inpatient care associated with the first fracture claim. COM and MAP members were analyzed separately. Costs were calculated and stratified for hip, vertebral, and NHNV fracture patients as paid amounts and were adjusted to 2009 dollars. The difference between the individual patient’s 12 month pre-fracture costs and 12 month post-fracture costs are reported to estimate the change in costs associated with fracture.

Results: The study identified 18,917 (COM 16,191; MAP 2,726) closed fragility fractures during the study period. The sample mean age was 58 yrs and 74 yrs for COM and MAP, respectively. In the COM group, the proportions of fractures were: 22% vertebral fractures, 4% hip fractures, and 74% NHNV fractures. For the COM members, the difference in healthcare cost 12 months before and after fracture was: $15,906 for vertebral fractures, $30,176 for hip fractures and $8,313 for NHNV fractures. In the MAP group, the proportions of fractures were: 38% vertebral fractures, 9% hip fractures, and 52% NHNV fractures. For the MAP members, the difference in healthcare costs 12 months before and after fracture was: $7,439 for vertebral fractures, $25,232 for hip fractures, and $6,561 for NHNV fractures. In both populations, mean healthcare cost per fracture was highest for hip fracture but hip fracture was the least common type of fracture.

Conclusion: Healthcare costs associated with fragility fractures in men are high. Hip fracture had the highest cost per fracture (~$30,000 in COM and ~$25,000 in MAP) but a lower incidence of fracture compared to NHNV and vertebral fractures.

Disclosures: Nicole Yurgin, United Health Group, 3
This study received funding from: Amgen Inc

MO0442
A Phase 3 Study of the Efficacy and Safety of Denosumab in Men With Low Bone Mineral Density: Design of the ADAMO Trial. Eric Orwoll1, Christinne Stubbe Teglbjerg2, Bente Langdahl3, Roland Chapurlat4, Edward Czerniakowski5, David L Kendler6, Jean-Yves Reginster7, Alan Kivitz8, E. Michael Lewiecki9, Paul Miller10, Michael A Bolognese11, Hensson Bone12, Osvald Ljungberg13, Go Abrahamsson13, Yu-Chung Yang14, Andreas Graeter15, Cesar Libanati16, Jesse W Halls17, Steven Bouxsein18, Orenstein Health & Science University, USA, 2Centre for Clinical & Basic Research, Denmark, 3Aarhus University Hospital, Denmark, 4Hospital Edouard Herriot, France, 5Krakow Medical Center, Poland, 6University of British Columbia, Canada, 7University of Liege, Belgium, 8Altoona Center for Clinical Research, USA, 9New Mexico Clinical Research & Osteoporosis Center, USA, 10Colorado Center for Bone Research, USA, 11Bethesda Health Research Center, USA, 12UMichigan Bone & Mineral Clinic, USA, 13Uppsala University, Sweden, 14University of Southern Denmark & Gentofte Hospital, Denmark, 15Amgen Inc., USA, 16Leuven University, Belgium

Purpose: Denosumab increased bone mineral density (BMD) and reduced fractures in both postmenopausal women with osteoporosis (N=7808; Cummings, NEJM, 2009) and in men with prostate cancer on hormone ablation therapy, ADAMO reported in the pivotal denosumab fracture trials of postmenopausal women with osteoporosis and of men with prostate cancer on hormone ablation therapy, ADAMO study had a mean age of 65.0 years, and 94.2% were white, and 37.2% had a history of fracture (Table 1). Mean T-scores at the femoral neck, trochanter, and 1/3 radius, and the percent change from baseline in bone mineral density (BMD) at the lumbar spine were determined by dual energy X-ray absorptiometry (DXA) at baseline and at 1 year. All subjects will receive open-label denosumab for an additional year.

Following the 1-year, double-blind, placebo-controlled study period, all subjects will receive open-label denosumab for an additional year.

Secondary endpoint is the percent change from baseline in lumbar spine BMD. Secondary efficacy endpoints include percent change from baseline in BMD of the total hip, femoral neck, trochanter, and 1/3 radius, and the percent change from baseline in serum C-telopeptide (CTX). Safety endpoints include incidence of adverse events. The primary efficacy endpoint is the percent change from baseline in lumbar spine BMD. Secondary efficacy endpoints include percent change from baseline in BMD of the total hip, femoral neck, trochanter, and 1/3 radius, and the percent change from baseline in serum C-telopeptide (CTX). Safety endpoints include incidence of adverse events. Following the 1-year, double-blind, placebo-controlled study period, all subjects will receive open-label denosumab for an additional year.

Results: The baseline characteristics of the men who were randomized in the ADAMO study (N=242) were similar to those of men enrolled in other completed male osteoporosis trials. Men in the ADAMO study had a mean age of 65.0 years, 94.2% were white, and 37.2% had a history of fracture (Table 1). Mean T-scores at the lumbar spine and femoral neck were -2.0 and -1.9, respectively. The study results are not available since the trial is ongoing and remains blinded.

Conclusions: In light of the BMD gains and associated fracture reductions reported in the pivotal denosumab fracture trials of postmenopausal women with osteoporosis and of men with prostate cancer on hormone ablation therapy, ADAMO is being performed to confirm the effects of denosumab on BMD and bone turnover markers in men with osteoporosis.

Disclosures: Eric Orwoll, Eli Lilly, Amgen, and Merck, 2; Eli Lilly, Merck, Amgen, and Wright Medical Technology, 5
This study received funding from: Amgen Inc

MO0443
Association Between Polymorphisms In Wnt Antagonist Genes and Bone Response to Hormone Therapy In Postmenopausal Korean Women, Jung-Gu Kim1, Hoon Kim2, Dong Ock Lee1, Seung-Yup Ku3, Seok Hyun Kim4, Young Min Cho5, 1Seoul National University Hospital, South Korea, 2Department of Obstetrics & Gynecology, Incheon Medical Center, South Korea, 3Department of Obstetrics & Gynecology, College of Medicine, Seoul National University, South Korea

Purpose: The purpose of this study was to investigate the association between polymorphisms in Wnt antagonist genes and bone response to hormone therapy (HT) in postmenopausal Korean women.

Methods: The sickle phenotype (DKK1 c.318 A > G, Dkk2 c.437 G > A, Dkk3 c.1003 A > G, secreted frizzled-related proteins (sFRP) 3 c.970 C > G, sFRP4 c.958 C > A, and c.1019 G > A) and sFRP5 c.20 G > C polymorphisms were analyzed by polymerase chain reaction-restriction fragment length polymorphism (PCR-REFLP), Taqman assay or direct DNA sequencing in 303 postmenopausal Korean women receiving sequential HT for 1 year. BMD at the lumbar spine and femoral neck was determined by dual energy X-ray absorptiometry.

Results: When a non-responder was defined as a woman who had lost more than 3% of BMD per year after HT, Dkk1 c.318 A > G polymorphism and the haplotype genotype of sFRP4 c.958 C > A and c.1019 G > A polymorphisms among gene polymorphisms studied was associated with the risk of non-response of HT. The GG genotype of Dkk1 c.318 A > G polymorphism showed 2.38 times higher risk of non-response at the lumbar spine and/or femoral neck, as compared with the AA genotype. Among major haplotype genotypes composed of sFRP4 c.958 C > A and c.1019 G > A polymorphisms, the AA/AG haplotype genotype showed a negative percent changes in BMD at the femoral neck after 1 year of HT. The AG/CG haplotype genotype showed a 2.4 times higher risk of non-response at the lumbar spine and/or femoral neck, compared with the AA/AG haplotype genotype.

Conclusions: The Dkk1 c.318 A > G genotype and haplotype genotype of sFRP4 c.958 C > A, and c.1019 G > A polymorphisms may be associated with risk of non-response to HT in postmenopausal Korean women.

Disclosures: Jung-Gu Kim, None.

Table 1

<table>
<thead>
<tr>
<th>Table 1: A Phase 3 Study of the Efficacy and Safety of Denosumab in Men With Low Bone Mineral Density: Design of the ADAMO Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose: Denosumab increased bone mineral density (BMD) and reduced fractures in both postmenopausal women with osteoporosis (N=7808; Cummings, NEJM, 2009) and in men with prostate cancer on hormone ablation therapy, ADAMO study had a mean age of 65.0 years, and 94.2% were white, and 37.2% had a history of fracture (Table 1). Mean T-scores at the femoral neck, trochanter, and 1/3 radius, and the percent change from baseline in C-telopeptide (CTX). Safety endpoints include incidence of adverse events. Following the 1-year, double-blind, placebo-controlled study period, all subjects will receive open-label denosumab for an additional year.</td>
</tr>
<tr>
<td>Results: The baseline characteristics of the men who were randomized in the ADAMO study (N=242) were similar to those of men enrolled in other completed male osteoporosis trials. Men in the ADAMO study had a mean age of 65.0 years, 94.2% were white, and 37.2% had a history of fracture (Table 1). Mean T-scores at the lumbar spine and femoral neck were -2.0 and -1.9, respectively. The study results are not available since the trial is ongoing and remains blinded.</td>
</tr>
<tr>
<td>Conclusions: In light of the BMD gains and associated fracture reductions reported in the pivotal denosumab fracture trials of postmenopausal women with osteoporosis and of men with prostate cancer on hormone ablation therapy, ADAMO is being performed to confirm the effects of denosumab on BMD and bone turnover markers in men with osteoporosis.</td>
</tr>
</tbody>
</table>