Background: Colorectal cancer occurs more frequently in elderly patients, and elderly patients also have a greater risk of colorectal cancer-associated mortality. Data on patients aged ≥65 years are limited. The phase III CORRECT study (ClinicalTrials.gov identifier: NCT01103323) assessed the efficacy and safety of regorafenib in patients who progressed on standard therapy.

Objectives: The primary objective was to assess overall survival (OS) in patients aged <65 (group A) and ≥65 (group B) years of age. Secondary objectives included comparison of progression-free survival (PFS) and overall response rate (complete or partial response) in the two age groups. Tolerability issues, in older patients (≥65 years) reflecting the typical age range of patients included in clinical trials, was also evaluated.

Methods: CORRECT was an international, multicenter, randomized, double-blind, placebo-controlled, phase III study (ClinicalTrials.gov identifier: NCT01103323). The intent-to-treat population included 760 patients aged ≥18 years who progressed on standard therapy, randomized 2:1 to regorafenib (n=505) or placebo (n=255). The median follow-up time was 14.2 months. Patients could have pre-existing dose interruptions or reductions for the management of regorafenib-related adverse events (AEs). The primary endpoint was OS. AE data were pooled from patients with dose modifications or interruptions.

Key findings: Regorafenib was associated with significantly longer OS in both age groups, with an interaction p-value of 0.405. In group A, placebo (95% CI) 0.418 (0.340–0.514) versus regorafenib (95% CI) 0.716 (0.561–0.914) vs placebo (95% CI) 0.856 (0.614–1.193) vs placebo (95% CI) 0.651 (0.496–0.855). Progression-free survival (PFS): HR 0.49, 95% CI 0.42–0.58; p<0.0001. OS and PFS in patient subgroups aged <65 and ≥65 years (n=383 and n=377): OS Regorafenib vs placebo: HR 0.54, 95% CI 0.39–0.76; p=0.0005. PFS Regorafenib vs placebo: HR 0.58, 95% CI 0.43–0.80; p=0.0015. OS and PFS in patients aged <65 (n=309) and ≥65 (n=189): OS Regorafenib vs placebo: HR 0.53, 95% CI 0.35–0.80; p=0.0042. PFS Regorafenib vs placebo: HR 0.57, 95% CI 0.40–0.83; p=0.0029.

Conclusions: Regorafenib was safe and effective in both younger (19%) and older (39%) patients, with similar tolerability profiles in both age groups. Very few patients aged ≥75 years were included in the CORRECT study (0.9%). The clinical benefit of regorafenib in patients aged ≥75 years should be the subject of further investigation. These data indicate that regorafenib can provide a clinical benefit, with very similar tolerability profiles in both age groups, opening the way to consider age-specific treatment options in the future.