NSCLC

UNRESECTABLE STAGE III NSCLC

IMFINZI®

Standard of care for stage III UR NSCLC patients[1,2,*]

PACIFIC

The **only** approved and reimbursed immunotherapy for stage III unresectable NSCLC after CRT[3,4]

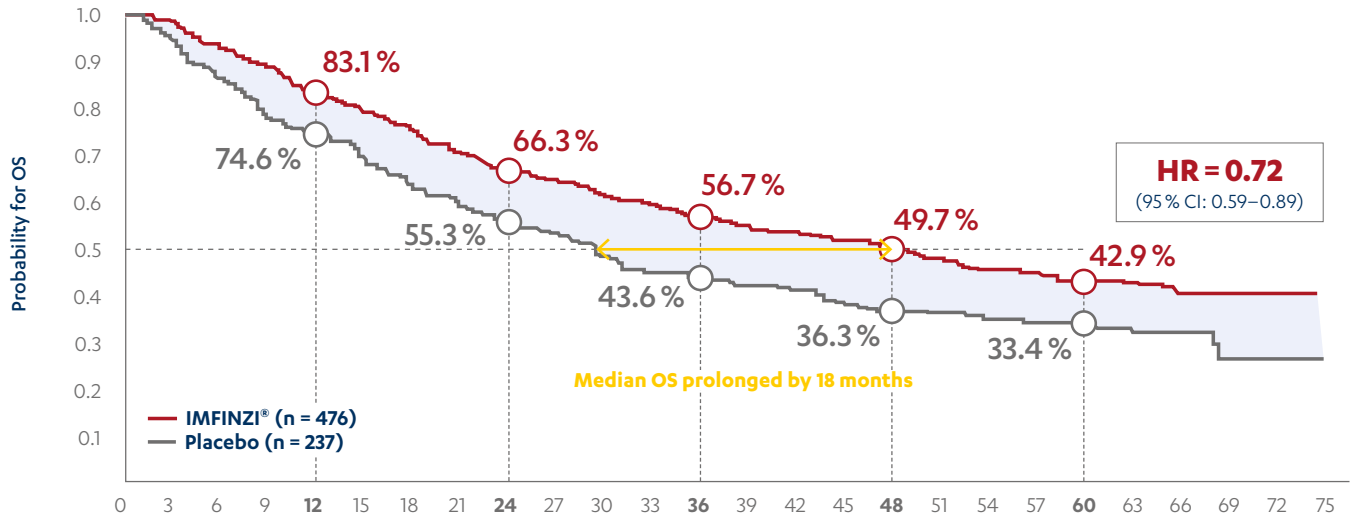
Extensive breadth of clinical evidence[5-11]

AstraZeneca

IMFINZI® durvalumab

PACIFIC: IMFINZI® in unresectable stage III NSCLC[5]

Sustained 5-year survival benefit with IMFINZI®[5]



Number of patients at risk

IMFINZI®	476	464	431	414	385	364	343	319	298	289	273	264	252	241	236	227	218	207	196	183	134	91	40	18	2	0
Placebo	237	220	199	179	171	156	143	133	123	116	107	99	97	93	91	83	78	77	74	72	56	33	16	7	2	0

Adapted according to Spigel et al., 2021.[5]

- 28 % reduction in risk of mortality with IMFINZI® versus placebo[5]
- 18 month longer medial overall survival with IMFINZI® versus placebo, with median OS 47.5 months (95 % CI, 38.1–52.9) vs 29.1 months (22.1–35.1)[5]
- Significant improvement in PFS (5-year PFS: 33.1 % with IMFINZI® vs 19.0 % with placebo)[5]

NSCLC dosage[3]

- Patient-oriented treatment regimen: 1× monthly administration
- Independent of PD-L1 status

START OF THERAPY

Concurrent CRT
or sequential CRT

1× MONTHLY MAINTENANCE THERAPY

IMFINZI® for 12 months
IMFINZI® for 12 months or until progression or intolerable toxicity

IMFINZI® 1500 mg fixed dose† every 4 weeks,
or 10 mg/kg every 2 weeks, intravenous infusion[3]

Extensive breadth of clinical evidence with long-term Follow-Up (PACIFIC, PACIFIC-R, PACIFIC-6, PACIFIC-IIIA-N2)[5-11]

	PACIFIC[5,6]	PACIFIC-R[7,8]	PACIFIC-6[9,10]	PACIFIC-IIIA-N2[11]
Trial design	Randomized, placebo-controlled, phase 3 trial	Ongoing, international, multicenter, **real-world** cohort study	European multicenter, open-label, phase 2 trial	Post hoc, exploratory subgroup analysis of PACIFIC trial outcomes
Number of patients	**IMFINZI®: 477** **Placebo: 237**	IMFINZI®: 1399	IMFINZI®: 117	IMFINZI®: 197 Placebo: 90
Tumour stage	Unresectable NSCLC Stage III	Unresectable NSCLC Stage IIIA: 43.4% Stage IIIB/C: 51.3%	Unresectable NSCLC Stage IIII	**Unresectable NSCLC Stage IIIA-N2**
Prior therapy	Platinum-based concurrent CRT	76.6% concurrent CRT 14.3% sequential CRT	Platinum-based **sequential** CRT	Platinum-based concurrent CRT
IMFINZI® dosing	10 mg/kg IV Q2W for up to 12 months	10 mg/kg IV Q2W for up to 12 months	1500 mg IV Q4W for up to 24 months	10 mg/kg IV Q2W for up to 12 months
Median duration of IMFINZI® treatment	40.1 weeks	47.8 weeks	32.0 weeks	–
IMFINZI® Efficacy Endpoints	56.7% 3-year OS 39.7% 3-year PFS Median OS: 47.5 months	63.2% 3-year OS 42.2% 3-year PFS Median OS: NR (95% CI: 46.3 months –NE)	56.5% 3-year OS 35.3% 2-year PFS Median OS: 39.0 months	68.3% 1.5-year OS 50.6% 1.5-year PFS Median OS: 34.9 months
Safety endpoints	Discontinuation rate due to AEs: 15.4% Incidence of pneumonitis: 4.8% Incidence of grade 3/4 AEs: 30.5%	Discontinuation rate due to AEs: 16.5% Incidence of pneumonitis/ILD: 17.9%	PRAEs leading to discontinuation: 16.2% Grade 3/4 PRAEs within 6 months: 4.3% Grade 3/4 PRAEs overall: 6.0%	With stage IIIA N2: AEs leading to discontinuation: 16.4 %

IMFINZI® - Standard of care for stage III UR NSCLC patients[1,2,*]

The only approved and reimbursed immunotherapy for stage III unresectable NSCLC after CRT[3,4]

Extensive breadth of clinical evidence with long-term Follow-Up (PACIFIC, PACIFIC-R, PACIFIC-6, PACIFIC-IIIA-N2)[5-11]

- **PACIFIC:** Sustained 5-year OS and PFS benefit with 28% reduction in risk of mortality and 18 months longer median overall survival versus placebo [5]
- **PACIFIC-R:** Real-world confirmatory evidence showing an improvement in PFS and OS comparable to the PACIFIC trial[5,8]
- **PACIFIC 6:** Good tolerability and encouraging efficacy of IMFINZI® after sequential CRT[9,10]
- **PACIFIC IIIA N2:** Post-hoc analysis confirming treatment benefits with IMFINZI® in patients with stage IIIA-N2 NSCLC[11]

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* IMFINZI® is indicated for the treatment of patients with locally advanced, non-resectable NSCLC whose disease has not progressed after a definitive platinum-based CRT.[3]
† The dosage must be adjusted to body weight in patients weighing 30 kg or less, equivalent to 10 mg/kg IMFINZI® every 2 weeks, or 20 mg/kg every 4 weeks, as a monotherapy until body weight increases to above 30 kg.[3]

AE: adverse event; **CI:** confidence interval; **CRT:** chemoradiotherapy; **HR:** hazard ratio; **ILD:** interstitial lung disease; **IV:** intravenous; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **NE:** not estimable; **NR:** not reached; **NSCLC:** non-small cell lung cancer; **OS:** Overall survival; **PFS:** progression-free survival; **PRAE:** adverse event possibly related to study treatment; **UR:** unresectable.

References:
1. ESMO Guidelines, online available: https://www.esmo.org/guidelines/guidelines-by-topic/lung-and-chest-tumours (last access: 12.01.2023). **2.** NCCN Guidelines, online available: https://www.nccn.org/professionals/physician_gls/pdf/NSCLC.pdf (last access: 12.10.2023). **3.** IMFINZI® Information for Healthcare Professionals. www.swissmedicinfo.ch. **4.** List of specialities. www.spezialitätenliste.ch. **5.** Spigel DR, et al. Five-Year Survival Outcomes From the PACIFIC Trial: Durvalumab After Chemoradiotherapy in Stage III Non-Small-Cell Lung Cancer. J Clin Oncol. 2022 Apr 20;40(12):1301-1311. **6.** Antonia SJ, et al. Overall Survival with Durvalumab after Chemoradiotherapy in Stage III NSCLC. N Engl J Med. 2018 Dec 13;379(24):2342-2350. **7.** Girard N, et al. Treatment Characteristics and Real-World Progression-Free Survival in Patients With Unresectable Stage III NSCLC Who Received Durvalumab After Chemoradiotherapy: Findings From the PACIFIC-R Study. J Thorac Oncol. 2023 Feb;18(2):181-193. **8.** Girard N, et al. Real-world overall survival (OS) with durvalumab (D) after chemoradiotherapy (CRT) in patients (pts) with unresectable stage III non-small-cell lung cancer (NSCLC): Interim analysis from the PACIFIC-R study. Immuno-Oncology and Technology. 2022; 16: 100163. **9.** Garassino MC, et al. Durvalumab After Sequential Chemoradiotherapy in Stage III, Unresectable NSCLC: The Phase 2 PACIFIC-6 Trial. J Thorac Oncol. 2022 Dec;17(12):1415-1427. **10.** Garassino MC, et al. Durvalumab after sequential chemoradiotherapy in patients with unresectable Stage III NSCLC: Final analysis from PACIFIC 6. Presentation LBA61, ESMO Congress 2023. Madrid, Spain, 20-24 October 2023. **11.** Senan S, et al. Outcomes with durvalumab after chemoradiotherapy in stage IIIA-N2 non-small-cell lung cancer: an exploratory analysis from the PACIFIC trial. ESMO Open. 2022 Apr;7(2):100410.

Imfinzi®
Comp: Durvalumab; concentrate for solution for infusion; 50 mg/mL; List A. **Ind:** For the treatment of patients with locally advanced, unresectable non-small cell lung cancer (NSCLC) whose disease has not progressed following definitive platinum-based chemoradiation therapy. In combination with etoposide and either carboplatin or cisplatin for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC). In combination with gemcitabine and cisplatin for the first line treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC). **Dos:** *NSCLC:* 10 mg/kg every 2 weeks or 1500 mg every 4 weeks. *ES-SCLC:* 1500 mg every 3 weeks (21 days) for 4 cycles, followed by 1500 mg every 4 weeks. *BTC:* 1500 mg every 3 weeks (21 days) for up to 8 cycles, followed by 1500 mg every 4 weeks. **CI:** Hypersensitivity to the active substance or to any of the excipients. **W&P:** Immune-mediated ADRs (pneumonitis, hepatitis, colitis, nephritis, rash, myocarditis, haemophagocytic lymphohistiocytosis (HLH)), immune-mediated endocrinopathies (hypothyroidism, hyperthyroidism, thyroiditis, adrenal insufficiency, type 1 diabetes mellitus, hypophysitis/hypopituitarism), aseptic meningitis, haemolytic anaemia, immune thrombocytopenia, cystitis noninfective, myositis, encephalitis, pancreatitis, ocular inflammatory toxicity, polymyositis, myasthenia gravis, infusion-related reactions, adverse reactions in transplant recipients, cerebrovascular events. **IA:** Corticosteroids and immunosuppressants before starting treatment. **ADRs:** *Monotherapy:* Very common: upper respiratory tract infections, hypothyroidism, cough/productive cough, diarrhoea, abdominal pain, rash, pruritus, pyrexia. Common: pneumonia, oral candidiasis, dental and oral soft tissue infections, influenza, hyperthyroidism, TSH increased, pneumonitis, dysphonia, aspartate aminotransferase increased or alanine aminotransferase increased, night sweats, myalgia, blood creatinine increased, dysuria, peripheral oedema, infusion related reaction. *In combination with chemotherapy:* Very common: neutropenia, anaemia, thrombocytopenia, leukopenia, decreased appetite, insomnia, cough/productive cough, nausea, constipation, vomiting, diarrhoea, abdominal pain, aspartate aminotransferase increased or alanine aminotransferase increase, alopecia, rash, fatigue, pyrexia. Common: upper respiratory tract infections, influenza, pneumonia, dental and oral soft tissue infections, sepsis, febrile neutropenia, pancytopenia, hypothyroidism, hyperthyroidism, adrenal insufficiency, hypomagnesaemia, hypokalaemia, hyponatraemia, dehydration, hypocalcaemia, cerebrovascular events, neuropathy peripheral, headache, tinnitus, tachycardia, hypotension, pneumonitis, dysphonia, dyspnoea, pulmonary embolism, hiccups, stomatitis, amylase increased, hepatitis, blood bilirubin increased, gamma-glutamyltransferase increased, blood creatinine increased, dysuria, acute kidney injury, proteinuria, pruritus, dermatitis, back pain, myalgia, muscle spasms, peripheral oedema, infusion related reaction, chills, oedema, malaise. Uncommon, rare, very rare: see www.swissmedicinfo.ch. Date of revision of the text: January 2023. Further information: www.swissmedicinfo.ch or AstraZeneca AG, Neuhofstrasse 34, 6340 Baar, Switzerland. www.astrazeneca.ch. Professionals can request the mentioned references to AstraZeneca AG.

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