Efficacy and safety of trifluridine/tipiracil in combination with bevacizumab in older and younger patients with refractory metastatic colorectal cancer: a subgroup analysis of the phase 3 SUNLIGHT trial


SUNLIGHT was a large, international, open-label, randomized, phase 3 study evaluating FTD/TPI + bev monotherapy vs. FTD/TPI + bev with prior treatment regimens, in patients with refractory metastatic colorectal cancer (mCRC) for treating mCRC patients by the European Medicines Agency and the U.S. Food & Drug Administration.

Methods

- **Study design and patient population**
  - **SUNLIGHT** was a large, international, open-label, randomized, phase 3 study evaluating FTD/TPI + bev monotherapy vs. FTD/TPI + bev with prior treatment regimens, in patients with refractory metastatic colorectal cancer (mCRC) for treating mCRC patients by the European Medicines Agency and the U.S. Food & Drug Administration.

- **Objective**
  - The aim of this subgroup analysis from SUNLIGHT was to examine efficacy and safety outcomes in patients with refractory mCRC by age (≥65, 65–74, and ≥75 years).

- **Results**
  - **Effect of FTD/TPI + bev on OS in age subgroups**
    - In all age groups, FTD/TPI + bev prolonged median OS vs. FTD/TPI monotherapy (Figure 1).
    - A higher OS CI in the ≥75 years age group was attributed to the small sample size.

- **Incidence of adverse events**
  - The most common EAs with FTD/TPI + bev in the ≥65, 65–74, and ≥75 years age groups included tumour necrosis (58.2, 67.1, 70.8%), nausea (41.1, 30.3, 33.3%), asthenia (27.4, 30.3, 37.3%), fatigue (21.2, 23.7, 16.7%), and neutrophil count decreased (11.6, 15.8, 20.8%), respectively.

Conclusions

The results of this age-based subgroup analysis of SUNLIGHT demonstrate the efficacy benefit in OS, PFS and time to ECOSG P5 worsening, and the tolerability of FTD/TPI + bev treatment, regardless of age in refractory mCRC patients.