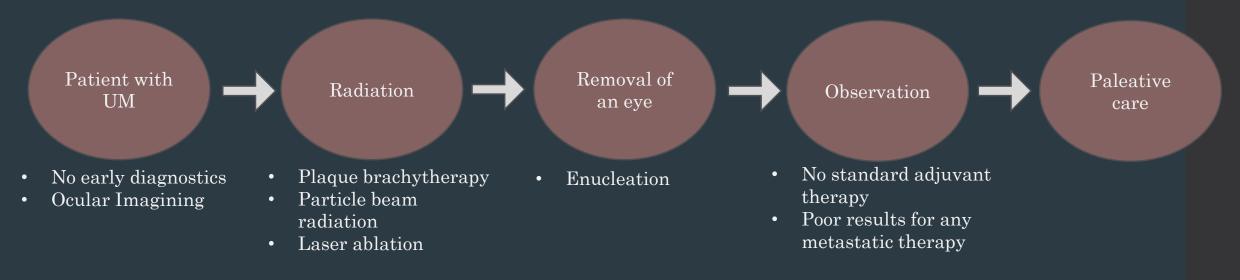




ECHO7UM

Oncolytic Virotherapy is immunotherapy discipline that uses oncotropic and oncolytic viruses which has the ability to find and destroy tumour cells

Poor treatment options



- · Since there is no standard adjuvant therapy, nothing can reduce the risk of metastasis
- About 50% of the patients develop metastases, with the liver being the most frequent site
- In case of metastases 1-year survival is reported to be 15% (median survival 4-15 months)

Safe therapy that can prevent metastasis and prolong survival for metastatic patients is required!

Source: Carvajal et al. Br J Ophthalmol. 2017 Jan; 101(1): 38–44. / NCCN Guidelines UVEAL Melanoma V 1.2018

Real medical need

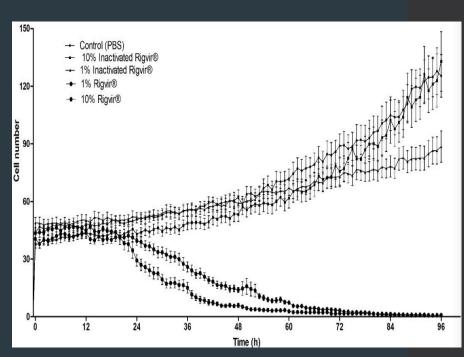
• The lack of effective therapies has led to the widespread use of systemic treatments of cutaneous melanoma for patients. BUT uveal and cutaneous melanomas are intrinsically different diseases

- Number of clinical trials are in place mainly focusing on metastatic disease, but the results are disappointing, for example:
 - Ipilimumab RR: 5-10%, OS: 6.8 mo, PFS: 2.8 mo
 - Nivolumab and pembrolizumab PFS: ~ 3 mo
 - Selumetinib MEK inhibitor (BRAF pathway) RR:14%; improved OS:2.7 mo; PFS 1.32 mo
 - Trametinib MEK1/2 inhibitor shows PFS 1.8 mo

Treatments are usually derived from skin Melanoma and focuses to metastatic setting

ECHO-7 Virotherapy for UVEAL MELANOMA

- ECHO-7 oncolytic virotherapy has oncolytic, oncotropic and immunomodulating properties
- It is administered by intramuscular injections
- ECHO-7 is Picornaviridae virus (30 nm) which might pass blood-brain barrier
- Retrospective studies suggests that ECHO-7 adjuvant therapy may prolong progression-free time and reduce mortality up to 6 times*
- ECHO-7 virus destroys 80-99% of Uveal melanoma cells
- Successfully used for more than 10 years Off-label for Uveal melanoma both in adjuvant and metastatic settings
- Real world data case report series on surprising treatment results under development

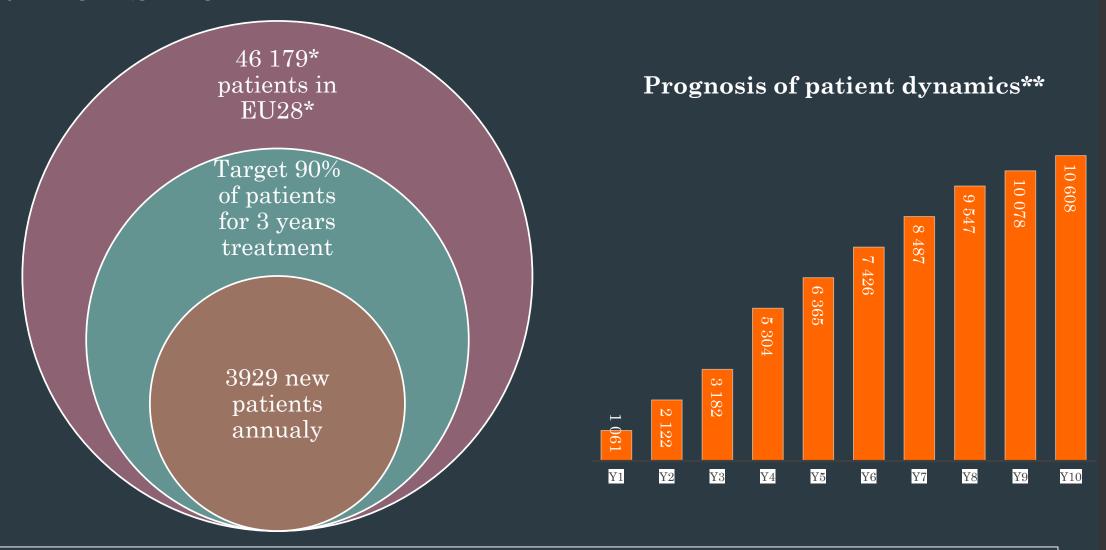


*Source: Doniņa et al. Melanoma Research 2015, 25, 421

Clear incentives from EMA



Market size



Other markets also will be reachable after EMA commercialization - CIS; FDA e.t.c.

Source: * http://www.rarecarenet.eu/fact_sheets.php / ** company assumptions

Project road model



- Targeted annual treatment cost EUR 25 000
- Target Market value at least 200 Million EUR annually



ECHO7UM will attract number of investors to finance the running and development costs

Intelectual Property Rights

- RIGVIR holding holds the necessary patents (EPO; PTS) to produce, sale and use in treatment ECHO-7 virus
- The IP of uvea melanoma indication would be fully derived and delegated for this project (ECHO7UM) with rights to distribute medicine globally
- The Latima ltd. would be manufacturer and producer with know-how of the production process (GMP)
- · The price for production will be agreed and fixed





Project developement Team



Head of Operations – Mr. Karlis Urbans, MBA, business development professional with experience in the field of Oncolytic Virotherapy and managing complementary teams



Head of R&D – Prof. Pēteris Alberts, PhD (Karolinska Institute, Stockholm, Sweden), pharmacologist / drug development scientist with more than 25 years' experience of different drug development and registration projects



Medical consultant - Prof. Simona Doniņa, PhD, MD, has extensive experience in oncology and immunology, including the prescription of ECHO-7 for UVEAL Melanoma patients



Head of Regulatory – Mr. Valdis Mikelsons, MBA, MD, more than 20 years experience leading and developing pharmaceutical companies with Takeda, Johnson&johnson, Nycomed



R&D Associate - Ms. Andra Tilgase MSC, PhD Candidate research object – ECHO 7 virus biological characteristics

Complete and complimentary team with comprehensive experience and knowledge

Investment Opportunity and Exit

- ECHO7UM project is looking to rise 1.2 Million EUR this round
- To finance:
 - Team, running costs and elaboration of regulatory strategy
 - Finalisation of scientific evidences and validation of biomarkers
 - Validation of Clinical trial protocol and EMA advice
- 18 Months till next round (B Series, ~10 Million EUR)
- Exit After the registration of the medicine, the project ECHO7UM (Spin Off) will be sold or the distribution would be licensed to existing market players with established network and focus on rare disease for example:











Summary

Medical Need

- No standard treatment and poor survival rates
- Safe therapy that can prevent metastasis and prolong survival for metastatic patients is required

Market

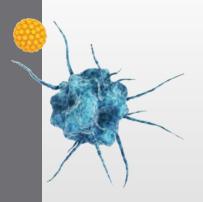
- Rare disease
- 46 179 patients in EU, 3929 new patients annually
- Target Market value at least 200 Million EUR annually

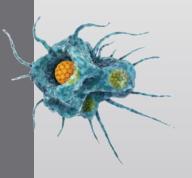
Advantages

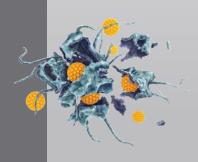
- Promising preclinical and Clinical data
- Off label used in treatment already more than 10 years
- Full set of IPR
- EMA support
- Experienced team

Spin-off project

- 1.2 Million EUR
- To build foundation for next rounds and clinical trial
- Project sale after registration







Thank you!

ECHO-7 Oncolytic virotherapy for UVEAL MELANOMA

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