FIRST LINE UNRESECTABLE HCC

IMJUDO® tremelimumab
Injection for Intravenous Use 20 mg/mL

IMFINZI® durvalumab
Injection for Intravenous Use 50 mg/mL

NOW APPROVED BY SWISSMEDIC

In the first line treatment of unresectable HCC[1,2]

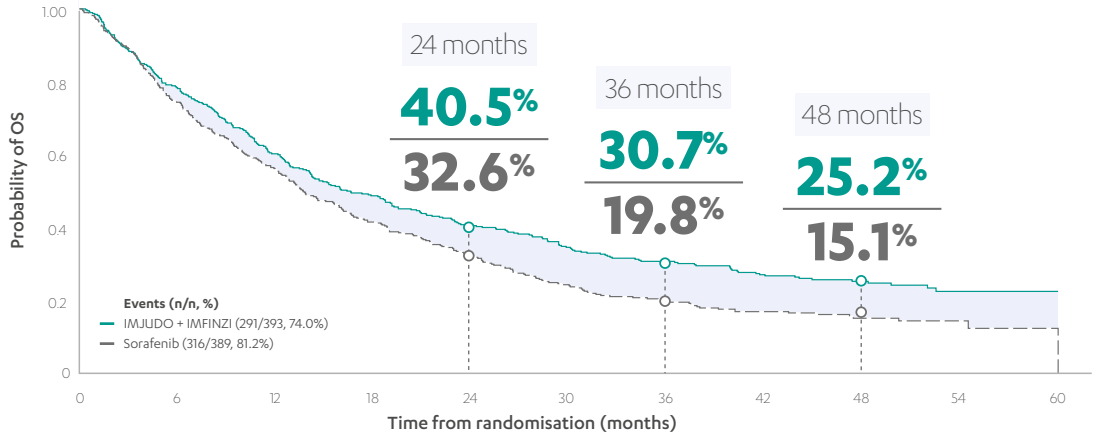
REACH BEYOND
with IMJUDO + IMFINZI

IMJUDO + IMFINZI is now approved by Swissmedic and recommended by the NCCN guidelines as first line treatment of unresectable HCC[1,3]

AstraZeneca

IMJUDO + IMFINZI is the first therapy to demonstrate unprecedented 25% OS rate at 4 years in 1L advanced or unresectable HCC, with 1 in 4 patients still alive[4]

OVERALL SURVIVAL IN THE INTENT-TO-TREAT POPULATION (UPDATED ANALYSIS)*,4



HR=0.78
(95% CI, 0.67–0.92);
p=0.0037

Number of patients at risk

IMJUDO + IMFINZI	393	308	235	190	158	131	103	88	54	19	0
Sorafenib	389	283	211	155	121	83	64	50	28	9	1

Median duration of follow-up: 49.12 months (range, 46.95–50.17) for IMJUDO + IMFINZI and 47.31 months (range, 45.08–49.51) for sorafenib.[4]

Adapted from Sangro B et al. 2023.[4]

Median OS was 16.4 months (95% CI: 14.2–19.6) with IMJUDO + IMFINZI vs. 13.8 (95% CI: 12.3–16.1) with sorafenib[4]

22% reduction in the risk of death with **IMJUDO + IMFINZI** vs **sorafenib**[4]

* OS HRs and 95% CIs were calculated using a Cox proportional hazards model adjusting for treatment, aetiology, ECOG PS and MVI. The 36-month OS rate had a nominal 2-sided p-value of 0.0006.
Updated analysis data cut-off: 23 January 2023.[4]

IMJUDO + IMFINZI demonstrated numerically lower rates of Grade 3 or 4 treatment-related adverse events vs sorafenib[2]

GRADE 3 OR 4 TREATMENT-RELATED ADVERSE EVENTS[2]

25.8%
Grade 3-4 TRAEs
IMJUDO + IMFINZI

vs.

36.9%
Grade 3-4 TRAEs
Sorafenib

No treatment-related gastrointestinal or oesophageal varices haemorrhage events were observed in the IMJUDO + IMFINZI arm[2]

TRAEs LEADING TO DISCONTINUATION[2]

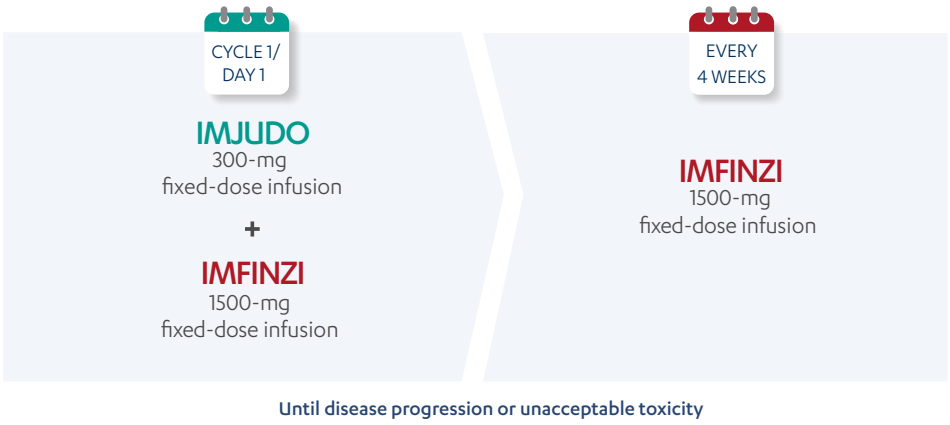
8.2%
with
IMJUDO + IMFINZI

vs.

11%
with
Sorafenib

THE INNOVATIVE STRIDE REGIMEN[1]

Single priming dose of IMJUDO combinded with continous administration of IMFINZI monotherapy



CI=confidence interval; HCC=hepatocellular carcinoma; HR=hazard ratio; L=line of treatment; NCCN=National Comprehensive Cancer Network; OS=overall survival; STRIDE=Single Tremelimumab Regular Interval Durvalumab; TRAEs=treatment-related adverse events; uHCC=unresectable hepatocellular carcinoma.

References

1. IMJUDO [Information for Healthcare Professionals for medicinal products for human use] www.swissmedicinfo.ch. **2.** Abou-Alfa GK, Lau G, Kudo M, et al. Tremelimumab plus durvalumab in unresectable hepatocellular carcinoma. NEJM Evid. 2022;1(8) (including Supplementary Appendix and Protocol). doi:10.1056/EVIDoa2100070. **3.** NCCN Guidelines Hepatocellular Carcinoma Version 1.2023 March 10, 2023 www.NCCN.org. **4.** Sangro B, Chan SL, Kelley RK, et al. Four-year overall survival update from the Phase 3 HIMALAYA study of tremelimumab plus durvalumab in unresectable hepatocellular carcinoma. Poster presented at: 2023 ESMO World Congress on Gastrointestinal Cancer; 26 June–1 July 2023; Barcelona, Spain (including supplementary information).

▼ This medicinal product is subject to additional monitoring. For further information, see Information for Healthcare Professionals for medicinal products for human use of IMJUDO® at www.swissmedicinfo.ch.

Imjudo®
Comp: tremelimumab; concentrate for solution for infusion; 20 mg/mL; List A. **Ind:** in combination with durvalumab for the treatment of patients with unresectable hepatocellular carcinoma (uHCC), who have not received prior systemic therapy. **Dos:** 300 mg as a single dose in combination with durvalumab 1500 mg in cycle 1 day 1, followed by durvalumab monotherapy (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, immune-mediated endocrinopathies (hypothyroidism, hyperthyroidism, thyroiditis, adrenal insufficiency, type 1 diabetes mellitus, hypophysitis/hypopituitarism), nephritis, rash, myocarditis, haemophagocytic lymphohistiocytosis (HLH), pancreatitis, meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy, uveitis, iritis and other ocular inflammatory toxicities, pericarditis, vasculitis, myositis, polymyositis and immune thrombocytopenia), infusion-related reactions, cerebrovascular accidents. **IA:** No metabolic drug-drug interactions. **ADRs:** *In combination with durvalumab:* Very common: Hypothyroidism, diarrhoea, abdominal pain, pyrexia, aspartate aminotransferase increased, alanine aminotransferase increase, cough/productive cough, rash, pruritus. Common: Hyperthyroidism, adrenal insufficiency, thyroiditis, lipase increased, amylase increased, colitis, oedema peripheral, hepatitis, upper respiratory tract infections, pneumonia, oral candidiasis, influenza, infusion related reaction, myalgia, blood creatinine increased, dysuria, pneumonitis, dysphonia, night sweats. Uncommon, rare, very rare: see www.swissmedicinfo.ch. Date of revision of the text: March 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.

Imfinzi®
Comp: Durvalumab; concentrate for solution for infusion; 50 mg/mL; List A. **Ind:** For the treatment of adult 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 adult 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, rhabdomyolyses, encephalitis, pancreatitis, Guillain-Barré syndrome, arthritis, uveitis and 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, unknown: see www.swissmedicinfo.ch. Date of revision of the text: March 2024.
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