



November 16, 2010

Astellas Pharma Inc.

National Institute of Technology and Evaluation

Astellas Pharma Inc. and NITE: Search for Microorganisms Overseas in Accordance with the Principles of the Convention on Biological Diversity
Industry-Government Collaborative Research Program

1. Astellas Pharma Inc. (“Astellas”, headquarters: Tokyo; President and CEO: Masafumi Nogimori), and The National Institute of Technology and Evaluation (NITE; headquarters: Tokyo; President: Itaru Yasui), will start, effective in November 2010, a joint research program that aims to search for new microorganisms in Vietnam and put these microorganisms to industrial use centered on drug discovery.
2. The collaborative research program that Astellas will participate in will be conducted according to a framework NITE has built up jointly with the Government of Vietnam that is a cooperative relationship as prescribed by the Convention on Biological Diversity.
3. Astellas and NITE jointly search, collect and isolate microorganisms in Vietnam and assess their potential for industrial use. For Astellas, this is a chance to collect microorganisms that meet its own needs.

[Objective]

- Numerous new strains of microorganisms have been discovered in a search undertaken by NITE in Indonesia and other Southeast Asian countries. Based on these discoveries, Astellas will collect and isolate microorganisms from Vietnam, where a wealth of living organisms are available through ways that meet the objectives of Astellas. Astellas will aim to discover lead compounds for drug candidates from these microorganisms.

[Background]

- This collaborative research program is the collaboration of industry and government that are backed up by government agencies. It provides access to biological genetic resources in Asia that since the Convention on Biological Diversity came into force would be a burden for a Japanese company to independently gain access to.
- NITE has previously distributed microorganisms which they collected abroad. At the same time, NITE has had access to countries rich in biological diversity such as Southeast Asia. NITE also has set up a framework to fulfill the need of private enterprise to search for unknown, new microorganisms. This forms part of the work for promoting the initiative called Access to Genetic Resources and Benefit Sharing (ABS) that is described in “Japan’s Proposal on the Post 2010 Biodiversity Targets” that was announced in January 2010 and proposed at the tenth Conference of the Parties to the Convention on Biological Diversity (CBD-COP10) that has just concluded.
- By NITE building up a framework with the Government of Vietnam for access to genetic resources, Astellas has realized this access in as little as half a year from the time Astellas expressed its wish to participate in the framework.
- Astellas in 2005 also participated in a collaborative research program of NITE to search for microorganisms in Vietnam. At that time, Astellas was able to confirm that diversified

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microorganisms including those new genera and species were obtained by the genetic analysis of isolated strains. The data also strongly suggested that these microorganisms produced many unique compounds, and they were judged to be highly valuable as a screening source.

[Overview]

- The Astellas and NITE team will visit to Vietnam from November to December for this collaborative research program.
- At facilities of the Vietnam National University, Hanoi, a research partner of NITE, Astellas will isolate the target microorganisms from the samples such as soils and litters collected in northern Vietnam.
- The isolated microorganisms will be transferred to Japan based on an agreement with the Government of Vietnam. These microorganisms will be supplied to Astellas and used for searching for useful substances for drug discovery. When the research outcome leads to patent registration or commercialization, a part of profit will be returned to the Government of Vietnam.

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Collecting samples such as soils and litters in Vietnam

Supplementary Material

Fermentation Research at Astellas

Astellas has been studying the fermentation of natural products as one of its core R&D fields and has developed a number of innovative drugs such as the immunosuppressant Prograf® (generic name: tacrolimus) and an antifungal agent Funguard®/Mycamine® (generic name: micafungin sodium). Through the new collaborative research project, Astellas will further accelerate the discovery and development of new compounds derived from natural products, which is one of its most significant strengths.

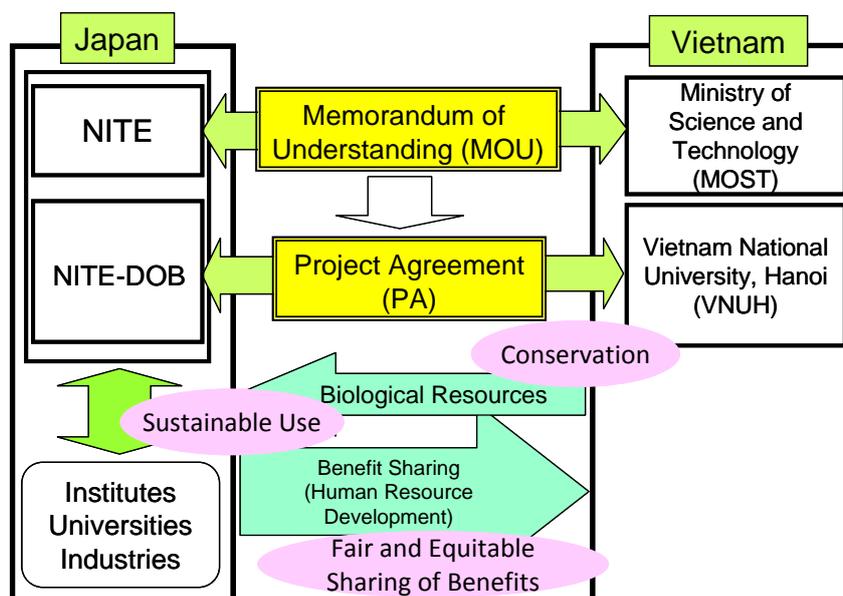
Achievements of the Overseas Programs of NITE

While strategically collecting, preserving and distributing microorganisms as a core Biological Resource Center with a focus on microorganisms in Japan, NITE represents government agencies of Japan, and has built up cooperative relationships with biodiversity-rich Asian countries based upon the Convention on Biological Diversity. Striving to establish close ties with biodiversity-rich Asian countries, NITE works jointly with those countries to isolate and collect the diverse and vast range of microorganisms that exist in these countries. Moreover, by finding useful application of these microorganisms, NITE aims for its activities to contribute to the development of related industry.

Working towards these goals, NITE abides by the Convention on Biological Diversity and by concluding accords with partner countries related to the conservation and sustainable use of microorganisms, it energetically promotes the research of microorganisms and the utilization of these resources. Exploration activities are currently being conducted in Vietnam, Mongolia and Brunei Darussalam, and NITE has established cooperative relationships with Indonesia, Thailand and China.

In 2004, NITE concluded two agreements with the Government of Vietnam: a comprehensive memorandum related to the conservation and sustainable use of microorganisms, and an agreement for the joint research related to taxonomic and ecological study of microorganisms in Vietnam and the utilization. While searching and collecting new microorganisms in Vietnam, transporting them to Japan and distributing them to the private sector, NITE is contributing to the development of microbiology in Vietnam through capacity building and human resource development in Vietnam.

(Schematic Diagram of Bilateral Cooperation with Vietnam)



Convention on Biological Diversity (CBD)

Convention on Biological Diversity came into force in 1993. The convention is comprised of three main pillars: (1) the conservation of biodiversity, (2) the sustainable use of biological genetic resources, and (3) the fair and equitable sharing of the benefits arising out of the utilization of biodiversity. Like the Washington Convention and the Ramsar Convention, the convention does not target only specific activities or specific habitats; rather, it extends a framework for the wildlife protection on two dimensions: as a convention on environmental protection to comprehensively conserve the biodiversity of living things on this planet, and as an economic convention on the fair and equitable sharing of the benefits arising out of the utilization of biodiversity.

The following means are defined for accomplishing the convention's objectives: (1) providing suitable opportunity for the acquisition of genetic resources (with consideration given to all rights), (2) appropriate transfer of related technologies (with consideration given to all rights), and (3) granting of funds.

Under the convention, with regard to the overseas acquisition of genetic resources, the sovereign rights over these genetic resources belong to the country that holds them and when access to that country's genetic resources are actually desired, then procedures in accordance with the domestic laws of that country must be followed.

Tenth Conference of the Parties to the Biodiversity Convention (COP10)

The Conference of the Parties (COP) is a conference (conference of contracted parties) at which countries contracted to international conventions meet. With respect to the Convention on Biological Diversity, which was concluded to protect diverse living creatures and habitat environments and the utilization into the future of these natural assets, the tenth Conference of the Parties to the Convention on Biological Diversity (COP10) was held in Nagoya, Aichi Prefecture, Japan in October 2010.

For reference see the following URL: http://www.cop10.go.jp/doc/html/Convention_E.html

Japan's Proposal on the Post 2010 Biodiversity Targets

Japan's Proposal on the Post 2010 Biodiversity Targets is a proposal delivered by the Government of Japan in its international role as the COP10 Chair to revise the convention's strategy plans examined at the tenth Conference of the Parties to the Convention on Biological Diversity (COP10). The medium to long term target to achieve by the year 2050 is "to realize the coexistence between human beings and nature all around the world, to improve the state of biodiversity from the current level as well as to sustainably increase the benefits of ecosystem services that the humans enjoy." To achieve this, short-term goals by the year 2020 have been established and various initiatives are being implemented to achieve these targets.

For reference see the following URL: www.cop10.go.jp/doc/pdf/Brochure_E.pdf

Lead Compound

Lead compounds are candidate compounds for drug discovery. According to the definition of the Japan Pharmaceutical Manufacturers Association (JPMA), a lead compound is a "novel chemical compound that has a clear pharmacologically active profile, whose activity is expected to be improved and whose toxicity is expected to be weakened through chemical modification."