Biomarkers for Emerging Biologics for Severe/Refractory Asthma

The use of biomarkers and personalized medicine is at a very early stage in asthma. Although most asthma patients can obtain disease control through treatment with available therapies, there remains a high unmet need for more-individualized therapies and therapeutic regimens that can be used in severe subpopulations of the heterogeneous asthma population. Although severe/refractory patients represent only a subset of the asthma population, novel agents that target this patient segment have the potential to command price premiums given these patients’ level of unmet need. As a result, a series of biologics targeted at specific subpopulations of asthma patients (e.g., IL-5 inhibitors for eosinophilic asthma patients, IL-13 inhibitors for severe asthma patients with elevated periostin or dipeptidyl peptidase-4 [DPP-4]). These targeted agents are being developed with the intention of using them in patients who express a particular biomarker. The development of targeted biologics represents the most active space in asthma research.

Questions Answered in This Report:

- The only currently approved targeted biologic in the asthma market is Roche/Novartis’s Xolair, which launched in 2003. What are the strengths and advantages of Xolair? What are the opinions of key opinion leaders regarding Xolair? To what extent does Xolair represent a barrier to new targeted biological therapies?

- The IL-5 inhibitors are likely to become the first new biologic drug class to launch in the asthma market in more than a decade. They are targeted at asthma patients with high levels of eosinophils. What do key opinion leaders think about the IL-5 inhibitors? What do they think about the need to test eosinophil levels before prescribing these agents? What do payers in the U.S. and the EU5 think about the IL-5 inhibitors and the proposed use of biomarkers to identify eligible patients?

- The IL-13 inhibitors are likely to join the IL-5 inhibitors for severe/refractory asthma within a few years. What do key opinion leaders think about the IL-13 inhibitors?

- Biomarker-driven therapies are a relatively new concept in the asthma market, and a number of new therapies are likely to launch for severe/refractory asthma in the next ten years. What steps do developers need to take to encourage uptake of their therapies? What reimbursement concerns exist for these therapies? What are physicians’ key concerns about these novel agents?
Scope:
Markets covered: United States, France, Germany, Italy, Spain, and United Kingdom.

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