OFFICE OF TECHNOLOGY LICENSING

INTELLECTUAL PROPERTY NEWSLETTER

2017 Issue

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PATIENTS AROUND THE WORLD BENEFIT FROM ST. JUDE RESEARCH THROUGH OTL LICENSING EFFORTS

Numbers are likely much greater, this is just what we can confirm. Descriptions of the indications and treatments continue below the table.

Indication	Treatment Tech.	Humans Treated
Influenza	Vaccine Production (Plasmid rescue)	14+ Million/yr.*
ALK Positive Cancer	Drug (Xalkori)	2500+/yr. (2014)**
ALK Positive Cancer	Drug (Zykadia)	200+/yr. (2014)
Cancer (ALL, CLL, NHL)	CAR Cell and Gene Therapy	200+
Hemophilia B***	Gene therapy (Factor IX)	20+
Neuropathy	Biologic (TACI)	13+
X SCID	Gene Therapy	5+, now in infants
Diagnostic	Thiopurine Tolerance (TMPT)	200,000+./yr.****
Diagnostic	B-cell detection (CD-19 MAb)	100,000+/yr.

Licensees include Bristol Myers Squibb, Juno, Novartis, Celgene, uniQure, AstraZeneca, Boehringer Ingelheim, Pfizer, Becton Dickinson, Insight Genetics, Quest Diagnostics and Prometheus Diagnostics. ALK drugs based on work done at St. Jude are made by Pfizer, Cephalon (now Teva), Ariad, Xcovery and Novartis. ALK diagnostics are now made by Abbott (now Abbvie), Cancer Genetics, Cell Marque, Cell Signaling, Cytocell, Dako, HTG Molecular, Insight Genetics, LabCorp (now ThermoFisher), Leica Biosystems, Pharmingen, Response Genetics, Santa Cruz Biotech, Ventana.

*Many more outside US and in animals (H5N1, chicken)

**Increasing to 7,200 by 2020 (of 11,000 ALK+NSCLC patients/yr.)

*** Hemophilia A FactorVIII trial in development

****Not all who are tested are patients

Flu Vaccine Made For 14 Million Humans In U.S., Billions More Doses Worldwide

St. Jude's plasmid rescue system is used to make 14 million doses (8% of total doses) of human live attenuated influenza vaccine in the U.S. each year and many more in the rest of the world for animals and humans. It is the only way vaccines for many deadly pandemic strains can be made. Vaccines made with this method have been used to help prevent outbreaks of dangerous flu strains in animals as well as create stocks for future use in humans in the event of an outbreak.

OTL Director Scott Elmer explains St. Jude's contributions to products used in lab research.

Alk Inhibitor Treatments For Childhood Leukemia And Adult Lung Cancer

The anaplastic lymphoma kinase (ALK) gene and its role in driving cancer cell growth was discovered at St. Jude in the early 1990s. This discovery was patented and licensed to pharmaceutical companies so they could identify drugs that inhibit ALK. The first ALK inhibitor, Xalkori, was approved in 2011 and the second, Zykadia, was approved in 2014. These drugs have proven useful for treating a variety of cancers that share the common property of being driven by abnormal ALK activity.

Chimeric Antigen Receptor Immunotherapies Get Closer To Approval

Juno Therapeutics, a startup company, licensed St. Jude's Chimeric Antigen Receptor (CAR) patent rights in 2013. The St. Jude CAR patent covers a CD19 41BB Zeta construct, and over 200 patients have been treated with this specific CAR. Juno partnered with Celgene to market and sell products outside the U.S. and sublicensed their rights to Novartis. Approval of the first CD19 CAR therapy is anticipated in 2017.

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Chad Riggs tells the story about how a drug candidate licensed for development in adult lung cancers from St. Jude was developed, approved, and is now used in the leukemia patient pollution in which the gene was first discovered at St. Jude.

Gene Therapy For Hemophilia B

Hemophilia B is caused by a mutation in the gene for Factor IX that can result in dangerously low levels of this essential clotting protein. For those with severe disease, scrapes and bumps are medical emergencies, and painful episodes of spontaneous bleeding can result in crippling joint damage early in life and/or an increased risk of death from brain bleeding. A gene therapy vector co-developed by St. Jude and University College London and currently in clinical trials is showing tremendous promise as a new, single administration therapy that could replace lifelong Factor IX injections for these patients. A video/TED talk describing the results thus far is at: https://www.youtube.com/watch?v=CN61zN8pg8I

Taci Treatment For Neuropathy

A St. Jude technology targeting the lymphocyte receptor TACI was licensed for treatment of inflammatory diseases. Currently, a neuropathy trial is open, which is expected to enroll approximately 100 patients.

Gene Therapy Vector To Treat XSCID In Infants

X-linked severe combined immunodeficiency disease (SCID-X1 or 'XSCID'), also known as "bubble boy" disease involves an extremely rare mutation that leaves sufferers with little to no immune protection. The gene therapy vector developed and produced at St. Jude corrects the mutant gene in the blood-producing stem cells of patients, and is combined with busulfan conditioning therapy to rebuild the immune system and lead to broad immunity. Results achieved in juveniles who had failed other therapeutic interventions have been so promising that the FDA allowed St. Jude to start treating patients less than one year old. Video at: https://www.youtube.com/watch?v=itcvg4_PYyc

Tpmt Diagnostic Helps Get Treatment Right For 200,000

Thiopurine drugs are used to treat patients with a variety of conditions including leukemia, rheumatic disease, inflammatory bowel disease and solid organ transplant. Mutations in the TPMT gene which lead to abnormal metabolism of these drugs were discovered at St. Jude. Diagnostic tests based on detection of these mutations have been developed by St. Jude licensees and are now widely used to screen patients before these drugs are administered.

100,000 B-Cell Tests A Year For CD-19

A diagnostics company licensed a St. Jude CD19 monoclonal antibody over 20 years ago to sell as part of a diagnostic test that is commonly used to detect B-cells in patient samples. They now sell approximately 100,000 kits annually.

A list of St. Jude inventions currently available for licensing can be found on our website. These include antibodies for research, biologics, diagnostics, drugs, drug discovery and development tools, software, vaccines and other technologies invented by those working for or with St. Jude and partner institutions.

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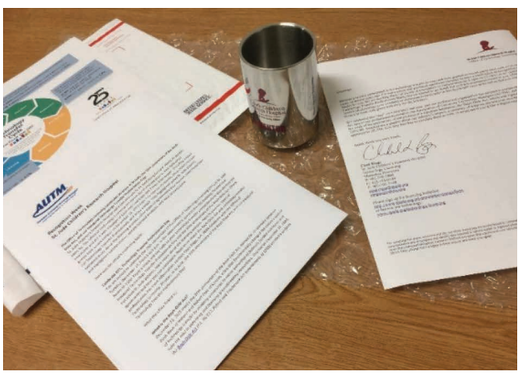
INVENTORS RECEIVE MORE THAN $5 MILLION FROM FY2016 LICENSE REVENUE

This last fiscal year was another good one financially for St. Jude's technology licensing operation. Licensing income is shared with inventors and creators of licensed materials, who receive an allocation of between 30 to 50 percent of net income produced by their inventions and reagents according to a formula set out in the faculty handbook. Total allocations for FY 2015 exceeded $5 million distributed to around 100 current and former St. Jude inventors.

All St. Jude employees have a risk-free opportunity to have their inventions or reagents considered for patenting and/or licensing by submitting invention disclosure forms to the Office of Technology Licensing. Employees can fill out and submit the simple disclosure form available at https://home.stjude.org/technology-licensing/Pages/forms.aspx or they can contact the Office of Technology Licensing for a Microsoft word version of the form.

Keep in mind that patience is a virtue when it comes to generating revenue from inventions. The vast majority of allocations this year were based on invention disclosures submitted more than 10 years ago. If you are interested in learning about some of the past inventions that have been developed into products and contributed to our licensing success, you can click the "Success Stories" link on our internet site http://www.stjude.org/technology-licensing.



Inventor mugs were mailed with the packet (pictured) to 30 former inventors whose patented inventions have led to successful products.

ST. JUDE OTL CELEBRATES TECHNOLOGY TRANSFER PROFESSIONALS DAY

On Monday, December 12, St. Jude celebrated Technology Transfer Professionals Day in the Marlo Thomas Center Atrium. This was the 36th anniversary of the Bayh-Dole Act which dramatically expanded the profession by engaging academic institutions in the technology transfer process. People who attended spoke with our technology transfer professionals to learn more about disclosing inventions, the licensing process, and ways to partner, participate and earn money. The day was first celebrated at St. Jude in 2015 to coincide with the 20th anniversary of the OTL as a separate department, and was formally adopted by the Association of University Technology Managers (AUTM) this year. The OTL also distributed exclusive stainless steel coffee mugs to inventors of recently awarded patents.

If you were contacted, please feel free to stop by our office to collect your mug, or we will deliver the remainders in a few weeks.

ST. JUDE OTL CONDUCTS SURVEYS FOR CLINICAL AND LABORATORY STAFF, FACULTY, AND POST-DOCS

The OTL conducted a customer satisfaction survey this past summer. We received responses from 66 staff, 39 faculty, and 37 post docs and thank all who participated. Overall the level of satisfaction in services provided by the OTL was high. Our website, speaking at seminars, and the newsletter were all identified as useful ways for people to learn about the OTL. The survey revealed that we have room to improve in the area of communicating with laboratory staff and marketing technologies that are available for licensing.

REGIONAL TECH TRANSFER PROFESSIONALS HOSTED BY OTL

On November 11, 2016, the St. Jude Office of Technology Licensing hosted an informal meeting at the Loflin Yard in downtown Memphis for representatives of technology transfer offices in the region. During the visit, the group discussed the upcoming "Technology Transfer Professionals Day", ways to market and encourage participation in the technology transfer process and other current issues affecting our offices. Attendees included Andrew Sustich, Brian Rogers, Hai Trieu, Lakita G Cavin, Luna Acosta, Richard Magid, Rob Clark, Delira Robbins, Stefan Schweizer, and Walt Chambliss representing Arkansas State University, the University of Memphis, the University of Mississippi, and University of Tennessee Health Science Center.

This chart describes the combined efforts of many licensing offices in 2015. At least 153 new drugs and vaccines were introduced to the market due to university and industry partnerships facilitated by the Bayh-Dole Act. Consumers and businesses benefited from the creation of 879 new products, with $28.7 billion net product sales. Strong intellectual property rights also help protect discoveries and ensure continued investment in research, and innovations at research institutions created 1,012 startups in 2015, up 11.3% over 2014.

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