Gastrointestinal Stromal Tumor | Niche and Rare Pharmacor | G7 | 2014

Gastrointestinal stromal tumors (GISTs) are rare cancers that belong to a group of cancers known as soft tissue sarcomas, which develop in supporting and connective tissues. GISTs account for approximately 20% of soft tissue sarcomas and are the most common mesenchymal tumors affecting the gastrointestinal tract. Treatment of GIST is largely dependent on tumor size, location, and growth rate, and is most commonly in the form of surgical resection and/or targeted therapies. Using primary research conducted with expert and European GIST specialists, including gastroenterologists and medical oncologists, this report provides a comprehensive analysis of the competitive landscape and market opportunities for GIST. This report includes a comprehensive analysis of patient populations, current therapies and medical practices, unmet needs, and emerging therapies. Of the targeted therapies used to treat GIST, imatinib (Novartis’s Gleevec/Glivec), the first targeted agent to gain regulatory approval in this indication, is the most commonly used agent. Sunitinib (Pfizer’s Sutent) is approved for patients who are resistant or intolerant to imatinib as a standard second-line therapy. Regorafenib (Bayer HealthCare’s Stivarga), rechallenge with imatinib, palliative treatment, or enrollment in clinical trials are considered as third-line options.

Questions Answered in This Report:

- The highest incidence of GIST occurs in people aged 50-80; however, the incidence of this disease is equally distributed across all geographic and ethnic groups, with both genders being equally affected. What is the number of diagnosed incident cases of GIST in the United States and EU5 (France, Germany, Italy, Spain, and the United Kingdom) and how will it change over the next ten years? How do we segment GIST into clinically and market-relevant drug-treatable populations? What are the sizes of these populations?

- The management and treatment of GIST patients can be highly complex given that tumor size, location, and growth rate dictate the involvement of certain medical experts and treatment options. What type of practitioner assumes care of GIST patients and does that differ depending on the stage of the disease and/or the geographical market? How are physicians managing treatment of GIST patients? Do they foresee any changes in medical practice over the next ten years?

- Imatinib is the standard of care in the first-line treatment of resectable and unresectable and/or metastatic GIST and is also prescribed in subsequent-line settings, thereby dominating the GIST treatment landscape. How is imatinib incorporated into the current treatment
algorithm of GIST and does this differ among the geographical markets under study? Will this algorithm change during our ten-year forecast period (2013-2023)? What therapies in clinical development, if any, pose a threat to imatinib's current positioning and market share?

- We have identified several unmet needs, challenges, and opportunities in the GIST landscape. What are the key unmet needs in the treatment of GIST according to interviewed thought leaders? Is it likely that these unmet needs will be addressed or partially addressed during our forecast period? What opportunities and challenges will remain?

- Only one therapy is in late-phase clinical development for GIST; however, a number of therapies are in early-phase clinical development. What do experts interviewed think about the prospects of these emerging therapies, especially in light of recent late-phase clinical trial failures for GIST? Which agents, if any, do we forecast will launch for treatment of this indication and how, if at all, will this impact the GIST landscape?

**Scope:**

Market covered: United States, France, Germany, Italy, Spain, and the United Kingdom.

Primary research: Eight country-specific interviews with thought leaders (gastroenterologists and medical oncologists).

Epidemiology: Diagnosed incident cases of GIST by stage of disease. Clinical- and market-relevant drug-treatable populations.

Emerging Therapies: Phase I: 4, Phase II: 10; Phase III: 1.

**Report Details**

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