Tofacitinib is a Viable Treatment for Ulcerative Colitis

Main Bullet Points:

- Currently in late-stage clinical trials for the treatment of ulcerative colitis, Tofacitinib was initially expected to gain FDA approval on August 21, 2012 for its use in treating rheumatoid arthritis.

- Analysts are predicting that annual sales of Tofacitinib could eventually exceed $2 billion.

- Ulcerative colitis is a devastating, chronic disease that causes inflammation and sores, called ulcers, in the inner lining of the large intestine, including the colon and the rectum.

- Ulcerative colitis affects roughly 700,000 Americans.

- Tofacitinib is an oral option for treatment of ulcerative colitis, which is easier for administration when compared to current comparable injectable treatments.

Tofacitinib is in the news as of late, causing quite a stir in the pharmaceutical arena. Pfizer’s prediction of an FDA approval for this blockbuster prospect to combat ulcerative colitis is upbeat and encouraging. Currently in late-stage clinical trials for the treatment of ulcerative colitis, Tofacitinib was initially expected to gain FDA approval on August 21, 2012 for its use in treating rheumatoid arthritis. Pfizer originally expected an FDA decision by Aug. 21, 2012. However, FDA Chief Executive Ian Read recently stated on August 16, 2012 that the agency may take longer to decide because Pfizer submitted additional information. This wait is not halting the current clinical trials involving Tofacitinib and ulcerative colitis, which is expected to be completed in 2015. Thus far studies are proving the efficacy of Tofacitinib, showing that at high doses, this oral treatment performed significantly better than a placebo in treating ulcerative colitis in a mid-stage study.

Analysts are predicting that annual sales of Tofacitinib could eventually exceed $2 billion. This oral administration option for current anti-inflammatory treatments, which are mainly injectable, such as Abbott Laboratories' Humira, paves the way for an easier and novel dosing method. Tofacitinib is a selective inhibitor of Janus kinase, also known as JAK, which are proteins in the body that play a role in certain auto-immune diseases.
These auto-immune diseases occur when the body's immune system attacks healthy cells, and lead to diseases such as rheumatoid arthritis, ulcerative colitis, psoriasis and Crohn's disease. With ulcerative colitis affecting roughly 700,000 Americans, this inflammatory-bowel disease is debilitating and life altering, causing patient's severe abdominal pain and diarrhea on a daily basis.

A Phase 2 study, funded by Pfizer, involved 194 adults with moderately-to-severely active colitis. Patients received varying doses of Tofacitinib or a placebo twice a day for eight weeks. The study was enabled to track the rates of clinical response, or improvements in patient’s symptoms, at the eight week mark. Roughly 42% of the placebo group patients had a clinical response, compared with rates of 32%, 48%, 61% and 78% for the four dose levels of Tofacitinib, which ranged in dosage amounts from 0.5 milligrams to 15 milligrams. These positive results were published online on August 16, 2012 in the New England Journal of Medicine. The chief of the division of gastroenterology at the University of California, San Diego School of Medicine and a study investigator, William J. Sandborn, relayed that the higher doses of Tofacitinib appeared effective. He said, “The magnitude of benefit is large enough that I think we can draw a conclusion the drug works in ulcerative colitis.” As aforementioned, late-stage trials of Tofacitinib are underway. In these Phase 3 studies of patients with ulcerative colitis, Pfizer plans to use higher doses of Tofacitinib than previously used in past studies. Adverse effects of Tofacitinib were limited and included infections, increases in cholesterol levels, and for some patients a depressed white-blood cell counts. In general, most adverse events were mild and no new safety signals have been reported, according to study authors.

Ulcerative colitis is a devastating, chronic disease that causes inflammation and sores, called ulcers, in the inner lining of the large intestine, including the colon and the rectum. As one of two main forms of chronic inflammatory disease of the gastrointestinal tract, also called inflammatory bowel disease, ulcerative colitis is painful and frustrating. The other form of inflammatory bowel disease is called Crohn’s disease. In patients suffering from ulcerative colitis, inflammation leads to the loss of the lining of the colon, causing bleeding, the production of pus, diarrhea, and abdominal discomfort for patients.
Ulcerative colitis typically develops in people between the ages of 15 and 30, although it can develop at any age. Men and women are affected equally, with some patients having a higher risk if they have a first-degree relative with an irritable bowel disease. In addition, people who are Caucasian or Jewish are also at a higher risk of developing ulcerative colitis. With this incurable and devastating disease affecting so many people worldwide, the need for treatment is critical, and hopes are now put on the timely approval of Tofacitinib.

YES Pharma is proud to be a leading supply source for Tofacitinib (CAS#: 540737-29-9) to several global pharmaceutical companies and academic research institutes, while recognizing that we play a significant part in promoting the struggle against various auto-immune diseases such as rheumatoid arthritis, ulcerative colitis, psoriasis and Crohn's disease. The Tofacitinib that YES Pharma supplies is intended for laboratory R&D use only.

References:
Fierce Biotech August 16, 2012
Nasdaq August 17, 2012 “Pfizer’s Tofacitinib Improves Colitis Symptoms in Mid-Stage Study”

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