

## DATELINE

## STRATEGIC PLANNING

## ROCHE MAKING UP FOR PAST IL-2 MISSTEPS

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REASONS

**Roche's interleukin-2 molecule now in clinical trials.**

NEW YORK—Although Hoffmann-La Roche (Basel, Switzerland) has been roundly criticized for its slow progress in getting interleukin-2 (IL-2) through clinical trials (*Bio/Technology* 8:396, May '90), the company is now making up for lost time. A new joint development and marketing agreement recently announced with Cetus (Emeryville, CA), its main IL-2 competitor, reaffirms Roche's commitment to bringing IL-2 to the market as a cancer therapeutic and also demonstrates the importance to the company of pursuing combination therapies of IL-2 and its already approved  $\alpha$ -interferon. As well, it reflects Roche's broader strategy for commercializing biotech products.

Under the Roche/Cetus deal, which covers most of the European Economic Community (EEC), each company will, in effect, "rent" its sales force to the other. Roche will sell Cetus' version of IL-2, Proleukin (with the recent announcement of pricing approval in Spain, it currently is available for sale in seven EC countries), and Cetus will sell Roche's Roferon  $\alpha$ -interferon. Commissions will be paid based on total sales of each product by both companies in the EEC, and sales territories will be divided between the companies under a formal, but as-yet undetermined, scheme. According to Cetus' president Robert Fildes, "Our sales force is focused on the hospitals, while Roche

will hit the large, peripheral centers, too."

Roche will thus be able to establish a marketing presence in the EEC even before its own IL-2 receives marketing approval. And for Cetus, using Roche to help sell Proleukin and also being able to sell  $\alpha$ -interferon will accelerate its penetration of the EEC market, where it has been building a sales force (now numbering 36) through its EuroCetus subsidiary. Steve Duzan, president of Immunex (Seattle, WA), which has cross-licensed patent rights to IL-2 with the Roche/Cetus duo and will earn royalties on their IL-2 sales, believes the deal "suggests a more rapid ramp-up in Europe for IL-2," and "establishes an immediate linkage between IL-2 and  $\alpha$ -interferon." It will also, he adds, hasten the physician education process about the benefits of combination therapy. As part of the agreement with Cetus, Roche also will fund clinical trials using IL-2 and  $\alpha$ -interferon in combination.

The dosing strategy used by Roche in its IL-2 clinical trials has been less aggressive than that pursued by Cetus. Says Roche's Paul Ostreicher, assistant director for public policy and communications at its Nutley, NJ offices, "We took a different track than Cetus. From the start, we were interested in IL-2 as an agent to be used by the wider population outside of an intensive care setting. We have been exploring out-patient protocols including subcutaneous dosing and self-administration, as well as other applications...And our real focus has been combination therapy." Its U.S. Phase II-III trials may take another year to complete.

Fildes, while acknowledging that Roche's goals may have been different, thinks its clinical trial design wasn't as useful. "There's a strong correlation in cancer between dose levels and response. The limiting factor is risk—the side effects (such as itching and headache) subside, unlike in chemotherapy. And the mortality associated with using IL-2 is only two percent—much lower than with chemotherapeutics now on the market." Adds Denise Gilbert of Montgomery

Securities (San Francisco, CA), "Cancer is a tough area: not picking the right patient population and protocols can slow you down."

Yet their different strategies may only fairly reflect the differences between the goals of a large pharmaceutical firm with many long-term research projects and steady present cash flow from existing products and a small biotech firm with just a few products in development—and a more immediate need to demonstrate a pay-off from its internal research. According to pharmaceutical analyst Patricia Padgett Lea of Vector Securities (Northbrook, IL) "Roche has been putting into place for some time a long-term strategy of being the number-one biotech company...It's what has driven their agreements and acquisitions." (For a list of Roche's U.S. biotech partners, see *Bio/Technology* 8:178, Mar. '90). Also, observes Gilbert, who follows some pharmaceutical as well as biotech companies, "Roche has a philosophy of getting to the market first." So when it became clear that Cetus had a commanding lead in developing IL-2, Roche was able to step in—albeit late—to get a piece of the market.

While Fildes notes that "From Roche's point of view, we're part of their grand strategy in biopharmaceuticals," anything Roche does in biotech these days must be viewed against the backdrop of its recent acquisition of a majority interest in Genentech (South San Francisco, CA). Having access to Genentech's scale-up, regulatory, and manufacturing expertise—as well as its product pipeline and U.S. sales force—may go a long way toward helping Roche redress past miscalculations in commercializing biotech products. Says Gilbert, "Roche's  $\alpha$ -interferon may be a perfect product for Genentech to sell in the U.S. And Roche could see substantial revenues in Europe through selling Genentech's products." Would Genentech eventually sell Roche's IL-2 in the U.S. to compete with Cetus? "Genentech would be more formidable than Roche," Gilbert believes.

—Mark Ratner