

## **Clinical Expert Summary Regorafenib (Stivarga<sup>®</sup>▼) 40 mg film-coated tablets**

Regorafenib (Stivarga<sup>®</sup>▼) for the treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumours (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib.

### **1. Existing guidelines**

Clinical experts highlighted the European Society for Medical Oncology (ESMO) clinical practice guidelines, the All Wales Guidelines and the North Wales Cancer Network Formulary.

### **2. Disease prevalence/incidence**

It was estimated that there are 1–2 patients per year with GIST in South East Wales and 5–10 patients per year in North Wales; however it was highlighted that not all cases will be appropriate for third-line therapy due to frailty or rapid progression.

### **3. Current treatment options**

Experts highlighted that there are no standard options available to these patients and the predominant treatment is currently best supportive care/palliative care. They added that continuation of imatinib/sunitinib occurs in some cases; one expert stated that some clinicians may consider high dose imatinib (particularly in patients with KIT exon 9 mutated GIST) or retriial of imatinib but was aware that evidence for efficacy of regorafenib (prolongation of progression-free survival) from the GRID study now exists.

One expert stated that their preferred treatment option would be regorafenib or a clinical trial, and imatinib 800 mg for patients with KIT exon 9 mutations. Another expert stated that they prefer palliative care plus continuation of imatinib/sunitinib in some cases.

### **4. Unmet needs**

It was highlighted that there is currently no effective treatment following disease progression on imatinib and sunitinib, although this small group of patients can be clinically well, with a good quality of life. If treatment is stopped the disease generally progresses quickly and treatment options are extremely limited. Doctors may therefore continue imatinib or sunitinib even in the face of disease progression. One expert added that very rare wild type GIST patients are often poorly responsive to imatinib and that the option of regorafenib is important for this group.

### **5. Knowledge of product in given indication**

Experts stated that regorafenib would be used as licensed in a third-line setting, after progression on imatinib and sunitinib, until evidence of progression or intolerance in patients fit enough to consider treatment.