IN brief

Dyax backs albumin

H. Thomas Watkins, Human Genome Sciences President and CEO.

Albumin fusion is being touted as a useful tool to extend the half-life of certain small peptides, so it's no surprise that the field has seen a bloom of activity lately. In May, Bagsvaerd, Denmark–based Novozymes licensed its albumin fusion technology, Albufuse, to Dyax, in Cambridge, Massachusetts, for use in a research collaboration around the development of Kunitz-domain proteins, disulfide-bonded domains forming a loop structure. "It could give us a way of targeting a wider range of chronic diseases with that scaffold," says Dyax's executive vice president, discovery research, Clive Wood. The most advanced clinical candidate using albumin fusion technology is Human Genome Sciences' closely watched Albuferon (albinterferon alfa-2b) for the treatment of hepatitis C. In January 2008, the company reduced the maximum dose of Albuferon in its phase 3 trials to 900 μg from 1200 μg, based on recommendations made by the studies' independent Data Monitoring Committee. President and CEO H. Thomas Watkins said, "For some time we have viewed the 900-μg dose administered every two weeks as the most likely marketed dose of Albuferon." But the Rockville, Maryland, biotech nonetheless saw its stock price cut in half on the news. A day after the Albuferon dosing change was announced, Jerusalem-based Teva Pharmaceutical, a generics company, announced the purchase of CoGenesys, also in Rockville, which Human Genome Sciences had owned and spun out into an independent company in 2006, during the development of Albuferon. Teva has identified biopharmaceuticals—primarily copies of biologicals—as a key, long-term growth opportunity. "With this acquisition, Teva is taking a significant step towards advancing its strategic goals, demonstrating its commitment to becoming a leading player in the biogenerics market, as that market evolves," it stated. CoGenesys is already developing long-acting versions of granulocyte colony-stimulating factor and interferon-beta; Teva already sells versions of both as well as a biogeneric human growth hormone. Albumin is an additional active ingredient, so it is difficult to call albumin fusion a technology for making follow-on biologics. But the traditional definition of therapeutic equivalence "isn't relevant to most products in this field," says Joseph Schwartz, an analyst at Leerink Swann in Boston, adding "the distinction is becoming blurred. If you have to do clinical trials anyway, which is looking like the way it will shape up to be in the biogenerics field, to show that their drugs work, it doesn't matter if you're therapeutically equivalent or not."

—Mark Ratner

Table 1 Scope of IMI calls

Area	Category	Number of companies	Budget, millions[a]
Safety	1. Improve predictivity of immunogenicity	12	€26 ($40.0)
	2. Nongenotoxic carcinogenesis	8	€25 ($38.5)
	3. Expert systems for *in silico* toxicity prediction	10	€10 ($15.4)
	4. Improved predictivity of nonclinical safety evaluation	11	€20 ($30.8)
	5. Qualification of translational safety biomarkers	12	€42 ($64.7)
	6. Strengthening the monitoring of benefit and risk	15	€30 ($46.2)
Efficacy	7. Islet cell research	11	€20 ($30.8)
	8. Surrogate markers for vascular endpoints	7	€40 ($61.6)
	9. Pain research	12	€15 ($23.1)
	10. New tools for the development of novel therapies in psychiatric disorders	13	€20 ($30.8)
	11. Neurodegenerative disorders	14	€15 ($23.1)
	12. Understanding severe asthma	10	€25 ($38.5)
	13. Chronic obstructive pulmonary disease patient-reported outcomes	9	€20 ($30.8)
Education and training	14. European Medicines Research Training Network	24	€10 ($15.4)
	15. Safety Sciences for Medicines Training Programme	24	€6 ($9.2)
	16. Pharmaceutical Medicine Training Programme	24	€8 ($12.3)
	17. Integrated Medicines Development Programme	24	€6 ($9.2)
	18. Pharmacovigilance Training Programme	24	€7 ($10.8)

[a]Includes funding and matching in-kind contributions from EFPIA companies

($15.4) million worth of in-kind contributions come from large and mid-sized pharma companies, which will conduct the animal experiments, underwrite the cost of '-omics' work and evaluate new assays, among other contributions.

The cash component of IMI—€1 ($1.5) billion overall and €123 ($190) million in the first round of calls—goes exclusively to consortia of small companies, patient groups, academics and other researchers. The application process is, by EC standards, a relatively unburdensome two-stage process. Stage 1 is the assembly of consortia, in which researchers must align themselves with other groups. The administrative burden is relatively low at this stage; all that is required—by July 15 for the first call—is a one-page credentials sheet from each participant and a two-page budget that outlines each participant's budget requirement. The applications will be assessed by the EC and EFPIA over several months, and then just one consortium will be selected to enter stage 2. In effect, only when success is assured does the real administrative effort begin. The most stringent requirement in stage 1, according to EFPIA's IMI advisor, Ian Ragan, is that the consortium must address all aspects of the call. Partial submissions will immediately fail, and IMI will not pick and mix elements from multiple applications to form a 'dream consortium'. There are no absolute requirements for a mix of consortium members in terms of either geography or institutional origin.

Irene Norstedt, the EC official who has been the prime mover of IMI and who has been dubbed "the mother of IMI," hopes that IMI will not only address the diminishing product returns from research in the pharmaceutical industry but also halt the exodus of pharmaceutical research from Europe. She also believes that IMI can address the malaise in life-science investment in Europe. "IMI is a risk-reduction process," she says. "By reducing the risk in the clinical trials phase, investors should become more enthusiastic."

Perhaps the most vital impact on smaller companies will be the IMI's potential role in the validation of their technologies. Small companies that develop predictive assays or other methods now have a funded framework for having the utility of their methods tested by the large company users. Regulatory validation may also spring from within IMI. Hans-Georg Eichler of the European Medicines Agency (EMEA) in London says that "the current tools are not optimal [for efficient drug development]" and that the EMEA must get involved because of its role in assessing new analytical methods. For Eichler, IMI will boost a trend that is already starting: "Independent of IMI, a company seeks EMEA's advice on whether its assay or biomarker system might become part of this efficient drug development process," he explains. "This is already happening but we hope to see a number of additional projects emerge as a result of IMI."

EMEA has already taken a lead role by acting as a nucleus around which research consortia can form to answer the IMI call on pharmacovigilance. "The activity of monitoring benefit-risk is obviously very close to our hearts," says Eichler. "We feel we cannot just stand and wait to see what happens."

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