

[1314] Health-Related Quality of Life (HRQoL) in Patients (Pts) with Chronic Immune Thrombocytopenic Purpura (ITP): Results from Two Placebo-Controlled Phase 3 Studies of AMG 531. Session Type: Poster Session, Board #468-I

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Pt-reported outcomes (PROs) are important tools for understanding the effects of treatment for various diseases. We developed the ITP Pt Assessment Questionnaire (ITP-PAQ) as the first disease-specific PRO instrument for adult chronic ITP. Further evaluation of its validity was assessed in ITP pts receiving AMG 531. AMG 531 is a novel thrombopoiesis-stimulating peptibody that is being studied for its ability to increase platelet production by stimulating the thrombopoietin receptor. The ITP-PAQ was used to examine HRQoL changes in both splenectomized and nonsplenectomized pts from 2 randomized, double blind, placebo-controlled Phase 3 studies of AMG 531 in adult pts with chronic ITP. It contains 44 items and 10 scales including Symptoms, Bother, Fatigue, Activity, Fear, Psychological, Work, Social Activity, Women's Reproductive Health, and Overall Quality of Life. Pts were blinded to their platelet counts before completing the ITP-PAQ. Changes in mean scores from baseline to week 24 were calculated for each ITP-PAQ scale by treatment arm, with positive values indicating improvement in HRQoL. Independent two-tailed t-tests were used to test differences. Specific items within each scale were also analyzed to provide further insights into the disease-specific areas of most concern for pts. Of the 125 pts enrolled, 63 were splenectomized (placebo, 21; AMG 531, 42), and 62 were nonsplenectomized (placebo, 21; AMG 531, 41). At baseline, splenectomized pts had lower scores on all ITP-PAQ scales than nonsplenectomized pts, especially Bother (51.0 vs 66.7), Fear (69.4 vs 81.3), Work (62.4 vs 77.5), and Overall Quality of Life (40.3 vs 56.5). Over the 24-week study, AMG 531-treated pts reported significantly greater improvement relative to placebo on 5 of 10 scales. Among splenectomized pts, significantly greater improvements in mean scores from baseline were found in the AMG 531 arm for Symptoms (placebo vs AMG 531; 0.2 vs 10.8, $p=0.02$), Bother (4.5 vs 24.6, $p=0.009$), Social Activity (-2.1 vs 16.9, $p=0.017$), and Women's Reproductive Health (-11.9 vs 10.1, $p=0.027$). Among nonsplenectomized pts, significantly greater improvement was found in AMG 531 pts for Activity (-1.8 vs 23.7, $p=0.016$). Particular improvements in items shown by both splenectomized and nonsplenectomized AMG 531-treated pts included bleeding (Symptoms), bruising (Symptoms), feeling unattractive due to bruising (Bother), and fear of infections (Fear). In summary, lower HRQoL was reported in splenectomized compared to nonsplenectomized pts with ITP, reflecting potentially different clinical needs for these 2 pt populations. Pts treated with AMG 531 showed greater improvement in HRQoL relative to placebo pts on most ITP-PAQ scales, and significant improvements were more common in splenectomized pts. Results from these 2 trials have provided further validation of the ITP-PAQ and can inform selection of key endpoints for future studies.

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