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Analysis from Phase 3 ATTR-ACT and Its Long-Term Extension Study Demonstrates VYNDAQEL® 80 mg/VYNDAMAX® 61 mg Significantly Improved Survival in Patients with Transthyretin Amyloid Cardiomyopathy (ATTR-CM) Compared to VYNDAQEL 20 mg

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—Analysis of the Phase 3 ATTR-ACT clinical trial combined with its long-term extension study published in European Journal of Heart Failure—

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today the publication of an analysis showing that VYNDAQEL® (tafamidis meglumine) 80 mg/VYNDAMAX® (tafamidis) 61 mg were associated with a statistically significant improvement in long-term survival in patients with transthyretin amyloid cardiomyopathy (ATTR-CM) compared to VYNDAQEL 20 mg, reaffirming optimal dosing for these patients.

Results from the analysis of the Phase 3 Tafamidis in Transthyretin Amyloid Cardiomyopathy Clinical Trial (ATTR-ACT) and its long-term extension study, which were published in the *European Journal of Heart Failure*, demonstrated a 30% relative reduction in the risk of death (p=0.0374) among patients with ATTR-CM initially treated with VYNDAQEL 80 mg and subsequently transitioned to VYNDAMAX 61 mg, versus patients initially treated with VYNDAQEL 20 mg and transitioned to VYNDAMAX 61 mg. When adjusting for covariates, including age, biomarkers and functional capacity, the reduction in risk was increased to 43% ($p<0.05$) for VYNDAQEL 80 mg/VYNDAMAX 61 mg versus VYNDAQEL 20 mg. Both VYNDAQEL 80 mg/VYNDAMAX 61 mg and VYNDAQEL 20 mg were associated with safety profiles similar to placebo.

“Results from this analysis provide valuable information for health care providers by reinforcing that VYNDAQEL 80 mg and the bioequivalent tafamidis free acid 61 mg VYNDAMAX are the appropriate doses for patients with ATTR-CM, demonstrating a clear survival benefit over VYNDAQEL 20 mg,” said Brenda Cooperstone, Chief Development Officer, Rare Disease, Pfizer Global Product Development. “This research, along with our continued work to better understand transthyretin amyloidosis, shows our commitment to addressing the needs of this significantly underserved patient population.”

ATTR-CM is a rare, underdiagnosed, progressive and life-threatening disease caused by unstable transthyretin proteins that misfold and aggregate into amyloid fibrils that can build up in the heart and other parts of the body.

The buildup of transthyretin amyloid in the heart causes the heart muscle to stiffen over time, eventually leading to heart failure. Once diagnosed, the median life expectancy in untreated patients with ATTR-CM, dependent on sub-type, is approximately two to 3.5 years.

“With additional patients and a longer duration of treatment, data from the extension study provided further confirmation that VYNDAQEL 80 mg and VYNDAMAX 61 mg are the optimal doses for the treatment of ATTR-CM,” said Thibaud Damy, MD, coordinator of the French Referral Centers for Cardiac Amyloidosis and past president of the French Heart Failure and Cardiomyopathy group, French Society of Cardiology. “These medicines, which provide a significant survival benefit, represent a breakthrough for patients with ATTR-CM who previously had limited treatment options.”

VYNDAQEL and VYNDAMAX are the first and only medicines approved for the treatment of wild-type and hereditary ATTR-CM. The wild-type form involves no mutation and is associated with aging, is thought to be more common and usually affects men over the age of 60. Hereditary, also known as variant, is caused by a mutation in the gene that produces transthyretin and can occur in people as early as their 50s and 60s. Previously, treatment options for patients with ATTR-CM were restricted to symptom management, and, in rare cases, heart (or heart and liver) transplant. The U.S. Food and Drug Administration approved dose VYNDAQEL 80 mg is taken orally once-daily as four 20 mg capsules, and VYNDAMAX 61 mg is a convenient single-capsule, once-daily formulation that has the same active ingredient as VYNDAQEL.

About ATTR-ACT and the Long-Term Extension Study

The Phase 3 study, ATTR-ACT, is the first and only completed global, double-blind, randomized, placebo-controlled clinical trial to investigate a pharmacologic therapy for the treatment of ATTR-CM in both hereditary and wild-type ATTR-CM. The primary analysis of the study, which compared a pooled tafamidis meglumine (80 mg and 20 mg) treatment group to placebo, demonstrated a significant reduction in the hierarchical combination of all-cause mortality and frequency of cardiovascular-related hospitalizations compared to placebo over a 30-month period in patients with wild-type or hereditary ATTR-CM ($p=0.0006$), the study’s primary endpoint. Additionally, individual components of the primary analysis demonstrated a relative reduction in the risk of all-cause mortality and frequency of cardiovascular-related hospitalization of 30% ($p=0.026$) and 32% ($p<0.0001$), respectively, with VYNDAQEL versus placebo.

The long-term extension (LTE) study, which is an ongoing, Phase 3, open-label safety study, was initially designed to obtain additional safety data for VYNDAQEL 20 mg or 80 mg in subjects diagnosed with ATTR-CM, and to continue to provide patients originally enrolled in ATTR-ACT with VYNDAQEL. The LTE study protocol has been more recently amended to transition patients treated with VYNDAQEL 20 mg or 80 mg to VYNDAMAX 61 mg.

In the analysis of the LTE, combined with data from ATTR-ACT, the median follow-up was 51 months and all-cause mortality was assessed using a Cox proportional hazards model (with treatment, baseline NYHA classification, and genotype included in the model); unadjusted; adjusted for age, NT-proBNP, and 6MWT distance as covariates separately; and adjusted for age, NT-proBNP, and six-minute walk test distance together.

About ATTR-CM

ATTR-CM is a rare but life-threatening condition that affects the heart and is associated with heart failure. ATTR-CM occurs when transthyretin, a normal transport protein becomes unstable. The unstable protein misfolds aggregating into amyloid fibrils that can buildup in the heart and other parts of the body. The buildup of transthyretin amyloid in the heart causes the heart muscle to stiffen over time, eventually leading to heart failure. Symptoms of ATTR-CM often mimic those of other more common heart conditions, resulting in the disease

being significantly underdiagnosed. Education, awareness and treatment are critical to improving the diagnosis and care of people affected by ATTR-CM.

There are two forms of ATTR-CM. One form, known as hereditary or variant ATTR-CM, is inherited. The other, a non-hereditary form known as wild-type ATTR-CM, is associated with aging and thought to account for the majority of all ATTR-CM cases.

About VYNDAQEL (tafamidis meglumine) and VYNDAMAX (tafamidis)

VYNDAQEL (tafamidis meglumine) and VYNDAMAX (tafamidis) are oral transthyretin stabilizers that selectively bind to transthyretin, stabilizing the tetramer of the transthyretin transport protein and slowing the formation of amyloid that causes ATTR-CM.

VYNDAMAX 61 mg is a once-daily oral capsule developed for patient convenience. VYNDAQEL and VYNDAMAX are not substitutable on a per milligram basis.

Tafamidis is approved for the treatment of ATTR-CM in 48 countries including the US, EU, Brazil, UAE and Canada, among others. VYNDAMAX 61 mg and VYNDAQEL 80 mg are the only U.S. Food and Drug Administration approved doses for the treatment of ATTR-CM.

VYNDAQEL (tafamidis meglumine) 20 mg was first approved in 2011 in the EU for the treatment of transthyretin amyloid polyneuropathy (ATTR-PN), in adult patients with stage 1 symptomatic polyneuropathy to delay peripheral neurologic impairment. Currently, it is approved for ATTR-PN in over 40 countries, including Japan, countries in Europe, Brazil, Mexico, Argentina, Israel, Russia, and South Korea. VYNDAQEL is not approved for ATTR-PN in the US.

In October 2020, VYNDAQEL and VYNDAMAX won the Prix Galien USA Best Biotechnology Product Award. Overseen by the Galien Foundation, the Prix Galien award is among the global health innovation industry's most celebrated honors, recognizing outstanding biomedical and medical technology product achievement that improves the human condition.

VYNDAQEL® (tafamidis meglumine) and VYNDAMAX ® (tafamidis) From the U.S. Important Safety Information

Adverse Reactions

In studies in patients with ATTR-CM the frequency of adverse events in patients treated with VYNDAQEL was similar to placebo.

Specific Populations

Pregnancy: Based on findings from animal studies, VYNDAQEL and VYNDAMAX may cause fetal harm when administered to a pregnant woman.

Lactation: There are no available data on the presence of tafamidis in human milk, the effect on the breastfed infant, or the effect on milk production. Tafamidis is present in rat milk. When a drug is present in animal milk, it is likely the drug will be present in human milk. Breastfeeding is not recommended during treatment with VYNDAQEL and VYNDAMAX.

The full prescribing information for VYNDAQEL and VYNDAMAX can be found here.

Pfizer Rare Disease

Rare disease includes some of the most serious of all illnesses and impacts millions of patients worldwide, representing an opportunity to apply our knowledge and expertise to help make a significant impact on addressing unmet medical needs. The Pfizer focus on rare disease builds on more than two decades of experience, a dedicated research unit focusing on rare disease, and a global portfolio of multiple medicines within a number of disease areas of focus, including hematology, neuroscience, and inherited metabolic disorders.

Pfizer Rare Disease combines pioneering science and deep understanding of how diseases work with insights from innovative strategic collaborations with academic researchers, patients, and other companies to deliver transformative treatments and solutions. We innovate every day leveraging our global footprint to accelerate the development and delivery of groundbreaking medicines and the hope of cures.

Click here to learn more about our Rare Disease portfolio and how we empower patients, engage communities in our clinical development programs, and support programs that heighten disease awareness, development programs, and support programs that heighten disease awareness.

Pfizer Inc.: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at https://www.pfizer.com/. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of November 12, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about VYNDAQEL (tafamidis meglumine) and VYNDAMAX (tafamidis), and Pfizer's rare disease portfolio, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of VYNDAQEL/VYNDAMAX; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any new or supplemental drug applications may be filed in any other jurisdictions for VYNDAQEL or VYNDAMAX; whether and when regulatory authorities in any other jurisdictions where applications for VYNDAQEL or VYNDAMAX may be pending or filed for the treatment of wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM) or any other potential indications for VYNDAQEL may approve any such

applications, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy, and, if approved, whether VYNDAQEL or VYNDAMAX will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of VYNDAQEL or VYNDAMAX, including for the treatment of ATTR-CM; the impact of COVID-19 on our business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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