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Expected Pricing and Access Hurdles in the US for Novel Rheumatoid Arthritis Therapies





Background

- Rheumatoid arthritis (RA) is a chronic autoimmune, inflammatory disease in which patients develop adverse long-term outcomes such as physical and work disability, reduced quality of life, and increased mortality
- In the US, approximately 1.3 million adults suffer from RA, representing
 0.6% to 1% of the adult population¹
- Over the last few decades, RA has seen significant pharmaceutical innovation leading to a crowded brand market
- The simultaneous introduction of biologics and generics will alter the pricing and access dynamics for novel therapies entering the RA landscape

Objectives

The objective was to outline the pricing and access considerations for successful US market entry in rheumatoid arthritis

Methodology

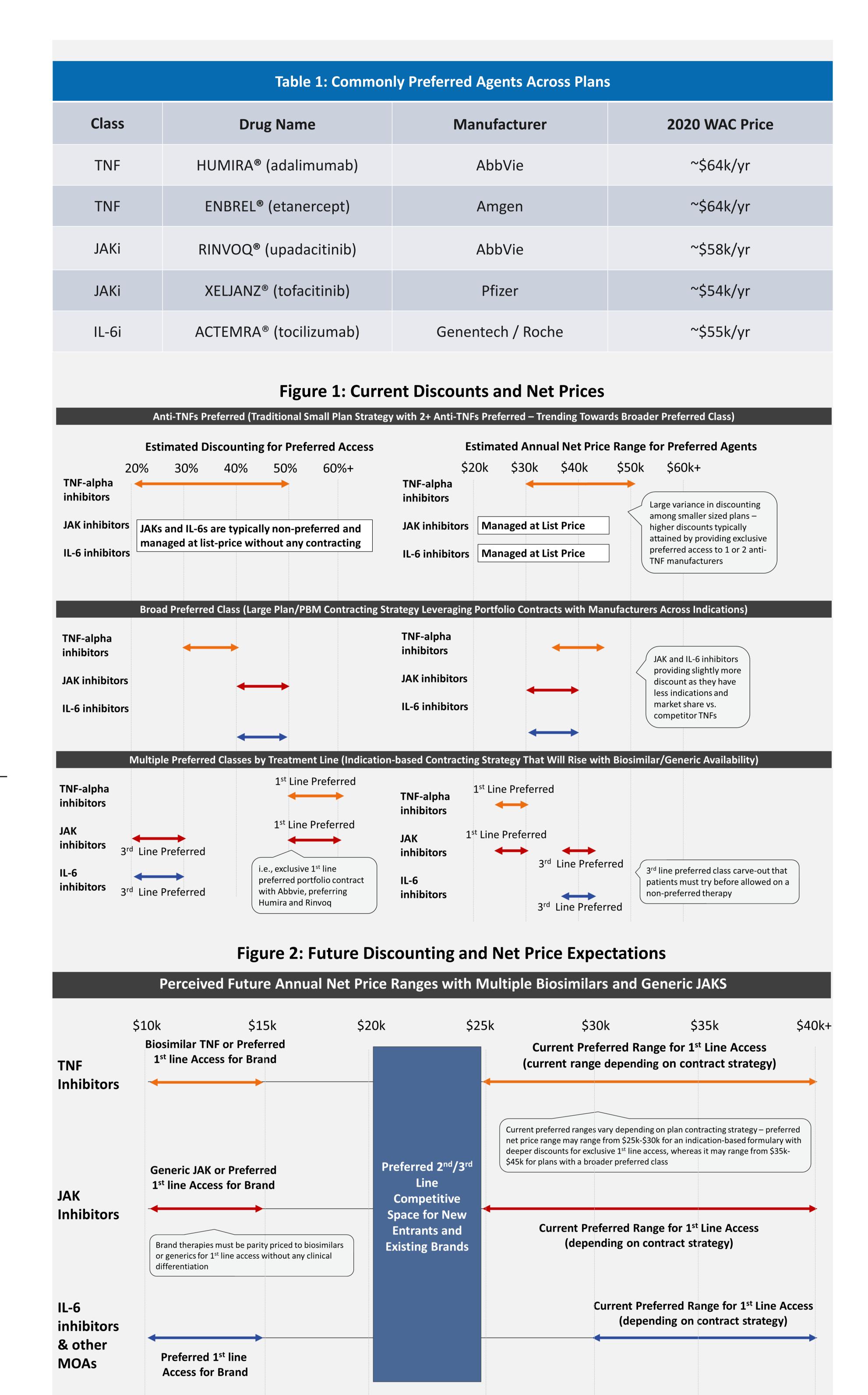
- Secondary research was conducted to assess the current RA landscape (HTA ratings, ICER evaluations of currently available therapies)
- The number of products in the pipeline and estimated time of launch were compiled to outline the expected environment over the next decade
- Hypothesis from these findings were developed and the assumptions were tested with in-market experts (plan representatives/executives)
- The respondents outlined the value drivers within the RA landscape including disease burden / unmet needs, current management, contracting and rebate strategies among various types of plans, and impact of generics / biosimilars while also defining the pricing and access expectations for future novel therapies

Findings

- Despite consensus on the existing unmet need in key subsegments
 (moderate-to-severe refractory RA patient population), respondents
 believe majority of access is driven by contracting and pricing strategy
- Currently, contracting strategies vary by size of plan, type of formulary design, and portfolio level discounts
 - Small to mid-sized plans focus on cost-containment to maximize on portfolio discounts/rebates and restrict access to several agents
 - Larger plans leverage the greater number of lives covered to capitalize on rebates by preferring 1 or 2 agents across multiple classes
- As biosimilars and generics enter the space, payers will re-evaluate portfolio contracts with potential net savings from lower cost options
 - Unless biosimilars can price at a minimum net 15%-20% discount to the current net price of preferred brands, payers will not be willing to break existing contracts and lose large discounts/rebates
 - Greater number of competitors will result in a compounding discount effect
 within the anti-TNF and JAK inhibitor class as subsequent launches compete
 for preferred access though this weakens portfolio contracts and unlocks
 the preferred access environment, most plans will likely gravitate towards a
 generic and/or biosimilar first policy as net prices fall across the board
 - With cheaply available generics and biosimilars, plan contracting style will shift towards an indication-based approach rather than portfolio approach across the autoimmune space, and will carve out a separate "preferred class" after failure to biosimilars and generics

References:

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Conclusion

In the current environment, small/mid-sized plan focus is on cost-containment to optimize the portfolio discounts and restrict access to multiple agents while larger plans leverage their covered lives to allow preferred access to multiple MOAs. In the future, biosimilars and generics will likely be the preferred 1st line agents across most plans, given the expected net price (~\$10k-\$15k). As a result, payers are expected to enforce 1 or 2 step-edits before allowing access to brand products, carving out a preferred 2nd or 3rd line for the latter. New entrants will be expected to provide significant discounts leading to biosimilar/generic-level net price for preferred access in small and mid sized plans, while access to larger plans will be based on initial share gains, due to hefty rebate requirements. Furthermore, novel therapies focusing on subsegments of population of greater unmet need will "force" managed care plans to provide access, while maintaining price premium over branded biologics.