

Poster Presentations

TITLE OF PRESENTATION:

ZOSTER PAIN CONTROLLED WITH CONTINUOUS AURICULAR STIMULATION

PRESENTER'S NAME: Robert A. Bonakdar, MD, FAAFP

PRESENTER'S BIOGRAPHY: Director of Pain Management at the Scripps Center for Integrative Medicine and University of California, San Diego, School of Medicine Assistant Clinical Professor, Department of Family and Preventative Medicine (Voluntary). He is the CAM section editor for the 7th edition of Weiner's Pain Management: A Practical Guide for Clinicians.

CO-PRESENTER(S): None

POSTER ABSTRACT: This case study describes the application of a recently FDA approved implantable auricular electrostimulation device (P-Stim) for management of refractory pain and symptoms associated with severe episode of Shingles. **INTRODUCTION:** Zoster associated pain (ZAP) is a severe neuropathic pain occurring in 95% of individuals suffering reactivation of latent varicella zoster virus. With current treatment standards, up to 50% of cases continue to have a refractory pain prompting interest in additional treatment avenues. Among these options include acupuncture and electrostimulation which have had promising but inconsistent results in trials. In this case report we describe the use of a continuous auricular electrostimulation device (PStim) as a potential treatment of ZAP. **CASE DESCRIPTION:** 70 year old female with a 10 week history of Herpes Zoster associated with vesicular outbreak and refractory neuropathic pain assessed as 9/10. Patient was treated initially with oral anti-virals and corticosteroids and subsequently with narcotic medications (Percocet & Vicodin) and Neurontin. **ASSESSMENT:** SF-36, Pain Impact Questionnaire-6, Visual Analogue Scale (VAS) for pain, medication intake diary. **RESULTS:** After initial PStim application, baseline pain was reduced from a 9 to 2/10 and remained at this level throughout the first application (4 days). The patient underwent weekly application over the next 5 weeks which provided consistent reduction in the range of pain on the Visual Analogue Scale between 0-5/10. The patient's average analgesic use was reduced from 18 to 4 tablets/day (>75% reduction). The patient's pre to post SF-36 scores were statistically improved ($p < .016$) and PIQ-6 parameters of pain improved between 9 to 29% in all categories. The treatment was well tolerated without significant adverse effects. **CONCLUSION:** We report the first application of PStim in the United States for the management of pain. In this case, PStim demonstrated adjunctive ability to significantly improve pain, analgesic medication requirement and level of functioning with no major side effects. Future controlled trials which examine the use of this device in the setting of ZAP and other refractory pain syndromes are recommended.

TYPE OF POSTER: Non-Product Specific

TITLE OF PRESENTATION:

SAFETY DATA FOR TRAMADOL CONTRAMID® OAD IN TREATMENT OF PAIN

PRESENTER'S NAME: Francis Burch, MD

PRESENTER'S BIOGRAPHY: Practicing ER physician, Vice President of Clinical Development and Regulatory Affairs at Labopharm, Inc. Dr. Bouchard has 18 years experience in clinical research and regulatory affairs in the United States, Canada and Europe.

CO-PRESENTER(S): Sylvie Bouchard, MD, PhD

POSTER ABSTRACT: The safety of Tramadol Contramid® once a day (OAD) over 12 weeks was evaluated in three randomized, double blind, placebo-controlled clinical trials in a total of 1763 patients with Osteoarthritis of the knee. One thousand ninety five (1095) patients were randomized to active treatment with Tramadol Contramid OAD® (range 100-300 mg), and 668 to the placebo arm. The most frequently reported adverse events (incidence > 10%) that were at least possibly related to treatment with Tramadol Contramid® OAD were nausea, constipation, and dizziness/vertigo. More than 90% of these adverse events, reported by patients randomized to Tramadol Contramid® OAD in any of the studies were mild or moderate. Approximately 18% (193/1095) of the patients discontinued treatment because of an adverse event. A total of 20 serious adverse events occurred in 18 patients. Five of these, which occurred in four patients, were considered to be at least possibly related to treatment with Tramadol Contramid® OAD. The extensive safety data from these studies compares favorably with that of other marketed formulations of controlled-release Tramadol and indicates that Tramadol Contramid® OAD is safe for patients with moderate to moderately-severe pain.

TYPE OF POSTER: Clinical Trial – Phase 1, 2, 3

TITLE OF PRESENTATION:

TRAMADOL CONTRAMID® OAD (ONCE A DAY) FOR TREATMENT OF PAIN

PRESENTER'S NAME: Sylvie Bouchard, MD, PhD

PRESENTER'S BIOGRAPHY: Practicing ER physician, Vice President of Clinical Development and Regulatory Affairs at Labopharm, Inc. Dr. Bouchard has 18 years experience in clinical research and regulatory affairs in the United States, Canada and Europe.

CO-PRESENTER(S): Sybil Skinner-Robertson, BScN

POSTER ABSTRACT: Four hundred thirty one (431) patients with moderate to severe osteoarthritis of the knee (WOMAC pain scores > 150 mm) entered this randomized, double-blind, parallel study (21 centers/4 countries) comparing Tramadol Contramid® once a day (OAD) to a twice-a-day (BID) Tramadol formulation marketed in Europe. Doses were titrated by increments of

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100 mg to optimum dose (range 100-400 mg), which was maintained for 12 weeks. The primary efficacy measure was percent change in the WOMAC pain score from Baseline to week 12. Secondary measures were daily efficacy rating (24-hours post Tramadol Contramid® OAD, 12 hours post Tramadol (BID)); pain ratings, and incidence of adverse events. WOMAC pain scores improved by 58% for Tramadol Contramid® OAD and by 59% for Tramadol BID. Findings were comparable between groups and met the 95% CI [-7.67; 3.82] for non-inferiority of Tramadol Contramid® OAD (median dose; 200 mg daily, both groups). Seventy three percent (73%) of patients had mild to no pain 24-hours post Tramadol Contramid® OAD and 12-hours post Tramadol BID. Pain ratings over 24-hours were similar, indicating full 24-hour efficacy for Tramadol Contramid® OAD. Patients and investigators rated both treatments as effective in 99% of cases. Other WOMAC scores gave similar efficacy results. The adverse events experienced were typical of Tramadol. There were no age-related differences in these results. All end points were met: Tramadol Contramid® OAD provided effective analgesia over the full 24-hour period and a favorable safety profile. The once daily dosing regimen of Tramadol Contramid® OAD combined with the favorable safety profile will be of clear clinical benefit.

TYPE OF POSTER: *Clinical Trial – Phase 1, 2, 3*

TITLE OF PRESENTATION:

DOSE CONVERSION FOR IMMEDIATE-TO-EXTENDED-RELEASE TRAMADOL

PRESENTER'S NAME: *Alexander P. Danyluk, PharmD*

PRESENTER'S BIOGRAPHY: *Director of Medical Communication at Ortho-McNeil Janssen SA L.L.C. Dr. Danyluk received his doctor of pharmacy degree from the Philadelphia College of Pharmacy and Science.*

CO-PRESENTER(S): *Bindu P. Murthy, PharmD; Donna Skee; Gary Vorsanger, PhD, MD; Vincent Brett, MS, RPh*

POSTER ABSTRACT: Extended-release (ER) tramadol HCl (UL-TRAM_ER), a non-scheduled centrally-acting synthetic opioid analgesic, is the first once-daily ER entity recently approved for the relief of moderate to moderately-severe chronic pain. This ER formulation uses Smartcoat™ technology, allowing for a 24-hour dosing interval. This pharmacokinetic (PK) modeling study evaluated tramadol exposure from immediate-release (IR-QID) and extended-release (ER-QD) formulations to support dosing guidelines for transitioning patients from IR to ER to help reduce the incidence of breakthrough pain and withdrawal symptoms. Population PK computer modeling and simulation were used to develop dosing guidelines for transitioning patients from IR to ER tramadol. ER and IR tramadol provided similar exposure with respect to C_{max} and AUC when administered at the same daily

dose; therefore, patients taking the 200- and 300-mg IR regimens may directly switch to the 200- and 300-mg ER doses, respectively, without having to titrate to these dosages by starting at ER 100 mg. The 125-, 225-, and 325-mg IR doses closely resembled the exposures observed with the 100-, 200-, and 300-mg ER doses, respectively. Tramadol exposure associated with the 100-mg ER daily doses was lower than that of the 150- and 175-mg IR daily doses (~ 30%-40%) as was the case with the 200-mg ER vs 250- and 275-mg IR (~15%-26% lower) and the 300-mg ER vs 350- and 375-mg IR (~8%-19% lower) dose comparisons. Based on these modeling data, patients taking these IR doses may be transitioned to the next lower 100-mg ER increment (ie, 125- to 175-mg IR transitions to 100-mg ER daily dose). If medically appropriate, clinical trials suggest acetaminophen may be used for breakthrough pain. Study supported by Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

TYPE OF POSTER: *Clinical Trial – Phase 1, 2, 3*

TITLE OF PRESENTATION:

TWELFTH RIB SYNDROME: CASE REPORT AND REVIEW

PRESENTER'S NAME: *Tamer Elbaz, MD*

PRESENTER'S BIOGRAPHY: *Graduated from Cairo University, School of Medicine in 1996. Dr. Elbaz trained in Anesthesiology at SUNY Downstate Medical Center. Pain Management Training at Roosevelt Hospital, NY, NY. Currently practices Pain Management at Roosevelt Hospital, NY, NY.*

CO-PRESENTER(S): *Ronny Hertz, MD, DDS*

POSTER ABSTRACT: Twelfth rib syndrome is a rare syndrome in which patients experience various symptoms including abdominal pain, loin pain, low back pain, chest wall pain and radiculopathy (1). All patients with Twelfth rib syndrome have tenderness over the Twelfth rib. We hereby present one of our patients who presented with abdominal pain and in whom Twelfth rib syndrome was diagnosed and treated successfully. We also presented a discussion on the etiology, incidence, presentation, and treatment of Twelfth rib syndrome.

TYPE OF POSTER: *Non-Product Specific*

TITLE OF PRESENTATION:

OVERVIEW OF THE DEVELOPMENT PROGRAM FOR ZOSTAVAX™

PRESENTER'S NAME: *Lawrence D. Gelb, MD*

PRESENTER'S BIOGRAPHY: *Dr. Gelb, Professor of Medicine Washington University School of Medicine, has held positions with the Vaccine and Related Biological Products Advisory Committee (FDA) and the VZV Research Foundation.*

CO-PRESENTER(S): *None*

POSTER ABSTRACT: ZOSTAVAX™, a vaccine for the prevention of herpes zoster (HZ) and postherpetic neuralgia (PHN), and

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reduction of HZ-related pain burden of illness (BOI) in individuals 60 years of age and older, has been generally well tolerated in clinical studies. Phase I, II, and III studies from the Clinical Development Program established the efficacy, immunogenicity and safety/tolerability of ZOSTAVAX™. ZOSTAVAX™ is currently licensed in Australia (2-May-2006), the EU (19-May-2006) and the U.S. (25-May-2006); regulatory review is ongoing in several other countries.

Vaccine Efficacy (VE): The results of the Shingles Prevention Study (SPS) showed that ZOSTAVAX™ prevents HZ (VE=51.3%) and PHN (VE=66.5%), and reduces HZ pain BOI (VE=61.1%). VE was demonstrated through 4 years of follow-up.

Immunogenicity: Six weeks following a dose of ZOSTAVAX™, both the varicella-zoster virus (VZV) antibody response measured by glycoprotein enzyme-linked immunosorbent assay (gpELISA), and the VZV CMI response measured directly by interferon-gamma enzyme-linked immunosorbent assay (IFN-g ELISPOT) and Responder-Cell Frequency (RCF) were significantly higher than following a dose of placebo.

Safety: Among healthy adults and adults with a variety of underlying medical conditions, ZOSTAVAX™ is generally well tolerated.

Additional clinical studies are being conducted, 2 of which have recently been completed: a study that bridges a refrigerator-stable formulation of ZOSTAVAX™ to the initial frozen formulation and a concomitant use study with inactivated influenza vaccine. Additional studies are ongoing: 1) Persistence of efficacy among SPS subjects; 2) Vaccination of up to 18,000 original placebo recipients in 2 clinical trials; 3) Vaccination of subjects with a prior history of HZ. Several more clinical studies are expected to be initiated in the next ~12 months.

TYPE OF POSTER: *Clinical Trial – Phase 1, 2, 3*

TITLE OF PRESENTATION:

EXTENDED-RELEASE TRAMADOL IMPROVES SLEEP IN OSTEOARTHRITIS

PRESENTER'S NAME: *Carmela C. Janagap, MA*

PRESENTER'S BIOGRAPHY: *Associate Director, Outcomes Research, Primary Care for Ortho-McNeil Janssen Scientific Affairs, L.L.C. Ms. Janagap has a Master of Statistics degree from the University of the Philippines.*

CO-PRESENTER(S): *Jeff Schein, Mark Kosinski, Gary Vorsanger*

POSTER ABSTRACT: Given once daily, extended-release (ER) Tramadol HCl (UltramA† ER) reduces pain and related symptoms of osteoarthritis (OA). Two 12-week, double-blind, placebo-controlled,

randomized, parallel-group studies were conducted to compare the analgesic efficacy, safety, and tolerability of Tramadol ER (at least 200 mg for Study A and 100, 200, 300, and 400 mg for Study B) as compared to placebo in patients (18-74 years) with moderate to severe pain due to radiographically-confirmed OA of the knee (Study A, N = 246, dose-titration) and knee or hip (Study B, N = 1020, dose-ranging). The effects of pain on sleep were evaluated using the Chronic Pain Sleep Inventory (CPS) based on a 100-mm VAS (0 = never 100 = always) for both studies. In addition, the overall quality of sleep was assessed using a 100-mm VAS (0 = very poor, 100 = excellent). In Study A (the ITT population used for sleep measure analyses = 219), the mean improvement in scores averaged over Weeks 1 – 12 was significantly greater for the Tramadol ER group compared to placebo for trouble falling asleep due to pain, awakened by pain during the night, awakened by pain in the morning, and overall quality of sleep ($P \leq 0.05$). In Study B (the ITT population used for sleep measure analyses = 1011), compared to placebo, all doses of Tramadol ER achieved significant improvement in scores averaged over Weeks 1-12 in overall sleep quality, trouble falling asleep due to pain, and being awakened by pain during the night and in the morning ($P \leq 0.05$). The most commonly reported adverse events for both studies were dizziness, nausea, constipation, headache, somnolence, and pruritus. Thus, a benefit of treating pain with Tramadol ER is a significant reduction in sleep-related problems in OA patients. These studies were supported by Biovail Corporation.

TYPE OF POSTER: *Clinical Trial – Phase 1, 2, 3*

TITLE OF PRESENTATION:

REGISTRY TO IMPROVE CHRONIC PAIN MANAGEMENT

PRESENTER'S NAME: *Girish Joshi, MD*

PRESENTER'S BIOGRAPHY: *Professor of Anesthesiology and Pain Management at UT Southwestern and Director of Perioperative Medicine and Ambulatory Anesthesiology at Parkland Hospital.*

CO-PRESENTER(S): *Ronald A. Christensen, MD; Sunil Dogra, MBBS, F.F.A.R.C.S.I.; M. Kay Worley Price, RN, MN, CCRC, CHE; Stephen L. Webb, BBA, BS*

POSTER ABSTRACT: Chronic pain affects an estimated 33% of individuals in the United States and is often under-treated. Under-treated pain can impact quality of life and increase health care costs. One of the major reasons for inadequate treatment is the lack of good published data that would allow development of evidence-based guidelines. Also, there are currently no long-term data available on the effectiveness and adverse effects of different treatment modalities and patient/clinician satisfaction with therapy. Development of a pain registry would provide information on current practice as well as the effectiveness and adverse

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effects of various analgesic therapies. **METHOD:** The Chronic Pain Management Registry™ (CPMR) is a physician-driven, modular, prospective, multi-center, longitudinal observational study designed to collect and report data on the management of patients with chronic intractable pain. Data are collected from a variety of practice settings, including academic center, community clinics, and group and private practices. Using a web-based platform, clinical data are obtained during routine patient visits. In addition, validated instruments are used to collect patient reported outcomes that are faxed into a central database. **DISCUSSION:** In contrast to a randomized, controlled trial, there are no pre-defined experimental interventions and no restrictive exclusion criteria in the registry. The clinician investigator makes decisions based on the patient's symptoms and current "best practice" guidelines. Thus, data captured and reported provide a "real world" perspective on diagnoses, treatment, and outcomes of patients with chronic pain. **CONCLUSION:** A national registry of chronic pain management provides a unique opportunity for clinician investigators to obtain prospective, longitudinal data on patients with chronic pain. Investigators benefit from participation in the registry by obtaining aggregate benchmark data on "real-world" practice, adherence to clinical guidelines and patient/clinician satisfaction with different treatment modalities that can drive clinical practice management and performance improvement activities.

TYPE OF POSTER: *Clinical Trial – Phase 1, 2, 3*

TITLE OF PRESENTATION:

SLIPPED CAPITAL FEMORAL EPIPHYSIS: NEED FOR EARLY DIAGNOSIS

PRESENTER'S NAME: *Danielle A. Katz, MD*

PRESENTER'S BIOGRAPHY: *Assistant Professor, Department of Orthopedic Surgery, SUNY Upstate Medical University. Specialty: Pediatric Orthopedic Surgery.*

CO-PRESENTER(S): *None*

POSTER ABSTRACT: Slipped capital femoral epiphysis (SCFE) results when there is displacement through the physis of the femoral neck relative to the femoral head. When diagnosed early and treatment provided promptly, outcomes often are good. However, diagnosis is delayed in up to 30% of patients – often with less favorable results. (1,2) The presenting history can be variable, but any adolescent complaining of hip, thigh, or knee pain must have SCFE included in the differential diagnosis. Physical examination is distinctive. Characteristic findings include out-toeing, antalgic gait, decreased hip internal rotation, decreased hip flexion, obligate external rotation (inadvertent external rotation with hip flexion), and decreased hip abduction. Definitive diagnosis typically is made with radiography in anteroposterior (AP and

“from lateral” (Lauenstein) views of the pelvis. The AP view allows evaluation of “Klein’s line” (line up superior edge of femoral neck should intersect epiphysis) and comparison to the asymptomatic side. SCFE in the very early stages may be evident only on the Lauenstein view. Once diagnosed, urgent surgical treatment is required. There is no role for non-operative management. Standard treatment is fixation in situ with a single screw across the physis with the assistance of intra-operative imaging. Because there is no reduction, the severity of SCFE is not improved with surgery. The greater the residual deformity, the greater the disability (limitation of range of motion, function) and the greater the risk of subsequent arthritis. (2) Therefore, a high index of suspicion, early diagnosis, and timely treatment are crucial for the prevention of adverse sequelae. (3) 1. Ledwith CA, Fleisher GR. Slipped capital femoral epiphysis without hip pain leads to missed diagnosis. *Pediatrics.* 1992;89 (4): 6660-2. 2. Cowell HR. The significance of early diagnosis and treatment of slipping of the capital femoral epiphysis. *Clin Orthop.* 1966;48:89-94. 3. Katz DA. Slipped capital femoral epiphysis: The importance of early diagnosis. *Pediatr Ann.* 2006;35(2):102-111.

TYPE OF POSTER: *Non-Product Specific*

TITLE OF PRESENTATION:

IMPROVING THE QUALITY OF PAIN MANAGEMENT FOR PHYSICAL THERAPISTS FOR PATIENTS WITH CRPS THROUGH MEASUREMENT AND ACTIONS

PRESENTER'S NAME: *Larry Kopelman, PhD, PT, IMD, DABDA, CPP, DAAPM, FAAPM*

PRESENTER'S BIOGRAPHY: *Dr. Kopelman is the founder and President of Healthworks of Staten Island, a freestanding multimodal outpatient accredited pain management center. Larry is a Certified Pain Practitioner and is completing a Transitional Doctor of Physical therapy degree from Widener University in the summer of 06. He is Board Certified in Integrative Medicine, Disability Determination. He Has a Ph.D. in Occupational Health and Safety Engineering from Columbia Southern University, Docor of Integrative Medicine from Capital University of Integrative medicine and completed a nine-month Fellowship in Integrative medicine with the Kaiser Institute of Colorado.*

CO-PRESENTER(S): *None*

POSTER ABSTRACT: Treating patients experiencing pain is often difficult and frustrating. With the right knowledge, treating patients with pain becomes a very rewarding experience for the physical therapist and contributes significantly to the health and welfare of our communities.

Traditionally, the primary therapeutic objectives for patients with pain are reduction of pain and associated disability, promotion of

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functional activity, and enabling meaningful return to work, play, family and social interactions.

Pain differs from any other pathological entity where the history usually provides information about the pathological process and its impact on the patient while the examination defines the anatomical structures involved.

An often-missed diagnosis is Reflex Sympathetic Dystrophy, now called Complex Regional Pain Syndrome (CRPS).

“CRPS describes a constellation of painful conditions with regional pain that seems to be disproportionate in time or degree to the usual course of any known trauma or other lesion.” The pain is regional (not in a specific nerve territory or dermatome) and usually has a distal predominance of abnormal sensory, motor, sudomotor, vasomotor and/or trophic findings. CRPS syndrome shows variable progression over time.

Patients affected with CRPS have symptoms and signs that do not follow patterns expected in painful neurological conditions and display protective behaviors often thought of as inappropriate illness behavior.

Physical therapists attempt to restore functional activity, range of motion, desensitization and normalization of sympathetic tone. The key goal of physical therapy for this population of patients is to get a painful limb moving to restore normative function.

In physical therapy practice one of the most rewarding experiences is to help a patient suffering from chronic pain particularly CRPS. This population seems to be under diagnosed and the syndrome is often treated inappropriately until someone with appropriate training recognizes the signs and symptoms and recommends the immediate appropriate intervention for this condition.

While there is no gold standard of care for this patient population, careful assessment leads to the initiation of an individualized plan of care with a multi-disciplinary team that will lead to a satisfactory outcome.

TYPE OF POSTER: *Non-Product Specific*

TITLE OF PRESENTATION:

COMMUNITY PHARMACISTS' PERCEPTIONS REGARDING CHRONIC PAIN PATIENTS

PRESENTER'S NAME: *Karen F. Marlowe, PharmD*

PRESENTER'S BIOGRAPHY: *Graduated from Auburn in 1995 with a*

Doctor of Pharmacy and completed a residency at Emory University. She returned to Auburn in 2000, and currently practices at the University of South Alabama Medical Center as a part of the Internal Medicine Department.

CO-PRESENTER(S): *None*

POSTER ABSTRACT: Pharmacists are an integral part of the process of pain management. Our hypothesis was that pharmacists' beliefs and understanding regarding chronic pain would influence their attitudes toward patient care. A forty question survey was distributed to 150 pharmacists in a two county area including both urban and rural locations between December 1, 2005 and February 15, 2006. Seventy-eight surveys were returned and the respondents were demographically balanced for gender, length of time in practice, location, age, and prescription volume. 53% of respondents were female and 47% male. 25% work in chain drug stores, 25% independent pharmacies, 20% hospitals, 16% superstores, and 14% grocery store. The majority indicated that pain medication (including NSAIDS) represented up to 25% of daily prescription volume. The respondents indicated that their primary concern was for compliance with controlled substance regulations. Questions regarding understanding of chronic pain revealed discomfort with the use of opiates. Pharmacists were asked to rate their education level regarding controlled substances and pain management, 49% felt that their education was good, 27% fair, 23% excellent and 0 poor. For education regarding opiates and pain management, 47% felt that their education was good. 35% felt that their education was fair, 14% said excellent and 4% poor. When asked if comfortable counseling patients on their pain medication, 35% were neutral, 1% were somewhat uncomfortable, 6% were completely uncomfortable. When asked if familiar with pain contracts, 56% said yes and 44% said no. Only a few indicated knowledge of specifics, related to the contracts. Questions addressing addiction and tolerance revealed a lack of distinction between the phenomenons. Open ended questions revealed skepticism regarding patients who require chronic medications for pain. This survey highlights the need to increase pharmacist understanding of chronic pain management.

TYPE OF POSTER: *Non-Product Specific*

TITLE OF PRESENTATION:

TOPIRAMATE FOR MIGRAINE PREVENTION

PRESENTER'S NAME: *Rosalyn S. Padiyara, PharmD*

PRESENTER'S BIOGRAPHY: *Assistant Professor of Pharmacy Practice, holds a joint position with Midwestern University of Swedish Covenant Hospital. Dr. Padiyara's research interests include medication reconciliation and collaborative ambulatory care pharmacy services.*

CO-PRESENTER(S): *None*

POSTER ABSTRACT: Migraine is a costly, recurrent condition

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affecting 28 million individuals in the United States and yet remains under diagnosed and under treated. In 2004, the U.S. Food and Drug Administration approved topiramate for prevention of migraine in adults, joining divalproex sodium, propranolol, and timolol. Topiramate's role in the treatment of migraine was evaluated based on published literature and clinical experiences. A qualitative systematic search of the literature from January 1966-December 2004 was conducted using MEDLINE. Three large, randomized, placebo-controlled trials of topiramate for migraine prevention in individuals experiencing 3-12 attacks/month have been published, as have several small studies and a comparator trial with propranolol. Results of these studies show 100 mg/day is the optimum topiramate dosage regarding efficacy and tolerability, decreasing the number of migraine attacks/month by approximately two. Other significantly reduced secondary outcomes measures included number of days/month with migraine and use of acute treatment/attack. Suboptimal efficacy was shown with the 50 mg/day whereas 200 mg/day caused considerably more tolerability issues. Paresthesia was dose-related and the most common cause of attrition. Cognitive dysfunction and weight loss were also commonly reported. The reduction by two migraines/month with topiramate in clinical trials is similar to the published results for other preventive agents, though most of those studies were small, antiquated, and poorly designed. In contrast, the topiramate trials enrolled a larger number of patients and adhered to the International Headache Society research recommendations, strengthening the quality of results. Topiramate 100 mg/day is an effective option in adults requiring migraine prophylaxis. Although published efficacy results of the various migraine preventive agents are comparable, the superior study design of the topiramate trials warrants consideration of topiramate as an agent of choice for migraine prevention. Future studies of preventive agents should include more refined quality of life outcomes. Published in *Pharmacotherapy* 2006;26(3):375-387.

TYPE OF POSTER: *Non-Product Specific*

TITLE OF PRESENTATION:

ALVIMOPAN FOR OPIOID-INDUCED BOWEL DYSFUNCTION: PHASE IIB STUDY

PRESENTER'S NAME: *John Francis Peppin, DO, FACP*

PRESENTER'S BIOGRAPHY: *Practices full time pain medicine, palliative care and internal medicine in Des Moines, where he founded his current practice, Iowa Pain Management Clinic.*

CO-PRESENTER(S): *Erick G. Carter, PhD, MD; Dr..med. Jan-Peter Jansen; Christi S. Kleoudis, MPH; Ben Lasko, MD; Erick Rudolph Mortensen, MD, PhD; Lynn R. Webster, MD, FACPM, FASAM*

POSTER ABSTRACT: *Alvimopan is a peripherally acting mu-opioid*

receptor (PAM-OR) antagonist in development for the management of gastrointestinal (GI) side effects associated with opioid use, including constipation, abdominal pain/bloating, and decreased appetite. A double-blind, placebo-controlled, multicenter study, SB-767905 / 011 randomized 522 subjects to alvimopan 0.5mg BID (group 1), 1 mg QD (group 2), 1 mg BID (group 3), or placebo for 6 weeks. Subjects receiving the equivalent daily dose of ≥ 30 mg oral morphine and reporting <3 spontaneous bowel movement (SBMs)/week, symptomatic in $\geq 25\%$ stools, were eligible. To avoid the confounding influence of prophylactic laxative use, a standardized 'rescue' laxative regiment was permitted. SBMs were defined as BMs in the absence of laxatives in the preceding 24 hours. All groups reported an average frequency of 1 SBM/week during the baseline period. Average increase in SBMs/week during treatment was approximately 3.5 in groups 1 and 2 ($P<0.001$) and 4.3 group 3 ($P<0.001$) compared with 1.7 in the placebo group. The increase in SBMs was apparent within 1 week, sustained throughout the 6-week treatment period, and returned towards baseline at discontinuation. During treatment, 63-68% of alvimopan-treated subjects reported ≥ 3 SBMs/week compared with 39% receiving placebo. Alvimopan subjects showed improvements in straining, stool consistency, completeness of evacuation, abdominal pain and bloating compared with placebo. Moreover, 40% of alvimopan-treated subjects reported moderate to substantial improvement in constipation compared with 14% in the placebo group ($p<0.001$). Alvimopan treatment groups also had a significant decrease in rescue laxative use ($p<0.05$ vs placebo). Alvimopan was well tolerated; most frequent AEs for placebo and alvimopan occurring at a similar frequency were abdominal pain (12% placebo, 11-26% alvimopan) nausea (9% placebo, 7-10% alvimopan), and diarrhea (5% placebo, 7-14% alvimopan). There was no evidence of opioid analgesia antagonism based upon pain intensity scores, opioid consumption, or systemic withdrawal assessment. This study was funded by GlaxoSmithKline and Adolor Corporation.

TYPE OF POSTER: *Clinical Trial – Phase 1, 2, 3*

TITLE OF PRESENTATION:

CURRENT AND FUTURE MIGRAINE THERAPEUTICS

PRESENTER'S NAME: *Nabih M. Ramadan, MD VP*

PRESENTER'S BIOGRAPHY: *Interprofessional Advancement and Community Relations, Professor and Chair, Neurology, Rosalind Franklin University. MD, American University of Beirut; post-MD training completed, Neurology and Stroke and Headache.*

CO-PRESENTER(S): *None*

POSTER ABSTRACT: *Approaches to migraine therapy are pharmacologic, including acute, preemptive and preventive and*

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non-pharmacologic. The overarching goal of migraine prevention is to reduce the burden of the illness by reducing the frequency of the attacks, their cumulative disability, and by providing synergy with the acute treatments. Today's migraine preventive strategies include drugs from various pharmacologic classes (e.g. beta-adrenergic blocker, anticonvulsant tricyclic antidepressants serotonin receptor antagonist), and non-pharmacological approaches such as cognitive-behavioral modification. Converging level I evidence and clinical experience support the use of the antidepressant amitriptyline, the anticonvulsants divalproex and topiramate, and the beta-adrenergic blockers propranolol, timolol and metoprolol in migraine prevention. Similarly, there is level I evidence in support of relaxation training, biofeedback and cognitive-behavioral therapy for migraine prevention. Other options for migraine prophylaxis exist (e.g., tizanidine, paroxetine, physical treatments) but the strength of the evidence for their use is not as robust. Migraine preventive approaches have varying degrees of adverse effects, some of which could be limiting. Balancing potential efficacy with risk of adverse effects, addressing patients' expectations and desires, compliance with management recommendations, adequate follow up, and accurate assessment of treatment goals are essential elements of a successful migraine prevention program. Migraine preventive pharmacotherapies are largely the produce of serendipitous clinical observations. To this end, propranolol, valproate, and topiramate, to name only a few, did not emerge as effective anti-migraine agents from the laboratory to the bedside. Future migraine preventive drugs likely will target migraine mechanisms more specifically, which undoubtedly will enhance the therapeutic index. Examples of such approaches include inhibitors of cortical spreading depression and glutamate receptor modulators.

TYPE OF POSTER: *Non-Product Specific*

TITLE OF PRESENTATION:

NON-SPONDYLOTIC ETIOLOGIES OF LUMBAR PAIN IN THE YOUNG ATHLETE

PRESENTER'S NAME: Dale T. Ratcliffe, DO

PRESENTER'S BIOGRAPHY: Completed residency in Physical Medicine and Rehabilitation at the University of Missouri. Dr. Ratcliffe is currently completing the Pain Management Fellowship at the Medical College of Virginia in Richmond.

CO-PRESENTER(S): David Xavier, CIFU, MD; Michael James DePalma, MD; Amit Bhargava, MD, MS

POSTER ABSTRACT: Approximately 50% of adolescent athletes with persistent lumbar pain can be diagnosed with spondylolysis or spondylolisthesis. The remaining 50% will have suffered injury of the vertebral body, intervertebral disc, ring apophysis, pelvis, articular process, spinous process, the interspinous ligament, or

other soft tissues of the lumbar spine. The adolescent spine is prone to these injuries as a consequence of the growth spurt and skeletal immaturity. Accurate diagnosis is mandatory in order to achieve successful treatment. History, physical exam, imaging modalities, and precision spinal injections can be employed to accurately diagnose the source of the symptom and optimally treat the adolescent spine injury. The lumbar functional spinal unit acts to transmit axial loads from one vertebra to the next, afford flexion-extension movements, provide stability, and prevent translatory and torsional shear. The risk of injury to the lumbar functional spinal unit is highest during rotation combined with lumbar flexion. The adolescent spine, due to growth imbalances across the functional spinal unit, is subject to increased shear force. Consequently, due to the high demands placed on the lumbar spinal units in athletic adolescents, the lumbosacral spine is subject to repetitive microtraumatic injury, which is manifested by pain and dysfunction. The repetitive movements involved in athletic activity, such as flexion-extension, can precipitate injury of the adolescent lumbar spine. Accurate diagnosis through the use of clinical history, physical examination, plain films, computed tomography, magnetic resonance imaging, nuclear imaging, and the use of precision spinal injections is necessary in order to accurately diagnose the etiology of the adolescent's symptoms facilitating successful treatment interventions. The spine specialist responsible for diagnosing and treating the adolescent athlete must have a firm knowledge of the biomechanic, pathophysiology and diagnostic and therapeutic algorithms of non-spondylotic lumbar pain in order to prescribe optimal treatments.

TYPE OF POSTER: *Non-Product Specific*

TITLE OF PRESENTATION:

NON-SURGICAL PINAL DECOMPRESSION VIA MOTORIZED DISTRACTION

PRESENTER'S BIOGRAPHY: Charlotte Richmond, PhD

PRESENTER'S BIOGRAPHY: Dr. Richmond is CEO of Biomedical Research and Education Foundation. She works closely with pharmaceutical and investigational device companies and has presented her research at national and international conferences.

CO-PRESENTER(S): Joseph V. Pergolizzi, Jr., MD; Alex Macario, MD, MBA; Sunil Panchal, MD

POSTER ABSTRACT: **OBJECTIVE:** Conduct retrospective chart audit to assess outcomes of a random sample of outpatients treated with motorized spinal decompression via the DRX9000 for chronic low back pain lasting more than 12 weeks. **METHODS:** Data from charts of 100 adults cared for in 2004-2006 at four clinics, one hospital-based and three free-standing, were abstracted using a standardized data collection form. Protected

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health information was accessed in accordance with the HIPAA privacy rule. Worker's compensation patients were excluded. DRX sessions (30 mins each) were for 9-12 weeks with 4-5 sessions the first week tapering to 1 session/wk (mean treatments=23). Treatment protocol included instruction on lumbar stretching exercises and ice or muscle stimulation after DRX sessions. Pain, analgesic use, and activities of daily living were assessed pre and post treatment. **RESULTS:** Subjects (62% female, 94% white, mean age 55, 53% employed) had mean pain score 5.99 on a 0 to 10 scale (0=no pain 10=worst pain) at time of initial presentation that decreased to 0.87 after last DRX treatment. NSAID (41% of patients) and opioid (24% of the patients) use decreased (<5%) after treatment. Patients reported a mean 90% improvement in back pain, and better function as measured by activities of daily living. On a 0 to 10 scale (0=Not satisfied 10=Very satisfied) patients rated the DRX9000 an 8.98. No patient required more invasive therapies (e.g., surgery). **CONCLUSION:** Overall, patients' pain improved after DRX treatment, requiring fewer analgesics, with better function. Practice variability exists in how clinics use the DRX 9000. We didn't have control groups, making it difficult to know how much of the benefit was placebo or spontaneous recovery and how much was due to the intervention. Randomized double-blinded clinical trials are needed to measure the efficacy of non-surgical spinal decompression systems. Disclosure: This study was partially funded by Axiom Worldwide.

TYPE OF POSTER: *Clinical Trial – Phase 1, 2, 3*

TITLE OF PRESENTATION:

LONG-TERM SAFETY: TRAMADOL CONTRAMID® OAD IN TREATMENT

PRESENTER'S NAME: *Sybil Robertson, BSc*

PRESENTER'S BIOGRAPHY: *BSc in nursing with a total of 15 years experience in clinical research and nursing. She is Deputy Head of Medical Affairs and Director, Clinical Development at Labopharm, Inc.*

CO-PRESENTER(S): *Sylvie Bouchard, MD, PhD*

POSTER ABSTRACT: Tramadol has been marketed for over 25 years. Nonetheless, few long-term safety data in the clinical setting have been published. Two long-term safety studies were conducted using the highest doses of Tramadol Contramid® once a day (OAD) for up to 12 months (200-400 mg; 628 patients). Efficacy and safety of this Contramid®-based Tramadol were originally established in a 3-month, comparative, multi-center, randomized, double-blind, non-inferiority study (Tramadol Contramid® OAD vs. Tramadol BID: 431 patients; 100-400 mg). It demonstrated that Tramadol Contramid® OAD provided comparable efficacy to Tramadol BID over 24 hours and a favorable safety profile. An open-label safety extension to the 3-month study followed 238

patients on Tramadol Contramid® OAD 200-400 mg for up to 12 months. An additional safety study followed 392 patients on Tramadol Contramid® OAD for up to 12 months on the 300 mg dose. Adverse events reported were typical of those quoted in the literature. The most frequent adverse events, reported in more than 10% of patients, were nausea, dizziness/vertigo, constipation, somnolence, headache, and vomiting. No seizures were reported. Sixty percent (60%) of the adverse events were mild, regardless of the duration of follow-up. Fifteen percent (15%) of patients discontinued early due to adverse events. The nature and incidence of the adverse events reported in these long-term safety studies indicate that this efficacious, once-daily Tramadol maintains a safe and consistent adverse-event profile over longer treatment periods.

TYPE OF POSTER: *Clinical Trial – Phase 1, 2, 3*

TITLE OF PRESENTATION:

SOMATIZATION AND STRESS PREDICT CHRONIC PAIN-RELATED IMPAIRMENT

PRESENTER'S NAME: *Arthur R. Smith, MD*

PRESENTER'S BIOGRAPHY: *Assistant Professor of Anesthesiology and Perioperative Medicine, and the Director of the Pain Management Clinic at the Medical University of South Carolina.*

CO-PRESENTER(S): *Jeffrey Borckardt, PhD*

POSTER ABSTRACT: OBJECTIVES: Recent neurobiological evidence supports the view of pain as a homeostatic emotion. Findings suggest that one's awareness of his/her own internal somatic, as well as affective/emotional states, may be associated with central sensitization processes seen in chronic pain relationships between pain intensity, functional impairment due to pain somatization and patients' ability to link general physical symptoms to an affective/emotional state. **METHODS:** 49 patients presenting to the Pain Clinic at the Medical University of South Carolina completed anonymous surveys inquiring about pain intensity, functional impairment, somatization and tendency to link physical problems to emotional states. **RESULTS:** Patients' tendencies to link physical symptoms with stress, anxiety, fear and worry were significantly positively related to functional impairment due to pain while controlling for average pain intensity and physical symptom frequency. Physical symptom frequency and severity were also positively related to functional impairment due to pain. **CONCLUSIONS:** Findings from this study suggest that further research on patients' awareness of psychological and somatic links is warranted as is the development of new ways to assess patients' tendencies to link physical complaints and affective/emotional states. As seen in this study, assessment of patients' tendencies to link physical and emotional problems

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may be important, as these tendencies may predict of functional impairment due to chronic pain.

TYPE OF POSTER: *Non-Product Specific*

TITLE OF PRESENTATION:

IDENTIFICATION OF A CARDIOVASCULAR-ADRENAL SYNDROME IN INTRACTABLE PAIN PATIENTS

PRESENTER'S NAME: *Forest Tennant, MD, DrPH*

PRESENTER'S BIOGRAPHY: *Director, Veract Intractable Pain Research Clinic.*

POSTER ABSTRACT: Common lore has it that pain severity can only be determined by a patient's self-report. While a patient's report of pain severity is essential to proper treatment, recent evidence suggests that severe intractable pain, per se, rather than an underlying medical condition may produce clinically detectable biologic abnormalities. These abnormalities are primarily believed to be the result of severe pain acting as a stressor releasing catecholamines and glucocorticosteroids from the adrenal gland and over-stimulating specific components of the immune or neurological systems. To determine if it is possible to identify a cardiovascular-adrenal syndrome among pain patients, fifty intractable pain patients were studied within the first week following referral to a research clinic. All reported that their pain was constant, interfered with sleep, and caused a house- or bed-bound state when undermedicated. Clinical screening was done to detect hypertension (BP above 140/90mmHg), tachycardia (pulse rate above 84/minute), and serum concentrations of the adrenal hormones, cortisol and pregnenolone. Despite being treated with standard dosages of opioids and ancillary medications at the time of clinical evaluation, these patients demonstrated a high prevalence of abnormalities for: (1) hypertension (28; 56.0%), (2) tachycardia (21; 42.0%), (3) high or low serum cortisol (19; 38.0%), and (4) low serum pregnenolone (18, 36.0%). Mean blood pressure, pulse rate, serum cortisol, and serum pregnenolone all positively and significantly ($P < 0.05$) reverted toward normal following three months of aggressive opioid treatment. This study demonstrates that untreated intractable pain may over-stimulate the cardiovascular and pituitary-adrenal systems and produce a detectable clinical syndrome consisting of tachycardia, hypertension, and abnormalities of the adrenal hormones, cortisol and pregnenolone. Considering the well-known, serious complications represented by these abnormalities, the presence of a cardiovascular-adrenal syndrome should prompt aggressive pain treatment.

TYPE OF POSTER: *Non-Product Specific*

TITLE OF PRESENTATION:

OPIOIDS BLOOD LEVELS IN HIGH DOSE, CHRONIC PAIN PATIENTS

PRESENTER'S NAME: *Forest Tennant, MD, DrPH*

PRESENTER'S BIOGRAPHY: *Director, Veract Intractable Pain Research Clinic.*

CO-PRESENTER(S): *None*

POSTER ABSTRACT: There is scant information concerning opioid blood concentrations in chronic pain patients treated with high doses of opioids. Blood concentrations, however, have the potential to monitor compliance with prescribing instructions, assess clinical effectiveness, and resolve medicolegal issues of tolerance, toxicity, and overdose. Physician readers of *Practical Pain Management* were asked to voluntarily submit a data sheet without a patient's name and report opioid blood concentrations of chronic pain patients treated with opioids. Data collected included age, sex, weight, cause of pain, opioid and daily dosage, and the patient's function status including the ability to drive and work. Patients had blood samples taken approximately 1 to 2 hours after a regularly, prescribed opioid dosage. The physician utilized his/her usual commercial laboratory. To date, 10 to 30 blood concentrations have been reported for each of the following opioids: methadone, morphine, oxycodone, hydromorphone, hydrocodone, fentanyl, and meperidine. Patients had well-known chronic, painful conditions such as spine degeneration, autoimmune disorders, and neuropathies. All patients were described as functional in that they could care for themselves, and over 80% could drive a car. Dosages of opioids were high. Daily morphine dosage ranged from 60 to 600mg, oxycodone ranged from 60 to 960mg, and methadone 80 to 400mg. The majority of blood concentrations were above the therapeutic ranges published for non-tolerant persons, and many concentrations were above levels often described as "toxic" or "lethal". Blood concentrations collected in this survey suggest that determination of opioid blood concentration should become routine clinical practice to aid in determining compliance with prescribing instructions, determination of therapeutic effectiveness, and medicolegal protection for the prescribing physician and pharmacist.

TYPE OF POSTER: *Non-Product Specific*

TITLE OF PRESENTATION:

PULSATING ELECTROMAGNETIC THERAPY FOR TREATMENT OF PAIN

PRESENTER'S NAME: *Aletha W. Tippet, MD*

PRESENTER'S BIOGRAPHY: *Family Physician with a subspecialty in pain management as well as wound consultation and palliative care. She has a private practice in Cincinnati, Ohio*

CO-PRESENTER(S): *None*

POSTER ABSTRACT: Electromagnetic therapy, such as electrical stimulation and magnet therapy, has been tried for many years for pain relief (1). Electromagnetic therapy that produces a pulsating

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electromagnetic force field increases oxygen tension in the treated tissue (2) and is reported to enhance healing of various tissues, as well as increasing arterial circulation. Based on reports of improved circulation, this treatment was tried as primary or adjunctive therapy in a physician pain management practice. Over a two year period conditions treated included: painful joints from arthritis; myalgia from chronic myofascial pain syndrome; gout; back pain; sprains and strains; contractures and stiffness; shoulder knee and hip pain, post-surgical pain and stiffness, carpal tunnel; rotator cuff syndrome. Treatment involves a 45 minute session of stimulation therapy, conducted one or two times per week until syndrome resolves. In a two year period, over one hundred patients have been treated with over 75% of patients responding to the therapy after 1-12 treatments. Positive results have been maintained with no recurrence. Typical cases include: 48 year old racquetball player with gout in his foot, with complete resolution of pain and return to competitive play after one treatment; 85 year old woman with stiff and painful rotator cuff, with complete relief of pain and return to full range of motion and function after 7 treatments; 72 year old male with chronic ankle pain from a prior injury, with complete relief of pain and return to full weight bearing, and avoidance of reparative surgery after 13 treatments; 65 year old woman with carpal tunnel symptoms resolved after 8 treatments. This non-invasive therapy has demonstrated significant benefit in treating a wide variety of painful syndromes in this series, and deserves to be considered for primary or adjunctive therapy used in addition to exercise therapy, medications, and other interventions. 1. Magnetic and Electromagnetic Therapy. Ramey, David W., DVM. <http://jeromekahn123.tripod.com/quackery/id4.html>. Nov. 26, 2005. 2. Unpublished data from University Health Science Center, Oklahoma City, Oklahoma. Effective Wound Treatment: The Importance of Tissue Oxygenation in Wound Healing, MicroVas Technologies, Inc. 2003.

TYPE OF POSTER: *Non-Product Specific*

TITLE OF PRESENTATION:

EFFECT OF EXTENDED-RELEASE TRAMADOL ON PAIN IN THE ELDERLY

PRESENTER'S NAME: *Gary Vorsanger, PhD, MD*

PRESENTER'S BIOGRAPHY: *Senior Director, Clinical Development of Analgesia/Mycology for Janssen Pharmaceutica, Products, L.P. He has both a Doctor of Medicine and Philosophy degree from Mount Sinai School of Medicine.*

CO-PRESENTER(S): *Jean E. Farrell, Med, BS, RN; Donna M. Jordan, BSN*

POSTER ABSTRACT: Once-daily extended-release (ER) Tramadol (ULTRAM[®] ER) was evaluated in a randomized, double-blind, placebo-controlled, parallel-group study in 1,020 patients with radiographically-confirmed OA of the knee or hip. Patients were

randomized to Tramadol ER 100, 200, 300, or 400 mg once daily or matching placebo for 12 weeks. Compared to placebo, all Tramadol ER doses achieved significantly better mean improvement from baseline to Week 12 in WOMAC OA Index composite score, and the subscale scores for pain, physical function, and joint stiffness ($\Delta \dagger 0.05$). All Tramadol ER doses, compared to placebo, achieve significant improvement in Chronic Pain Sleep Inventory (SCSI) scores averaged over Weeks 1-12 in sleep quality, trouble falling asleep due to pain, and being awakened by pain during the night and in the morning ($P \leq 0.05$). The current analysis evaluated Tramadol ER in patients >65 years ($n=283$) in this study. Patients rated their arthritis pain utilizing a 100-mm (0=no pain, 100 = extreme pain) visual analog scale (VAS). Sleep effects were evaluated using the CPSI based on a 100-mm VAS (0 = never, 100 = always). Post-hoc analysis from pooled data for the currently marketed Tramadol ER doses of 100, 200, 300 mg showed significant mean improvement in pain intensity scores (index and non-index joints) from baseline to Week 12 ($P < 0.047$) and for the Patient's Global Assessment averaged over Weeks 1-12 ($P=0.041$) compared to placebo; WOMAC OA Pain Index from baseline to Week 12 approached significance ($P=0.062$). Compared to placebo, these pooled data also showed significant improvement in CPSI scores from baseline to Week 12 in trouble falling asleep due to pain, and being awakened by pain during the night and in the morning ($P \Delta \dagger 0.010$). The most commonly reported adverse events were constipation (23.3%), dizziness (20.6%), nausea (22.2%), and vomiting (6.3%). This study was supported by Biovail Corporation.

TYPE OF POSTER: *Clinical Trial – Phase 1, 2, 3*