SAVE THE DATE

Vyndaqel▼ (tafamidis) 61 mg for ATTR-CM

VYNDAQEL® 61MG LAUNCH MEETING

A paradigm shift in the diagnosis & treatment of ATTR-CM

A Pfizer Virtual Symposium

VYNDAQEL® is indicated for the treatment of wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM)*

*VYNDAQEL® Summary of Product Characteristics

Thursday 31st March 2022 at 6-9pm local time

Speaker Topics:

- Diagnosis & management of ATTR-CM patients
- Patient case examples
- Results of the long-term data of tafamidis & follow up of ATTR-CM patients

Register via QR code or on bit.ly/3hkw93D

When registered, you will automatically receive a confirmation email with a calendar appointment and information on how to access the event.

SPEAKERS

Dr. Ross Murphy
Consultant Cardiologist at St. James's Hospital, Dublin and Clinical Senior Lecturer at TCD. Special interests include cardiac imaging and valve disease and cardiac CT; research interests include the genetics of cardiomyopathy, newer echo modalities, and the vascular biology of coronary plaque.

Prof. Emer Joyce
Consultant Cardiologist specialising in Heart Failure, Mechanical Circulatory Support and Cardiac Transplantation at Mater University Hospital Dublin. She is the National Clinical Lead in Advanced Heart Failure and an Assistant Clinical Professor at UCD.

Dr. Pablo Garcia-Pavia
Director of the Inherited Cardiac Diseases and Heart Failure Unit at Hospital Universitario Puerta de Hierro, Madrid, Spain. Areas of research include heart failure, amyloidosis, and cardiomyopathies.

Dr. Sarah Cuddy
Cardiologist at the Brigham and Women's Hospital Amyloidosis Program and Instructor of Medicine at Harvard Medical School, Boston, MA.

AGENDA

18:00-18:05	**Welcome Address** **Mr. Richard Stakelum, Pfizer Rare Disease Lead**
18.05-18.10	**Introduction and Chair** **Dr. Ross Murphy**
18:10–19:00	**Diagnosis and Management of ATTR-CM** **Prof. Emer Joyce**
19:00–19.45	**Patient Case Examples** **Dr. Sarah Cuddy**
19:45–19:55	**Short Break**
19:55–20:35	**Results of the LT Data of Tafamidis & How to Follow ATTR Patients** **Dr. Pablo Garcia-Pavia**
20.35–20.50	**Q&A Session** **Dr. Murphy, Prof. Joyce, Dr. Cuddy, Dr. Garcia-Pavia**
20.50–21.00	**Closing Remarks** **Dr. Ross Murphy**

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.

PP-VYN-IRL-0100 - February 2022

Pfizer Rare Disease

Vyndaqel▼ 61 mg soft capsules (tafamidis) Prescribing Information: Before prescribing Vyndaqel please refer to the full Summary of Product Characteristics. **Presentation: Vyndaqel 61 mg soft capsules.** Each soft capsule contains 61 mg tafamidis. **Uses:** Vyndaqel is indicated for the treatment of wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM). **Dosage:** Treatment should be initiated under the supervision of a physician knowledgeable in the management of patients with amyloidosis or cardiomyopathy. When there is a suspicion in patients presenting with specific medical history or signs of heart failure or cardiomyopathy, etiologic diagnosis must be done by a physician knowledgeable in the management of amyloidosis or cardiomyopathy to confirm ATTR-CM and exclude AL amyloidosis before starting Vyndaqel, using appropriate assessment tools such as: bone scintigraphy and blood/urine assessment, and/or histological assessment by biopsy, and transthyretin (TTR) genotyping to characterise as wild-type or hereditary. The recommended dose is one capsule of Vyndaqel 61 mg (tafamidis) orally once daily. Vyndaqel 61 mg (tafamidis) corresponds to 80 mg tafamidis meglumine, tafamidis and tafamidis meglumine are not interchangeable on a per mg basis. Vyndaqel should be started as early as possible in the disease course when the clinical benefit on disease progression could be more evident. Conversely, when amyoid-related cardiac damage is more advanced, such as in NYHA Class III, the decision to start or maintain treatment should be taken at the discretion of a physician knowledgeable in the management of patients with amyloidosis or cardiomyopathy. There are limited clinical data in patients with NYHA Class IV. If vomiting occurs after dosing, and the intact Vyndaqel capsule is identified, then an additional dose of Vyndaqel should be administered if possible. If no capsule is identified, then no additional dose is necessary, with resumption of dosing the next day as usual. There are no recommended dosage adjustments for elderly patients or patients with renal or mild and moderate hepatic impairment. Limited data are available in patients with severe renal impairment (creatinine clearance less than or equal to 30 mL/min). Tafamidis has not been studied in patients with severe hepatic impairment and caution is recommended. There is no relevant use of tafamidis in the paediatric population. **Method of Administration:** The soft capsules should be swallowed whole and not crushed or cut. Vyndaqel may be taken with or without food. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients as listed in section 6.1 of SPC. **Warnings and Precautions:** Contraceptive measures should be used by women of childbearing potential during treatment with tafamidis and for one month after stopping treatment. Tafamidis should be added to the standard of care for the treatment of patients with transthyretin amyloidosis. Physicians should monitor patients and continue to assess the need for other therapy, including the need for organ transplantation, as part of this standard of care. As there are no data available regarding the use of tafamidis in organ transplantation, tafamidis should be discontinued in patients who undergo organ transplantation. Increase in liver function tests and decrease in thyroxine may occur. This medicinal product contains no more than 44 mg sorbitol in each capsule. Sorbitol is a source of fructose. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. **Pregnancy and Lactation:** Tafamidis is not recommended during pregnancy and in women of childbearing potential not using contraception. Available data in animals have shown excretion of tafamidis in milk. A risk to the newborns/infants cannot be excluded. Vyndaqel should not be used during breastfeeding. **Interactions:** In a clinical study in healthy volunteers, 20 mg tafamidis meglumine did not induce or inhibit the cytochrome P450 enzyme CYP3A4. *In vitro* tafamidis inhibits the efflux transporter BCRP (breast cancer resistant protein) at the 61 mg/day tafamidis dose with IC50=1.16 μM and may cause drug-drug interactions at clinically relevant concentrations with substrates of this transporter (e.g. methotrexate, rosuvastatin, imatinib). In a clinical study in healthy participants, the exposure of the BCRP substrate rosuvastatin increased approximately 2-fold following multiple doses of Page 2 of 2 2020-0065522 61 mg tafamidis daily dosing. Likewise, tafamidis inhibits the uptake transporters OAT1 and OAT3 (organic anion transporters) with IC50=2.9 μM and IC50=2.36 μM, respectively, and may cause drug-drug interactions at clinically relevant concentrations with substrates of these transporters (e.g. non-steroidal anti-inflammatory drugs, bumetanide, furosemide, lamivudine, methotrexate, oseltamivir, tenofovir, ganciclovir, adefovir, cidofovir, zidovudine, zalcitabine). Based on *in vitro data*, the maximal predicted changes in AUC of OAT1 and OAT3 substrates were determined to be less than 1.25 for the tafamidis 61 mg dose, therefore, inhibition of OAT1 or OAT3 transporters by tafamidis is not expected to result in clinically significant interactions. No interaction studies have been performed evaluating the effect of other medicinal products on tafamidis. **Undesirable Effects:** The following adverse events were reported more often in 176 ATTR-CM patients treated with tafamidis meglumine 80 mg compared to placebo: flatulence [8 patients (4.5%) versus 3 patients (1.7%)] and liver function test increased [6 patients (3.4%) versus 2 patients (1.1%)]. A causal relationship has not been established. Safety data for tafamidis 61 mg are not available as this formulation was not evaluated in the double-blind, placebo-controlled, randomised phase 3 study. **Legal category:** S1A. **Marketing Authorisation Numbers:** EU/1/11/717/003– 61mg (30 capsules). **Marketing Authorisation Holder:** Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium. For further information on this medicine please contact: Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500. **Last revised:** 04/2021

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