

Follow-up: IMI unveils first call

By Mike Ward, Senior Editor

Europe's **Innovative Medicines Initiative** has unveiled details of the first 18 projects it will fund under a 5-year, €2 billion (\$3.1 billion) program to relieve bottlenecks in drug discovery and development. In addition to programs focusing on safety prediction, pharmacovigilance, and education and training, the first-call projects include

a trio of therapeutic areas: brain disorders, metabolic disease and pulmonary inflammatory indications.

As initially reported in *SciBX*, the first-call projects will receive up to €122.7 million (\$189.2 million) from the EU to support research activities and an estimated in-kind contribution of €172.5 million (\$266 million) from participating members of the **European Federation of Pharmaceutical Industries and Associations (EFPIA)**.¹

In its official rollout last week, the Innovative Medicines Initiative (IMI) also reveals the EFPIA members that have signed up to participate in each project (see **Table 1, "Innovative Medicines Initiative projects"**).

European academic groups, biotechs, charities and regulatory agencies are being encouraged to establish consortia to apply for EU funding and work alongside the established pharma consortia. Initial expressions of interest on the first projects are due between June 1 and July 15.

Table 1. Innovative Medicines Initiative projects. The first call for 18 projects as part of the Innovative Medicines Initiative (IMI) was recently released. The projects for the initiative, which was jointly established by the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA), are listed below, with each program's expected contributions from EFPIA and IMI. Of the 24 participating EFPIA companies, **Boehringer Ingelheim GmbH**, **Novartis AG** (NYSE:NVS; SWX:NOVN), **AstraZeneca plc** (LSE:AZN; NYSE:AZN), **Pfizer Inc.** (NYSE:PFE) and **Roche** (SWX:ROG) participated in 15 or more projects each.

Project title	EFPIA Participants	Contribution (millions)		Duration (years)
		EFPIA	IMI	
[1] Improve predictivity and minimization strategies of immunogenicity for biotherapeutics in man	12 companies: AstraZeneca; Bayer Healthcare, a subsidiary of Bayer AG (Xetra: BAY); Boehringer Ingelheim; Genzyme Corp. (NASDAQ:GENZ); H. Lundbeck A/S (CSE:LUN); Merck & Co. Inc. (NYSE:MRK); Merck Serono S.A., a subsidiary of Merck KGaA (Xetra:MRK); Novartis; Novo Nordisk A/S (CSE:NVO; NYSE:NVO); Pfizer; Roche; UCB Group (Euronext:UCB)	€13 (\$20)	~ €9 (\$13.9)	5
[2] Nongenotoxic carcinogenesis: identification of early markers and molecular classification of tumors	8 companies: Bayer Healthcare; Boehringer Ingelheim; Lundbeck; Novartis; Novo Nordisk; Pfizer; Solvay S.A. (Euronext:SOLB); UCB	€12.5 (\$19.3)	~ €9 (\$13.9)	5
[3] Development of expert systems for <i>in silico</i> toxicity prediction	10 companies: AstraZeneca; Bayer Healthcare; Boehringer Ingelheim; Esteve S.A.; GlaxoSmithKline plc (LSE:GSK; NYSE:GSK); Lundbeck; Novartis; Pfizer; Roche; UCB	€5 (\$7.7)	~ €4 (\$6.2)	5
[4] Improved predictivity of nonclinical safety evaluation	10 companies: Bayer Healthcare; Boehringer Ingelheim; Merck Serono; Novartis; Orion Pharma, a subsidiary of Orion Corp. (HSE:ORNAV; HSE: ORNBV); Roche; sanofi-aventis Group (Euronext:SAN; NYSE:SNY); Servier; Solvay; UCB	€10 (\$15.4)	~ €7 (\$10.8)	3
[5] Qualification of translational safety biomarkers from nonclinical to early clinical studies	12 companies: Laboratorios Almirall S.A.; Amgen Inc. (NASDAQ:AMGN); AstraZeneca; Boehringer Ingelheim; Eli Lilly and Co. (NYSE:LLY); GlaxoSmithKline; Johnson & Johnson (NYSE:JNJ); Merck Serono; Novartis; Pfizer; Roche; Solvay	€21 (\$32.4)	~ €15 (\$23.1)	5
[6] Improving and strengthening the monitoring of the benefit and risk of medicines marketed in the EU	15 companies: Amgen; AstraZeneca; Bayer Healthcare; Boehringer Ingelheim; Eli Lilly; Genzyme; GlaxoSmithKline; Lundbeck; Merck Serono; Novartis; Novo Nordisk; Pfizer; Roche; sanofi-aventis; Sigma-Tau S.p.A.	€15 (\$23.1)	~ €11 (\$17)	5
[7] Islet cell research: improving β -cell function and identification of diagnostic biomarkers for treatment monitoring in diabetes	11 companies: Amgen; AstraZeneca; Boehringer Ingelheim; Eli Lilly; Merck; Novartis; Novo Nordisk; Roche; sanofi-aventis; Servier; Solvay	€10 (\$15.4)	~ €7 (\$10.8)	5
[8] Surrogate markers for micro- and macrovascular hard endpoints to shorten clinical trials on diabetes	7 companies: Boehringer Ingelheim; Eli Lilly; Novo Nordisk; Laboratoires Pierre Fabre S.A.; Roche; Servier; Solvay	€20 (\$30.8)	~ €14 (\$21.6)	5

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Table 1. Innovative Medicines Initiative projects (continued).

Project title	EFPIA Participants	Contribution (millions)		Duration (years)
		EFPIA	IMI	
[9] Pain research: innovative preclinical and clinical rapprochement to produce biomarkers for safer and more effective treatments	12 companies: AstraZeneca; Boehringer Ingelheim; Eli Lilly; Esteve; GlaxoSmithKline; Merck; Orion Pharma; Pfizer; Pierre Fabre; sanofi-aventis; UCB; Wyeth (NYSE:WYE)	€7.5 (\$11.6)	~ €5 (\$7.7)	5
[10] New tools for the development of new therapies in psychiatric disorders	13 companies: AstraZeneca; Eli Lilly; GlaxoSmithKline; Johnson & Johnson; Lundbeck; Novartis; Merck Serono; Pfizer; Pierre Fabre; Roche; Servier; Solvay; Wyeth	€10 (\$15.4)	~ €7 (\$10.8)	5
[11] Neurodegenerative disorders: bridging the preclinical-clinical divide	14 companies: AstraZeneca; Boehringer Ingelheim; GlaxoSmithKline; Johnson & Johnson; Eli Lilly; Lundbeck; Merck Serono; Novartis; Pfizer; Pierre Fabre; Roche; Servier; Solvay; UCB	€ 7.5 (\$11.6)	~ €5 (\$7.7)	5
[12] Understanding severe asthma: the fundamental bottleneck to advancing new medicines for the syndrome	10 companies: Almirall; AstraZeneca; Boehringer Ingelheim; Chiesi Farmaceutici S.p.A.; GlaxoSmithKline; Merck; Novartis; Pfizer; Roche; UCB	€12.5 (\$19.3)	~ €9 (\$13.9)	5
[13] Chronic obstructive pulmonary disease patient-recorded outcomes: a major bottleneck to understanding patient and economic benefits of new therapies	9 companies: Almirall; AstraZeneca; Boehringer Ingelheim; Chiesi; GlaxoSmithKline; Merck; Novartis; Pfizer; UCB	€10 (\$15.4)	~ €7 (\$10.8)	6
[14] Establishment of a network to facilitate and coordinate European training and education relevant for stakeholders of medicines R&D	24 companies: Almirall; Amgen; AstraZeneca; Bayer; Boehringer Ingelheim; Chiesi; Eli Lilly; Esteve; Genzyme; GlaxoSmithKline; Johnson & Johnson; Lundbeck; Merck; Merck Serono; Novartis; Novo Nordisk; Orion; Pierre Fabre; Pfizer; Roche; sanofi-aventis; Servier; Sigma-Tau; UCB	€5 (\$7.7)	~ €4 (\$6.2)	7
[15] IMI safety sciences for medicines training program	24 companies: Almirall; Amgen; AstraZeneca; Bayer; Boehringer Ingelheim; Chiesi; Eli Lilly; Esteve; Genzyme; GlaxoSmithKline; Johnson & Johnson; Lundbeck; Merck; Merck Serono; Novartis; Novo Nordisk; Orion; Pierre Fabre; Pfizer; Roche; sanofi-aventis; Servier; Sigma-Tau; UCB	€3 (\$4.6)	~ €2 (\$3.1)	5
[16] IMI pharmaceutical medicine training program	24 companies: Almirall; Amgen; AstraZeneca; Bayer; Boehringer Ingelheim; Chiesi; Eli Lilly; Esteve; Genzyme; GlaxoSmithKline; Johnson & Johnson; Lundbeck; Merck; Merck Serono; Novartis; Novo Nordisk; Orion; Pierre Fabre; Pfizer; Roche; sanofi-aventis; Servier; Sigma-Tau; UCB	€4 (\$6.2)	~ €3 (\$4.6)	5
[17] IMI integrated medicines development course program for nonspecialists	24 companies: Almirall; Amgen; AstraZeneca; Bayer; Boehringer Ingelheim; Chiesi; Eli Lilly; Esteve; Genzyme; GlaxoSmithKline; Johnson & Johnson; Lundbeck; Merck; Merck Serono; Novartis; Novo Nordisk; Orion; Pierre Fabre; Pfizer; Roche; sanofi-aventis; Servier; Sigma-Tau; UCB	€3 (\$4.6)	~ €2 (\$3.1)	5
[18] IMI pharmacovigilance training program	24 companies: Almirall; Amgen; AstraZeneca; Bayer; Boehringer Ingelheim; Chiesi; Eli Lilly; Esteve; Genzyme; GlaxoSmithKline; Johnson & Johnson; Lundbeck; Merck; Merck Serono; Novartis; Novo Nordisk; Orion; Pierre Fabre; Pfizer; Roche; sanofi-aventis; Servier; Sigma-Tau; UCB	€3.5 (\$5.4)	~ €3 (\$4.6)	5

Winning consortia are expected to be notified by the end of September, and they and the corresponding EFPIA-backed consortium will construct a full joint proposal to submit to the European Commission by the end of November. The first grants are expected to be awarded at the start of 2009.

The overarching goal of the IMI—finding better methods for predicting the safety and efficacy of new medicines—is similar to the FDA's Critical Path Initiative but has a larger public funding commitment.

IMI is also expected to recover some of the European pharma industry's perceived loss of competitiveness. Speaking at the Brussels launch of IMI last week, **Roche's** Jonathan Knowles said Europe's biomedical sciences would receive targeted strategic support through the public-private partnership. "This in turn will help to improve Europe's competitiveness in biopharmaceutical innovation and make it a more attractive place for pharmaceutical R&D," he said.

Knowles is the pharma company's head of research and chairman

of both IMI's governing board and EFPIA's research directors group.

"We have no problem to admit that we cannot solve all these issues by ourselves," added Arthur Higgins, EFPIA president and CEO of **Bayer AG's** Bayer HealthCare subsidiary. "Rather, we need to join forces with partners to address the main causes of delays, or bottlenecks, in drug discovery."

Potential participants in the program are being directed to the IMI website, where guidelines for applications, rules for participation and IP rules have been posted (http://imi.europa.eu/calls-01_en.html). A joint undertaking model agreement will be added to the site.

REFERENCES

1. Ward, M. *SciBX* 1(9), 7–8; March 27, 2008

COMPANIES AND INSTITUTIONS MENTIONED

Bayer AG (Xetra:BAY), Leverkusen, Germany
European Federation of Pharmaceutical Industries and Associations, Brussels, Belgium
Innovative Medicines Initiative, Brussels, Belgium
Roche (SWX:ROG), Basel, Switzerland