# Hospital Pharmacy & Medicines Optimisation Seminar

## Updates from the Carter Review & The Emergence of Trastuzumab Biosimilars

## Save the Date

# 5th April 2019

## Friday 5th April 2019 | Meeting Room 18
## Conference Centre, Crowne Plaza, Santry, Dublin 9

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| 6.30 pm | Welcome Address:<br>**An Update from Pfizer Oncology Ireland** | **Ms. Miriam Adamson**,<br>Biosimilar Commercial Lead,<br>Pfizer Healthcare Ireland |
| 6.40 pm | Pharmacy & Medicines Optimisation:<br>**Trastuzumab & Carter** | **Prof. Ann Jacklin**, BPharm, CHSM, FRPharmS;<br>Professional Lead;<br>Hospital Pharmacy & Medicines Optimisation;<br>Project NHS Productivity and Efficiency Programme;<br>Independent Pharmacy Advisor at AJ Advisory, UK. |

Buffet Dinner Served

To register your intention to attend please contact: Caroline Reidy | Caroline.Reidy@pfizer.com | **087-6844291**

Pfizer Oncology

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PP-BIO-IRL-0066
Date of Preparation: March 2019

**PRESCRIBING INFORMATION TRAZIMERA®▼ (TRASTUZUMAB) POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION**

▼ 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. Refer to section 4.8 of the SPC for how to report adverse reactions.

Please refer to the full Summary of Product Characteristics (SmPC) before prescribing.

**Presentation:** Vial containing 150 mg of trastuzumab powder for concentrate for solution for infusion.

**Indications:** See SmPC for full details. *HER2 positive metastatic breast cancer (MBC)* as monotherapy for patients who have received at least two chemotherapy regimens and failed hormonal therapy (if applicable). In combination with paclitaxel, docetaxel or an aromatase inhibitor in appropriate patients. *HER2 positive early breast cancer (EBC)* following surgery, chemotherapy and radiotherapy (if applicable). Following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel. In combination with adjuvant chemotherapy consisting of docetaxel and carboplatin. In combination with neoadjuvant chemotherapy followed by adjuvant trastuzumab therapy, for locally advanced (including inflammatory) disease or tumours > 2 cm in diameter. *HER2 positive metastatic gastric cancer (MGC)* in combination with capecitabine or 5-fluorouracil and cisplatin in patients who have not received prior anti-cancer treatment for metastatic disease. **Dosage and administration:** See SmPC for full details. Prior HER2 testing is mandatory. To be initiated by a physician experienced in the administration of cytotoxic chemotherapy and administered by a healthcare professional, by intravenous infusion only. Ensure that the drug prepared and administered is Trazimera (trastuzumab) and not Kadcyla (trastuzumab emtansine). *MBC or EBC. Three-weekly schedule.* Loading dose of 8 mg/kg. Maintenance dose of 6 mg/kg at three-weekly intervals beginning three weeks after the loading dose. *Weekly schedule.* Loading dose of 4 mg/kg. Maintenance dose of 2 mg/kg beginning one week after the loading dose. See SmPC for details of chemotherapy combination dosing. *MGC.* Loading dose of 8 mg/kg. Maintenance dose of 6 mg/kg at three-weekly intervals beginning three weeks after the loading dose. Treat patients with MBC or MGC until progression of disease. Treat patients with EBC for 1 year or until disease recurrence, whichever occurs first. No reductions in the dose of trastuzumab were made during clinical trials. Monitor patients during periods of reversible, chemotherapy-induced myelosuppression. See SmPC for details of administration if left ventricular ejection fraction drops or doses are missed. Initial loading dose should be administered as a 90-minute intravenous infusion by a healthcare provider prepared to manage anaphylaxis and an emergency kit should be available. Observe patients for at least six hours after the start of the first infusion and two hours after the start of subsequent infusions for infusion-related symptoms. If the initial loading dose was well tolerated, subsequent doses can be administered as a 30-minute infusion.

**Contraindications:** Hypersensitivity to trastuzumab, murine proteins, or excipients. Severe dyspnoea at rest due to complications of advanced malignancy or requiring supplementary oxygen therapy.

**Warnings and precautions:** See SmPC for full details. Record name and batch number of administered product. HER2 testing must be performed in a specialised laboratory with adequate validation of testing procedures. No clinical trial data are available on re-treatment of patients with previous exposure to trastuzumab in the adjuvant setting. *Cardiac dysfunction.* Perform baseline cardiac assessment and, as a minimum, repeat every 3 months during treatment and every 6 months following discontinuation of treatment until 24 months from the last administration. A careful risk-benefit assessment should be made before deciding to treat with Trazimera. See SmPC for futher details of monitoring and management of cardiac function. *Infusion-related reactions (IRRs) and hypersensitivity.* Serious IRRs have been reported. Pre-medication may be used to reduce risk of occurrence of these events. See SmPC for further details. *Pulmonary events.* Severe pulmonary events have been reported. These events have occasionally been fatal. Patients experiencing dyspnoea at rest due to complications of advanced malignancy and comorbidities may be at increased risk and should not be treated with trastuzumab. See SmPC for further details. *Interactions.* Clinically significant interactions with the concomitant medicinal products used in clinical trials have not been observed. See SmPC for further details. *Pregnancy and lactation*. Women of childbearing potential should use effective contraception during treatment and for 7 months afterwards. Trastuzumab should be avoided during pregnancy unless the potential benefit for the mother outweighs the potential risk to the foetus. Women should not breast-feed during treatment and for 7 months after the last dose.

**Undesirable effects:** Amongst the most serious and/or common adverse reactions reported in trastuzumab usage (intravenous and subcutaneous formulations) to date are cardiac dysfunction, infusion-related reactions, haematotoxicity (in particular neutropenia), infections and pulmonary adverse reactions. See SmPC for further details. *Very common (≥1/10).* Infection, nasopharyngitis, febrile neutropenia, anaemia, neutropenia, white blood cell count decreased/leukopenia, thrombocytopenia, weight decreased/weight loss, anorexia, insomnia, tremor, dizziness, headache, paraesthesia, dysgeusia, conjunctivitis, lacrimation increased, blood pressure decreased/increased, heart beat irregular, palpitation, cardiac flutter, ejection fraction decreased, hot flush, wheezing, dyspnoea, cough, epistaxis, rhinorrhoea, diarrhoea, vomiting, nausea, lip swelling, abdominal pain, dyspepsia, constipation, stomatitis, erythema, rash, swelling face, alopecia, nail disorder, palmar-plantar erythrodysaesthesia syndrome, arthralgia, muscle tightness, myalgia, asthenia, chest pain, chills, fatigue, influenza-like symptoms, infusion related reaction, pain, pyrexia, mucosal inflammation, peripheral oedema. *Common ≥1/100 to <1/10).* Neutropenic sepsis, cystitis, herpes zoster, influenza, sinusitis, skin infection, rhinitis, upper respiratory tract infection, urinary tract infection, erysipelas, cellulitis, pharyngitis, hypersensitivity, anxiety, depression, thinking abnormal, peripheral neuropathy, hypertonia, somnolence, ataxia, dry eye, cardiac failure (congestive), supraventricular tachyarrhythmia, cardiomyopathy, hypotension, vasodilatation, pneumonia, asthma, lung disorder, pleural effusion, pancreatitis, haemorrhoids, dry mouth, hepatocellular injury, hepatitis, liver tenderness, acne, dry skin, ecchymosis, hyperhydrosis, maculopapular rash, pruritus, onychoclasis, dermatitis, arthritis, back pain, bone pain, muscle spasms, neck pain, pain in extremity, renal disorder, breast inflammation/mastitis, malaise, oedema, contusion. *Uncommon (≥1/1,000 to <1/100).* Deafness, pericardial effusion, urticaria. *Rare (≥1/10,000 to <1/1,000).* Paresis, pneumonitis, jaundice. *Incidence not known*. Neoplasm / malignant neoplasm progression, hypoprothrombinaemia, immune thrombocytopenia, sepsis, anaphylactic reaction, anaphylactic shock, hyperkalaemia, brain oedema, papilloedema, retinal haemorrhage, cardiogenic shock, pericarditis, bradycardia, gallop rhythm, pulmonary fibrosis, respiratory distress, respiratory failure, lung infiltration, acute pulmonary oedema, acute respiratory distress syndrome, bronchospasm, hypoxia, oxygen saturation decreased, laryngeal oedema, orthopnoea, pulmonary oedema, interstitial lung disease, hepatic failure, angioedema, glomerulonephritis membranous, glomerulonephropathy, renal failure, oligohydramnios, renal hypoplasia, pulmonary hypoplasia.

**Legal category:** S1A

**Marketing Authorisation Number:**
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**Marketing Authorisation Holder:**
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Boulevard de la Plaine 17, 1050 Bruxelles, Belgium.

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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.