Roche Abandons HIV Research

July 10, 2008 By Peter Staley

Hoffmann-La Roche, a pharmaceutical company with a checkered history in AIDS drug development, has recently announced that they are ending their efforts against HIV/AIDS. Some activists have pointed to news like this in the past to warn that big pharma is about to abandon AIDS research in droves, because AIDS activists have given them too much grief, or forced them to give their drugs away in Africa, or that there's just not enough money in it for them anymore. Wrong, wrong, wrong.

HIV/AIDS always has been, and sadly, probably always will be, a profitable business. Pharma isn't going anywhere. Individual companies have come and gone, but that's true with any disease area. Over time, the overall pool of companies working in AIDS has actually increased, however slowly. In the late 80's, it was 2 to 3 companies, then 5 to 7 in the 90's, and now it averages around 10.

As long as overall antiretroviral sales average over $10 billion a year, industry isn't going to walk away. And with HIV infections continuing to rise, this is sadly a growth industry.

But back to Roche. They've always been one of the weakest links in the chain. They were the third company to bring an antiviral to market, with a me-too drug called ddC (Hivid, 1992), which followed AZT (Retrovir, 1987) and ddI (Videx, 1989). It paled in comparison, and eventually become the first AIDS drug pulled from the market due to lack of sales.

Then came the first protease inhibitor, saquinavir (starting as Invirase, then reformulated as Fortovase, then back to an easier-to-take boosted Invirase - at least they kept trying!), which quickly got out-marketed by stronger and easier-to-take PIs.

When they finally brought a useful AIDS drug to market, it wasn't even theirs! Fuzeon, the first entry inhibitor, became a crucial salvage therapy over the last five years, offering thousands of people with AIDS their last hope after becoming resistant to first- and second-line therapies. But another company, a small biotech called Trimeris, discovered it. They partnered with Roche to help them market it. Even still, the drug is now faltering as easier-to-take salvage therapies have hit the market.

Roche fumbled the development and marketing of all three of these drugs, working poorly with and infuriating AIDS activists along the way. I was one of hundreds of activists from ACT UP and TAG that completely blocked over a dozen entrances to their Nutley, NJ headquarters in February, 1993, protesting Roche's refusal to offer ddC on expanded access. Then they tried to abuse the

accelerated approval process with saquinavir, causing a huge policy schism among AIDS activists over AIDS drug development and the FDA drug approval process.

Finally, they infuriated activists by pricing Fuzeon at close to $25,000 for a year's supply, the highest price ever charged for an anti-HIV drug. There were many demonstrations, but the company never budged on the price. We all cheered when Tibotec (Prezista, approved in 2006) and Merck (Isentress, approved in 2007) actually listened to AIDS activists and priced their salvage therapies at levels more typical of other HIV drugs on the market.

Roche got one big thing right. They have been a leader in drug development for hepatitis C, especially for those coinfected with HIV. Since almost a third of people living with HIV in the U.S. are coinfected with HCV, Roche's commitment in this area has been of huge benefit to our community.

For the record, here's Roche's letter to AIDS activists announcing their decision:

> In response to your request, we are writing to provide further clarity on Roche's presence in the HIV field. Please share this information with other community members as you deem appropriate.
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> As you know, Roche has a long-standing heritage of innovation in HIV since we initiated our protease inhibitor discovery project more than twenty years ago. Our work has resulted in major contributions in this field, among them the development of PCR diagnostic and viral load technology, the introduction of the first protease inhibitor, and the introduction of the first fusion inhibitor to patients in 2003 - despite the considerable technical challenges we faced in producing this very complex molecule on a large scale.
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> For several years, we have been investigating compounds targeting the CCR5 entry pathway and the reverse transcriptase enzyme. All these compounds were in pre-clinical studies, and therefore at least six years away from availability to patients. While we had initially been hopeful about their potential, we now have concluded that none would provide a true incremental benefit for patients compared to medicines currently on the market - and therefore do not warrant further development. We had hoped to provide you with this information in an in-person meeting.
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> Assessing this setback in the context of our overall Virology Disease Area, we have decided to refocus our resources within Virology on diseases in which we can deliver substantial

improvements over existing medicines. However, when we identify a significant scientific breakthrough in HIV externally, we would certainly assess our ability to make a further contribution to the field, as we did with Fuzeon.

Developing new treatments for viral diseases continues to be a priority.

In particular, we have a promising pipeline of new drugs for the treatment of hepatitis C, which is one of the most significant causes of mortality among patients living with HIV. Furthermore, our scientists are currently examining a range of other viral diseases to determine those which offer the potential for us to make a difference.

Roche will, of course, continue to support our medicines that are currently available for the treatment and monitoring of HIV-related disease, including Fuzeon, Invirase and Viracept, as well as our molecular diagnostic tests. In addition, we remain committed to increasing the access to our HIV medicines for people living with HIV in resource-limited countries with programmes such as our preferential patent and pricing policy and the AIDS Technology Transfer Initiative.

If you would like additional information on the discontinued HIV programmes, we would be happy to engage in further dialogue with you.

Sincerely

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