

Grifols receives FDA clearance of IND application for Phase 2 trial of immunoglobulin drops for dry eye disease

- *Study could lead to first-ever ocular surface indication for an immunoglobulin (IG) and potential new treatment for dry eye disease (DED)*
- *The trial builds on a pilot study that achieved a significant reduction in the signs and symptoms of DED treating patients with eye drops based on a Grifols IG*
- *Grifols is increasingly leveraging its deep knowledge of IG and its therapeutic properties to enhance people's health and well-being*

Barcelona, Spain, May 21, 2025 - Grifols (MCE: GRF, MCE: GRF.P NASDAQ: GRFS), a global healthcare company and leading producer of plasma-derived medicines, today announced that the United States Food and Drug Administration (FDA) cleared the company's Investigational New Drug (IND) application to initiate a Phase 2 trial evaluating its immunoglobulin (IG) drops – GRF312 Ophthalmic Solution – for what could become the first-ever ocular surface indication for an IG and a potential new treatment for dry eye disease (DED).

DED is a common inflammatory condition affecting more than 100 million people globally. It is characterized by inadequate moisture on the eye's outer surface, which in severe cases could lead to permanent vision damage.

The study, which will analyze safety, tolerability and efficacy in 100 patients with DED, is expected to begin in the third quarter of 2025. It will build on a pilot Phase 1/2 trial conducted at the University of Illinois College of Medicine, Department of Ophthalmology, by Grifols' partner Selagine, a company focused on developing novel therapeutics for ocular diseases. Results showed that when treated with eye drops based on a Grifols IG product twice daily for eight weeks, patients achieved a significant reduction in DED signs and symptoms, with no difference in tolerability or adverse events compared to placebo.

"We believe our immunoglobulin eye drops have the potential to make a qualitative leap in how dry eye disease is treated," said Dr. Jörg Schüttrumpf, Grifols Chief Scientific Innovation Officer. "Research suggests that the broad-spectrum anti-inflammatory and immunomodulatory properties of an ocular surface IG are superior to currently approved therapies, including artificial tears and anti-inflammatories. We are using our extensive and deep knowledge of immunoglobulins to benefit the millions of patients globally who aren't receiving sufficient relief."

"Selagine and Grifols joining efforts and complementary expertise successfully led the treatment to a phase 2 clinical trial," said Dr. Sandeep Jain, MD, founder and President of Selagine and BA Field Professor of Ophthalmology at the University of Illinois Chicago. "The results obtained to date and this promising development reinforce the potential of this novel treatment approach to significantly improve the quality of life of dry eye disease patients."

In March 2023, Grifols and Selagine announced a collaboration and licensing agreement under which Grifols would have worldwide exclusive rights to Selagine's treatment, which is being developed by combining Grifols' expertise in developing and manufacturing innovative IG therapies as well as Selagine's cutting-edge research, medical expertise and clinical experience in treating debilitating eye diseases.

About Dry Eye Disease

It is a common and chronic multifactorial inflammatory disease characterized by insufficient moisture in the outer surface of the eye, leading to dryness, pain, discomfort, diminished quality of life and, in severe cases, permanent vision impairment. Currently approved treatments, such as artificial tears and anti-inflammatories (corticosteroid therapy, cyclosporine therapy and lifitegrast), may take weeks or even months to demonstrate activity.

About Grifols

Grifols is a global healthcare company founded in Barcelona in 1909 committed to improving the health and well-being of people around the world. A leader in essential plasma-derived medicines and transfusion medicine, the company develops, produces and provides innovative healthcare services and solutions in more than 110 countries.

Patient needs and Grifols' ever-growing knowledge of many chronic, rare and prevalent conditions, at times life-threatening, drive the company's innovation in both plasma and other biopharmaceuticals to enhance quality of life. Grifols is focused on treating conditions across four main therapeutic areas: immunology, infectious diseases, pulmonology and critical care.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's largest with close to 400 across North America, Europe, Africa and the Middle East, and China.

As a recognized leader in transfusion medicine, Grifols offers a comprehensive portfolio of solutions designed to enhance safety from donation to transfusion, in addition to clinical diagnostic technologies. It provides high-quality biological supplies for life-science research, clinical trials and for manufacturing pharmaceutical and diagnostic products. The company also supplies tools, information and services that enable hospitals, pharmacies and healthcare professionals to efficiently deliver expert medical care.

Grifols, with more than 23,800 employees in more than 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership.

The company's class A shares are listed on the Spanish Stock Exchange, where they are part of the IBEX-35 (MCE:GRF). Grifols non-voting class B shares are listed on the Mercado Continuo (MCE:GRF.P) and on the U.S. NASDAQ through ADRs (NASDAQ:GRFS).

For more information about Grifols, please visit www.grifols.com

About Selagine Inc.

Selagine Inc. is a clinical-stage spin-out company from the University of Illinois Chicago (UIC) that is commercializing technology which was developed within the University of Illinois College of Medicine (UI COM), Department of Ophthalmology & Visual Sciences. UI COM places a strong emphasis on supporting faculty's efforts towards academic entrepreneurship through initiatives such as an entrepreneur-in-residence program led by Dr. Michael Flavin.

The immunoglobulin eye drops were the result of research & development efforts spanning over a decade. The basic research underlying the clinical development of IG eye drops was funded by grants from the National Eye

Institute (NEI)/National Institutes of Health (NEI R24EY032440), Research to Prevent Blindness and UIC's Office of Technology Management.

Selagine is focused on developing novel therapeutics to help patients suffering from a variety of debilitating ocular diseases, and to improve the quality of life in conditions where effective therapies do not exist. Selagine's office is located within the Illinois Medical District and its R&D laboratory is housed in UIC's Incubator Laboratory Facility, a hub for entrepreneurship and innovation at the University.

For more information, visit www.selagine.com

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