

HOPE FOR KIDNEY CANCER TREATMENT

Sutent, a new kidney cancer drug, was given early approval by the EMEA in January 2006. Pfizer's Dr Charles Baum tells James Drury that this rapid development was the result of a good collaborative relationship and strong trial results.



Profile

Charles Baum is vice president of Pfizer Global research and development and is oncology clinical leader. The R&D group has over 200 cancer studies underway, examining potential new treatments across a broad range of tumour types. Pfizer's scientists are working to reach a deeper understanding of cancer at the molecular level, designing and developing new medicines to influence these molecular defects.

P Pfizer has received early, conditional marketing authorisation from the European Medicines Agency (EMA) for Sutent, a treatment for advanced and/or metastatic renal cell carcinoma (mRCC), a type of advanced kidney cancer. This is a major advance for patients, who for the last 20 years have had no other options after the failure of the interferon alfa and interleukin-2 therapies.

JD: Why were you able to get an early approval?

CB: We carried out two phase 2 studies: one was done in the initial study of 63 patients, the other in 106 patients. The second study confirmed what we saw in the first; there was a very high objective response rate. Many patients had shrinkage of the tumour – more than had been seen previously. Almost half saw a significant decrease according to radiological measurements. That was a lot better than what had been seen over 20 years through experimental treatment and standard chemotherapeutics.

There's a long history of people trying different treatments and none of them had very good results. It was striking that with Sutent we were able to see this kind of response and see it in two separate studies. It was this information, along with the increased duration of patient response, that was significant in the EMA's decision.

We had been in discussions with the EU along the way. We had meetings with the oncological advisory group to discuss how this would be handled, and we had a good collaborative relationship with the EMA.

JD: Was there much concern about the decision for early approval?

CB: Agencies worldwide are concerned about the issue, so they are asking for as much information as possible. We performed these studies in a very rigorous way and there was a strong support from European investigators, who treated patients with the drug and spoke directly with the agency.

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We started first-line renal cell study long before we finished the approval process for the second line, so we had initial preliminary results that we could share with the oncology advisory group at the EMA. I think that helped them to realise the data looked promising and there was a low risk that the data would be changed or first line indications would not be positive. There was a lot of care taken on both sides – it's not good for anyone if a drug is approved too early.

JD: The studies have shown interesting additional indications outside renal cell. What have you learned?

CB: We hope the drug will also get approval for first-line patients, as it performed well against Interferon in phase 3 trials with first-line patients. Sutent shows significant improvements for first- and second-line patients in terms of response rate. As reported at ASCO, there was about a four-fold difference in response rate and two-fold progression-free survival.

Now we are starting to look at additional indications for outside renal cell. We have seen some encouraging data at ASCO in patients with lung cancer and last year with breast cancer. So we're further investigating those indications as well as others to see if we can provide similar kind of benefits to those patients.

JD: Have the studies been significant in furthering the understanding of cancer?

CB: The drug is a breakthrough for patients with mRCC, as well as for scientists. It's been a really interesting area because RCC has been so difficult to treat for 20 years and now we are seeing a very strong response with some of the targeted agents, especially Sutent. As we learn more about cancer, it shows how cells work and how cancer occurs. We can apply that scientific knowledge to our research and come up with better treatments. **END**