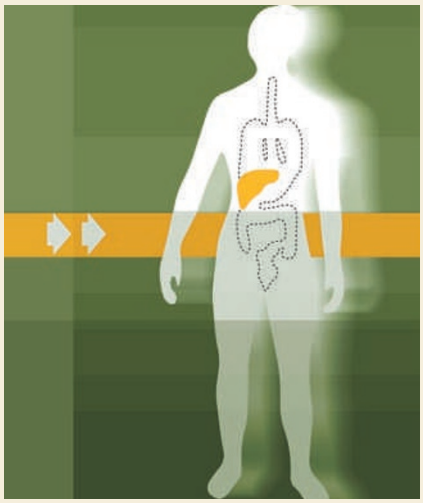
NEWS IN BRIEF

Hepatitis drugs shine at liver meeting



Vertex/Tibotec and Merck & Co are due to file regulatory submissions for their hepatitis C virus (HCV) drug candidates — telaprevir and boceprevir, respectively — by the end of the year, after data presented at the American Association for the Study of Liver Diseases (AASLD) meeting continued to impress.

The lowdown: The current standard of care for HCV infection — 48 weeks of treatment with the generic antiviral ribavirin and pegylated interferon — has a cure rate of less than 50% and an often off-putting side-effect profile. Vertex/Tibotec and Merck are racing, neck and neck, towards the approval of a first-in-class NS3 serine protease inhibitor that could change the HCV treatment paradigm (*Nature Rev. Drug Discov.* **9**, 501–503; 2010). Detailed pivotal trial data for both candidates were presented at the AASLD meeting in Boston, Massachusetts, USA.

In the ILLUMINATE and ADVANCE Phase III trials sponsored by Vertex/Tibotec, treatment-naive patients receiving a telaprevir-based regimen (telaprevir plus pegylated-interferon and ribavirin) achieved sustained virologic response (SVR) of 72–75%. Recent top-line results from the REALIZE trial, which were not presented at the conference, also showed that telaprevir combination therapy induced SVR in 65% of prior treatment-failure patients. In Merck's SPRINT-2 trial, 63–66% of treatment-naive patients receiving a boceprevir-based regimen (boceprevir plus pegylated-interferon and ribavirin) achieved SVR. In the RESPOND-2 trial, 59–66% of prior treatment-failure patients achieved SVR when dosed with boceprevir combination therapy.

"While some of the efficacy numbers do not look as strong for boceprevir as for telaprevir, physicians at the AASLD conference were hesitant to conclude that one was more efficacious than the other, given differences in the studies," said analysts at BioMedTracker, an institutional research service. The companies used different definitions of prior non-responders in their treatment-experienced patient trial, for example, which complicates the comparison of results. "Some physicians added that adverse events could make a difference in how the drugs are used," the analysts also noted. Telaprevir is associated with a higher incidence of rash, whereas boceprevir is associated with higher rates of anaemia.

Promising Phase II HCV candidates that were also showcased at the conference include Roche's NS5B polymerase inhibitor RG7128, Medivir/Tibotec's NS3/4A serine protease inhibitor TMC435 and Bristol-Myers Squibb's combination NS3/NS5A inhibitor BMS-650032/BMS-790052.

Biotechs reap US$1 billion in tax credits

The US Internal Revenue Service (IRS) issued US$1 billion in tax credits to nearly 3,000 small biotech firms spread across the United States.

The lowdown: In July this year, the IRS announced plans to issue grants worth $1 billion in tax credits to small biotech firms (that is, with fewer than 250 employees). The Qualifying Therapeutic Discovery Project Program, created as part of the health-care reform act, was directed towards "projects that show significant potential to produce new therapies, address unmet medical needs, reduce the long-term growth of health care costs and advance the goal of curing cancer within the next 30 years." Although the programme was administered by the IRS, projects were assessed by the Department of Health and Human Services.

In total, the IRS received more than 5,600 submissions, requesting funds in excess of $10 billion in total. The list of successful applicants includes nearly 3,000 companies for over 4,600 different projects. Many projects received just under $245,000, prompting some firms to speculate that the money had been spread too thinly. The largest beneficiary was Wellstat Group — which includes Wellstat Therapeutics — who received $3.5 million for programmes in gout, type I diabetes, cancer, multiple sclerosis and inflammatory disorders. Other big winners included Immunomedics, who were granted $2.9 million, Arisaph Pharmaceuticals, who received $2.8 million, and Theravance, who received $2.7 million.

Biotechnology Industry Organization President and Chief Executive Officer Jim Greenwood welcomed the grants, and immediately called for the Qualifying Therapeutic Discovery Project Program to be extended and expanded.

FDA calls for more broadly applicable drug development tools

Draft guidance from the US Food and Drug Administration (FDA) pushes for the collaborative development of broadly applicable biomarker and patient-reported outcome instrument drug development tools (DDTs).

The lowdown: When the Critical Path Initiative was launched in 2004, it recognized the value of DDTs as a means to address industry concerns and to speed the delivery of new therapies. Until now, however, the agency says that DDT acceptance has been on a "sponsor-by-sponsor, drug-by-drug basis". The new guidance outlines a pathway for tools that will have broader generalizability, such as use across multiple clinical disorders, drugs or drug classes. Citing the "substantial work needed to achieve qualification," it also calls for the collaborative group development of these tools "to increase the efficiency of joint efforts and to lessen the resource burden upon any individual person or company working to gain qualification for a tool."

The draft specifically addresses patient-reported outcome instruments, as well as prognostic, predictive, pharmacodynamic and surrogate biomarkers. The agency does note, however, that surrogate markers have a "substantial risk of" adversely affecting public health and so are consequently likely to be qualified less frequently than the other types of biomarker. It also details a two-stage evaluation process — a consultation and advice period, followed by a review process — that will be used for the acceptance of these DDTs. The FDA is accepting comments and suggestions on the draft guidance until the end of January 2011.