2021 Fourth Annual National Conference

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Jointly provided by the Annenberg Center for Health Sciences at Eisenhower and Gastroenterology and Hepatology Advanced Practice Providers.
Future of IBD Therapies

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Disclosures

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Disclosures

Jamie Thale Brogan, APRN

Speakers Bureau: AbbVie, Clinical Area – IBD
Current Medical Therapies

Ulcerative colitis
- Steroids
- 5-ASA
- Immunomodulators
- aTNF
- A integrin
- A interleukins
- JAK-I
- S1P

Crohn’s Disease
- Steroids
- Immunomodulators
- aTNF
- A Integrins
- A Interleukins
Biosimilars – What Are They?

Biosimilars are biologic products that are highly similar to a previously approved reference (or originator) biologic drug in terms of safety, purity, and potency (efficacy).
Currently available biosimilars

- Inflectra (infliximab-dyyb)
- Renflexis (infliximab-abda)
- Avsola (infliximab-axxq)

Coming soon to a patient near you!

- Many FDA approved Adalimumab biosimilars that are not yet marketed
Pros

• Can be taken the same way as the original biologic medication
• Same efficacy and safety
• Same standard of manufacturing
• Improve cost
• Improve access

Cons

• Similar not same increases risk for not the exact response and potential for ADAb
• Concern for switching frequently between products
Zeposia – FDA Approved 2021

• Oral once daily S1P
  – MOE reduces the capacity of lymphocytes to migrate from lymphoid tissue, reducing the number of circulating lymphocytes in peripheral blood

• Approved for treatment of Ulcerative colitis and previous approved for MS

• Currently in clinical trials for Crohn’s Disease

• Zeposia was able to meet clinical endpoints at both week 10 and week 52

• Contraindicated in patients with cardiac concerns primarily HF or arrhythmias, on MAOI therapy, untreated sleep apnea, current infections, macular degeneration, liver injury, and Zeposia has not been evaluated in pregnant or nursing patients
• Currently approved for treatment of recurrent Clostridioides difficile (C. diff.)
• Used to impact the microbiome (bacteria lining the intestines)
• With regards to treatment in IBD. More research is needed to determine its role in the treatment of IBD
Coming soon to a Patient near you

Medication currently in clinical trials and or pending FDA approval
Etrolizumab

• Dual-action anti-integrin antibody, a slightly different MOA to Entyvio
• 105 mg vs. 210 vs placebo self injection q4 weeks
• Phase 3 clinical program in ulcerative colitis (UC) and Crohn's disease is ongoing
Filgotinib

- Oral JAK1 inhibitor Once daily dose of 100mg vs 200mg
- MOE: JAK signals stimulate immune cells to produce inflammatory proteins (cytokines), resulting in persistent inflammation in autoimmune conditions. JAK inhibitors slow down the progression of these diseases by interrupting the transmission of intracellular signals
- SE: infections including TB, Shingles, decreased renal fx, abnormal liver fx tests and abnormal blood counts
- Currently in trials for UC, Crohn’s Disease and perianal fistulizing Crohns Disease
Risankizumab

- Risankizumab binds p19 subunit of human interleukin 23 (IL-23) cytokine
- Currently FDA approved for treatment of plaque psoriasis
- Self injection (currently approved dose indicated approved dose for SKYRIZI is 150 mg (two 75 mg injections), administered by subcutaneous injection at week 0 and 4, and every 12 weeks thereafter
- Dosing for IBD of 600mg and 1200mg showing promise in IBD clinical trials
Mirikizumab

- Mirikizumab is a humanized IgG4 monoclonal antibody that binds to the p19 subunit of interleukin 23. Mirikizumab is being studied for the treatment of immune diseases, including psoriasis, ulcerative colitis and Crohn's disease.
- Currently in phase III for CD and UC clinical trial results should be available in early 2022
Upadacitinib

- A selective and reversible JAK inhibitor discovered and developed by AbbVie (slightly differs from current JAK-i)
- Being studied as an oral therapy for moderate to severe ulcerative colitis, Crohn’s Disease, and several other immune-mediated diseases
- Currently in Phase III clinical trials
Considerations prior to treatment

• Infections
  – No active infection
  – Latent infections

• Immunizations

• Routine care considerations
Thank you!
Enjoy the conference!