Leukemia team building

By Chris Cain, Senior Writer

The **Leukemia & Lymphoma Society** has announced its first research partnership with a large biopharma company—a four-year, multimillion-dollar deal with **Celgene Corp.** to solicit and fund proposals from academics and smaller biotechs. The not-for-profit organization expects the deal's framework to serve as a template for future collaborations and is in talks with additional big biotech and pharma companies.

In its first year, the partnership will support up to 10 projects that explore basic disease mechanisms underlying hematological malignancies and up to 2 product development programs for advanced preclinical or early stage clinical candidates. Celgene will provide all research funding and will have right of first negotiation on any IP resulting from the projects.

“Over the last five years we’ve been partnering with biotech companies in earnest through the Therapy Acceleration Program, where we look for small companies that have assets that might be useful in treating blood cancers. What we hadn’t had were partnerships with big pharma or big biotech,” said Louis DeGennaro, EVP and chief mission officer of the Leukemia & Lymphoma Society (LLS).

Through the Therapy Acceleration Program (TAP), LLS funds the development of preclinical or early clinical assets discovered by academics or small biotechs. In return, recipients agree to pursue the funded project for a prescribed period of time and LLS is eligible to receive a fixed-multiple ROI that is fulfilled through a small royalty on net sales if a product makes it to market.

TAP currently supports 14 programs (see Table 1, “Programs on TAP”).

DeGennaro said a new program was needed to complement TAP and enable LLS to coordinate with biopharma companies to cofund external research projects. “We needed a new framework onto which we could build a partnership that would ensure that our mission was being fulfilled while at the same time ensuring that the pharma would get something out of the collaboration,” he said.

Thus, the organization created the Targets, Leads and Candidates Program (TLCP) to support research via two distinct funding

mechanisms: one tailored to early stage research into mechanisms of disease and one tailored to advancing preclinical or Phase I drug candidates.

Early and late

Celgene is the first participant in TLCP. The majority of the projects funded by the partners will explore basic science questions, such as identifying pathways and mechanisms that underlie the development of hematological malignancies. To narrow down research topics, Celgene and LLS will first form a joint steering committee tasked with identifying specific focus areas.

LLS then will issue a call for proposals from academic investigators, which will be peer reviewed in a process handled solely by the foundation. Applications that pass muster will be reviewed by the steering committee for final approval. DeGennaro said this selection and peer-review process is the key contribution LLS makes to the partnership.

“We have a well-established, proven infrastructure to identify high-quality research and have been doing this for 50 years. Our research grant funding has touched the discovery and development of every therapy used to treat blood cancers. What Celgene and other big companies can expect to get is access to that infrastructure and peer-review process and industry-quality project management by the LLS research team,” he said.

Celgene spokesperson Greg Geissman said infrastructure indeed was a driver of the company’s partnering decision. “We believe that LLS has a particular strength in its network and ability to identify promising

early stage, foundational research at academic centers,” he said.

DeGennaro said retaining internal control over the review process was essential to the structure of the partnership. “While the joint steering committee has the final go/no-go decision, the LLS vetting and peer-review process is intact. These are the rules that we felt we had to play by. At the end of the day it must be our internal review processes that judge what is worthy of funding,” he said.

Unlike other academic project grants funded by LLS, the TLCP projects will have specific timelines, milestones and deliverables, with progress overseen by the foundation’s staff.

TLCP will not operate in a vacuum, and to fund preclinical or early clinical-stage research the program will leverage the existing infrastructure used to identify projects eligible for the TAP program. LLS staff members will vet candidate projects as is currently done for TAP, and projects then will be presented to the joint steering committee, which will decide whether to adopt them as Celgene-funded projects.

Although the amount of research funding being provided by Celgene is undisclosed, DeGennaro said that projects will be funded over multiple years with annual budgets of between \$200,000 and

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**—Louis DeGennaro,
Leukemia & Lymphoma Society**

Table 1. Programs on TAP. The **Leukemia & Lymphoma Society** (LLS) has partnered with academic institutions or biotech companies to fund the development of at least 14 therapeutics in preclinical through Phase III development via its Therapy Acceleration Program (TAP).

Source: *BCIQ: BioCentury Online Intelligence; Leukemia & Lymphoma Society*

Partner	Year	Compound name	Description	Indication	Clinical status	LLS commitment
University Health Network/BioTherX Inc. ^A	2008	Ciclopirox	Repurposed small molecule antifungal	Hematological malignancies	Phase I	Undisclosed
Celgene Corp. ^B	2010	CC-292	Small molecule Bruton's tyrosine kinase (Btk) inhibitor	B cell malignancies	Phase Ib	\$3.2 M
Onconova Therapeutics Inc./Baxter International Inc. (NYSE:BAX)	2010	Rigosertib	Small molecule phosphoinositide 3-kinase (PI3K) and polo-like kinase 1 (PLK1; STPK13) inhibitor	Myelodysplastic syndrome (MDS)	Phase III	\$12.5 M
Shape Pharmaceuticals Inc.	2010	SHP-141	Topical histone deacetylase (HDAC) inhibitor	Cutaneous T cell lymphoma (CTCL)	Phase I	\$3.3 M
University of Colorado Denver	2011	Not applicable	Combination of cyclosporin A and tyrosine kinase inhibitor	Drug-resistant leukemia	Phase I	Undisclosed
Acetylon Pharmaceuticals Inc. ^C	2011	ACY-1215	Small molecule HDAC6 inhibitor	Multiple myeloma (MM)	Phase I	\$5.6 M
Memorial Sloan-Kettering Cancer Center	2011	MSK-777	Small molecule inhibitor of cell division cycle 7-related protein kinase (CDC7)	Acute leukemias	Preclinical	Undisclosed
University of Florida ^D	2011	Oxi4503	Combretastatin A1 diphosphate (CA1P) tubulin inhibitor	Acute myelogenous leukemia (AML)/MDS	Phase I	Undisclosed
Not applicable	2011	RI-BPI	Retro-inverso B cell CLL lymphoma 6 (BCL6) peptide inhibitor	Diffuse large B cell lymphoma (DLBCL)	Preclinical	Undisclosed
Curis Inc.	2011	CUDC-907	Small molecule dual PI3K and HDAC inhibitor	B cell lymphoma and MM	Preclinical	\$4 M
University of Michigan Medical School	2012	Undisclosed	Small molecules that block the interaction of myeloid-lymphoid or mixed-lineage leukemia (MLL; HRX) with multiple endocrine neoplasia I (MEN1; menin)	MLL	Preclinical	Undisclosed
The Johns Hopkins University School of Medicine	2012	PD-0332991	Small molecule inhibitor of cyclin dependent kinase 4 (CDK4) and CDK6	Acute leukemias/ MDS	Phase I	Undisclosed
Celator Pharmaceuticals Inc.	2012	CPX-351	Liposomal formulation of cytarabine and daunorubicin	Secondary AML	Phase III	\$5 M
Constellation Pharmaceuticals Inc.	2012	Undisclosed	Small molecule inhibitor of the bromodomain and extra terminal domain (BET) family of bromodomain-containing proteins	Hematological malignancies	Preclinical	\$7.5 M

^ALLS has a \$4.5 M equity investment in BioTherX. ^BProgram was known as AVL-292 prior to the purchase of Avila Therapeutics Inc. by Celgene in March 2012. Avila is now Celgene Avilomics. ^CAcetylon has received investment from Celgene. ^DOxi4503 is under development by **OxiGene Inc.** (NASDAQ:OXGN) for additional oncology indications.

\$1 million, depending on the type of research and stage of development.

The partners hope to identify research areas of joint interest and issue the first call for proposals before year end.

DeGennaro said LLS is in discussions with potential biopharma partners to set up additional independent collaborations using the TLCP framework.

With additional reporting from Sydney Blankers, Research Analyst.

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COMPANIES AND INSTITUTIONS MENTIONED

Celgene Corp. (NASDAQ:CELG), Summit, N.J.

Leukemia & Lymphoma Society, White Plains, N.Y.