Conclusions: In this pilot study, milnacipran used for pain and fatigue in older adults with RA showed some promise in improving severity of arthritis, and trends for pain and psychomotor retardation. They showed an increase in the NF kappa B response to stimulation. The results will be confirmed in a larger placebo-controlled trial.

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Poster Number: NR 46

Elder courts: transforming a crisis into a therapeutic opportunity

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Introduction: South Carolina is rapidly aging. The population age 60 and above is expected to double in the next 25 years growing from 635,673 to 1,290,00. A long-term strategy to manage this population's needs is crucial so the impact of this growth can be manageable by state institutions (AARP 2000). Although, most seniors are independent and are active independent members of society, the percentage of persons with any or severe disabilities increases significantly with age. Thirty percent of citizens 65 or older and 71 percent of those over 80 have significant functional or cognitive impairment. Unfortunately, elder disability has consequences. Disabled elders are often targets of financial, psychological and physical abuse. Sometimes, disabled elders appear to be the abusers, when cognitive and mental disorders generate violent or abusive behavior often directed to the caregiver that devotes their time to the care of the disabled elder.
Methods: Once the need for elder courts in South Carolina was established, a working group was developed consisting of a magistrate judge, an Alzheimer's expert, and a government affairs specialist. The project was divided into four steps. These steps were modeled from a specialty court developed in both South Carolina and in other states in the country. Steps: 1) Develop an alliance with potential groups that will benefit from the creation of elder courts 2) Develop background materials 3) Develop the legal structure and functions of the court 4) Develop a community based support system of agencies and stakeholders that will provide support for the court functioning
Results: An alliance was developed between the South Carolina chapter of the Alzheimer's Association, the American Association of Retired Persons (AARP), the office of the South Carolina Chief Justice, the office of the Lieutenant Governor, a not-for-profit hospital, and political figures with interest in the elderly. A white paper was developed that describes the detailed process for the development of the courts. To that end, the Executive Director of the S.C. Institute of Medicine and Public Health, a local think tank concerned with judicial and health issues, was brought on to the team to develop a number of workshops and work-groups to include state senators and prominent jurists, to develop the scope of the court activities. A list was generated to include agencies willing to provide in-kind resources to assist the court in its functions to include the Area Agency on Aging, the Alzheimer's Association, South Carolina Ombudsmen, and first responders.
Conclusions: This abstract describes the development of a model that attempts to convert situations that may result in elderly frail persons or their caregivers being wrongly incarcerated into an opportunity to gather resources utilizing the power of the court system to protect patients and caregivers. It also provides a structure that will facilitate community based intervention developed in collaboration between the judiciary and community stakeholders. The presenters expect to receive important feedback from the audience regarding the scope, depth, and breadth of this model of intervention.

Poster Number: NR 47

The Safety and Tolerability Profile of Vortioxetine in the Treatment of Patients With Major Depressive Disorder Aged 65 Years and Older

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Introduction: Depression affects over 20% of individuals aged 65 years or older, with many experiencing episodes of depression throughout their lives. Special consideration must be given to adverse side effects, drug interactions, and patient comorbidities when treating geriatric depression. Vortioxetine is a recently approved antidepressant agent for the treatment of adult patients with major depressive disorder (MDD). The mechanism of action of vortioxetine is thought to be related to its multimodal activity: direct modulation of serotonin receptor activity and inhibition of the serotonin transporter. In vitro studies suggest

vortioxetine is a 5-HT_3, 5-HT_7, and 5-HT_{1D} receptor antagonist, 5-HT_{1B} receptor partial agonist, 5-HT_{1A} receptor agonist, and 5-HT transporter inhibitor.
Methods: This analysis of 9 randomized, placebo-controlled, short-term studies was designed to evaluate the safety and tolerability of vortioxetine (5-20 mg/day) in patients with MDD aged ≥65 years. The efficacy of vortioxetine was evaluated in a specific elderly study (NCT00811252) using a single dose of 5 mg/day. Patient-level data from 9 randomized, double-blind, placebo-controlled, short-term studies of vortioxetine (5 to 20 mg/day) in patients with MDD were integrated for analysis (NCT00672958, NCT00672620, NCT00735709, NCT01153009, NCT01163266, NCT01179516, NCT00635219, NCT00811252, and NCT01140906). All patients were ≥18 years of age, met the DSM-IV criteria for a major depressive episode (MDE), and had a MADRS score ranging from 22 to 30 on the MADRS. Safety was evaluated through assessment of adverse events, and laboratory assessments. Suicidal ideation and behavior were prospectively assessed using the C-SSRS. Integration of clinical efficacy data was not possible due to small patient numbers at different doses, but efficacy of vortioxetine was specifically assessed in a trial (NCT00811252) of elderly patients (aged ≥65 years, MMSE score ≥24 with one MDE prior to age 60) using vortioxetine 5 mg/day or placebo.
Results: A total of 498 patients aged 65 or older were included in the safety analysis of vortioxetine 5 to 20 mg/day (n=286) and placebo (n=212). Treatment-emergent adverse events (AEs) led to discontinuation in 9.1% of vortioxetine-treated patients aged ≥65 compared with 5.2% in the placebo group. The most common AEs (≥5%) in the elderly population group treated with vortioxetine or placebo were nausea (22.4% vs. 7.5%), headache (9.8% vs. 16.0%), dizziness (8.4% vs. 7.1%), constipation (7.3% vs. 3.8%), diarrhea (5.9% vs. 7.1%), dry mouth (5.9% vs. 4.2%), and fatigue (5.2% vs. 2.8%). The incidence of insomnia and sleep-related disturbances was low in patients treated with vortioxetine compared to placebo (5.6% vs. 3.8%; 8.7% vs. 5.7%, respectively), with no report of treatment-emergent sexual dysfunction (0.0% vs. 0.5%) in patients treated with vortioxetine. No signal of increased suicidal ideation or behavior was detected in the C-SSRS data analysis. Additionally, no signals were noted regarding adverse events often associated with SSRI treatments, such as serotonin syndrome, seizures, and increased fracture risk. While drug exposure did increase up to 30% in elderly patients compared to non-elderly subjects, no dose-adjustment should be necessary due to the wide therapeutic index of vortioxetine. No clinically significant findings within or between groups emerged regarding clinical laboratory parameters. In the specific elderly study (NCT00811252), mean age at baseline was 71 years with 34% male. In the primary efficacy analysis, vortioxetine 5 mg (n=157) was statistically significantly (p=0.001) better than placebo (n=145) in reducing HAM-D24 total score at Week 8, with a least-squares mean difference from placebo of -3.3 points. Similar changes from baseline at Week 8 were observed in the MADRS total score: -15.5 points with vortioxetine 5 mg compared with -11.2 points with placebo.
Conclusions: In this analysis of patients aged ≥65 years across 9 randomized, placebo-controlled, short-term studies, vortioxetine at doses of 5 to 20 mg/day was generally safe and well tolerated in the treatment of MDD, with no signals of safety concerns specific to an older adult population.

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Asenapine in older adults with bipolar disorder

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Introduction: Of the 6 million American adults with bipolar disorder (BD), roughly 1 million are over the age of 60 years. Traditional mood stabilizers such as lithium are used for late-life BD, however side effects reduce tolerability, and treatment failure is common. The atypical antipsychotic asenapine is effective and well tolerated among mixed-aged adults with BD, both as monotherapy and as an adjunct mood stabilizing agent. A recent open-label trial (N=11) in acute geriatric mania found good efficacy and tolerability with a mean dose of 20 mg/day. We are conducting a 12-week prospective, open-label pilot trial to assess efficacy and tolerability effects of adjunct asenapine in non-demented elderly (≥60 years) ambulatory patients who have sub-optimal response to current BD treatments.
Methods: Type 1 or 2 BD diagnosis was confirmed with the Mini International Neuropsychiatric Interview (MINI). Asenapine was initiated at 5 mg/day and titrated as clinically indicated. Effects on mood and global psychopathology were measured with the Montgomery Asberg Depression Rating Scale (MADRS), Young Mania Rating Scale (YMRS) and Brief Psychiatric Rating Scale (BPRS). Other outcomes included the WHO-Disability Assessment Schedule II (WHO-DAS II), SF-12, Simpson Angus Scale (SAS), Barnes Akathisia Rating Scale (BARS), safety laboratory testing, EKG and observed side effects.
Results: Assessment of the first 11 enrollments (mean age 68.45 (SD 5.65), 64% female, 64% Caucasian, 18% African-American, 9% Asian) found that 4/11 (36%) individuals prematurely terminated study participation while 7/11 (64%) either completed