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NEWS BLOG

Hepatitis C drug trial halted after patient death

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Bristol-Myers Squibb has halted development of a potential hepatitis C drug after nine participants in a clinical trial of the therapy were hospitalized and one died (see press release).

Hepatitis C (HCV) is a chronic viral infection transmitted via blood and, occasionally, other bodily fluids. In a large proportion of cases, patients develop chronic liver disease, which can remain symptomless for decades. Cirrhosis and cancer occur in a number of cases, leading to a 1–5% death rate. The US Centers for Disease Control estimates that approximately 3.2 million people in the United States are living with chronic HCV infection, making a new and improved HCV drug a potentially very profitable investment.

Bristol-Myers Squibb (BMS), based in New York, acquired the rights to the drug BMS-986094 (formerly known as INX-189) when it bought Inhibitex, based in Alpharetta, Georgia, for US\$2.5 billion in January (see 'Pharma giants buy up hepatitis C hopefuls'). The drug works by inhibiting a polymerase enzyme called NS5B, which is essential for viral replication. It was being tested in a phase II clinical trial until 1 August, when BMS announced that they had voluntarily suspended the research (see press release). It has since been revealed that this was owing to suspected heart and kidney toxicity effects, although the company cautioned that a causal link between the drug and adverse effects has not been proven. Two trial participants remain in hospital (reported in the *New York Times*). Abandoning the drug amounts to writing off about \$1.8 billion of what BMS paid for Inhibitex. After the news of the safety crisis broke, shares in BMS fell, reducing its market value by billions (see FierceBiotech).

This is a major blow for BMS, which had been hoping to capitalize on the multibillion-dollar market for a new HCV treatment. The company is just one of the competitors in a hot field that has seen some big acquisitions in recent years. In February, Gilead Sciences, based in Foster City, California, bought out Pharmasset, of Princeton, New Jersey, for \$11 billion to take control of their hepatitis drug candidate (see *Nature Biotechnology's* news story — subscription required). In the same month, Enanta Pharmaceuticals, based in Watertown, Massachusetts, secured a hepatitis C drug-development deal with Novartis, based in Basel, Switzerland, with a \$34-million up-front payment and another \$440 million if the drug reaches required goals, plus a double-digit percentage of worldwide sales (see Xconomy). Roche, also based in Basel, bought Anadys Pharmaceuticals, based in San Diego, California, for \$230 million in October 2011, after eyeing a hepatitis C drug in its pipeline (see *Nature*). These acquisitions had led to the share prices of other HCV drug developers to rise in anticipation of a buyout (see InvestorPlace).

For many years, the only available treatment for HCV was a combination of interferon- α and ribavirin. The interferon acted to boost the patient's immune system, while ribavirin inhibited virus replication. A modified version of interferon- α , pegylated-interferon- α , which remains in patients' bodies for longer, was introduced in 2001. But the treatment had severe side effects, including anaemia, severe depression and flu-like symptoms, and was not effective in all patients. Last year, two new drugs, boceprevir and telaprevir, were approved by the US Food and Drug Administration (FDA). Both of these drugs target HCV's NS3-4A protease, which the virus needs to generate functional proteins. Both drugs, however, do have side effects. Because they are taken in combination with interferon- α and ribavirin to prevent the emergence of resistance, the side effects of the original treatment regimen are still a problem. Telaprevir was recently relabelled to take into account its potential for causing cardiac arrhythmias (FDA update) and boceprevir has been found to interact with HIV protease inhibitors, so co-administration is not recommended (FDA update).

Pharmaceutical companies are trying to find new drugs that are more effective and have fewer side effects. In addition to protease inhibitors, other potential drugs (including BMS-986094) act on the NS5B RNA polymerase enzyme, preventing amplification of viral RNA. Another class of drugs aim to stop viruses penetrating the

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an NS5B inhibitor in phase III trials, and Vertex, also based in Cambridge, is working on a similar drug.

CORRECTION: An earlier version of this post incorrectly implied that Vertex and Gilead HCV drugs are being investigated by the FDA, when both companies have stated that they have not been contacted by the FDA (see *Business Week*).

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