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GlaxoSmithKline takes another big swing at cancer drug R&D

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Contrary to a common misperception in the industry, GlaxoSmithKline ($GSK) still has big plans in the burgeoning field of cancer drug R&D. And one of the pharma giant's top cancer drug R&D execs says Glaxo is ready to strike new deals to beef up the pipeline as it considers rebuilding a late-stage research effort and new commercial operations to support marketing the most successful drugs to come out of it.

GSK's Axel Hoos

Glaxo's big asset flip with Novartis ($NVS) spun out its late-stage cancer programs, a portfolio of drugs and hundreds of workers concentrated around tumor signaling. And now that the swap is completed, exchanging cancer drugs for a vaccine portfolio, the pharma giant's cancer drug discovery division has refocused, according to Axel Hoos, who runs the immuno-oncology group.

Just last month, says Hoos, the cancer division completed the big internal review it does for all its drug development teams every three years. GSK's remaining 185 cancer R&D staffers has regrouped around two key fields--next-gen immuno-oncology work and cancer epigenetics, extinguishing the last of the early-stage tumor signaling work. The cancer team is dedicating itself to hitting one or more new oncology drugs out of the proverbial ballpark, looking for some clear evidence that it can mount a transformational advance in oncology as it ponders rebuilding a late-stage pipeline effort and a whole new commercial effort to support it.

"I have no interest in developing a marginal drug," says Hoos, a veteran developer who headed up the development effort for Bristol-Myers Squibb's ($BMY) Yervoy (the pioneering CTL-4 immuno-oncology drug ipilimumab).

In the process, Hoos says, you can expect more collaborations and acquisitions that fit this focus, with recruiting to continue in key areas of expertise where the company feels it's shorthanded.

"The aim is to create transformational medicines, with bigger effects for mono-therapies or combinations," says Hoos, who participated in a *FierceBiotech* panel discussion on cancer drug R&D at BIO's annual conference in Philadelphia. "In the next 2 to 3 years we will know if we have a transformational drug, and then we can decide to rebuild a late-stage development organization, if we have a blockbuster and want to progress quickly. The same is true for commercialization; we will rebuild if we have a reason to rebuild."

Transformational drug development has been the goal at GSK for years, but it's proven easier to ask for than it has been to deliver. The rap at Glaxo is that they've had some modest successes in cancer

and respiratory ailments, but never connected on their big home run swings in R&D. Revenue suffered and the inevitable retrenching followed. With a big commitment to a few major fields--respiratory, HIV and vaccines, now the domain of former R&D chief Moncef Slaoui--the company has been tagged as an industry laggard among the top 10, with little that's exciting to show analysts or investors.

For the cancer R&D division, which is primarily concentrated in Glaxo's facilities in the Philadelphia area with cell and gene work being done at Stevenage in the U.K., any new drugs that don't measure up to a potential breakthrough are going to be handed off to Novartis, which has a first-right-of-refusal, or some other company looking for cancer drug assets.

Cancer epigenetics is the older of the two groups, adds Hoos, dating back some 6 years, when Glaxo was rolling out its biotech-like DPU model in R&D. There are now 4 drugs in the clinic, says Hoos, "and the pipeline is the industry's leading pipeline. There is no other company with the same level of epigenetics pipeline as GSK."

Those programs, led by Chris Carpenter, include one for BET, which is still in early stage development.

The immuno-oncology effort is much younger, says Hoos. It started in February of 2013. The plan now is to catch a next-gen wave and ride it into a significant niche.

The first generation in immuno-oncology was really Yervoy and Dendreon's Provenge, says Hoos. And while the biotech's drug ultimately proved a commercial flop, it was a major scientific advance that helped open the door for the whole field.

The second generation, he says, are the PD1 and PDL1 drugs like Keytruda and others that are now shaking up the way cancer is treated, with broad applicability to a wide variety of cancers. But that wave is already delivering products, with more close behind, making it a more mature field than Glaxo wants to be in as it takes a second crack at success.

Where Hoos as his team are focused is on generation three: "Generation two could be a backbone," says the researcher, "but that doesn't mean that generation three can't be big. We are focused on building a program that nobody else has."

There's an OX40 program, one of only a handful in the industry, as well as small molecule drugs that can influence the tumor microenvironment--a shot at amping up the efficacy of T cells in tumors. There's also a next gen program that Hoos says goes beyond IDO, "but I'm not telling you what they are yet." Add in new work on bispecific molecules and the company's cell and gene therapy programs, exemplified by the deal it did last year with fast-growing Adaptimmune in the U.K., and you have the broad outlines of what Hoos is in charge of.

Time is a luxury GSK can't afford right now.

Says Hoos: "We want to move this fast."

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