Crohn’s Disease (Moderate to Severe) | Decision Base | US | 2015

Crohn’s disease (CD) is a chronic gastrointestinal inflammatory disorder affecting over 1 million people in the major markets in our study, with a sizable market opportunity. TNF-α inhibitors infliximab (Janssen/Merck/Mitsubishi Tanabe’s Remicade) and adalimumab (AbbVie/Eisai’s Humira) dominate the biologics market space; however, this market will be increasingly competitive, starting with the recent launch of a new agent, vedolizumab (Takeda’s Entyvio). Significant opportunity exists for emerging therapies to differentiate themselves by addressing important unmet needs such as increased benefit to induction of remission and maintenance of clinical remission (without corticosteroids), achieving mucosal healing, and/or providing a more-convenient delivery formulation (oral). Several compounds in new drug classes currently in clinical development show promise in some of these areas but will also need to demonstrate safety profiles comparable to or better than TNF-α inhibitors to experience significant uptake.

Questions Answered in This Report:

• Induction and maintenance of clinical remission are key goals in the treatment of moderate to severe CD. What are the primary and secondary clinical trial end points with which new therapies are evaluated? How do U.S. and European gastroenterologists weight specific efficacy end points and other drug attributes in their prescribing decisions for moderate to severe Crohn’s disease?

• Infliximab is the 2013 major-market sales leader for moderate to severe CD. What weaknesses exist in this drug’s profile that would allow emerging therapies to gain a foothold in the market? Have emerging therapies demonstrated potential on the attributes that surveyed gastroenterologists indicated are the most important in their prescribing decisions? Which emerging therapies will offer the clinical improvements over currently available therapies that surveyed MCO PDs seek from new therapies?

• Induction of clinical remission and mucosal healing are key drivers of physicians’ prescribing decisions and/or are the focus of drug development for new CD therapies. What trade-offs across these and other clinical attributes are U.S. gastroenterologists willing to make when considering the use of emerging therapies for the treatment of CD? Based on the trade-offs in price and performance across key drug attributes that U.S. gastroenterologists are willing to make, how do physician preference and prescribing likelihood vary across different target product profiles for CD?
By 2018, ustekinumab (Janssen’s Stelara) will emerge as the gold-standard therapy in our Drug Comparator Model because of its superior clinical profile over the key current therapies we evaluated. On what clinical attributes is ustekinumab most differentiated from its competitors? Which current therapies are at greatest risk of being replaced by ustekinumab?

Scope:
Attributes included in conjoint analysis-based assessment of target product profiles for moderate to severe CD:
- Effect on induction of clinical remission at four weeks: % of patients with a CDAI score ≤ 150 points (placebo-adjusted).
- Effect on maintenance of clinical remission at 54 weeks: % of patients with a CDAI score ≤ 150 points (placebo-adjusted).
- Effect on closure of all draining fistulas at 54 weeks: % of patients achieving fistula closure (placebo-adjusted).
- Effect on mucosal healing at 54 weeks: % of patients demonstrating mucosal healing on endoscopic examination (placebo-adjusted).
- Incidence of serious infections (e.g., tuberculosis, sepsis, pneumonia, abscess): % of patients reporting at least one serious infection at one year (not placebo-adjusted).
- Delivery burden (dosage formulation and dosing frequency).
- Price/day (CD maintenance setting).

Attributes included in assessment of U.S. payers’ receptivity to new therapies for moderate to severe CD:
- Effect on induction of remission.
- Effect on maintenance of remission.
- Risk of serious/opportunistic infections.
- Lower burden of delivery.

Physicians surveyed: 61 U.S. and 30 European gastroenterologists.
Payers surveyed: 20 U.S. MCO PDs.

Comprehensive List of Therapies Included in Our Research and Modeling:

Current Therapies
- Infliximab (Janssen/Merck/Mitsubishi Tanabe’s Remicade)
- Adalimumab (AbbVie/Eisai’s Humira)
- Certolizumab pegol (UCB’s Cimzia)
- Vedolizumab (Takeda’s Entyvio)
- Natlizumab (Biogen's Tysabri)
- Azathioprine (GlaxoSmithKline/Prometheus Laboratories/UCB's Imuran, Eisai's Imurek, generics)

**Emerging Therapies**
- Ustekinumab (Janssen's Stelara)
- Tofacitinib (Pfizer's Xeljanz)
- GED-0301 (Celgene)

**Report Details**
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