



Laboratoires KÔL secures government France 2030 funding clinical trial in AMD

Laboratoires KÔL has secured government funding under the France 2030 Plan to support its SKY2 study, a clinical research programme aimed at developing a breakthrough therapeutic approach to age-related macular degeneration (AMD). By introducing a topical treatment (eye drops) for a condition currently managed with intravitreal injections, SKY2 paves the way for a new treatment modality that is simpler, better accepted by patients and likely to reduce the need for intraocular injections. This funding marks a milestone in the development of Laboratoires KÔL and confirms their commitment to innovative therapeutic solutions, extending beyond their long-standing expertise in rare diseases.

About Laboratoires KÔL:

Laboratoires KÔL is a French pharmaceutical company dedicated to providing 'what is missing'. As such, they have built their reputation on the development of and access to medicines for rare eye diseases. With recognised expertise in corneal conditions and innovative dosage forms, Laboratoires KÔL have extensive experience in Compassionate Use Program.

Laboratoires KÔL work closely with hospitals, research institutes and regulatory authorities to offer innovative, patient-centred therapeutic solutions on a global scale.

Building on this foundation of expertise, and thanks to its international patents on a unique antisense oligonucleotide, KÔL is now applying its expertise to develop eye drops for the treatment of age-related macular degeneration (AMD), for which injections are currently the only treatment option, thereby continuing its mission to provide 'what is missing'.

About AMD:

Age-related macular degeneration (AMD) is a chronic, progressive condition that is one of the leading causes of central vision loss in older people.

AMD presents in various clinical forms, reflecting the complexity of the condition. Among these, exudative AMD, also known as neovascular or 'wet' AMD, represents a major public health challenge.

Exudative AMD is characterised by the formation of abnormal new blood vessels beneath the retina, in the macula. These fragile vessels lead to leaks of fluid or blood, which can cause rapid and severe deterioration of central vision, making this form the primary cause of the most significant vision loss associated with AMD.

Anti-VEGF therapies administered via intravitreal injections have become the standard of care. However, the high frequency of intravitreal injections places a significant burden on patients, carers and healthcare systems. The 'treat and extend' (T&E) treatment regimen has been developed to tailor treatment intervals to individual patient response. Nevertheless, for a significant number of patients, the intervals remain short (≤ 8 weeks), reflecting the existence of an unmet medical need.

To reduce this treatment burden, new molecules administered via intravitreal injection have been developed with the aim of extending the intervals between injections, without compromising the principle of invasive and repeated treatment. In this context, the emergence of a topical therapy (eye drops) would represent a genuine breakthrough in exudative AMD: a non-invasive method of administration, which can be carried out at home, could improve patient acceptance and potentially reduce dependence on frequent injections. To date, no topical therapy is available for exudative AMD, even though this route of administration could offer major advantages in terms of patient comfort, treatment adherence and safety.

About the SKY2 study:

The SKY2 study is a clinical trial conducted in patients with exudative AMD, particularly those who have shown an inadequate response to standard treatment and require frequent intravitreal injections (at intervals of ≤ 8 weeks). It is evaluating the efficacy and safety of aganirsen, an antisense oligonucleotide administered topically as eye drops, developed by Laboratoires KÔL, which acts via the messenger RNA pathway to modulate angiogenesis and inflammation by inhibiting IRS1, thereby leading to a downstream reduction in VEGF and IL-1 β .

As part of the SKY2 study, the eye drops are administered twice daily, in addition to standard treatment with intravitreal injections of 8 mg aflibercept, following a 'Treat and Extend' approach. This strategy aims to shift the treatment paradigm by introducing a non-invasive modality that may reduce the need for repeated injections. The primary objective is to extend the interval between injections, whilst maintaining clinical efficacy, in order to reduce the treatment burden on patients, carers and healthcare facilities. Ultimately, the results could help to advance the management of exudative AMD and pave the way for a topical approach to complement injectable treatments.

Strategic funding under the France 2030 plan

The support granted under the generic call for projects No. 4, 'i-Démo – Support for structural Research, Development and Innovation projects', funded by France 2030 and managed by Bpifrance, is a major driver in supporting the development of the SKY2 study and fostering French therapeutic innovation in ophthalmology. It demonstrates recognition of the innovative nature and high medical potential of this clinical research programme.

This funding, awarded under the 'Biotherapies and bioproduction of innovative therapies' acceleration strategy, is fully in line with the strategic priorities of the Health Innovation Agency, which aim to:

- Accelerate health research and innovation for the benefit of patients;
- Strengthen France's appeal as a centre of excellence for clinical development;

- Foster the emergence of breakthrough therapeutic solutions with a significant and lasting medical impact.

For KÔL, this recognition provides a key driver for continuing the development of a breakthrough eye drop, which has the potential to transform the management of conditions that are currently treated with heavy-duty therapies, and to bring this innovation to the international stage.

About France 2030

The France 2030 investment plan:

- ✓ reflects a dual ambition: to bring about lasting transformation in key sectors of our economy (energy, automotive, aerospace and space) through technological innovation, and to position France not merely a player, but a leader in the world of tomorrow. From fundamental research, through the emergence of an idea, to the production of a new product or service, France 2030 supports the entire life cycle of innovation right through to its industrialisation.
- ✓ It is unprecedented in its scale: €54 billion will be invested to ensure that our businesses, our universities and our research organisations can successfully complete their transitions in these strategic sectors. The aim is to enable them to respond competitively to the environmental and attractiveness challenges of the world to come, and to foster the future champions of our sectors of excellence. France 2030 is defined by two cross-cutting objectives: to devote 50 per cent of its expenditure to the decarbonisation of the economy, and 50 per cent to emerging players driving innovation without expenditure that is harmful to the environment (in accordance with the 'Do No Significant Harm' principle).
- ✓ It will be implemented collectively: designed and rolled out in consultation with economic, academic, local and European stakeholders to determine its strategic directions and flagship initiatives. Project leaders are invited to submit their applications via open, rigorous and selective procedures to benefit from government support.
- ✓ It is led by the General Secretariat for Investment on behalf of the Prime Minister and implemented by the Agency for Ecological Transition (ADEME), the National Research Agency (ANR), the Public Investment Bank (BPI France) and the Caisse des Dépôts et Consignations (CDC).

Further information at: www.gouvernement.fr/secretariat-general-pour-l-investissement-sgpi

About Bpifrance

Bpifrance provides finance to businesses – at every stage of their development – in the form of loans, guarantees and equity. Bpifrance supports them in their innovation and international expansion projects. Bpifrance also supports their export activities through a wide range of products. Advice, academic partnerships, networking and acceleration programmes aimed at start-ups, SMEs and mid-cap companies are also part of the support offered to entrepreneurs. Thanks to Bpifrance and its 50 regional offices, entrepreneurs benefit from a local, dedicated and effective point of contact to help them tackle their challenges.

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