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Mitotech Announces Phase 2 Data Showing Positive Effect of SkQ1 in Patients with Dry Eye Syndrome

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Mitotech S.A, a Luxembourg-based clinical-stage biotechnology company developing novel antioxidant molecules targeting mitochondria, today announced that it has achieved significant positive results in its U.S. Phase II clinical trial of SkQ1 compound in patients with moderate to severe dry eye syndrome. SkQ1 is a small molecule engineered specifically for reducing oxidative stress inside mitochondria, which proved to be effective in a topical ophthalmic formulation for treatment of dry eye syndrome.

“SkQ1 is the first mitochondria-targeted antioxidant to reach clinical phase of development for an ophthalmic indication”, said Natalia Perekhvatova, Chief Executive Officer of Mitotech S.A.. “We achieved statistically significant treatment effects in both signs and symptoms of dry eye syndrome. These findings are especially encouraging since they were obtained in the Intent-to-Treat (ITT) population in a small number of patients (30 patients per treatment arm). Results of this U.S. study are very valuable because they confirmed SkQ1 efficacy for the same dry eye signs and symptoms that our previous clinical study conducted in Russia and Ukraine already succeeded on. Ophthalmic formulation of SkQ1 called Visomitin has already been on the Russian pharmaceutical market since 2012 and this U.S. Phase II study is an important milestone for Mitotech S.A. in its path to other markets. Dry eye syndrome is a growing and hugely underserved indication and our company is now well-positioned for delivering a break-through product in this therapeutic area.”

The 90-patient study (ClinicalTrials.gov Identifier: NCT02121301) used Ora’s Controlled Adverse Environment (CAE) chamber to measure dry eye patients’ ability to withstand a stressful environment on the eye. This study was performed at a single investigational site in Andover, MA over a 2-month period from first patient to last patient visit. SkQ1 demonstrated superiority over placebo in several endpoints such as central ($p = 0.036$) and total corneal ($p = 0.045$) fluorescein staining pre to post CAE and grittiness ($p = 0.058$) pre to post CAE at week 4 in the ITT population. “The unique mechanism-of-action of reducing oxidative stress inside mitochondria in conjunction with these study results suggest that SkQ1 provides a significant protective benefit for dry eye patients” said George Ousler, Vice President of Dry Eye at Ora, Inc.. SkQ1 was comfortable, well tolerated and there were no unexpected or serious ocular adverse events. Additional information on study results can be found on Mitotech’s poster accepted for presentation at the 2015 ARVO Annual Meeting held May 3-7, 2015, in Denver, Colorado.

Mitotech had a successful “End of Phase II” meeting with the FDA in January 2015 confirming the remaining requirements for the clinical development plan. “Following a very positive meeting with the FDA, we have begun preparations for the next clinical and non-clinical studies”, said Ms. Perekhvatova “The Agency provided invaluable

guidance for starting our next clinical study and we are looking forward to initiating a Phase III trial in Q4 2015. Having established a roadmap to SkQ1 approval, we are now initiating discussions with potential Pharma partners to engage in a strategic collaboration that would help us to deliver this highly promising new drug to the market as effectively as possible.”

About Mitotech S.A

Mitotech S.A. is a Luxembourg-based biotechnology company developing novel drugs for the treatment of age-related disorders. Mitotech S.A. was founded in 2009 as a spinoff from the bioengineering department of the Moscow State University. The core technology behind Mitotech products is based on the world-renowned work by Professor Vladimir Skulachev in designing mitochondrially addressed antioxidants. Company’s lead compound SkQ1 is being developed into several drugs covering a variety of therapeutic areas and methods of administration.

About Ora, Inc.

Ora is the world’s leading independent, full-service ophthalmic CRO and product development firm with offices in the United States and Japan. Ora’s Dry Eye System (including both mobile and stationary CAESM chambers) addresses the challenges of evaluating treatments for dry eye disease, such as environmental and seasonal variability, through a combination of scientific and operational methods.

News & Events

- [Mitotech S.A. is granted a patent in anti-aging](#)
- [Mitotech S.A. announces its Ophthalmic Scientific Advisory Board](#)
- [Oxidative stress and dry eye in Review of Ophthalmology](#)
- [Mitotech S.A. to present at ARVO 2016](#)
- [Mitotech CEO to present at the annual BIO CEO and Investor Conference 2016](#)

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