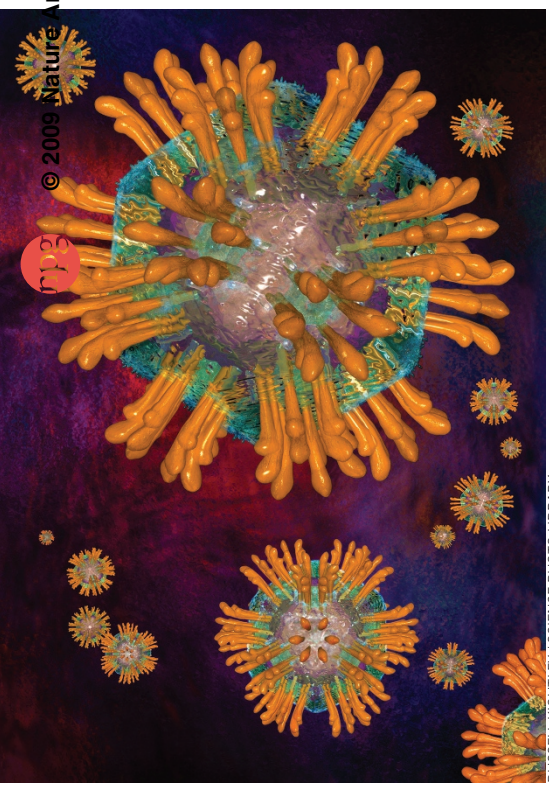
Competition intensifies around hepatitis C

Competition for a slice of the hepatitis C market continues to heat up, with positive news on the clinical front for a second-generation interferon (IFN)-α and a spate of lucrative deals for antivirals with novel mechanisms of action. In January, Bristol-Myers Squibb (BMS) struck a megadeal with ZymoGenetics to provide the biotech firm with $1.1 billion to develop the latter's polyethylene glycol (PEG)-modified IFN-λ currently in phase 1 trials. In March, Vertex Pharmaceuticals of Cambridge, Massachusetts, consolidated its existing hepatitis C pipeline, buying two small-molecule drugs from Laval, Canada–based ViroChem Pharma for $375 million. The same month, Rockville, Maryland–headquartered Human Genome Sciences announced positive phase 3 data for Albuferon—a fusion protein of IFN-α2b and albumin. Overall, competition in the field remains fierce, as whoever manages to offer patients a treatment more efficacious than standard therapies could potentially achieve blockbuster sales. Improved IFN products are likely to arrive first, but in the long term, market watchers are touting cocktail treatments as the most promising.



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Hepatitis C virus infections are likely to be treated with cocktails of improved interferon products and novel small-molecule antivirals.

The generous terms of the deal between BMS and ZymoGenetics, located in Seattle, Washington, indicate just how much hepatitis C virus (HCV) treatments with novel mechanisms could be worth. New York–based BMS will pay $85 million in up-front cash and $20 million in license fees to develop ZymoGenetics' PEG-IFN-λ, a type III IFN otherwise known as interleukin (IL)-29. The Seattle-based biotech also stands to gain another $1 billion in milestone payments if all goes according to plan. "The deal illustrates the ambition of BMS to be a player in the hepatitis C arena," says Holger Rovini, lead analyst at Datamonitor. "With only three small-molecule antivirals in early-stage development, BMS has not been active so far [in this area], and this will bolster its position."

Of the drugs currently in clinical practice, the market leader is Pegasys, a recombinant PEG-IFN-α2a commercialized by Roche of Basel, Switzerland that earns well over $1 billion a year in worldwide sales. Close behind Pegasys is Peg-Intron, a recombinant PEG-IFN-α2b developed by Kenilworth, New Jersey–based Schering Plough, which announced last month that it was merging with Merck of Whitehouse Station, New Jersey (and which is also currently testing a macrocyclic small-molecule inhibitor of HCV nonstructural protein 3/4a (NS3/4a) in phase 2). Both PEGylated type I IFNs have longer serum half-lives than their unmodified predecessor molecules.

Chronic hepatitis C is the most common blood-borne infection in the US and is four times more common than HIV. HCV is transmitted via blood and body fluids and attacks the liver; genotype 1 of the virus accounts for the majority (70–75%) of infections. An estimated 170 million people worldwide—3% of the global population—are infected, and up to 4 million acquire the infection each year. The hepatitis C market was worth $2.3 billion in 2007 and is expected to grow to $4.5 billion by 2017, according to Datamonitor's projections.

To eliminate detectable virus from the blood, current standard of care for hepatitis C patients is a combination of PEG-IFN-α and ribavirin, a nucleoside analog with antiviral activity. IFN-α is secreted naturally by cells in response to viral double-stranded RNA and helps boost the host's immune response. Ribavirin used alone has no effect on HCV, but it synergizes the immune-boosting effects of PEGylated IFN, though the mechanism is not fully understood.

These combination treatments are protracted, however, and typically involve 48

IN brief

Indian biotechs partner with government

The Indian government has selected the first batch of biotech companies to join a cost-and-risk sharing scheme. The government-backed Biotechnology Industry Partnership Programme (BIPP), conceived to promote innovation and support "high risk, cutting edge" research within the biotech industry, will provide as much as half the cost of approved projects. Nine biotech firms are in line to receive the first $20 million out of a total $72 million earmarked for the program by the government's Department of Biotechnology (DBT). "BIPP is the biggest public-private partnership program in the country for discovery research," says Maharaj Kishan Bhan, secretary for DBT. "It will push company [people] to forge collaborations with public sector institutions and also expand their own in-house R&D work force." The first awards have been allocated to projects on vaccines, biopharmaceuticals and in the areas of agriculture, bio-energy and clinical trials. The projects were selected from 92 proposals that DBT received from 65 companies in response to its call in December 2008. The next call will go out by May 2009. V.N. Balaji, a director of Bangalore-based Jubilant Biosys, is upbeat about the public-private initiative. "If properly implemented, it should give a boost to industry," he says. DBT will spend one-third of its annual budgets on the partnership program. Industry is being squeezed right now and "it is our duty to go and fund their R&D," says Bhan. *K S Jayaraman*

Malaysia seeks biotech partners

The Malaysian biotech sector is set to benefit from RM13.7 ($3) billion government funding into healthcare, and a recently announced stimulus package worth RM60 ($16) billion, which also includes biotech. This cash injection will help Malaysia strengthen biotech links with India, in particular, and China, countries which the government views as a strategic platform to Western markets. "We need to go regional before going global and get good companies coming in," says Selvam Ramaraj, vice president of healthcare, BiotechCorp, the federal agency charged with developing biotech through policy and funding. In 2005, the Malaysian government identified biotech as a key driver for growth and has made it a priority since then. Foreign or local companies with strong R&D proposals can acquire so-called BioNexus status, which grants ten tax-free years from the first year of generating a profit. So far, there are 97 BioNexus companies, mostly startups, including 38 healthcare, 33 agricultural and 23 industrial biotechs as well as three bioinformatics companies. Aurigene, a Bangalore, India–based small-molecule and peptide drug discovery [service] company; Olipro Biotechnology, Kuala Lumpur, a microarray diagnostics firm; and the regenerative medicine company Stempeutics, Bangalore, are among them. "Although biotech is a young industry here, we are expecting positive growth," says Ramaraj. *Susan Aldridge*