Translational tidbits

By Kai-Jye Lou, Senior Writer

AstraZeneca plc had a busy March, announcing five new public-private partnerships and the launch of its Open Innovation website to list additional partnership opportunities (*see Table 1, “Selected public-private partnerships for March 2014”*).

One of the public-private partnerships (PPPs) was a five-year alliance with the U.K.’s **Medical Research Council** (MRC) to give academic researchers access to more than two million of the pharma’s molecules.

MRC will select and fund up to 15 screening projects per year. Topics for prospective projects are expected to cover a range of therapeutic areas and diseases and will not be restricted to AstraZeneca’s areas of focus—cancer, cardiovascular and metabolic diseases, respiratory disorders, inflammation and autoimmune diseases.

Project proposals will be sourced from U.K. scientists based at academic or noncommercial research institutions, including MRC. Initial projects may start as early as 2015.

The pharma will have the first option to license rights to any resulting drug discovery programs.

The partners also plan to form the AstraZeneca MRC U.K. Centre for Lead Discovery at the pharma’s Cambridge Biomedical Campus. The center is expected to open in 2016.

Financial details were not disclosed.

AstraZeneca and MRC previously partnered in December 2011 to provide academic researchers with MRC grant funding and access to 22 of the pharma’s discontinued compounds free of charge to carry out mechanistic studies in new indications.¹ MRC awarded £7 million (\$11.3 million) in funding to 15 research projects in October 2012.

Also in March, AstraZeneca signed a memorandum of understanding with the **Korea Health Industry Development Institute** to provide support for 12 early stage translational research projects from Korean oncology investigators.

Scientists will receive research funding from the pharma and will have priority access to a list of its compounds for preclinical evaluation. The investigators also will have access to technological advice and collaboration opportunities with AstraZeneca.

The pharma’s Oncology iMed group will review and select four project preproposals by May. Preproposals are abridged proposals that summarize a research project and include project aims, a preliminary budget estimate, expected key deliverables and milestones.

Together with other companies, AstraZeneca also is involved in

Table 1. Selected public-private partnerships for March 2014. AstraZeneca plc (LSE:AZN; NYSE:AZN) had a busy March. The pharma is embarking on a broad, five-year screening campaign with the U.K.’s **Medical Research Council** (MRC) and participating in the **Innovative Medicines Initiative** (IMI)’s GetReal project, and its **MedImmune LLC** biologics unit announced a pair of cancer deals to advance the development of immunotherapies and tumor-targeted therapies. Infectious diseases also had a strong showing last month, with a quartet of public-private partnerships that could get up to \$52.1 million in new support.

Source: *BioCentury Archives*

Companies	Institutions	Business area	Disclosed value	Purpose
Emergent BioSolutions Inc. (NYSE:EBS); Mapp Biopharmaceutical Inc. ; Zalgen Labs LLC	Ben-Gurion University of the Negev ; NIH ; Public Health Agency of Canada ; The Scripps Research Institute ; Uganda Virus Research Institute ; The University of Texas Medical Branch ; University of Wisconsin–Madison ; U.S. Army Medical Research Institute of Infectious Diseases ; Yeshiva University	Infectious disease	Up to \$28 million	Consortium to develop immunotherapies for filoviruses and arenaviruses that cause severe hemorrhagic fever
Amgen Inc. (NASDAQ:AMGN); AstraZeneca ; Bayer AG (Xetra:BAYN); Boehringer Ingelheim GmbH ; Bristol-Myers Squibb Co. (NYSE:BMJ); Eli Lilly and Co. (NYSE:LLY); GlaxoSmithKline plc (LSE:GSK; NYSE:GSK); Johnson & Johnson (NYSE:JNJ); LASER Analytica ; Merck & Co. Inc. (NYSE:MRK); Merck KGaA (Xetra:MRK); Novartis AG (NYSE:NVS; SIX:NOVN); Novo Nordisk A/S (CSE:NVO; NYSE:NVO); Roche (SIX:ROG; OTCQX:RHHBY); Sanofi (Euronext:SAN; NYSE:SNY); Takeda Pharmaceutical Co. Ltd. (Tokyo:4502)	University Medical Center Utrecht ; University Medical Center Groningen ; Health Care Insurance Board of the Netherlands ; EMA ; EORTC ; French National Authority for Health ; London School of Hygiene & Tropical Medicine ; National Institute for Health and Care Excellence ; University of Ioannina ; University of Berne ; University of Leicester ; International Alliance of Patients’ Organizations ; IMI	Pharmaceuticals	€16.3 million (\$22.7 million)	GetReal project to help companies generate real-world data for payers during drug development process and clinical data necessary for regulatory approval

(Continues on p. 2)

Table 1. Selected public-private partnerships for March 2014. (Continued)

Companies	Institutions	Business area	Disclosed value	Purpose
Japan BCG Laboratory Ltd.; Astellas Pharma Inc. (Tokyo:4503); Dainippon Sumitomo Pharma Co. Ltd. (Tokyo:4506); Eisai Co. Ltd. (Tokyo:4523); Merck KGaA	Aeras; Drugs for Neglected Diseases initiative; Liverpool School of Tropical Medicine; National Institute of Biomedical Innovation; Swiss Tropical and Public Health Institute; TI Pharma; University of Liverpool	Infectious disease	\$12.5 million	Four partnerships to develop drugs and vaccines to treat schistosomiasis, Chagas disease, parasitic roundworms and tuberculosis
None	Fred Hutchinson Cancer Research Center; NIH; The Rockefeller University; Seattle Biomedical Research Institute; Seattle Children's Hospital; University of Washington	Infectious disease	\$9.8 million	Consortium to develop a vaccine to elicit broadly neutralizing antibodies against HIV-1
4SC AG (Xetra:VSC)	Heidelberg University Hospital	Infectious disease	€1.3 million (\$1.8 million)	Partnership to conduct preclinical testing of small molecule antimalarial compound
Bicoll Group	Charité–University Hospital Berlin; German Federal Ministry of Education and Research	Neurology	Over €1 million (\$1.4 million)	EPICLEAP project to evaluate traditional Chinese medicine pharmaceutical recipes to identify therapeutic leads
Advaxis Inc. (NASDAQ:ADXS)	University of California, San Francisco	Cancer	Undisclosed	Partnership to evaluate immunotherapy constructs against targets important in effective immunotherapies to treat prostate cancer
AstraZeneca	Korea Health Industry Development Institute	Cancer	Undisclosed	Partnership to establish an oncology research program to support 12 early stage translational research projects from Korean investigators
AstraZeneca	MRC	High throughput screening	Undisclosed	Partnership to evaluate over two million AstraZeneca molecules over five years
AstraZeneca; MedImmune	University of Cambridge	Cancer	Undisclosed	Partnership to study tumor-targeted therapies, including antibody-drug conjugates
AstraZeneca; MedImmune	The University of Texas MD Anderson Cancer Center	Cancer	Undisclosed	Partnership to develop immunotherapies for cancer through MD Anderson's Moon Shots Program
Genocea Biosciences Inc. (NASDAQ:GNCA)	Dana-Farber Cancer Institute; Harvard Medical School; Ludwig Institute for Cancer Research Ltd.	Cancer	Undisclosed	Partnership to characterize immune responses stimulated by treatment with melanoma drug Yervoy ipilimumab
GlaxoSmithKline	EMBL-EBI; Wellcome Trust Sanger Institute	Functional genomics	Undisclosed	Partnership to form the Centre for Therapeutic Target Validation, which will use genome sequencing and big-data tools to research drug targets
Insight Genetics Inc.	Vanderbilt-Ingram Cancer Center	Pharmacogenetics	Undisclosed	Partnership to identify genetic markers that could help select targeted therapeutics for triple-negative breast cancer
Ono Pharmaceutical Co. Ltd. (Tokyo:4528)	Tohoku University; The University of Tokyo	Pharmaceuticals	Undisclosed	Research collaboration network called Orientem Innovation to identify and develop bioactive lipid-based therapeutics
Rosetta Genomics Ltd. (NASDAQ:ROSG)	Rabin Medical Center	Diagnostics	Undisclosed	Partnership to develop a noninvasive, microRNA-based assay to diagnose chronic allograft dysfunction in kidney transplant recipients

the **Innovative Medicines Initiative (IMI)**'s GetReal project aimed at helping companies generate real-world data for payers during the drug development process, along with the clinical data necessary for regulatory approval. IMI formally launched the project last month.

GlaxoSmithKline plc and **University Medical Center Utrecht** are leading GetReal, which has a budget of €16.3 million (\$22.7 million), including €8 million (\$11.1 million) from IMI and €6 million (\$8.3 million) of in-kind contributions from consortium members.

The last two PPPs announced by AstraZeneca involve a pair of three-year oncology partnerships by its **MedImmune LLC** unit.

The first is between MedImmune and the **University of Cambridge** and will study tumor-targeted therapies, including antibody-drug conjugates. The second PPP pairs MedImmune and **The University of Texas MD Anderson Cancer Center** in an effort to evaluate the company's immunotherapy candidates in clinical settings through MD Anderson's Moon Shots Program.

Financial details of the deals were not disclosed.

In addition to these five PPPs, AstraZeneca launched its Open Innovation website in March. The site lists 47 compounds the pharma is making available to interested parties for clinical, translational research and disease biology studies. The list includes both active and discontinued compounds.

The website includes a way for interested parties to submit proposals to the pharma for grants of up to \$100,000 for target validation partnerships, as well as an R&D Challenges section through which the pharma plans to crowdsource solutions to problems.

Starting in May, the website will begin accepting proposals for projects to identify new molecules and profile their activity in relevant disease biology assays. The external partner will retain rights to the generated data and IP covering compounds evaluated under such projects.

Hitting infectious diseases

Last month, Japan's **Global Health Innovative Technology Fund (GHIT Fund)** announced its second round of grant awards, which will support projects focused on tuberculosis (TB) and three neglected tropical diseases.

The GHIT Fund is an infectious disease initiative that plans to disburse \$100 million over 5 years to support partnerships between Japanese and non-Japanese companies and research institutions that focus on HIV/AIDS, malaria, TB and neglected tropical diseases.²

The initiative was launched in April 2013 and announced its first round of grant awards in November. In the latest round, the GHIT Fund awarded \$12.5 million in aggregate to 4 partnerships.

Japan's **National Institute of Biomedical Innovation**, **Create Vaccine Co. Ltd.** and **Aeras** are getting \$5.7 million to fund development of a new vaccine candidate for TB. The award is on top of an initial \$700,000 grant to the partnership.

The candidate is targeted to the mucous membranes and is designed to enhance mucosal immunity to prevent bacteria from getting into the lungs. The new funding will support the preclinical work needed to advance the candidate into a Phase I trial.

Create Vaccine is a joint venture between **Dainippon Sumitomo Pharma Co. Ltd.** and **Japan BCG Laboratory Ltd.**

The next three partnerships to receive GHIT Fund grants are focused on neglected tropical diseases.

Eisai Co. Ltd. and the **Drugs for Neglected Diseases initiative** are getting \$3.8 million to fund a Phase II trial of benznidazole in combination with Eisai's E1224 to treat Chagas disease. E1224 is a prodrug of the antifungal ravuconazole.

Benznidazole is a generic antiparasitic drug used to treat Chagas disease but is poorly tolerated in adults and frequently fails to cure chronic infections.

Astellas Pharma Inc., **TI Pharma**, **Merck KGaA** and the **Swiss Tropical and Public Health Institute** are getting \$1.9 million to fund the development and registration of a pediatric formulation of Merck's schistosomiasis drug **Cesol praziquantel**.

The partners have produced test batches of two new praziquantel formulations—racemate praziquantel and levo-praziquantel. Both formulations will be tested first in adults and followed with taste tests in children. Missing clinical data, pill size and bitter taste have all been factors that hamper the use of Cesol in infants and young children.

Finally, Eisai, the **Liverpool School of Tropical Medicine** and the **University of Liverpool** are getting \$1.1 million to investigate new compounds to treat *Wolbachia* bacterial infections. The partners will focus on compounds from 2 chemical groups known to have potential as anti-infectives and run a 12-month, head-to-head comparison study.

The partners are aiming to identify a single candidate for drug development within two years.

Overall, PPPs that focus on infectious diseases had a strong showing in March, taking in almost 70% of the \$76.2 million in new support for PPPs disclosed that month.

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COMPANIES AND INSTITUTIONS MENTIONED

Aeras, Rockville, Md.

Astellas Pharma Inc. (Tokyo:4503), Tokyo, Japan

AstraZeneca plc (LSE:AZN; NYSE:AZN), London, U.K.

Dainippon Sumitomo Pharma Co. Ltd. (Tokyo:4506), Osaka, Japan

Drugs for Neglected Diseases initiative, Geneva, Switzerland

Eisai Co. Ltd. (Tokyo:4523), Tokyo, Japan

GlaxoSmithKline plc (LSE:GSK; NYSE:GSK), London, U.K.

Global Health Innovative Technology Fund, Tokyo, Japan

Innovative Medicines Initiative, Brussels, Belgium

Japan BCG Laboratory Ltd., Tokyo, Japan

Korea Health Industry Development Institute, Gangneung, Gangneung, South Korea

Liverpool School of Tropical Medicine, Liverpool, U.K.

Medical Research Council, London, U.K.

MedImmune LLC, Gaithersburg, Md.

Merck KGaA (Xetra:MRK), Darmstadt, Germany

National Institute of Biomedical Innovation, Osaka, Japan

Swiss Tropical and Public Health Institute, Basel, Switzerland

TI Pharma, Leiden, the Netherlands

University Medical Center Utrecht, Utrecht, the Netherlands

University of Cambridge, Cambridge, U.K.

University of Liverpool, Liverpool, U.K.

The University of Texas MD Anderson Cancer Center, Houston, Texas