

Some Cantons support international business development for SMEs. The table below shows current opportunities in Cantons. Notice: please check with your local representatives for changes and application processes.

Cantonal support for participation at trade fairs.^{1,2}

Do you need financial support to participate at the Swiss/Group Pavilions? Please contact the appropriate department/organization listed below.

Canton	Department/Organization	Support
BE	Economic promotion Canton Berne www.wfb.ch	Will provide support up to a maximum of 50% of the costs, up to limit of 10'000 CHF per exhibitor. A company may be supported a maximum of two times per year.
GE	Canton Geneva	The canton Geneva does not provide support, but support is available through its partners Alp Ict, BioAlps and Micronarc.
GL	Canton Glarus	The canton Glarus basically provides no support. Occasionally they may contribute support for a company, if the canton Glarus itself can benefit from the exhibit.
GR	Department for Economy and Tourism Grisons AWT www.awt.gr.ch	Will provide support, but only if the requirements of all legal ordinances are fulfilled.
TI	Canton Tessin www.ti.ch/fiere	Will support national and international trade fairs up to a maximum of 50% of the costs. Applications may be submitted more than once a year, however each company is limited to 20'000 CHF per year.
VD	Canton Vaud www.vd.ch	Will provide support up to a maximum of 50% of the costs, up to limit of 5'000 CHF per exhibitor. For events in Switzerland they will support the first two participations at the same event. For events that occur abroad they will support the first five participations at the same event.
VS	Centre de Compétence Financières SA www.ccf-valais.ch	Will provide support up to a maximum of 50% of the costs, up to limit of 20'000 CHF per exhibitor. Restrictions apply.
JU	République et Canton du Jura, Bureau du développement économique eco.jura.ch	Will provide support up to a maximum of 50% of the costs, up to limit of 10'000 CHF per exhibitor. Each company is limited to 20'000 CHF per year.
BE/FR GE/JU NE/VD VS	BioAlps www.bioalps.org	BioAlps support medtech companies for travelling and accommodation at foreign fairs up to 50% and up to 1'000 CHF. Restrictions apply.

¹ No responsibility is assumed for the correctness of all information provided. Numbers of exhibitors, visitors, and exhibition area based on previous year data.

² Non-comprehensive list; please inform us of additional support opportunities (

swiTT

The Swiss Technology Transfer Association is the association of technology transfer professionals who are active in the transfer of technology from institutes of public research and education, university hospitals, and other not-for-profit research organizations to the private sector. It was founded in October 2003 and has grown to include a large number of members from all of Switzerland.

The annual survey „swiTTreport“ is the most comprehensive analysis of the technology transfer activities of Swiss public research institutions. It contains data and success cases from different science disciplines



SWISS BIOTECH™

NTN News Bulletin

One Nation, One Biotech Cluster

No 4, December 2013

Editorial

Domenico Alexakis



Dear Readers,

The 4th bulletin of this year covers interesting experiences made during the year and presents results and interpretations. One goal of

the NTN (national thematic network) is motivation, information and support for new collaborations between academy and industry. CTI (Commission of Technology and Innovation) is the federal funding agency for such projects and initiator of the NTN's. Through the year, a whopping 13 projects with a total combined value of just under CHF 3.0 million were generated, supported and approved by the CTI experts. Details of the projects are presented in this bulletin.

For the upcoming holidays, our team wishes you some restful time and a good start into 2014.

Switzerland Global Enterprise

The recent trade fair and conference in Hannover, Biotechnica, held for the 20th time, chose Switzerland as guest country. This honour reflected the past involvement of Swiss Biotech™.

Our association relies for big international events on the formerly known OSEC. Since May this year, OSEC has changed its name to Switzerland Global Enterprise (S-GE). The organisation has many service offers and supports business development on foreign soil.

S-GE works all over the world to support entrepreneurs and promote Switzerland as a business location. Its role as a center of excellence for internationalization is to foster exports, imports and investments, to help clients develop new potential for their international businesses and to strengthen Switzerland as an economic hub. S-GE is a strong and trusted partner for its clients, the cantons and the Swiss government, with a global network of experienced advisers and experts.

S-GE is represented abroad by Swiss Business Hubs. Following an initial consulting session in Switzerland, the Swiss Business Hubs are the next point of contact with S-GE in the export country concerned. All hubs have a first-rate network of contacts abroad on account of their official status. In addition, these hubs are responsible for promoting Switzerland as a business location abroad.

In the biotech sector, S-GE works in close cooperation with the Swiss Biotech Association. Together many successful Swiss Pavilions at international biotech shows were organized. (e.g. BIO International Convention, BIOTECHNICA).

SWISS Pavilion at BIOTECHNICA 2013 organized by S-GE and SBA



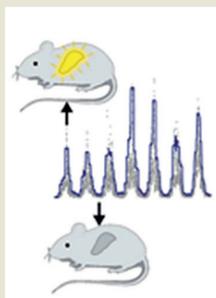
FIRST REAL TIME-BIOLUMICORDER TO MEASURE LONG-TERM GENE EXPRESSION IN FREELY MOVING RODENTS



swiTT CASE

Problem – Challenge

Virtually all mammalian physiological functions regularly fluctuate during the day. This fluctuation is orchestrated by a central clock located in the brain and local oscillators named clock genes, which are present in all organs. Clock genes are transiently expressed during the day, conferring circadian rhythms within individual cells throughout the organisms. The disruptions of circadian rhythms contribute to numerous pathologies including metabolic and cardiovascular disorders, cancer and aging, which have lead many research laboratories to investigate the mechanism of clock genes expression. The circadian rhythms are usually studied by detection of bioluminescence emitted by luciferase, a reporter gene fused to clock genes. However, due to the lack of appropriate in vivo bioluminescence recording technologies, studies on circadian rhythms have been mainly restricted to in-vitro experiments using mammalian cell lines.



Solution

The Real Time Biolumicorder has been developed to monitor and analyze rhythmic clock gene expression in real time. The machine was designed to record the bioluminescence emitted by a target cell population that has been genetically engineered to express a luciferase reporter gene in organs of freely moving mice over many consecutive days. The RT-Biolumicorder consists of a cylindrical cage equipped with a PMT, a feeding machine, a water flask and a photon-reflecting wall. The RT-Biolumicorder has proven to be a useful tool to study circadian rhythms but will also find wide and fruitful applications in other areas of biomedical research such as revealing the kinetics of signaling by hormones, cytokines, metabolites and medical drugs. The University of Geneva has patented the machine and granted an exclusive license to IESA-Technology SA to manufacture and sell The RT-Biolumicorder. The measurement of bioluminescence in real time allows scientists to track the expression of clock genes in mouse livers.

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Published 3 times a year (print or pdf.)

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NTN partners:



Biotechnica project partner:



University Medicine Zurich (Hochschulmedizin Zürich)



Corina Schütt

«University Medicine Zurich» is a strategic initiative of the University of Zurich, ETH Zurich and the University Hospitals promoting collaboration between these institutions. The academic setting in Zurich offers a wide range of relevant disciplines from basic research all the way to diverse applied sciences (life sciences, engineering sciences, clinical disciplines) and therefore embraces a unique potential of innovative, interdisciplinary, translational research (“from bench to bedside”). Several inter-institutional collaborations have existed for decades. However, a coordinating umbrella organization, which condenses all activities in biomedical research and education and thus constitutes a formal basis for cross-linking medicine and basic research, was missing until the foundation of «University Medicine Zurich» in 2011. «University Medicine

Zurich» thereby serves as a platform to kick off new projects, to enhance existing collaborations and to define and develop new strategic focus projects in the field of translational medicine. Fields with inherent synergy potential should be revealed and bundled, e.g. in the form of joint institutes, competence centers, technology platforms and collaborative educational programs. The coordination of activities promotes visibility of the projects and facilitates funding. «University Medicine Zurich» is also a point of contact for internal researchers as well as industry partners looking for a certain expertise or research partners.

The partner institutions strive to reach highest scientific quality in the field of translational medicine and within the scope of this collaboration aim to ensure and extend the internationally well-known reputation of excellence of Zurich's university medicine.

News on Regulatory Solutions



Tobias Ostler

In September 2013 EMA approved Inflectra®.

Inflectra® (infliximab) is a biosimilar medicine to the reference medicinal product Remicade® (infliximab), and is the first therapeutic monoclonal antibody approved via the EMA biosimilars regulatory pathway.

The regulatory pathway for approval as a biosimilar is based on the proof that the follow on product is similar to the reference product on a molecular and biological level. This process follows a case-by-case, scientifically driven risk-based evaluation to ensure the similarity of the biosimilar and the reference product in respect to quality, efficacy and safety. The proof of biosimilarity is guided via a structured, stepwise process in which the molecular, safety and efficacy comparability of the new molecule need to be studied and interpreted.

As a first step, a comprehensive in vitro comparison is made of the reference molecule and the biosimilar molecule including physiochemical, biological and production-related quality attributes. Further development includes a comparative non-clinical as well as a clinical and post marketing authorization program designed to detect differences between the reference and biosimilar products. Every difference at a molecular or biological level should be interpreted for its potential impact on safety, and study designs should address these differences and not response per se. Therefore, the design of clinical tests to demonstrate comparability should be flexible and adaptable throughout the development of the product.

This regulatory science-based approach has been successfully applied in Europe since the first biosimilar was approved in 2006.

Despite continuously growing experience from different stakeholders including the EMA, the development and approval of the first biosimilar therapeutic antibody means that a new level of complexity for follow on products has been reached. All biosimilar molecules which have been approved

since 2006 have a relative small molecular size (~6 – 30 kDa). In contrast, Inflectra® (~150 kDa) represents a molecule not only an order of magnitude larger, but with a complex mode of action.

The EU guideline concerning the development of monoclonal antibody biosimilars allows for extrapolation based on solid scientific evidence compiled by the applicant. This approach has been chosen for Inflectra®. The drug's safety, efficacy and tolerability have been established through a clinical trial program. In a phase III randomized, double-blind study with rheumatoid arthritis patients, Inflectra® met its primary endpoint of therapeutic equivalence to the reference product. This positive risk/benefit profile has been extrapolated to Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis.

With regard to safety, as for all biosimilar products a risk management plan has been developed which serves as an important tool to monitor and collect post marketing safety data.

Within the safety data evaluation of biosimilar antibodies, immunogenicity is recognized to be of prime importance. In this context it remains prudent, however, to avoid multiple switching between the originator and biosimilar monoclonal antibody until more extensive clinical experience is available.

Tobias Ostler
November 28th 2013



Successes – 1st year NTN Swiss Biotech™

The following new CTI projects were approved during the first period of the NTN Swiss Biotech™.

The CTI support mechanism is open to all innovators. For more information please contact: alexakis@swissbiotech.org.

Titel/Thema	Duration	Partner Economy	Partner Academy
HIT to LEAD to Preclinical Candidate development	2 years	Bioversys AG	ZHAW + 4
Identification and pre-clinical development of novel integrin modulators	2 years	Alloocyte Pharm plus Polyphor	FHNW + 2
SwissBody-enabled small molecule drug discovery	4 years	F. Hoffmann-La Roche AG	Uni Zürich + 2
Optimierung des INTX-CRP Card Test	2 years	INTEX Pharmazeutica AG	FHNW
A simplified optical read-out to quantify contractility in cardiac microtissues	2 years	Insphero	CSEM
Soft tissue management advanced cell adhesion via modification of a hydrogel	2 years	Straumann AG	Empa
Establishment of biologically relevant soft material for permeation studies	2 years	CellIntec Advance Cell Systems AG	ZHAW
Polymeric nanosegments for electro-functional textiles	2 years	HeiQmaterials AG	FHNW
Development of a novel hydrogel based miniature platform for 3D micro-tissues	2 years	NCL NewConceptLab	FHNW
Effectiveness of soft material to enable periodontal ligament regeneration	2 years	Credentis AG	ZHAW
Bio-printing platform to manufacture lung tissue for risk assessment	2 years	RegenHu	Uni Fribourg
Synthetisches Peptid für die Regeneration des Zahnhalteapparates (MedTech, Produktentwicklung für die dentale Medizin)	2 years	Credentis AG	ZHAW / FHNW
Entwicklung einer Single-Use nano Dosiereinheit	3 years	ReseachChem GmbH	BFH + 1

Swiss Biotech™ on the road 2014

Our successful program 1Nation1Cluster for Biotechnology is present abroad and in Switzerland. Following events are planned. Where the date/location is not yet fixed, we will communicate as soon as dates are fixed.

Top 10 Biotech Events: Swiss Biotech Presence 2014

Conference	Delegates	Background	Lead	Target Audience	Involvement
BIO-Europe Spring Torino March 10 - 12	> 1'800	High caliber partnering opportunities.	SBA	Biotech and pharmaceutical executives, investors	table top Organiser: EBD
BIO International Conference San Diego June 23 - 26	> 15'000	Global event for biotechnology	SGE (ex. Osec)	Biotech and pharmaceutical executives, investors	Swiss Pavilion Organiser: BIO
Biotrinity London May 12 - 14	> 800	Partnering and investment	SBA	R&D, Pharma, Investors	OBN
BioPharm America™ Boston September 22 - 24	> 900	Meeting place to identify and enter strategic relationships	SBA	Biotech and pharmaceutical executives	Table top Organiser: EBD
Nordic Life Science Days Stockholm, September 7-9	?	European Partnering Event second event	SBA	Biotech and pharmaceutical executives	Table top Organiser: SwedenBIO
BIO-Europe® Frankfurt November 3 - 5	> 2'900	Largest European partnering conference	SBA	Dealmakers from biotech, pharma and finance	Table top Organiser: EBD
Swiss Biotech Day Zürich – Kongresshaus April 8	< 400	Top event for Biotech in Switzerland (including General Assembly of SBA)	SBA/NTN	Members SBA, investors, dealmakers, analysts, policy makers	Co-organiser
NTN Swiss Biotech Fair Basel – 1st week September	< 500	Industry projects presented by academia and industry	NTN	Academia, students, industry, authorities	Co-organiser
Swiss Biotech Fall Day Lausanne 6-10 October	< 300	Top event for Biotech in Switzerland – part 2	NTN	Companies, regions, innovations	Co-organiser
Regulatory Event Bern September ?	< 120	Update on regulatory issues - National - International	SBA	Companies / members of SBA	Lead