IN brief

Awards bridge 'valley of death'

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A cash boost for advancing cancer therapies

The National Cancer Institute (NCI) has named the first recipients of a new award designed to help companies developing promising cancer therapies and technologies overcome the so-called 'valley of death'. The Phase II Bridge Awards are intended for

small businesses that might need extra support to plug the gap between early-stage funding—typically provided by National Institutes of Health grants—and the later stages when financing depends on capital supplied by investors. "Looking at our portfolio of companies over the last few years, [we realized that our funding] was not enough to advance promising drugs and devices to key technical and commercial milestones where they could then raise funding from private investors," explains Michael Weingarten, Director of NCI's Small Business Innovation Research (SBIR) program. The new Bridge Award provides companies with up to \$3 million additional nondilutive funding over three years—tripling the money available to applicants through the SBIR program. To qualify, companies must already have received a Phase II SBIR Award and, crucially, raise matching funds from third-party investors and/or strategic partners. "The mechanism is turning out as we hoped it would," says Weingarten. "We are hearing from companies that the promise of potentially getting NCI funds is really helping close deals and raise private financing." Moreover, Simcha Jong, university lecturer in management science and innovation at University College London, points out that the new grants will help avoid some of the ownership dilution that comes with sole reliance on equity investments from venture capitalists and other private investors. "This new grant program is excellent news for managers of SBIR companies," he says. The first two companies to receive the Phase II Bridge Awards are lipodomics firm Lpath Therapeutics, of San Diego, and OptoSonics, in Oriental, North Carolina, a company developing molecular imaging instrumentation. LPath founder and CSO Roger Sabbadini, says the prospect of getting the bridge grant was "absolutely critical" in helping the company raise funding and establish its partnership with Merck Serono, of Geneva. Without this grant, LPath would have had to raise money through institutional venture capitalists, which is difficult at this time, he says. Lpath plans to advance its lead candidate ASONEP, a potentially first-in-class antibody therapeutic that inhibits sphingosine-1-phosphate, through phase 1 and 2a studies

Emma Dorey

1984, lets small-molecule generics achieve US Food and Drug Administration (FDA) approval on bioequivalence studies and gives branded products up to five years of market-exclusivity on top of the 20 granted at the issuance of a patent.

No doubt, Hatch-Waxman juiced price competition. A decade after its passage, consumers in the US were saving at least \$8 billion by using generics, according to estimates from the Congressional Budget Office. But the bill also put the squeeze on drug companies (and thus on public health), which need to recoup more than \$1 billion in development costs spent during an average 12 years of work. They must do it fast because patents typically are sought before the drug reaches the market and the 20-year clock starts ticking. What's more, the protection shield isn't guaranteed because the molecules are so intricate that competitors can find patent loopholes.

It all means that some promising candidates may reach a point in development, which Hollingshead calls the "no man's land," where the chance for profit dissolves. At this point, it's more practical for the company simply to drop them. The situation has led developers to focus more on blockbuster compounds to the neglect of others that are just as important but for smaller patient populations—another drawback for public health.

The biotech industry has "made great strides and remarkable discoveries, but the science is really only about 25 years old," he says, noting that pharmaceutical science was more than a century old when Hatch-Waxman was enacted. Early-stage research especially is more dependent on venture capital, Hollingshead says. "If you reduce returns 10 or 15% [by reducing data exclusivity], the big successful players will find a way to cope," he says. As venture capitalists shift funding patterns to cope with a lower return and move to lower-risk bets, many important molecules may never be developed, he warns.

Neither pharma nor biotech has proved eager to trumpet opinions on the data-exclusivity issue, lying low while BIO's lobbyists do their job. Their arguments are easy enough to guess, as are the sharply contrasting

positions of generic and drug-development firms. But one major player speaking out is Petach Tikva-based Teva Pharmaceutical Industries, which makes generics as well as novel drugs. According to Debra Barrett, vice president of government affairs, "To say, 'we really need a lot of innovation, so we're going to give 14 years of exclusivity' doesn't make sense," she says, pointing to Thousand Oaks, California-based Amgen's blockbuster anemia drug Epogen (epoetin alfa). First approved in 1989, Epogen has maintained a monopoly in the market for Amgen, which has subsequently created Aranesp (darbepoetin alfa)—only a "slight improvement" on Epogen. Barrett asks, "Why would you spend the time and money to go find a new molecule if you've got a franchise that's working just great?"

Teva "started at the Hatch-Waxman five and three [years]," Barrett says, referring to a provision in Hatch-Waxman that bars small molecule generics for the first five years after the branded drug is approved, and for the first three years beyond approval of either a new formulation or a new therapeutic use of a previously approved small-molecule drug. "That's the horse we know, and it's worked well, and we have yet to hear a good argument against it. We're still at that spot." Drug companies can earn plenty from their inventions under the Hatch-Waxman frame, and patents provide enough protection, she says.

Teva, in February, disclosed its plan to seek the FDA's blessing for a biogeneric version of Neupogen (filgrastim), Amgen's compound that boosts red blood cells in chemotherapy patients. "This will be a great case study to see how this all works out," Frost & Sullivan's Ravi notes.

Greenwood and BIO have their hands deep in those details, and the debate over biogenerics legislation will not be settled until "easily past Labor Day," Greenwood says. Meanwhile, members of his group remain "advocates, not opponents" of the legislation, if the details are right. "At the end of the day, as members of the Senate committee began to understand that this is as much about small biotech, which is pretty wobbly-legged because of the economy, as anything else—more about them, frankly," he says. "But we're not claiming success yet."

Randy Osborne Atlanta

New product approval

Ilaris (canakinumab) Novartis (Basel)

The US Food and Drug Administration approved Ilaris on June 18, a fully human monoclonal antibody that blocks interleukin-1 β , for children and adults with cryopyrin-associated periodic syndrome (CAPS). It is the first drug approved for individuals as young as four to treat familial cold auto-inflammatory syndrome and Muckle-Wells syndrome, both forms of CAPS.