UI Health Care

Center for Digestive Disease

Active Research

Updated: 5/16/2019

Basic:

- Dr. David Elliott - (VA Merit) – Paleobiomic regulation of mucosal inflammation.
- Dr. Nedim Ince – (NIH bridge) -Mucosal immune regulation of graft-vs-host disease.
- Dr. Warren Schmidt – (VA Merit) - Anti HCV protease activities of metallopophyrins.
- Dr. Mohamad Mokadem - (KO8 submitted) – Intestinal energy absorption, appetite and regulation of circadian clock signaling.

Clinical:

Celiac:

- Dr. David Elliott – (Nexvax2-2006) - A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study In Hla-Dq2.5+ Adults With Celiac Disease To Assess The Effect Of Nexvax2 On Symptoms After Masked Gluten Food Challenge

IBD:

- Dr. Steven Polyak – (Gilead GS-US-419-3895)- Combined Phase 3, Double-Blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Crohn's Disease
- Dr. Steven Polyak – (Gilead GS-US-419-3896) – A Long-Term Extension Study to Evaluate the Safety if Filgotinib in Subjects with Crohn's Disease
- Dr. Steven Polyak – (Gilead GS-US-418-3898) – Combined Phase 2b/3, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Ulcerative Colitis
- Dr. Steven Polyak – (Gilead GS-US-418-3899) – A Long-Term Extension Study to Evaluate the Safety of Filgotinib in Subjects with Ulcerative Colitis
- Dr. Steven Polyak – (Gilead GS-US-418-4279) – A Randomized, Double-Blind, Placebo-Controlled Phase 2 Study to Evaluate the Testicular Safety of Filgotinib in Adult Males with Moderately to Severely Active Ulcerative Colitis
- Dr. Steven Polyak – Tofacitinib response in UC (TOUR) – a real world prospective multicenter study

- Dr. Steven Polyak- (AbbVie M14-234)- A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to evaluate the safety and efficacy of ABT-494 for induction and maintenance therapy in subjects with moderately to severely active Ulcerative Colitis.
- Dr. Steven Polyak – (AbbVie M14-675) – A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study to Evaluate the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Ulcerative Colitis
- Dr. Steven Polyak – (AbbVie M14-533) – A Phase 3 Multicenter, Open-Label Extension (OLE) Study to Evaluate the Long-Term Safety and Efficacy of ABT-494 in Subjects with Ulcerative Colitis (UC)
- Dr. Steven Polyak – (AbbVie M14-431)- A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Crohn's Disease who have Inadequately Responded to or are Intolerant to Biologic Therapy
- Dr. Steven Polyak – (AbbVie M14-433) – A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Crohn's Disease who have Inadequately Responded to or are intolerant to Conventional Therapies but have not Failed Biologic Therapy
- Dr. Steven Polyak – (AbbVie M14-430) – A Multicenter, Randomized, Double-Blind, Placebo-Controlled Maintenance and Long-Term Extension Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Crohn's Disease who Completed the Studies M14-431 or M14-433
- Dr. Steven Polyak – (AbbVie, Legacy) - A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of Adalimumab in Patients with Moderately to Severely Active Ulcerative Colitis
- Dr. Steven Polyak- (Takeda Pharmaceuticals USA, Inc., PASS)-Entyvio (vedolizumab) long –term safety study: An international observational prospective cohort study comparing vedolizumab to other biologic agents in patients with ulcerative colitis or Crohn's disease.- in initial stages of submission.
- Dr. Steven Polyak – TARGET-IBD: A 5-Year Longitudinal Observational Study of Patients Undergoing Therapy for Inflammatory Bowel Disease

Motility:

- Dr. Yehudith Assouline-Dayan – (Forest Research Institute) - An Open-Label, Multiple-Dose, Milk-Only Lactation Study in Lactating Women Receiving Linaclotide Therapeutically
- Dr. Yehudith Assouline-Dayan – (Shire) – Oral Budesonide Suspension (OBS) in Adolescent and Adult Subjects (11 to 55 Years of Age, Inclusive) with Eosinophilic Esophagitis: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study
- Dr. Yehudith Assouline-Dayan – (Shire) – A Phase 3, Multicenter, Double-Blind Extension Study to Evaluate Maintenance of Efficacy of Oral Budesonide

Suspension (OBS) an Long-Term Treatment Effect of OBS in Adolescent and Adult Subjects (11 to 55 Years of Age, Inclusive) with Eosinophilic Esophagitis (EoE)

- Dr. Yehudith Assouline-Dayan – (Shire) – A Phase 3, Multicenter, Open-Label Continuation Study with Budesonide Oral Suspension (BOS) for Adolescent and Adult Subjects with Eosinophilic Esophagitis (EoE)
- Dr. Yehudith Assouline-Dayan – (ESCOPOR III) – A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety, Tolerability, and Efficacy of SER-109 vs. Placebo to Reduce Recurrence of Clostridium Difficile Infection (CDI) in Adults who have Received Antibacterial Drug Treatment for Recurrent CDI (RCDI)
- Dr. Yehudith Assouline-Dayan – (ESCOPOR IV) – An Open-Label Extension of Study Seres-012 Evaluating SER-109 in Adult Subjects with Recurrent Clostridium Difficile Infection (RCDI)
- Dr. Yehudith Assouline-Dayan – (Allergan) – A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Safety and Efficacy of Relamorelin in Patients with diabetic Gastroparesis
- Dr. Yehudith Assouline-Dayan – (Allergan) – A 46-Week, Double-Blind, Placebo-Controlled, Phase 3 Study with a 6-Week Randomized-Withdrawal Period to Evaluate the Safety and Efficacy of Relamorelin in Patients with Diabetic Gastroparesis
- Dr. Yehudith Assouline-Dayan – (Allergan) – A 52-Week, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Safety and Efficacy of Relamorelin in Patients with Diabetic Gastroparesis
- Dr. Yehudith Assouline-Dayan – A Phase 2, Multicenter, Open-Label, Extension Study to Evaluate the Safety and Tolerability of AK002 in Patients with Eosinophilic Gastritis and/or Eosinophilic Gastroenteritis
- Dr. Yehudith Assouline-Dayan – A Phase 3, Randomized, 3-Part Study to Investigate the Efficacy and Safety of Dupilumab in Adult and Adolescent Patients with Eosinophilic Esophagitis
- Fields J, Go J and Schulze K: Pill properties that cause dysphagia and treatment failure. Curr ther res clin exp. August 2015, 77: 79-84
- Subash Chandra and Schulze K initiated project; The endoscopic recognition of sigmoid myochosis complicating diverticular disease.

Liver:

- Dr. Warren Schmidt-(@ THE VA Merck MK-5172 Protocol 017) A Long-Term Follow-Up Study to Evaluate the Durability of Virologic Response and/or Viral Resistance Patterns of Subjects With Chronic Hepatitis C Who Have Been Previously Treated withMK-5172 in a Prior Clinical Trial
- Dr. Antonio Sanchez--(Merck MK-5172 Protocol 017) A Long-Term Follow-Up Study to Evaluate the Durability of Virologic Response and/or Viral Resistance Patterns of Subjects With Chronic Hepatitis C Who Have Been Previously Treated with MK-5172 in a Prior Clinical Trial

- Dr. Warren Schmidt – A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of Emricasan, an Oral Caspase Inhibitor, in Subjects with Decompensated Non-Alcoholic Steatohepatitis (NASH) Cirrhosis
- Dr. Warren Schmidt – (Stellaris) – A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Cenicriviroc for the Treatment of Liver Fibrosis in Adult Subjects with Nonalcoholic Steatohepatitis
- Dr. Warren Schmidt – A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Selonsertib in Subjects with Nonalcoholic Steatohepatitis (NASH) and Bridging (F3) Fibrosis
- Dr. Antonio Sanchez – A Phase 2 dose Ranging, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety, Tolerability, Pharmacokinetics and Efficacy of EDP-305 in Subjects with Primary Biliary Cholangitis (PBC) with or without an Inadequate Response to Ursodeoxycholic Acid (UDCA)
- Dr. Antonio Sanchez – (Salix) – A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Multicenter Study to Assess the Efficacy and Safety of Rifaximin Soluble Solid Dispersion (SSD) Tablets Plus Lactulose for the Treatment of Overt Hepatic Encephalopathy
- Dr. Antonio Sanchez – A Multicenter, Randomized, Placebo-Controlled, Double-Blind Study to Confirm Efficacy and Safety of Terlipressin in Subjects with Hepatorenal Syndrome Type 1
- Dr. Antonio Sanchez – A Single Arm, Open-Label Study to Evaluate the Efficacy and Safety of Glecaprevir (GLE)/Pibrentasvir (PIB) in Treatment Naïve Adults with Chronic Hepatitis C Virus (HCV) Genotype 1 - 6 Infection and Compensated Cirrhosis
- Dr. Huy Tran – (Intercept) – A Phase 3, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Obeticholic Acid in Subjects with Compensated Cirrhosis due to Nonalcoholic Steatohepatitis
- Dr. Arvind Murali – A Phase 3, Matrix Design, Partially Double-Blind, Randomized Study of the Efficacy and Safety of 50mg Lonafarnib/100mg Ritonavir BID With and Without 180mcg PEG IFN-alfa-2a for 48 Weeks Compared with PEG IFN-alfa-2a Monotherapy and Placebo Treatment in Patients Chronically Infected with Hepatitis Delta Virus Being Maintained on Anti-HBV Nucleos(t)ide Therapy (D-LIVR)
- Dr. Arvind Murali – A Placebo-Controlled, Multi-Dose, Phase 2/3 Study to Determine the Safety, Tolerability and Effect on Liver Histologic Parameters in Response to ARO-AAT in Patients with Alpha-1-Antitrypsin Deficiency (AATD)
- Dr. Arvind Murali – (Emminence) - A Phase 2, Randomized, Double-Blind, Placebo-Controlled, 12-Month, Multiple-Dose Study to Evaluate the Safety, Tolerability and Efficacy of Three Dose Levels of MSDC-0602K in Patients with NASH
- Dr. Kyle Brown - A 5-year Longitudinal Observational Study of Patients With Nonalcoholic Fatty Liver or Nonalcoholic Steatohepatitis
- Dr. Randhir Jesudoss - A 5-year Longitudinal Observational Study of Patients With Primary Biliary Cholangitis

- Dr. Tomohiro Tanaka - A 5-year Longitudinal Observational Study of the Natural History and Management of Patients with HCC

Polyp:

- William Silverman - (NIH- contract site) - Vitamin D/Calcium Polyp Prevention Study (PPS4)

Pancreatobiliary:

- Rajab MA, Silverman WB Surg Laparosc Endosc Percutan Tech. 2014 -Clinical outcome of single plastic stent treatment of benign iatrogenic biliary strictures: is the outcome predetermined?

Clinical – Investigator initiated:

Dr. Henning Gerke

1) Outcomes of cyanoacrylate obliteration of gastric varices (retrospective study)
2) Underwater polypectomy for sessile polyps (retrospective review)
3) Yield of EUS with tissue sampling for gastrointestinal spindle cell neoplasms (retrospective study)
4) Randomized Controlled Trial Comparing SharkCore FNB Needles with Acquire FNB Needles Regarding Specimen Quality and Diagnostic Accuracy

William Silverman MD FACG FASGE AGAF:

1) Comparison of long-term benefits complications and quality-of-life in metal versus plastic stenting in patients with distal common bile duct obstruction and pancreas head carcinoma.
2) Fenestrated covered self-expanding metal stent feasibility in patients with patent cystic duct and distal common bile duct malignant extraction

Dr. Yehudith Assouline-Dayan:

1) Evaluation of psychosocial profiles in patients with fecal incontinence, constipation, and mixed symptoms; a retrospective study
2) Domperidone for the Treatment of Chronic Nausea and Vomiting Secondary to Gastroparesis
3) Gastric Electrical Stimulation (Enterra) for Treatment of Chronic Intractable (Drug Refractory) Nausea and Vomiting Secondary to Gastroparesis
4) Gastrointestinal Bleeding in Patients with Left Ventricular Assist Device: A Retrospective Study in a Tertiary Care Center
5) Esophageal Dysmotility
6) Eosinophilic Esophagitis (EoE)-- A Retrospective Study
7) Barrett's esophagus: retrospective review of the endoscopic eradication therapy

Dr. Antonio Sanchez:

1) Efficacy of Sofosbuvir combination therapies for Hepatitis C recurrence after liver transplantation.

2) Screening and Management of Hepatocellular Carcinoma - Report of a Global Survey. Prospective project to evaluate the patterns of screening and management of hepatocellular amongst liver and transplant specialists worldwide, members of the American Association for the Study of Liver Diseases (AASLD).
3) Effects of rural residence on surveillance for hepatocellular carcinoma in VA primary care patients with cirrhosis

Dr. Arvind Murali

1) Hepatitis E/DILI: - A study to determine hepatitis E seroprevalence in patients with drug induced liver injury in Iowa.

Dr. Kyle Brown

1) Factors influencing progression of iron overload in human livers (hemosiderosis in explants)
2) Progression of hepatic hemosiderosis in chronic hepatitis C.
3) UIHC experience with hepatocellular carcinoma and hemosiderosis.
4) Review of UIHC experience with alcoholic hepatitis.
5) Presentations of hemochromatosis in the era of genetic testing

Dr. Konrad Schulze

1) The endoscopic recognition of sigmoid myochosis complicating diverticular disease. (w/ Subash Chandra)