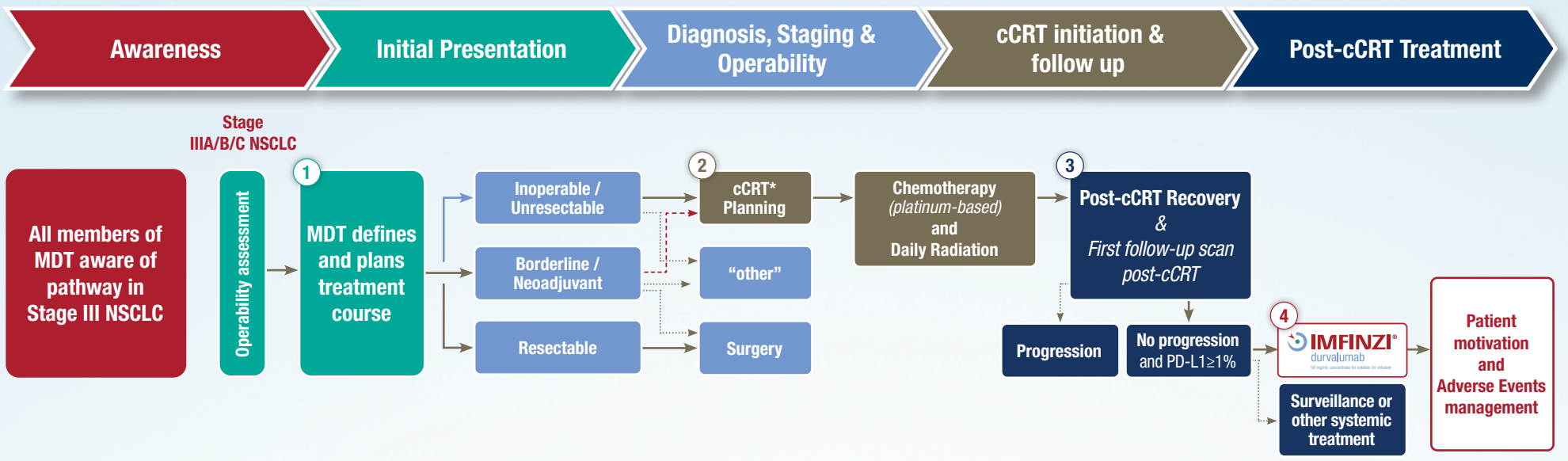
IMFINZI as monotherapy is indicated for the treatment of locally advanced, unresectable non small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on ≥ 1% of tumour cells and whose disease has not progressed following platinum based chemoradiation therapy.[1]

IMFINZI® ▼ durvalumab
50 mg/mL concentrate for solution for infusion

Optimising the Stage III Unresectable NSCLC Patient Journey to Imfinzi ▼ (durvalumab)



4 KEY PLANNING POINTS	1 Step 1: MDT Treatment Decision	2 Step 2: cCRT Management	3 Step 3: Post cCRT – Confirm eligibility for IMFINZI and educate patient	4 Step 4: IMFINZI treatment
Description	• MDT decide patients' treatment plan based on initial presentation, staging and eligibility for surgery • PD-L1 Test requested for unresectable patients if no Reflex testing • Decision on concurrent or sequential CRT based on patient fitness and radiation planning • If PD-L1 score ≥1%, patients are educated on their treatment plan (potential IO treatment post CRT)	• Coordination of chemotherapy and radiation treatment • Patients eligible for IMFINZI require minimum of two cycles of overlapping platinum based chemotherapy • Monitor and manage cCRT adverse events • Once cCRT scheduled: ✓ Book post cCRT CT scan to occur 2 - 4 weeks post completion of CRT ✓ Book virology screen and baseline bloods prior to IMFINZI treatment ✓ Schedule IMFINZI first dose within 42 days of completion of cCRT	• Check CT scan results to ensure patients had no progression of disease • Check blood results & virology screen • Continue to monitor and manage patient for AEs post cCRT • Patient is educated and motivated to start IMFINZI treatment	• Initiate IMFINZI • Monitor and manage patient for immune mediated AEs as per SmPC guidance • Motivate patient to continue IMFINZI treatment • Discontinue IMFINZI after 12 months of therapy • Arrange appropriate follow up and monitoring

*cCRT: concurrent chemo-radiation; **IO: Immuno-Oncology.

Reference: 1. Imfinzi-Ireland Summary of Product Characteristics.

ABRIDGED PRESCRIBING INFORMATION

IMFINZI® ▼ (durvalumab) 50mg/ml Concentrate for Solution for Infusion

Consult Summary of Product Characteristics (SmPC) before prescribing.

Indication: IMFINZI as monotherapy is indicated for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on ≥ 1% of tumour cells and whose disease has not progressed following platinum-based chemoradiation therapy. IMFINZI in combination with etoposide and either carboplatin or cisplatin is indicated for the first-line treatment of adults with extensive-stage small cell lung cancer (ES-SCLC).

Presentation: Each ml of concentrate for solution for infusion contains 50mg durvalumab.

Dosage and administration: Treatment must be initiated and supervised by a physician experienced in the treatment of cancer. Patients with locally advanced NSCLC should be evaluated for treatment based on the tumour expression of PD-L1 confirmed by a validated test. For locally advanced NSCLC, the recommended dose of IMFINZI is 10 mg/kg administered as an intravenous infusion over 1 hour every 2 weeks or 1500 mg every 4 weeks, until disease progression, unacceptable toxicity, or a maximum of 12 months. For ES-SCLC, the recommended dose for IMFINZI in combination with chemotherapy (etoposide and either carboplatin or cisplatin) is 1500mg, administered as an intravenous infusion over 1 hour, every 3 weeks (21 days) for 4 cycles, followed by 1500mg every 4 weeks as monotherapy, until disease progression or unacceptable toxicity. Patients with a body weight of 30kg or less must receive weight-based dosing, please consult Section 4.2 in the SmPC for more information. Dose escalation or reduction is not recommended. Dose withholding or discontinuation may be required based on individual safety and tolerability. **Suspected immune-mediated adverse reactions:** Adequate evaluation should be performed to confirm aetiology or exclude alternate aetiologies. Based on the severity of the adverse reaction, IMFINZI should be withheld and corticosteroids administered. Guidelines for the management of immune mediated adverse reactions are described in Table 2, Section 4.2 in the SmPC. Consider increasing dose of corticosteroids and/or using additional systemic immunosuppressants if there is worsening or no improvement. Upon improvement to ≤ Grade 1, corticosteroid taper should be initiated and continued over at least 1 month. After withhold, IMFINZI can be resumed within 12 weeks if the adverse reactions improved to ≤ Grade 1 and the corticosteroid dose has been reduced to ≤ 10 mg prednisone or equivalent per day. IMFINZI should be permanently discontinued for recurrent Grade 3 (severe) immune-mediated adverse reactions and for any Grade 4 (life-threatening) immune-mediated adverse reactions, except for endocrinopathies that are controlled with replacement hormones. For myasthenia gravis, if there are signs of respiratory or autonomic insufficiency, IMFINZI should be permanently discontinued. **Non-immune-mediated adverse reactions:** Withhold IMFINZI for Grade 2 and 3 adverse reactions until ≤ Grade 1 or baseline. IMFINZI should be discontinued for Grade 4 adverse reactions. **Special populations: Elderly:** No dose adjustment is required for elderly patients (≥ 65 years of age). **Renal impairment:** No dose adjustment is recommended in patients with mild or moderate renal impairment. Data from patients with severe renal impairment are too limited to draw conclusions on this population. **Hepatic impairment:** Data from patients with moderate and severe hepatic impairment are limited. Due to minor involvement of hepatic processes in the clearance of durvalumab no dose adjustment of IMFINZI is recommended for patients with hepatic impairment as no difference in exposure is expected.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Warnings and precautions: Traceability: In order to improve the traceability of biological medicinal products, the tradename and the batch number of the administered product should be clearly recorded. **Immune-mediated pneumonitis:** Monitor for signs and symptoms of pneumonitis or radiation pneumonitis. Suspected pneumonitis should be confirmed with radiographic imaging and other infectious and disease-related aetiologies excluded. **Immune-mediated hepatitis**: Monitor for abnormal liver tests prior to and periodically during treatment with IMFINZI, and as indicated based on clinical evaluation. **Immune-mediated colitis:** Monitor for signs and symptoms of colitis or diarrhoea. **Immune-mediated hypothyroidism, hyperthyroidism and thyroiditis:** Monitor for abnormal thyroid function tests prior to and periodically during treatment and as indicated based on clinical evaluation. **Immune-mediated adrenal insufficiency:** Monitor for clinical signs and symptoms of adrenal insufficiency. **Immune-mediated type 1 diabetes mellitus:** Monitor for clinical signs and symptoms of type 1 diabetes mellitus including diabetic ketoacidosis. **Immune-mediated hypophysitis/hypopituitarism:** Monitor for clinical signs and symptoms of hypophysitis or hypopituitarism. **Immune-mediated nephritis:** Monitor for abnormal renal function tests prior to and periodically during treatment with IMFINZI. **Immune-mediated rash:** Events of Stevens-Johnson Syndrome or toxic epidermal necrolysis have been reported in patients treated with PD-1 inhibitors. Patients should be monitored for signs and symptoms of rash or dermatitis (including pemphigoid). **Immune-mediated myocarditis:** Patients should be monitored for signs and symptoms of immune-mediated myocarditis. **Other immune-mediated adverse reactions:** Myasthenia gravis, myositis, polymyositis, meningitis, encephalitis Guillain-Barre syndrome, immune thrombocytopenia, cystitis noninfective and pancreatitis have been observed. Monitor for signs and symptoms. **Infusion related reactions:** Monitor for signs and symptoms of infusion related reactions. **All immune-mediated adverse events should be managed as recommended in Table 2 Section 4.2 of the SmPC. Patients excluded from clinical trials:** Patients with: a baseline ECOG performance score ≥ 2; active or prior documented autoimmune disease within 2 years of initiation of the study; a history of immunodeficiency; a history of severe immune-mediated adverse reactions; medical conditions that required systemic immunosuppression, except physiological dose of systemic corticosteroids (≤ 10 mg/day prednisone or equivalent); uncontrolled intercurrent illnesses; active tuberculosis or hepatitis B or C or HIV infection or patients receiving live attenuated vaccine within 30 days before or after the start of IMFINZI. Durvalumab should be used with caution in these populations after careful consideration of the potential benefit/risk on an individual basis. The safety of concurrent prophylactic cranial irradiation (PCI) with IMFINZI in patients with ES-SCLC is unknown.

Drug Interactions: The use of systemic corticosteroids or immunosuppressants before starting durvalumab, except physiological dose of systemic corticosteroids (≤ 10 mg/day prednisone or equivalent), is not recommended because of their potential interference with the pharmacodynamic activity and efficacy of durvalumab. However, systemic corticosteroids or other immunosuppressants can be used after starting durvalumab to treat immune-related adverse reactions.
PK drug-drug interaction between durvalumab and chemotherapy was assessed and showed concomitant treatment did not impact the PK of any of the drugs involved. Additionally, based on population PK analysis, concomitant chemotherapy treatment did not meaningfully impact the PK of durvalumab.

Pregnancy and Lactation: Durvalumab may cause foetal harm when administered to a pregnant woman and is not recommended during pregnancy and in women of childbearing potential not using effective contraception during treatment and for at least 3 months after the last dose. A decision must be made whether to discontinue breast feeding or to discontinue or abstain from durvalumab therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Undesirable events: Consult SmPC for full list of adverse events. **IMFINZI Monotherapy: Very common (≥ 1/10; any grades):** Upper respiratory tract infections, hypothyroidism, cough/productive cough, diarrhoea, abdominal pain, rash, pruritus, pyrexia, arthralgia. **Common (≥ 1/100 to < 1/10; any grades):** Pneumonia, dental and oral soft tissue infections, oral candidiasis, influenza, hyperthyroidism, pneumonitis, dysphonia, aspartate aminotransferase increased or alanine aminotransferase increased, night sweats, myalgia, blood creatinine increased, dysuria, peripheral oedema, infusion related reaction. **Uncommon (≥ 1/1,000 to < 1/100; any grades):** Thyroiditis, adrenal insufficiency, interstitial lung disease, colitis, pancreatitis, hepatitis, dermatitis, myositis, nephritis. **Rare (≥ 1/10,000 to < 1/1000; any grades):** Type 1 diabetes mellitius, hypophysitis/hypopituitarism, diabetes insipidus, myocarditis, polymyositis, myasthenia gravis, meningitis, pemphigoid, immune thrombocytopenia, cystitis noninfective. **Not known:** Noninfective encephalitis, Guillain-Barre syndrome. **IMFINZI Combined with Chemotherapy: Very common (≥ 1/10; any grades):** Neutropenia, anaemia, thrombocytopenia, leukopenia, decreased appetite, cough/productive cough, nausea, constipation, vomiting, alopecia, fatigue. **Common (≥ 1/100 to < 1/10; any grades):** Upper respiratory tract infections, pneumonia, dental and oral soft tissue infections, febrile neutropenia, pancytopenia, hypothyroidism, hyperthyroidism, thyroiditis, adrenal insufficiency, pneumonitis, diarrhoea, abdominal pain, stomatitis, aspartate aminotransferase increased or alanine aminotransferase increased, hepatitis, rash, pruritus, dermatitis, myalgia, arthralgia, blood creatinine increased, dysuria, pyrexia, peripheral oedema, infusion-related reaction. **Uncommon (≥ 1/1,000 to < 1/100; any grades):** Oral candidiasis, influenza, Type 1 diabetes mellitus, dysphonia, interstitial lung disease, colitis, night sweats.

Legal Category: Product subject to prescription which may not be renewed (A).

Marketing Authorisation Number: EU/1/18/1322/001; EU/1/18/1322/002.

Marketing Authorisation Holder: AstraZeneca AB, SE-151 85, Södertälje, Sweden.

Further information available on request from: AstraZeneca Pharmaceuticals (Ireland) DAC, College Business and Technology Park, Blanchardstown Road North, Dublin 15 **Tel:** +353 1 6097100.

IMFINZI® is a registered trade mark of the AstraZeneca group of companies.

Date of API Preparation: 07/2022 **Veeva ID:** IE-4002

▼ **This medicinal product is subject to additional monitoring.** Adverse events should be reported directly to: HPRA Pharmacovigilance. **Website:** www.hpra.ie. **Adverse events should also be reported to AstraZeneca Patient Safety on** Freephone 1800 800 899

Veeva ID: IE-4036 | Date of Preparation: July 2022

AstraZeneca