New Sub-group Analyses from the Tafamidis Phase 3 Transthyretin Amyloid Cardiomyopathy (ATTR-ACT) Study Presented at 2018 HFSA Annual Scientific Meeting

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—Findings from sensitivity and post-hoc analyses were presented during a Late Breaking Clinical Trials Session at the Heart Failure Society of America 22 nd Annual Scientific Meeting— —Results of new analyses of all-cause mortality favored tafamidis across all sub-groups— —29% and 31% reduction in the risk of death observed in wild-type and hereditary sub-groups, respectively—

NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) announced today that additional sensitivity and post-hoc analyses from the Tafamidis Phase 3 Transthyretin Amyloid Cardiomyopathy (ATTR-ACT) study provide further detail on the effect of tafamidis across wild-type, hereditary, and New York Heart Association (NYHA) class sub-groups of patients with transthyretin amyloid cardiomyopathy (ATTR-CM).1 Tafamidis is the only investigational treatment that has completed a Phase 3 trial evaluating its safety and efficacy for the treatment of ATTR-CM.1 ATTR-CM is a rare, fatal, and underdiagnosed condition associated with progressive heart failure for which there are currently no approved pharmacologic treatments.2

The findings were presented today during the Late Breaking Clinical Trials session at the Heart Failure Society of America 22nd Annual Scientific Meeting in Nashville, TN. The primary results were presented at the ESC Congress 2018 in Munich, Germany on August 27, 2018 and simultaneously published online in the New England Journal of Medicine

(NEJM).

The broader primary results showed tafamidis significantly reduced the hierarchical combination of both all-cause mortality and frequency of cardiovascular-related hospitalizations compared to placebo over a 30-month period (P=0.0006) in patients with wild-type and hereditary ATTR-CM.1 A new sensitivity analysis presented today also demonstrated a significant reduction in the combination of all-cause mortality and frequency of all-cause hospitalization compared to placebo over a 30-month period (P=0.0088).1

In addition, tafamidis reduced the risk of all-cause mortality across all sub-groups (wild-type, hereditary and NYHA I, II and III functional class) versus placebo. This included a 29% and 31% reduction in the risk of death observed in wild-type (HR 0.71; 95% CI [0.474, 1.052]) and hereditary (HR 0.69; 95% CI [0.408,1.167]) sub-groups, respectively.1 Across wild-type and hereditary sub-groups, tafamidis consistently reduced the decline in the six minute walk test distance, a measure of functional capacity, and aspects of quality of life measured by the Kansas City Cardiomyopathy Questionnaire – Overall Score, compared with placebo at Month 30. Tafamidis was also well tolerated, with an observed safety profile comparable to placebo.1

“These additional insights further support tafamidis as a potential treatment option for people with wild-type or hereditary ATTR-CM,” said Brenda Cooperstone MD, Senior Vice President and Chief Development Officer, Rare Disease, Pfizer Global Product Development. “We look forward to learning more through further analyses of this study and continue to work with global regulatory authorities to bring this medicine to patients.”

“Following statistically significant results from the primary analysis of the Phase 3 ATTR-ACT trial, we were eager to look deeper into the efficacy of tafamidis in these key ATTR-CM sub-populations,” said Mathew S. Maurer, MD, Medical Director, HCM Center, New York-Presbyterian Hospital/Columbia University Medical Center, and ATTR-ACT study presenter at the HFSA Scientific Annual Meeting 2018. “The results of these additional analyses of the data reinforce the findings presented at the ESC Congress 2018 and published in the New England Journal of Medicine a matter of weeks ago, underscoring the importance of increasing awareness of this potentially deadly condition and diagnosing patients early in the course of their disease journey.”

In light of the seriousness of the disease and the lack of pharmacologic treatment options, Pfizer has established an expanded access treatment protocol to make tafamidis

available to ATTR-CM patients who may benefit from treatment prior to regulatory approval. The expanded access treatment protocol is posted on clinicaltrials.gov (NCT02791230) and additional information about requesting access may be found at www.pfizercares.com. Access to these programs may vary by country; physicians may contact their local Pfizer Medical department for further information. Interested ATTR-CM patients should contact their local physician to discuss whether accessing tafamidis may be an appropriate option.

Tafamidis was granted Orphan Drug Designation for ATTR-CM in both the EU and US in 2012 and in Japan in 2018. In June 2017 and May 2018, respectively, the US Food and Drug Administration (FDA) granted tafamidis Fast Track and Breakthrough Therapy designations for ATTR-CM. Additionally, in March 2018, the Ministry of Labor Health and Welfare in Japan granted SAKIGAKE designation to tafamidis for this indication.

About the ATTR-ACT Study1

ATTR-ACT is a Phase 3 international, multicenter, double-blind, placebo-controlled, randomized, 3-arm clinical study in 441 patients with ATTR-CM that investigated the efficacy, safety, and tolerability of an oral daily dose of 20 mg or 80 mg tafamidis meglumine capsules compared to placebo. The study included both patients with the hereditary (ATTRm) form of the disease, and those with wild-type (ATTRwt) form, which is not hereditary and may occur as people age. The primary analysis of the study, which compared a pooled tafamidis (80 mg and 20 mg) treatment group to placebo, was the hierarchical combination of all-cause mortality and frequency of cardiovascular-related hospitalizations over a 30-month period in patients with transthyretin amyloid cardiomyopathy.

The ATTR-ACT study demonstrated tafamidis significantly reduced all-cause mortality (29.5% vs. 42.9%; hazard ratio = 0.70, 95% confidence interval [CI] 0.51-0.96, P=0.0259) and cardiovascular-related hospitalizations (0.48 vs 0.70 annualized rate; relative risk ratio = 0.68, 95% CI 0.56-0.81, P<0.0001), compared to placebo.1 This represents a 30% reduction in the risk of mortality and 32% reduction in the rate of cardiovascular-related hospitalization. The findings also showed a consistent directional mortality benefit of tafamidis across all sub-groups.1

Secondary study endpoints also showed tafamidis reduced the decline in the six minute walk test distance (P<0.0001), a measure of functional capacity, and reduced the decline in aspects of quality of life measured by the Kansas City Cardiomyopathy Questionnaire – Overall Score (P<0.0001), compared with placebo at Month 30. Tafamidis was also well

tolerated, with an observed safety profile comparable to placebo.1

For more information on the ATTR-ACT study, go to www.clinicaltrials.gov.

Tafamidis is an investigational treatment for transthyretin amyloid cardiomyopathy and is not approved for this indication.

About ATTR-CM

ATTR-CM is a rare, progressive, and underdiagnosed disease caused by destabilization of a transport protein called transthyretin, which is composed of 4 identical sub units (a tetramer).3 In ATTR-CM, heart failure occurs when unstable tetramers dissociate, resulting in misfolded proteins that aggregate into amyloid fibrils and deposit predominantly in the heart.2,4

Pfizer Rare Disease

Rare disease includes some of the most serious of all illnesses and impacts millions of patients worldwide,4 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.1

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.

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known consumer health care products. 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 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 September 18, 2018. 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 a potential indication for tafamidis for the treatment of transthyretin amyloid cardiomyopathy (the “Potential Indication”) 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, the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; 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 jurisdictions for tafamidis for the Potential Indication; whether and when regulatory authorities in any such jurisdictions where applications for tafamidis may be pending (including the application pending with the FDA for the potential treatment of transthyretin familial amyloid polyneuropathy, for which the company received a complete response letter in 2012) or filed may approve any such applications, which will depend on the assessment by such regulatory authority of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted, and, if approved, whether tafamidis will be commercially successful; decisions by regulatory authorities regarding labeling and other matters that could affect the

availability or commercial potential of tafamidis, including for the Potential Indication; 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, 2017 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.

_____ 1 Data on file. Pfizer Inc. New York, NY. 2 Rapezzi C, Quarta CC, Riva L, et al. Transthyretin-related amyloidoses and the heart: a clinical overview. Nat Rev Cardiol. 2010;7:398-408. 3 Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013;8:31. 4 Pfizer Inc. Rare disease. https://www.pfizer.com/health-wellness/disease-conditions/rare-diseases/areas-of-focus. Accessed September 13, 2018.

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