Japan's regulator approves Grifols' Lynspad™ [alpha-1 proteinase inhibitor] for the treatment of alpha-1 antitrypsin deficiency

- ***Grifols collaborating with Japan's OrphanPacific, Inc., which facilitated regulatory approval and will commercialize Lynspad™***
- ***Lynspad™ (intravenous infusion 1000 mg) is used to treat patients diagnosed with severe alpha-1 antitrypsin deficiency***

Barcelona, Spain, and Tokyo, January 22, 2021 - Grifols (MCE:GRF, MCE:GRF.P, NASDAQ:GRFS), one of the world's leading producers of plasma-derived medicines with a more than 100-year track record of contributing to the health and well-being of people around the world, and OrphanPacific, Inc., which provides drugs for rare diseases and disorders in Japan, today announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has granted manufacturing and marketing approval for Lynspad™ (intravenous infusion 1000 mg), an alpha-1 proteinase inhibitor to treat severe alpha-1 antitrypsin deficiency (AATD) in Japan.

Grifols developed Lynspad™ (sold as Prolastin-C® in other markets) and designated OrphanPacific as the Appointed Marketing Authorization Holder (AMAH) to obtain manufacturing and marketing approval for the AATD treatment in Japan under the Foreign Exceptional Approval System, an approach for companies looking to commercialize an overseas-manufactured product in Japan without a license to manufacture and distribute pharmaceutical products in the country.

OrphanPacific will also support Grifols in discussion with the MHLW to establish Lynspad's™ pricing within the country's National Health Insurance system, as well as with the commercialization of the treatment.

The collaboration between Grifols and OrphanPacific is the result of the Innovative Pharma Model (IPM) that CMIC Group created to support the market-entry strategy of foreign pharmaceutical companies in Japan. OrphanPacific is a joint-venture of CMIC Group, a leading contract research organization, and MEDIPAL, a leading pharmaceutical wholesale distributor in the country.

As a pharmaceutical business license organization in Japan, OrphanPacific delivers the IPM and provides full pharmaceutical-firm capabilities that enable international companies to introduce their innovative treatments in the Japanese market.

Lynspad™ is used to treat patients diagnosed with severe AATD [serum alpha-1 antitrypsin level < 50 mg/dL (measured by nephelometry)] and with pulmonary disease such as chronic obstructive pulmonary disease (COPD) and emphysema accompanied by airflow obstruction.

In patients with AATD, serum and tissue levels of alpha-1 proteinase inhibitor are reduced, resulting in an imbalance between neutrophil elastase and its inhibitor, alpha-1 proteinase inhibitor. The imbalance causes inappropriate proteolysis in lung tissue, but Lynspad™ augmentation therapy enhances protection against proteinases by increasing and maintaining the level of alpha-1 proteinase inhibitor in serum and pulmonary airway epithelial lining fluid, and corrects proteinase vs. inhibitor imbalance. It is believed that correction of this imbalance suppresses the onset and progression of emphysema and delays the progression of pathological condition of COPD.

Summary of Approval Details:

Product Name	Lynspad™ for Intravenous Infusion 1000 mg
Non-proprietary name	Alpha-1 Proteinase Inhibitor (Human)
Indication	Severe alpha-1 antitrypsin deficiency
Dosage and administration	For adults, 60 mg/kg is normally intravenously infused once a week as Alpha1-Proteinase Inhibitor (Human).
Foreign Exceptional Approval Holder	Grifols Therapeutics LLC
Appointed Marketing Authorization Holder (AMAH) in Japan (Appointed Manufacturer /Distributor of Foreign-manufactured Pharmaceutical Product)	OrphanPacific, Inc.

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About alpha-1 antitrypsin deficiency (AATD)

Alpha-1 antitrypsin deficiency (AATD) is an inherited disorder that causes a deficiency or absence of the alpha1- antitrypsin protein in the plasma. While AATD symptoms vary depending on the degree of severity and type of genetic mutation, the most common is a progressive loss of pulmonary function.

About Foreign Exceptional Approval System

Japanese regulations allow a foreign pharmaceutical company to receive manufacturing and marketing approval in Japan when it intends to sell a pharmaceutical product manufactured outside the country. The foreign pharmaceutical company must appoint a pharmaceutical manufacturer/distributor in Japan (Appointed Marketing Authorization Holder, AMAH), and entrusts this AMAH with post-marketing quality assurance and safety management operations to manufacture and sell their pharmaceutical product in Japan. This system provides the equivalent of the approval granted to a pharmaceutical manufacturer/distributor based in Japan.

About Grifols

Grifols is a global healthcare company that since its founding in Barcelona in 1909 has enhanced the health and well-being of people around the world. Its four divisions – Bioscience, Diagnostic, Hospital and Bio Supplies – develop, produce and market innovative solutions and services that are sold in more than 100 countries.

Pioneers in the plasma industry, Grifols operates a growing network of donation centers worldwide. It transforms collected plasma into essential medicines to treat chronic, rare and, at times, life-threatening conditions. As a recognized leader in transfusion medicine, Grifols also offers a comprehensive portfolio of solutions designed to enhance safety from donation to transfusion. In addition, the company supplies tools, information and services that enable hospitals, pharmacies and healthcare professionals to efficiently deliver expert medical care.

Grifols, with more than 24,000 employees in 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership.

In 2019, Grifols' economic impact in its core countries of operation was EUR 8.5 billion. The company also generated 148,000 jobs, including indirect and induced.

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, please visit www.grifols.com

About OrphanPacific

OrphanPacific was founded by CMIC HOLDINGS, a leading and pioneering contract research organization (CRO) in Japan, and MEDIPAL HOLDINGS, a leading pharmaceutical products wholesaler providing services to medical institutions and pharmacies nationwide. Extensive collaboration with our parent companies, which both have robust track records in the medical field, allows OrphanPacific to cover the whole spectrum of pharmaceutical activities in Japan, from development to promotion. OrphanPacific is dedicated to providing orphan drugs and also developing sales of essential drugs in Japan. By doing so, OrphanPacific can achieve its mission to bring therapeutic solutions to rare-disease patients in Japan.

OrphanPacific is pivotal to the CMIC's Innovative Pharma Model (IPM) strategy, designed to provide support and expertise to global specialty pharmaceutical companies that focus on acquiring the manufacturing and marketing rights of prescription medicines across a broad range of therapeutic areas

worldwide but don't have a license to manufacture and distribute the pharmaceutical products in Japan. For more information, please visit www.orphanpacific.com/en/

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