

New developments

Innovative drug for colorectal cancer now available in France

Rhône-Poulenc Rorer Inc. (NYSE: RPR) has announced that Campto® (irinotecan/CPT-11), the first new therapeutic innovation to be marketed for the treatment of colorectal cancer in nearly 40 years, is now available in France. France is the first country in the world outside Japan to make this drug available to patients.

Campto was developed and brought to market in France in near record time by RPR. The license application was submitted to regulatory authorities in December 1994, received approval only 5 months later in May 1995, and, just 4 months later, is being made available in France for the treatment of advanced colorectal cancer which has failed standard chemotherapy with 5-fluorouracil (5-FU) and folinic acid. A large French clinical trial showed Campto has significant anti-tumor activity in these difficult to treat patients.

'Campto has demonstrated significant activity in advanced colorectal cancer and, more importantly, there appears to be no cross-resistance between Campto and 5-FU', said Dr Philippe Rougier, a principal clinical investigator at the Institute Gustave Roussy in Villejuif, France, one of Europe's leading cancer centers.

Colorectal cancer is the second most prevalent cancer in the Western world. More than 140 000 people are diagnosed with it each year in Europe (26 000 in France). While about 50% of patients are cured by surgery, the other half become metastatic and require treatment with an anti-cancer drug. For 40 years, 5-FU has been the only effective agent in the treatment of advanced colorectal cancer with about 10–25% of patients experiencing a clinical response. In most cases, however, the disease progresses despite treatment with 5-FU.

'We've been waiting many years for an agent to use in the treatment of colorectal cancer apart from 5-FU', said Professor Herbert Pinedo, head of the Department of Medical Oncology at the Free University Hospital in Amsterdam. 'Campto is certainly an advance in the treatment of colorectal cancer and we are excited to continue our studies of the drug to determine its role either alone or in combination with 5-FU or with other promising agents in development'.

In a pivotal phase II clinical trial completed last year, 20% of the patients enrolled in the study experienced a clinically significant response to treatment with Campto. Of the 156 evaluable patients with advanced colorectal cancer given Campto as a 350 mg/m² i.v. infusion every 3 weeks (one treatment cycle), four experienced a complete response (a total disappearance of all measurable signs of cancer) and 28 had a partial response (at least a 50% reduction in measurable tumors). The median duration of response was 9.1 months (range 1.6–17) and more than one-third of patients were free from progression for 6 months.

'Achieving a significant reduction in the tumor mass for an average period of up to 9 months in the responder group is something new and has not been seen with other drugs', said Dr Eric Van Cutsem, Associate Professor of Medicine at the University Hospital Gasthuisberg and a Campto clinical investigator in Leuven, Belgium.

In the body, Campto acts as a potent inhibitor of topoisomerase I, an enzyme essential for cell division. Inhibition of this enzyme's activity kills cancer cells. As is often seen with cancer chemotherapy agents, side effects have been observed during clinical trials, such as neutropenia (a decrease in white blood cells) and moderate to severe diarrhea. These effects have been controlled through concomitant medications such as loperamide and antibiotics.

Licensed by RPR from Yakult Honsha Co. Ltd in Japan, Campto is being developed throughout Europe by RPR. An additional clinical trial in patients who failed to respond while on 5-FU treatment has been completed in Belgium, the UK, the Netherlands, Germany, Switzerland, Austria and Greece. Advanced clinical trials have begun or are being planned in most European countries.

'We are committed to aggressively supporting and conducting clinical trials so people in other European countries suffering with colorectal cancer can benefit from Campto as quickly as possible', said Manfred Karobath, President of RPR's research and development.