

【Press release】



Essex Bio-Technology and Mitotech Complete Enrollment in VISTA-2 – a Pivotal Phase 3 Clinical Study of SkQ1 for Dry Eye Disease

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Essex Bio-Technology Ltd ("EssexBio" or the "Group", Stock Code: 1061.HK) and Mitotech S.A., a Luxembourg-based clinical-stage biotechnology company developing novel pharmaceuticals targeting mitochondria, today announced completion of enrolment in its pivotal U.S. Phase 3 VISTA-2 study of SkQ1 ophthalmic solution in patients with moderate to severe Dry Eye Disease (DED). SkQ1 belongs to the class of cardiolipin peroxidation inhibitors developed for treatment of a spectrum of age-related disorders, including Dry Eye Disease (DED).

VISTA-2 is a multi-centre, randomized, double-blind, placebo-controlled clinical study involving two treatment arms: SkQ1 ophthalmic solution and vehicle solution, administered BID. 610 patients have been enrolled in the study across multiple centres in the U.S. to receive treatment over a 2-month period.

"We are proud to have reached full enrollment in our pivotal study", said Natalia Perekhvatova, Chief Executive Officer of Mitotech S.A. "At the same time, we recognize that COVID-19 pandemic is a challenging environment for patients and healthcare industry worldwide. Mitotech and EssexBio remain in close contact with medical centres and investigators to ensure the safety of trial participants as well as medical professionals involved in the study. With multiple layers of safeguards in place we are looking forward to completing the study in Q4 2020."

VISTA-2 is Mitotech's first pivotal study in Dry Eye Disease designed to confirm outcome of its VISTA-1 study conducted back in 2019. VISTA-1 facilitated dose and primary endpoint selection for VISTA-2 having demonstrated statistically significant SkQ1 impact against vehicle on multiple signs and symptoms of Dry Eye Disease over the 2-month course of treatment. At the same time the study highlighted excellent safety profile of the drug with tolerability being statistically similar to that of an artificial tear.

"Our appreciation to everyone involved for their ongoing efforts in supporting timely completion of study enrolment," said Malcolm Ngiam, President of Essex Bio-Investment Limited. "We look forward to evaluating the study read-out and to moving one step closer to making SkQ1 available for the world-wide DED market."

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About SkQ1

SkQ1 addresses DED through a novel mechanism of action, acting on the mitochondria at a cellular level. Unlike current standards of care, which act primarily as anti-inflammatory agents, SkQ1 has been shown to not only relieve inflammation but also improve tissue degeneration and tear quality deficit by targeting oxidative stress within the eye. In VISTA-1 – a Phase 2b/3 clinical study in the United States (NCT03764735) - SkQ1 showed evidence of efficacy in reducing both the signs and symptoms in dry eye subjects.

About Mitotech S.A.

Mitotech S.A. is a Luxembourg-based biotechnology company developing novel drugs for treatment of predominantly age-related disorders. The core technology behind Mitotech products is based on a novel class of small molecules – mitochondria targeting cardiolipin peroxidation inhibitors. Company's lead compound SkQ1 is being developed in several drug formulations covering a variety of therapeutic areas with major focus on ophthalmology and neurodegenerative diseases.

About Essex Bio-Technology

Essex Bio-Technology is a bio-pharmaceutical company that develops, manufactures and commercialises genetically engineered therapeutic rb-bFGF (FGF-2), having five commercialised biologics marketed in China since 1998.

The products of the Company are principally prescribed for the treatment of wounds healing and diseases in Ophthalmology & Dermatology, which are marketed and sold through approximately 8,880 hospitals and managed directly by its 43 regional sales offices in China.

Leveraging on its in-house R&D platform in growth factor and antibody, the Company maintains a pipeline of projects in various clinical stages, covering a wide range of fields and indications.

Contact

EssexBio

IR: Investors@essex.com.cn

PR: Media@essex.com.cn