

Ulcerative Colitis [2017]

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Abstracts

Will oral therapies transform the treatment of ulcerative colitis?

With Pfizer's Xeljanz (tofacitinib) pending approval in the US, new oral therapies are set to transform the ulcerative colitis (UC) treatment landscape. While Pfizer's JAK inhibitor clearly has a head-start, other companies have more selective JAK1-inhibitors in late-stage development, including AbbVie's upadacitinib and Galapagos/Gilead Sciences' filgotinib. Celgene has taken a different approach with its oral molecule, ozanimod. Do KOLs believe they'll all be successful? Other late-stage programmes, including Roche's subcutaneous integrin inhibitor, etrolizumab, and Johnson & Johnson's Stelara (ustekinumab), will also add complexity and choice to the treatment algorithm. How will these products fare in an increasingly competitive environment, where anti-TNF biosimilars look set to dominate? KOLs provide candid insights on these and other new therapies, their likely use, and how they'll affect current mainstays such as anti-TNFs and Takeda's Entyvio (vedolizumab), in KOL Insight: Ulcerative Colitis.

Twelve North American and European KOLs provide their insight on 5 marketed/registered products and 9 late-stage pipeline programmes.

Top takeaways

An addition to mild-to-moderate disease? Mild-to-moderate UC is currently treated with cheap, generic 5-ASA, but can Lipid Therapeutics' LT-02 add clinical value? What do KOLs view as LT-02's specific advantages?

Optimism for biosimilar anti-TNFs continues to grow. An increasing number of KOLs are using these products. But in which patients are these agents used, and are they having an equal impact in both the US and EU markets?

Etrolizumab set to challenge Entyvio? Roche's etrolizumab is a subcutaneous integrin inhibitor undergoing late-stage evaluation. Do KOLs believe this agent will be a threat to Takeda's Entyvio (vedolizumab)?

Stelara (ustekinumab) will add more choice to the treatment algorithm. KOLs agree that Johnson & Johnson's Stelara has shown great efficacy in Crohn's disease. But can this translate to UC, and what are Stelara's specific advantages?

KOLs excited by the arrival of oral therapies. With Pfizer's Xeljanz (tofacitinib) pending approval for UC in the US, several other JAK inhibitors in late-stage development and Celgene's ozanimod in Phase III trials, KOLs are understandably excited. How are these agents expected to be used?

Will enema formulations for moderate-to-severe disease succeed? InDex Pharmaceuticals' Kappaproct (cobitolimod) and Atlantic Healthcare/Ionis Pharmaceuticals' alicaforsen are being evaluated as potential enemas for moderate-to-severe disease. According to KOLs, how clinically and commercially attractive are these products?

Quote

"We were apprehensive [about biosimilar TNF inhibitors] at first. We had no experience using these products and the patients also had some doubts; patients saw the drug was cheaper, and for this reason, thought it was worse. Things have changed, and nowadays we have gained experience and we know that there is no difference between Remicade and biosimilar infliximab." European Key Opinion Leader

Sample of therapies covered

Marketed/Registered Therapies

Uceris/Cortiment (budesonide MMX; Cosmo/Salix/Ferring)

Remicade (infliximab; Merck & Co./Johnson & Johnson)

Humira (adalimumab; AbbVie)

Simponi (golimumab; Merck & Co./Johnson & Johnson)

Entyvio (vedolizumab; Takeda)

Pipeline (P3) Therapies

LT-02 (phosphatidylcholine controlled-release; Lipid Therapeutics/Dr Falk Pharma/Nestlé Health Science)

etrolizumab (RG 7413; Roche)

Stelara (ustekinumab; Johnson & Johnson)

Xeljanz (tofacitinib; Pfizer)

upadacitinib (ABT 494; AbbVie)

filgotinib (GLPG 0634; Galapagos/Gilead Sciences)

ozanimod (RPC 1063; Celgene)

Kappaproct (cobitolimod; InDex Pharmaceuticals)

alicaforsen (Atlantic Healthcare/Ionis Pharmaceuticals)

KOLs interviewed

KOLs from North America

Dr. Edward V. Loftus, Jr., MD, is a Professor of Medicine in the division of Gastroenterology at Mayo Clinic College of Medicine, Rochester, MN

Dr. Hans Herfarth, MD, PhD, is a Professor of Medicine at University of North Carolina, Chapel Hill, NC

Dr. Ashwin Ananthakrishnan, MBBS, MPH, is an Assistant Professor of Medicine at Harvard Medical School and is medical co-director at the MGH

Crohn's and Colitis center

Dr. James Vecchio, MD, is a gastroenterologist in Burlington, Vermont and is affiliated with University of Vermont Health Network University of Vermont Medical Center

Dr. Joseph D Feuerstein, MD, is an Assistant Professor of Medicine at Harvard Medical School. He is affiliated with Harvard Medical Faculty Physicians (HMFP) at Beth Israel Deaconess Medical Center

Anonymous, US KOL, is a Professor of Medicine at a leading US university

KOLs from Europe

Dr. Ayesha Akbar, MBChB, MRCP, PhD, is a Consultant Gastroenterologist at St. Mark's Hospital and Academic Institute, London, UK

Dr. Sami Hoque, FRCP, FRCPE, PhD, FACG, is a Consultant Gastroenterologist and Honorary Senior Lecturer at Queen Mary's University of London, and Lead Physician for digestive disease and nutrition in Barts Health NHS trust, Whipps Cross University Hospital, London, UK

Dr. T. Paupard, MD, is a Consultant at Centre Hospitalier Dunkerque, Dunkerque, France, and Head of Department of Hepato-Gastroenterology

Dr. Silvio Danese, MD, PhD, is Head of the Inflammatory Bowel Disease Clinical and Research Unit at the Humanitas Research Hospital, Milan, Italy. He is also a Professor in Gastroenterology at Humanitas University, Milan, Italy

Dr. Sonia Romero Izquierdo, MD, is a gastroenterologist who works in a university hospital in Spain

Anonymous, German KOL, is a Professor at a leading German university hospital

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