

IN brief

Jazz beefs up with EUSA biologic

Dublin-based Jazz Pharmaceuticals announced in April it would be acquiring specialty pharmaceutical company EUSA Pharma, of Langhorne, Pennsylvania, and Oxford, for \$650 million in cash. EUSA's only marketed product is Erwinaze (asparaginase *Erwinia chrysanthemi*), approved in November 2011 by the US Food and Drug Administration for treating acute lymphoblastic leukemia in combination with other anti-neoplastic agents. Because it is produced in *Erwinia chrysanthemi*, this drug does not induce the immune reaction observed among 15–20% patients taking the L-asparaginase grown in *Escherichia coli*. Although Erwinaze is an attractive asset, Jazz appeared to be paying a high price for what seems to be a one-approved-product company. But EUSA has two other key drug candidates in its pipeline: a pegylated recombinant version of Erwinaze (Asparec) in phase 1 studies in Europe and an anti-CD25 monoclonal antibody (inolimomab; Leukotac) in a phase 3 pivotal study in Europe to treat steroid-refractory cases of acute graft-versus-host disease.

Sabine Louët

UK's life sciences pitch

Viewing support for the UK biosciences industry as a way to stimulate the economy, British science minister David Willetts announced £250 (\$383) million in funding, as part of a five-year biosciences research strategy. The recipients are among the Biotechnology and Biological Sciences Council's (BBSRC) national research institute network. The funds, meant to help ensure the UK's biosciences research base remains internationally competitive, were allocated to 26 different agricultural, livestock and health programs. Crop innovation, such as broadening the wheat gene pool, and using plants to source new chemical entities and produce pharmaceuticals and energy, is receiving substantial support. The John Innes Centre in Norwich (which houses the UK's wheat germplasm) was awarded the largest sum of £42 (\$64) million and the 160-year-old agricultural station, Rothamsted Research in Harpenden, received £41 (\$63) million. The £13 (\$20) million award to the Institute of Biological, Environmental and Rural Sciences in Aberystwyth was to help establish a new national plant phenotyping center. The Institute for Animal Health received £38 (\$58) million to continue virology research on the protection of livestock from vector-borne diseases. Another of the larger grants (£37 (\$57) million) went to the life sciences-oriented Babraham Institute in Cambridge for research on aging and health. Two of the nation's genomic centers, Roslin Institute in Edinburgh and the Genome Analysis Centre in Norwich, received £23 (\$35) million and £19 (\$29) million, respectively. Improving livestock productivity and approaches to data storage and handling are among the projects being funded.

Barbara Nasto

Europe's largest university clinics—and the Helmholtz-Zentrum Geesthacht (HZG), part of the Helmholtz Association—Germany's largest research association. BCRT is currently managing 130 ongoing translational research projects. Lauter and his colleagues have developed an evaluation system to predict the likelihood of success of each project and the level of financial risk involved. Potential investors “really like working with us,” says Lauter, “because we’ve done most of the risk evaluation for them.”

Collaborations that enable partners to take advantage of each other's assets are also gaining popularity. BCRT, for example, through its partnership with the HZG, has access to the Helmholtz Center for Biomaterial Development—a nearby facility that can manufacture medical grade biomaterials for preclinical and clinical studies. “That’s not trivial,” says Lauter. “Those are expensive and highly specialized facilities that not all translational centers have.”

One example, Christof Stamm, a cardiac surgeon at the German Heart Institute in Berlin, points out, is an ongoing phase 3 trial in Germany that involves treating heart failure patients with their own bone marrow stem cells. The therapy was first tested in patients undergoing bypass surgery at the University of Rostock translational medicine center, headed by Gustav Steinhoff. Researchers found that patients who also received an injection of autologous bone marrow stem cells into the heart had better heart function than those who only received bypass surgery. But when researchers repeated the experiment at the German Heart Institute, they could not replicate the results. Researchers at the two clinics decided to collaborate and harmonize protocols for extracting and injecting the cells as well as to determine a single facility where the cells would be processed. The collaboration has turned into a multicenter, prospective, randomized, double-blind clinical trial involving 142 patients funded by the German Federal Ministry of Education and Research (BMBF).

Lauter, who worked at Stanford in the early 1990s, was impressed by scientists' zest for sharing ideas. Three years ago, he helped forge a collaboration between stem cell scientists based in Germany and those in California, by approaching Alan Trounson, president of the California Institute of Regenerative Medicine (CIRM; San Francisco). As the BMBF funds about 75% of BCRT's budget, he approached them as well. The effort resulted in both BMBF and CIRM signing a memorandum in 2009 agreeing to

jointly fund collaborative research projects in regenerative medicine. After consulting with other experts in his field, he spearheaded the idea of the RMC coalition last year to help quicken the pace of translational research in the field. BMBF hosted the RMC signing event. The RMC hopes to expand in the near future by partnering with other regenerative medicine translational centers in other parts of the world.

Needless to say, many challenges remain, particularly for cell therapies based on pluripotent cells, such as hESCs or human induced pluripotent stem cells. Foremost among the challenges are the vagaries of politics; in the US, federal money is once again flowing into hESC research under the Obama administration, but the tide could turn with the upcoming election. In Europe, Germany has some of the strictest laws governing hESC research in the European Union (EU; Brussels). German researchers are prohibited from creating stem cells from human embryos but they are allowed to import such cells for research with certain restrictions.

Strict laws aren't necessarily a hindrance, says Lauter. Regenerative medicine involves many different kinds of cells, not just those derived from human embryos. Moreover, the fact that different countries have different laws governing stem cell research underscores the importance of international collaboration, he says. Some therapies will progress in some places, others elsewhere. And even though the types of cells, molecules and biomaterials used in regenerative medicine are diverse, there's lots of overlap, and collaboration will enable researchers to share expertise.

Although group effort may certainly speed up translational research, other roadblocks on the way to market remain. Last year, the EU's Court of Justice decided in favor of the environmental group Greenpeace (Amsterdam) when it ruled that processes and products that involve hESCs are not patentable (*Nat. Biotechnol.* **29**, 1057–1059, 2011). The court's ruling might discourage companies from developing hESCs and other cell-based therapies in Europe.

And despite the strides made by translational medical centers in bridging some of the funding gap, money is still scarce.

“The biotech sector had been driven by easy access to cheap capital,” says Bonfiglio. “But the old funding model doesn't exist.” Researchers need to learn how to trim excess and become capital efficient, he adds. Working together will enable partners “to do more with less.”

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