ASSESSMENT OF THE FUTURE IMPACT OF BIOSIMILARS AND GENERICS FOR ULCERATIVE COLITIS IN THE US & EUROPE

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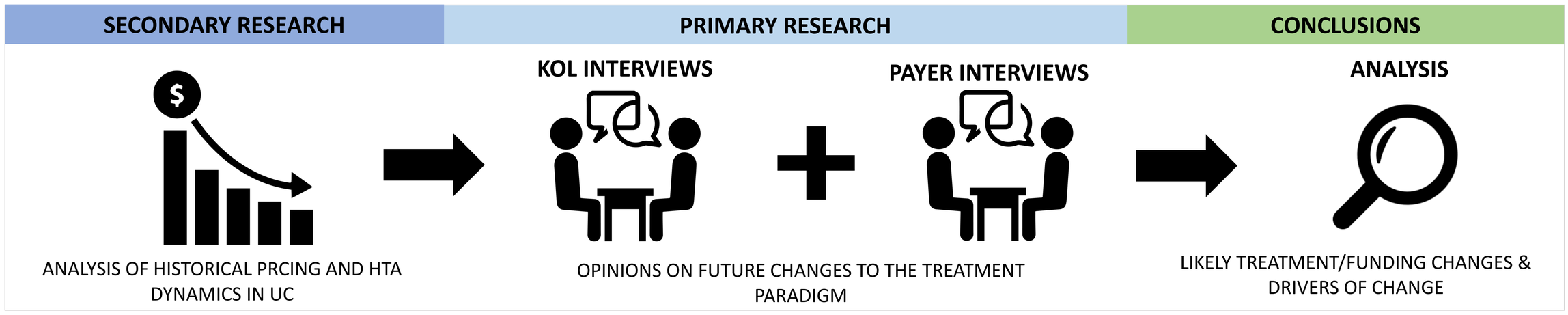
INTRODUCTION/OBJECTIVES

Ulcerative colitis (UC), is a chronic inflammatory bowel disease with a relapse-remitting course. First-line, or, 'conventional therapy' (CT) typically consists of corticosteroids and aminosalicylates, followed by biologics as second-line treatment (adalimumab, infliximab). Vedolizumab and tofacitinib (the first oral targeted therapy for UC) are typically reserved for third-line use. With the advent of biosimilars (adalimumab and infliximab), this has transformed the treatment paradigm, with lower costs increasing patient access to biologics, which is set to change further with the potential introduction of generic tofacitinib (estimated to be in 2027). Although the branded counter-part is restricted to third-line, the objectives of this research were to discover how generic tofacitinib may enter earlier lines of treatment due to expected reduced cost, and henceforth how the paradigm may shift, and what the impact on low-cost alternatives will have on prescribing, HTA outcomes (EU) and formulary placement (US)

METHODS



RESULTS

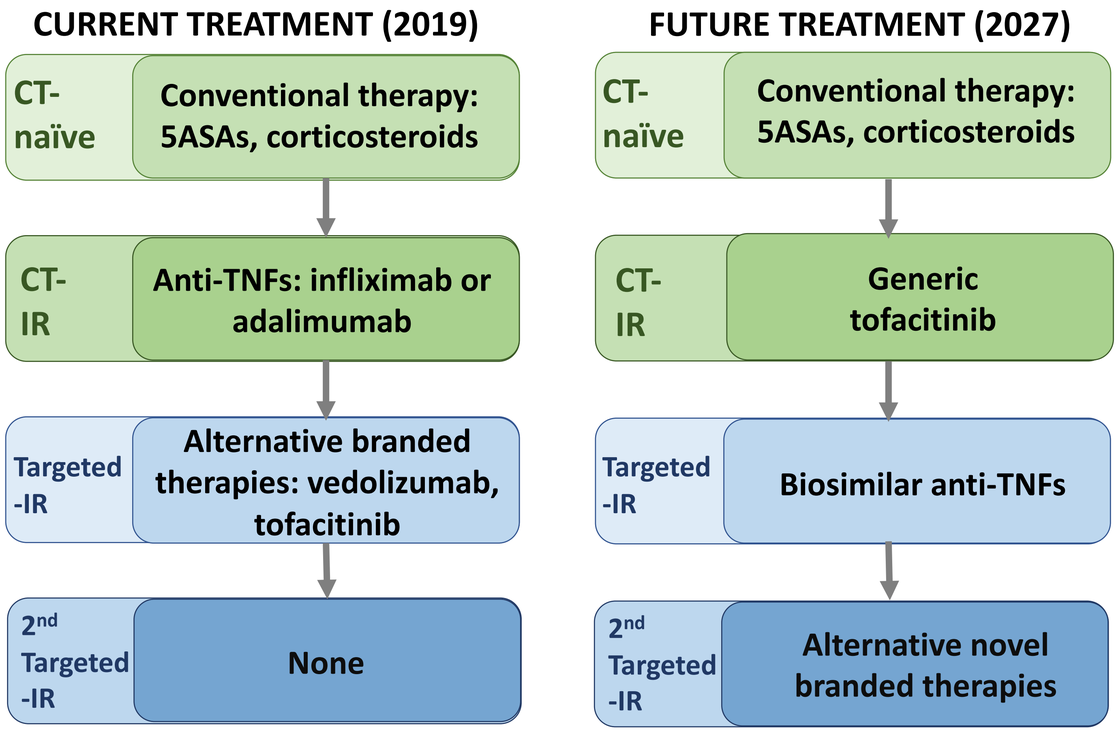


Figure 1 Changes to the UC treatment paradigm *Source: Access-Infinity (2019)*

Due to the wealth of expected treatments available in the future market, payers and clinicians alike had high efficacy expectations from a new treatment, stating that it would need to have a ~30% improvement in remission to SoC to consider earlier use than lower-cost alternatives. Due to safety concerns with tofacitinib, improved safety was also considered to be a key parameter which could be leveraged for earlier line use (Fig. 2).

Although mandates (from CCGs in the UK for use of biosimilars) and policies to encourage biosimilar use (PLFSS, or, 'pay for performance' in France), payers and clinicians did consider there is still an opportunity for access for a novel agent through individual funding requests (in the UK), through demonstration of significant efficacy and safety (particularly in France). Although contracting may be necessary for favorable formulary positioning in the US (Fig. 3)

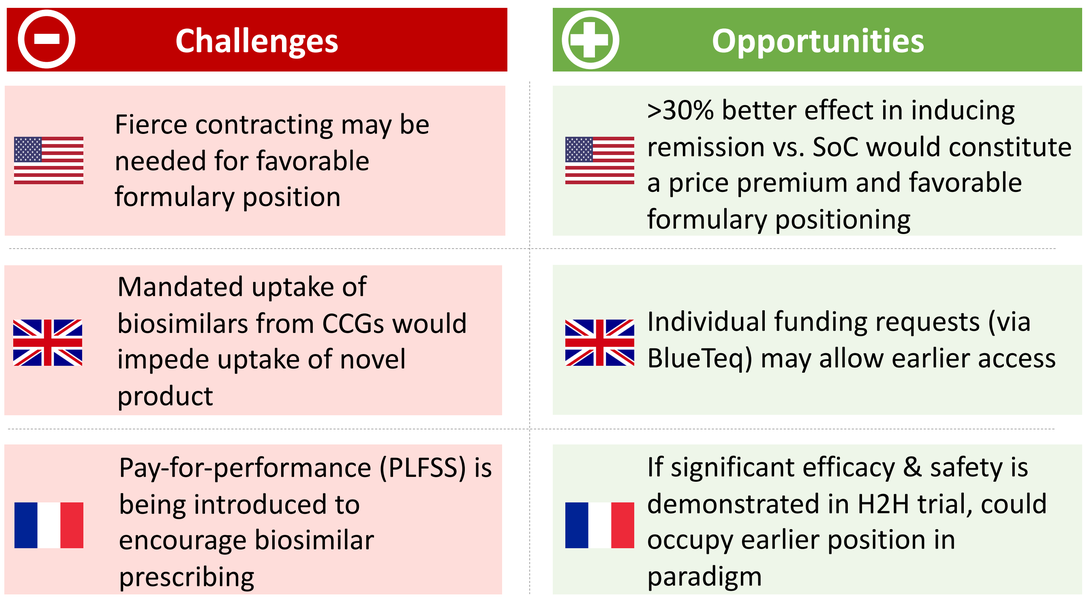


Figure 3 Key challenges and opportunities for drug innovation in UC *Source: Access-Infinity (2019)*

Currently, conventional treatments (corticosteroids) are the mainstay of first-line therapy. According to clinicians and payers, as they are inexpensive and clinicians having extensive experience using them, even upon the introduction of generic tofacitinib, these are likely to remain as a first-line therapy (Fig. 1).

Introduction of generic tofacitinib (expected to be in 2027) will likely supersede the placement of biosimilars in the treatment paradigm (Fig. 1). Which was largely driven by it being an oral treatment, which could provide significant cost-offsets due to mitigation of costly and inconvenient infusions and/or subcutaneous injections.

Payers considered this future ordering of treatment to be driven largely by net cost (Fig. 1 and 2), with future novel branded entrants being subjected to being the 'last resort' treatment for non-responders. These branded entrants will likely be subjected to predatory pricing, due to emerging biosimilars and generics which are expected to have a much lower net cost than branded counter-parts

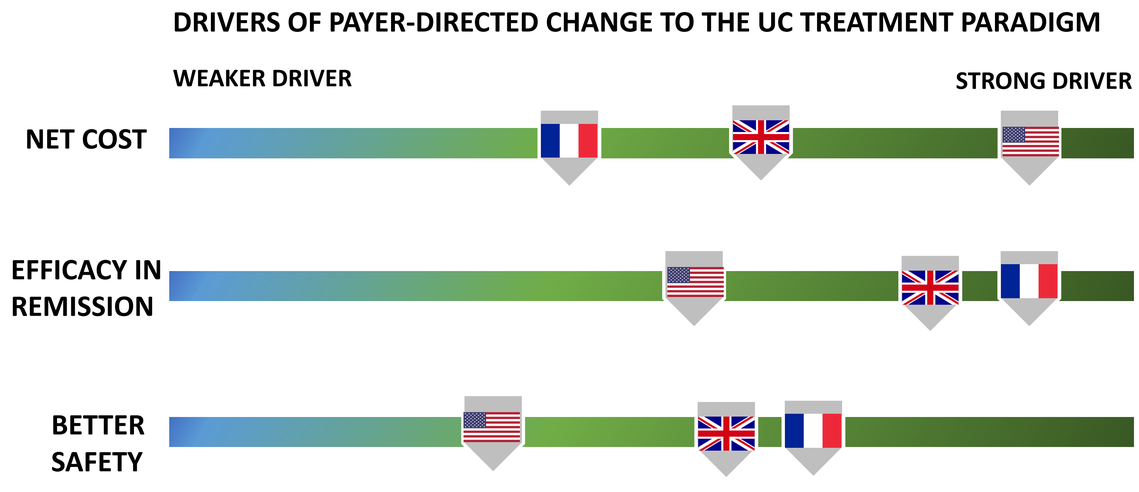


Figure 2 Drivers of payer-directed change to the UC treatment paradigm *Source: Access-Infinity (2019)*

CONCLUSIONS

The UC treatment paradigm will likely evolve in the next 10 years to domination by biosimilars and generic tofacitinib (providing net costs are significantly lower than originators). Although there are still opportunities for novel branded entrants, if they are able to demonstrate a significant improvement in remission vs. SoC (especially in France and the UK), and can contract there way to defend a favourable formulary position (US)

ACRONYMS

CT: conventional therapy; IR: inadequate response; SoC: standard of care; UC: ulcerative colitis; CCGs: clinical commissioning groups

REFERENCES

All insights from clinician (n=10) and payer (n=20) interviews in the US, UK and France

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