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Grifols partners with BARDA for proof-of-concept testing of ocular immunoglobulin as treatment for sulfur mustard-induced eye injury

- ***Initiative will test Grifols ocular surface immunoglobulin (OSIG) eye drops to evaluate their nonclinical efficacy in neutralizing symptoms from exposure to sulfur mustard, a chemical warfare agent***

- ***A successful preclinical study of this potentially innovative therapeutic could lead to an FDA license for one of the first medical treatments for sulfur mustard ocular injury***

- ***Grifols also plans to start a phase 2 clinical trial of an OSIG for dry eye disease in the first half of 2025, part of the company's broadening innovation pipeline to enhance the lives of patients***

Barcelona, Spain, Oct. 22, 2024 – Grifols (MCE:GRF, MCE:GRF.P, NASDAQ:GRFS), a global healthcare company and leading manufacturer of plasma-derived medicines, today announced it has established a partnership with the Biomedical Advanced Research and Development Authority (BARDA) to test investigational ocular surface immunoglobulin (OSIG) eye drops for their ability to treat ocular damage from sulfur mustard exposure. BARDA is part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS).

If the preclinical evaluation is successful, the United States Food and Drug Administration (FDA) could eventually license what would be one of the first medical treatments to counteract the long-term effects of sulfur mustard ocular injury. Sulfur mustard, sometimes referred to as mustard gas, is a chemical warfare agent that reacts rapidly with ocular tissue and can cause pain, photophobia and mustard gas keratopathy, a corneal injury that can lead to blindness.

Grifols will develop a treatment for sulfur mustard ocular exposure by repurposing an investigational OSIG therapeutic currently in development for dry eye disease (DED). The nonclinical studies, conducted in partnership with BARDA, may provide evidence for the anti-inflammatory and immunomodulatory properties of OSIG and its ability to alleviate the long-term effects of sulfur mustard exposure.

Specifically, research will investigate how OSIG's anti-inflammatory properties can prevent the immune system from mistakenly attacking self-antigens, which in this case are proteins modified due to exposure to sulfur mustard. In cases of sulfur mustard exposure, the

immune system can errantly target these self-antigens. By neutralizing the immune response caused by the self-antigens, OSIG could help protect ocular tissue and support recovery in people exposed to sulfur mustard.

Grifols announced in March 2023 a collaboration with Chicago-based Selagine, which focuses on developing novel therapeutics for ocular diseases, to treat DED with immunoglobulin eye drops. The potential treatment, expected to enter clinical development in the first half of 2025, would become the first immunoglobulin medicine indicated for DED, which affects more than 100 million people globally.

“Grifols is applying its leadership in immunoglobulins, a powerful class of medicines with a unique mechanism of action, to develop safe, effective and readily available IG-based ocular treatments to alleviate conditions that seriously impact people’s eyesight and quality of life,” said Joerg Schuettrumpf, Grifols Chief Scientific Innovation Officer. “We continue to build an innovation pipeline focused on providing more and better treatments for patients.”

Grifols’ work with BARDA to create an OSIG to neutralize the effects of sulfur mustard ocular exposure comes shortly after the company’s GigaGen subsidiary announced a contract with BARDA, worth up to $135 million over six years, to develop recombinant polyclonal antibody therapies for biothreats including botulinum neurotoxins.

This project has been supported in whole or in part with federal funds from the HHS, ASPR and BARDA under contract number 75A50124C00050.

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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. Grifols is focused on treating conditions across a broad range of therapeutic areas: immunology, hepatology and intensive care, pulmonology, hematology, neurology, and infectious diseases.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's largest with over 390 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 23,000 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 grifols.com

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