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VYNDAQEL® (tafamidis) Receives Approval in Brazil by ANVISA for the Treatment of Transthyretin Familial Amyloid Polyneuropathy

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Genetic, Rare, Neurodegenerative Disease May Affect Thousands of People in Brazil

NEW YORK, N.Y., November 7, 2016 - Pfizer Inc. (NYSE:PFE) announced today that the Brazilian National Health Surveillance Agency (ANVISA, Agência Nacional de Vigilância Sanitária) has granted regulatory approval to VYNDAQEL® (tafamidis) for the treatment of early- or intermediate-stage transthyretin familial amyloid polyneuropathy (TTR-FAP) on November 7, 2016. Recent prevalence estimates for TTR-FAP suggest there may be thousands of people living with this rare disease in Brazil.[1]

A relentlessly progressive, and irreversible neurodegenerative disease, TTR-FAP is caused by a mutation in the transthyretin (TTR) protein gene, resulting in production of unstable forms of the protein that can aggregate into amyloid fibrils that deposit in nerves and other organs, resulting in neurodegeneration and loss of normal function.[2,3] VYNDAQEL is a medicine designed to specifically stabilize TTR to slow the formation of abnormal TTR proteins and subsequent amyloid deposits.[4]

"Until the ANVISA approval of VYNDAQEL, there was no other approved medication in Brazil to delay disease progression in TTR-FAP," said Nanette Cocero, Regional President, Emerging Markets, Pfizer Innovative Health. "Achieving this regulatory milestone demonstrates Pfizer's commitment to delivering life-changing therapies that improve the lives of individuals affected by rare diseases, and we are proud to be able to offer new hope in Brazil to people living with TTR-FAP and their families."

People with TTR-FAP experience a considerable burden of illness early in the course of disease and this burden increases with disease progression. If they do not receive

disease-modifying treatment, people with TTR-FAP typically require assistance with walking 5 to 6 years after initial symptoms.[5,6] As TTR-FAP symptoms progress, patients are often unable to care for themselves, and may become bedridden or require hospitalization. When left untreated, people with TTR-FAP die within 10 years of symptom onset, on average.[7,8]

Brazil is home to many people of Portuguese and Japanese ancestries,[9,10] and TTR-FAP is more common among families of these ancestries.[2] Given the high prevalence estimates of TTR-FAP in Brazil, the Brazil Ministry of Health has designated TTR-FAP as a top priority in rare diseases, highlighting the need for treatment advances.[11]

VYNDAQEL is also approved in the European Union, Japan, Mexico, Argentina, Israel, and South Korea. It is not approved in the United States.[12]

Indication for VYNDAQEL in Brazil

VYNDAQEL is indicated for the treatment of amyloidosis associated with transthyretin in adult patients with early or intermediate stage symptomatic polyneuropathy to delay peripheral neurologic impairment and is subject to medical prescription.

Important Safety Information

- VYNDAQEL is contraindicated in patients who had previous hypersensitivity to the active substance or to any excipients of VYNDAQEL.
- In the clinical program, the safety and tolerability profile of VYNDAQEL was studied in 127 patients. In the pivotal study, adverse events (AEs) in both treatment groups were generally mild or moderate in severity. The adverse drug reactions reported in the pivotal study are diarrhea, upper abdominal pain, urinary tract infection, and vaginal infection.[13]
- There are no data available regarding use of VYNDAQEL post-liver transplantation; therefore, VYNDAQEL should be discontinued in patients who undergo liver transplantation.
- There are no data on the use of VYNDAQEL in pregnant or nursing women. VYNDAQEL is not recommended for use during pregnancy, in women who are breast feeding or in women of childbearing age not using contraception. Women of childbearing potential should use appropriate contraception when taking VYNDAQEL and continue to use appropriate contraception for 1-month after stopping treatment with VYNDAQEL.

- Children and adolescents do not have the symptoms of TTR Amyloid Polyneuropathy. VYNDAQEL is therefore not used for children and adolescents.

About Pfizer and Rare Diseases
Rare diseases are among the most serious of all illnesses and impact 350 million patients worldwide, often children. Although there are over 7,000 known rare diseases, only five percent have an approved medication. For rare disease patients and their loved ones, better treatment options cannot come soon enough. At Pfizer, we share their urgency and passionately dedicate our resources, expertise and global reach to bring them the transformative medicines they need. The Pfizer focus on rare diseases builds on more than two decades of experience, a pipeline of more than 20 compounds and a global portfolio of more than 20 medicines approved worldwide that treat rare diseases in the areas of hematology, neuroscience, inherited metabolic disorders, and pulmonology. Pfizer Rare Disease is inspired by patients, born from science and powered by the passion of the hundreds of colleagues in Pfizer who dedicate their work to helping patients with rare diseases.

As a leader in the TTR-FAP community, Pfizer Inc. has been at the forefront of educational initiatives to raise awareness of TTR-FAP among health care professionals and to facilitate dialogue between patients, their families, and their physicians. These efforts have contributed to a global increase in diagnosis rates and treatment.[13]

Working together for a healthier world®
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. Our global portfolio includes medicines and vaccines as well as many of the world's best-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 @PfizerNews, LinkedIn, YouTube and like us on Facebook at

Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of November 7, 2016. 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 tafamidis, including its 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 tafamidis, the uncertainties inherent in research and development, including, without limitation, 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; whether and when any new or supplemental drug application may be filed in any other jurisdictions for tafamidis; whether and when the FDA or regulatory authorities in any other jurisdictions where applications for tafamidis may be pending 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; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of tafamidis; 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, 2015 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(link is external) and www.pfizer.com.

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