

Office of Technology Licensing Intellectual property *newsletter*

St. Jude, Johns Hopkins and Medarex enter license agreement



Dario Vignali, PhD

St. Jude and Johns Hopkins have entered into a license agreement with Medarex to develop treatments based on inhibition of LAG-3 function.

Dr. Dario Vignali, Immunology, is working on the lymphocyte antigen gene-3 (LAG-3), a protein found on the surface of T lymphocytes (T-cells). Dr. Vignali and Dr. Creg Workman, a postdoctoral fellow at St. Jude, along with investigators at Johns Hopkins University, discovered that LAG-3's normal function is to act as a global negative regulator of T-cell function. Furthermore, they found the LAG-3 response to be more potentiated in regulatory T-cells (Tregs) than in the other subsets of the T-cell population. Tregs are important for

keeping the immune system in check, thereby limiting autoimmunity. However, they also suppress beneficial immune responses to parasites and viruses as well as antitumor immunity induced by therapeutic vaccines.

See Medarex, p.2

MTAs: What are they and why are they needed?

A Material Transfer Agreement (MTA) is a document executed between two entities when proprietary biological materials (cell lines, cDNA, nucleic acid probes or promoters, viruses, antibodies, whole animals, etc.) are transferred from one to the other.

The purpose of the MTA is to protect the providing party's rights and interests in the material it is providing. For example, the standard St. Jude MTA (i) assures that our investigators are appropriately acknowledged in publications which report results of research performed by requestors using materials developed at St. Jude, (ii) prohibits recipients from distributing St. Jude materials to others, (iii) preserves St. Jude's interest in the materials, and (iv) protects St. Jude from liability that may arise from the recipient's use of the St. Jude material.

Not-for profit organizations and universities generally exchange research materials freely with each other for little or no compensation and do not demand rights to inventions arising from the use of such materials. As a result, a standard MTA can usually be used to send materials to a not-for-profit organization with little or no negotiation involved.

Companies, on the other hand, do not usually exchange research materials freely and typically demand certain rights for access to their material. A company

See MTAs, p. 2

Medtrack database searches now available

The OTL recently obtained a subscription to Medtrack, a database of private and public biomedical companies. The database contains information on over 9000 companies and 38,000 drugs at various stages of development. We may now obtain pipeline, financial, competitive product, deal, mechanism of action, partnering and patent information on biomedical companies and products worldwide. For example, we can find the number of drugs a company has in its pipeline, the stage of development of each drug from preclinical research to on the market, the drugs' mechanism of action and the disease being treated. For public companies, financial information, including stock price, market capitalization and years of cash on hand, is available. If any of this information would be of benefit to you and your research, feel free to contact Scott Elmer, Shawn Hawkins or Esther Allay. We can perform a search upon your request or you can join us if you would like to participate in the search process either in our offices or at your computer.

MTAs, cont. from p. 1

MTA usually requests rights to St. Jude intellectual property generated through use of the company's material. Any company MTA provided to a St. Jude investigator must be reviewed by the OTL to make sure that it complies with institutional policy and is reasonable. All corporate MTAs are signed by the OTL Director, whether or not the company requests such approval.

Often, a company will request reagents from St. Jude for the company's internal use. In this instance St. Jude uses a different form of agreement, designated as a research license, and will normally charge a fee so that St. Jude receives a fair compensation for provision of its materials for commercial research. All requests for St. Jude materials from corporate researchers should be forwarded to the OTL so that an appropriate research license can be executed and fee received before the material is provided.

Can I take materials with me when I leave St. Jude?

When St. Jude faculty members and postdoctoral research associates leave St. Jude they are required to checkout with the OTL. If the departing employee is not taking any research reagents to his/her new position, the employee must sign a statement confirming this. If the departing employee wants to take materials with them to their new institution, they must first have an MTA covering the transfer executed by both St. Jude and their new institution. Employees are prohibited from taking materials with them to their new institution unless and until an MTA is in place.

The first step in the process is for the employee to submit a list of all the reagents they want to take to Esther Allay (esther.allay@stjude.org). If the departing employee is a postdoctoral fellow, he/she must obtain permission from the principal investigator (PI) of his/her laboratory to transfer the materials. Esther will talk with the departing employee and the PI to determine which materials are proprietary to St. Jude or other institutions. She will then draft and provide the departing employee with the appropriate MTA(s). This is a legal document between St. Jude and the departing employee's new institution. Therefore, an authorized official of the new institution must sign the agreement as well as the departing employee. Since the entire process of obtaining necessary approvals and getting the MTA(s) in place can take several weeks, employees who want to take materials with them are encouraged to contact Esther well in advance of their departure date to get the ball rolling.

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St. Jude Research Reagents for Sale

A list of research reagents, mainly antibodies, developed at St. Jude and currently being sold for research purposes is available on the OTL intranet site. This list provides a link to the website of each company that sells the reagent and identifies the St. Jude investigator who developed it.

Investigators who work with the OTL to license their reagents for sale to the research community receive a share of the license income generated from this activity. If you have a reagent that is or may be in strong demand from the research community, you can contact the OTL to see about licensing your reagent.

Medarex, cont. from p. 1

If a drug that binds LAG-3 is developed, it could block Treg function and allow the immune system to reconstitute more quickly. Such a treatment would be beneficial to patients who have suffered a blow to their immune system, such as stem cell transplant patients following myeloablation, HIV/AIDS patients and cancer patients who have gone through debilitating chemotherapy.

In 2003, St. Jude and Johns Hopkins jointly filed a provisional application claiming the LAG-3 technology. An international patent application was filed in 2004 and applications in foreign countries, including Australia, Canada, Europe, Hong Kong and Japan were later filed.

Medarex, a New Jersey based biopharmaceutical company, obtained an exclusive license in the spring of 2006 from St. Jude and Johns Hopkins to their jointly owned patent rights to develop human therapeutics. Medarex is focused on the discovery, development, and potential commercialization of fully human antibody-based therapeutics to treat life-threatening and debilitating diseases, including cancer, inflammation, autoimmune and infectious diseases.

St. Jude and Medarex more recently entered into a sponsored research agreement under which Medarex will provide funds to Dr. Vignali's laboratory to identify additional novel proteins on the Treg surface that regulate its function. These novel proteins may provide additional targets for therapeutic intervention with monoclonal antibodies.

In addition to the license and sponsored research agreements with Medarex, the OTL non-exclusively licensed LAG-3 monoclonal and polyclonal antibodies that were made in Dr. Vignali's laboratory for his research purposes. These antibodies were licensed to reagent companies for sale to the research community.