

# STRATIFY YOUR mCRC PATIENTS FOR OPDIVO® (NIVOLUMAB) + YERVOY® (IPIILIMUMAB) WITH THE IDYLLA™ CDx MSI TEST

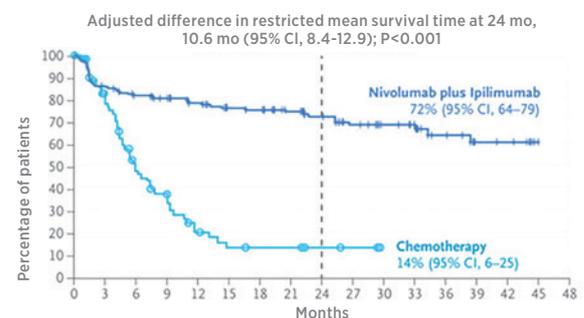
## CheckMate-8HW Trial

CheckMate-8HW<sup>1,2</sup> showed that central confirmation of MSI-H/dMMR test results with the Idylla™ CDx MSI Test improved outcomes for mCRC patients eligible for OPDIVO® (nivolumab) + YERVOY® (ipilimumab).

PFS at 24 months for dMMR/MSI-H mCRC patients was **72%** with 1L OPDIVO® in combination with YERVOY® and **14%** with chemotherapy, following central confirmation of dMMR/MSI-H results (CheckMate-8HW) - see Figure<sup>2</sup>.

**13%** of enrolled patients classified as MSI-H/dMMR by local testing were classified as MSS/pMMR on central confirmation. The improved survival and higher response rates in the centrally confirmed population indicate that the local results were false positives, underscoring the **importance of standardized testing** to accurately identify MSI-H/dMMR status<sup>2</sup>.

### Progression-free Survival (Kaplan-Meier Curve)



## Idylla™ CDx MSI Test

The Idylla™ CDx MSI Test was used as one of the **central confirmation testing methods** in CheckMate-8HW, where the PFS benefit of OPDIVO® plus YERVOY® over chemotherapy was consistently observed (HR 0.20), supporting the **Test's ability to accurately identify eligible MSI-H mCRC patients**.

The Idylla™ CDx MSI Test is a **fully automated, sample-to-result companion diagnostic** for mCRC patients, approved under the EU's IVDR<sup>3</sup>. The Test delivers fast and standardized MSI results, **supporting optimal therapy decisions, reducing patient anxiety<sup>4</sup>, and overcoming outcome disparities<sup>5</sup>**.



## YOUR PATIENTS, OUR PRIORITY.

“ The results obtained with the CheckMate-8HW trial establish OPDIVO® + YERVOY® as the potential to be a standard-of-care treatment for MSI-H/dMMR mCRC

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## REFERENCES

- (1) CheckMate 8HW, a Phase 3 clinical trial, evaluated the efficacy of nivolumab plus ipilimumab combination therapy or investigator's choice chemotherapy for the treatment of subjects with deficient mismatch repair/microsatellite instability - high (dMMR/MSI-H) metastatic colorectal cancer (NCT04008030).
- (2) André, T. et al. (2024). Nivolumab plus Ipilimumab in Microsatellite-Instability-High Metastatic Colorectal Cancer. *The New England journal of medicine*, 391(21), 2014–2026. <https://doi.org/10.1056/NEJMoa2402141>
- (3) Idylla™ CDx MSI Test (A0220/6) is CE-marked in Europe in compliance with the EU IVD Regulation 2017/746 (IVDR).
- (4) Miles, A. (2017). The psychological implications of diagnostic delay in Colorectal Cancer patients. In L. Olsson (Ed.), *Timely diagnosis of symptomatic cancer: Colorectal cancer* (pp.103-119). Springer International Publishing. [https://doi.org/10.1007/978-3-319-65286-3\\_7](https://doi.org/10.1007/978-3-319-65286-3_7)
- (5) Froelich, W. (2020). Disparities in MSI/MMR Biomarker Testing for Colorectal Cancer. *Oncology Times*, 42(22), 35. <https://doi.org/10.1097/01.COT.0000723664.21999.cc>

## ABBREVIATIONS

1L: first-line; CI: confidence interval; CRC: colorectal cancer; HR: hazard ratio; IVDR: European In Vitro Diagnostic Medical Device Regulation; mCRC: metastatic or unresectable colorectal cancer; MSI-H: microsatellite-high; MSS: microsatellite stable; dMMR: deficient mismatch repair; pMMR: proficient mismatch repair; PFS: progression-free survival; CDx: companion diagnostic

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