



PRESS RELEASE

**AVIZOREX PHARMA, S.L. submits Clinical Trial Application for its lead compound AVX-012 for Dry Eye Syndrome**

*AVX-012, a Small Molecule with a novel mechanism of action, to be investigated as a potential new treatment for mild to moderate Dry Eye Syndrome.*

**Barcelona, Spain - 1 JULY 2016 - AVIZOREX PHARMA, S.L.**, an ophthalmology biotech company focused on developing novel therapies for Dry Eye Syndrome, today announced the submission of a Clinical Trial Application (CTA) to the Spanish Competent Authority, requesting clearance to initiate a Phase I/II clinical trial investigating the use of AVX-012 Ophthalmic Solution to treat patients suffering from mild to moderate Dry Eye Syndrome (DES).

The multicenter study, entitled, “Phase I/II, double-blind, placebo-controlled study assessing the safety and efficacy of AVX-012 Ophthalmic Solution in subjects with mild-to-moderate Dry Eye Syndrome”, has been designed to confirm AVX-012 Ophthalmic Solution safety, tolerability and efficacy in DES patients, and if cleared, is expected to be initiated in late 2016 in multiple sites across Spain.

“We believe AVX-012 has the potential to significantly improve both signs and symptoms in this large population of DES patients, due to its selective action on temperature/humidity detecting neurons in the cornea and thereby regulating basal tear production to stabilize tear film and might contribute some analgesic effects that reduce ocular discomfort associated with dry eye”, commented Patrick Tresserras, Chief Executive Officer of Avizorex Pharma, S.L. , who also stated, “Initiation of this trial is another significant milestone in our strategy to create maximum value around the company Dry Eye program”.

**About Dry Eye Syndrome (DES)**

DES is “a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolality of the tear film and inflammation of the ocular surface”. Prevalence reported in the USA, Australia and Europe (Spain) is approximately 5-15 %, 25% in Canada and 30-50% in Asia, with the

highest prevalence being observed in subjects of Asian and Hispanic origin (Gayton, 2009; EMA/450332/2012, 2012). DES is more common in women, especially in postmenopausal women, and the prevalence increases with age in both gender (Gayton, 2009).

Treatment of dry eye is mainly symptomatic; very few pharmacological treatments for Dry Eye Syndrome are currently approved in the world. Nowadays, artificial tear preparations are the mainstay of therapy and are generally based on lubricating or viscosity increasing agents. There is no evidence that any type of artificial tear or ocular lubricant is markedly better than others (Doughty *et al.*, 2009).

Dry Eye therapeutics market will grow to \$4.6 Billion by 2024, being one of the fastest growing indications in ophthalmology, while pharmaceutical sales were approximately \$2.5 Billion in 2015, although there are no effective treatment options today available for the millions suffering from Dry Eye Syndrome.

### **About Avizorex Pharma, S.L.**

Avizorex Pharma, S.L. is a Spanish ophthalmology biotech company founded in 2013 in Alicante and backed by Inveready, the seed to early stage Venture Capital Company based in Barcelona. Based in Alicante, Comunitat Valenciana, and with offices in Barcelona Science Park, Avizorex Pharma S.L., is focused on developing novel therapies for Dry Eye Syndrome (DES) based on Prof. Carlos Belmonte's research on the role of temperature-sensitive neurons in tear film regulation at the prestigious Alicante Neuroscience Institute.

The company lead product candidate, AVX-012, is a Small Molecule with a novel Mechanism of Action, that is expected to initiate clinical trials by late 2016 to confirm its safety and efficacy in mild to moderate Dry Eye Syndrome patients.

Visit [www.avizorex.com](http://www.avizorex.com) for more information.

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This press release contains forward-looking information that involve various risks and uncertainties regarding future events, including statements regarding our approach and our technology, expected and planned upcoming milestones and events, and the timing of trials. Such forward-looking information can include without limitation statements based on current expectations involving a number of risks and uncertainties and are not guarantees of future performance of Avizorex Pharma, S.L. There are numerous risks and

uncertainties that could cause actual results and Avizorex Pharma, S.L. plans and objectives to differ materially from those expressed in the forward-looking information, including: approval to conduct clinical trials; negative results from the Company's clinical trials; the effects of government regulation on the Company's business; risks associated with the Company's ability to obtain and protect rights to its intellectual property; risks and uncertainties associated with the Company's ability to raise additional capital; and other factors beyond the Company's control. Actual results and future events could differ materially from those anticipated in such information. These and all subsequent written and oral forward-looking information are based on estimates and opinions of management on the dates they are made and are expressly qualified in their entirety by this notice. Except as required by law, Avizorex Pharma, S.L. does not intend to update these forward-looking statements.