Drug delivery systems: topical micellar delivery technology for poorly soluble drugs and injectable controlled drug release technology for small molecules, peptides and proteins.

Summary

A Swiss SME developed 2 drug delivery technologies. A micellar polymeric technology highly improving the solubility of poorly soluble drugs, enhancing tissue penetration and creating an in-situ drug depot after topical application and a liquid polymer that creates a controlled release of small molecules, peptides or proteins up to 6 months. The technologies are non-toxic. Degradation products are safe compounds. Service agreement, technical cooperation, licensing with pharma/biotech are sought.

Creation Date	19 July 2017
Last Update	16 August 2017
Expiration Date	16 August 2018
Reference	TOCH20170719001

Details

Description

A Swiss SME, active in the development of pharmaceutical products and drug delivery systems, has developed 2 drug delivery technologies.

Drug delivery refers to technologies and formulations to transporting therapeutics in the body. Common routes of administration are e.g. through the mouth, skin, transmucosal or by injection. Among other important factors the applied drug delivery technology has influence on the drug release profile, absorption and distribution of the drug in the body and the elimination of the drug. Current research aims to develop engineered technologies for the targeted delivery and/or controlled release of therapeutic agents.

The Swiss SME offers the following drug delivery technologies.

Nanocarrier technology:
The nanocarrier is solubilizing poorly soluble drugs and increasing tissue penetration of active ingredients when applied topically to the skin, eye or mucosa. The technology is based on co-polymers of methoxy poly-ethylene glycol (mPEG) and hexyl substituted poly-lactide acid (hexPLA). In an aqueous environment, the nanocarrier spontaneously forms nanosized micelles in a self-assembly process. Micelles are aggregates of amphiphilic molecules with the hydrophilic parts exposed to the aqueous phase, while the hydrophobic tails are sequestered in the micelle core. During the self-assembly process of the co-polymers, poorly water-soluble active ingredients are incorporated in the lipophilic core of the micelles and their solubility could

be increased 10x to 100x or more. This nanocarrier is suitable for topical applications in dermatology, ophthalmology and gastroenterology.

Liquid drug delivery system:
The developed liquid drug delivery system is suitable for sustained release of small molecules, peptides and proteins. Release of therapeutic drug amounts can last up to 6 months following a single injection. The delivery system is a hexyl substituted poly-lactic acid (hexPLA) with a molecular weight of 2500 g/mol. The manufacturing is done without the use of catalysts by melt polycondensation process. It is a liquid controlled release system, which could be prepared into ready to use syringes.

The Swiss company is looking for partners having difficulties to formulate a poorly soluble compound for topical application and which would require a delivery technology such as the nanocarrier described above. The company is also looking for partners with proprietary compounds such as small molecules, peptides or proteins requiring a controlled release for up to 6 months following a single injection. Both, the nanocarrier and the liquid drug delivery system are protected (granted and applied patents), therefore an extended protection of the formulation (protection of a drug combined with delivery system) is possible. An initial feasibility study could be performed, followed by an extended collaboration and a commercial license granted for market exploitation. Both technologies are produced in good manufacturing practice (GMP) qualified manufacturing sites. Preclinical studies have shown the technologies as safe. The nanocarrier will be used in humans in a clinical study for the first time in late 2017.

Partners from pharma and biotech are sought for technical cooperation, service agreements or technology in-licensing.

Advantages and Innovations

Advantages of the nanocarrier (compared to liposomes, micellar surfactant formulations, mucosal penetrating particles):

- Significant solubility increase (up to 100x or more) and bioavailability of poorly soluble drugs.
- Clear, water-like formulation appearance (important in ophthalmology).
- In dermatology, easy to apply, hydrating, quickly dispersing gel with no trace.
- Release of the cargo inside the biological target site with a creation of a drug depot. A drug depot creation allows less applications per day or even one daily application.
- Facilitated transport into biological structures due to the nanosize range of the carrier.
- Limited systemic side effects.
- Lyophilisable.

Advantages of liquid drug delivery system (compared to microspheres, implants, poloxamers):

- Minimal initial burst, steady release.
- Liquid, easily injectable even with small needles.
- No catalyst use.
- Superior release profile due to surface erosion of a plastic and constantly reshaping polymer droplet -suitable for poorly water soluble drugs, but also for water soluble molecules such as therapeutic proteins or peptides.
- The water-free matrix protects incorporated active pharmaceutical ingredients (APIs) from hydrolytic or enzymatic degradation and allows a stable, long-term release.
- Biodegradable.
- One-step mixing procedure of the drug and the liquid drug delivery system (no solvents).
- Suitable for peptides and proteins.
- Highly stable.

Stage of Development

Field tested/evaluated

Comments Regarding Stage of Development

Preclinical stage, first clinical trial is currently in preparation.

IPR Status

Secret Know-how,Patent(s) applied for but not yet granted,Patents granted

Comment Regarding IPR status

4 layers patent protection: synthesis method of nanocarrier and liquid drug delivery system (granted in EP), nanocarrier and liquid drug delivery system compound (granted in US 2x, JP, CA, EP), their pharmaceutical use (applied) and formulation (applications possible with an active pharmaceutical ingredient (API) protections.

Profile Origin

National or Regional R&D programme

Keywords

Technology

03004007	Pharmaceutics
06001013	Medical Technology / Biomedical Engineering
06001015	Pharmaceutical Products / Drugs
06006004	Biopolymers
06006006	Biological Nanomaterials

Market

05003005	Drug delivery and other equipment
05005002	Ophthalmology, ear, nose and throat diseases
05005003	Endocrinology
05005004	Gastroenterology
05005014	Oncology

NACE

M.72.1.1	Research and experimental development on biotechnology
Q.86.9.0	Other human health activities

Network Contact

Issuing Partner

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Open for EOI : Yes

Dissemination

Send to Sector Group

Bio Chem Tech

Client

Type and Size of Organisation Behind the Profile

Industry SME <= 10

Year Established

2011

Already Engaged in Trans-National Cooperation

Yes

Languages Spoken

English
German
Russian
French

Client Country

Switzerland

Partner Sought

Type and Role of Partner Sought

The specific area of activity of the partner:

Pharmaceutical and biotech companies.

The tasks to be performed by the partner sought:

Perform late preclinical studies including toxicology, clinical studies and market preparation, marketing and distribution.

Type and Size of Partner Sought

SME 11-50,R&D Institution,251-500,SME 51-250,>500

Type of Partnership Considered

Services agreement
License agreement
Technical cooperation agreement

Attachments

In vivo testing platform for biomedical research

Summary

A German SME offers a range of services around small and big laboratory animals according to international standards (e.g. FELASA) on the basis of technology or contract research agreements for preclinical studies and medical devices research and development. Services agreements, technology cooperation and subcontracting in European research and innovation projects is also possible.

Creation Date	20 April 2016
Last Update	17 October 2017
Expiration Date	01 May 2018
Reference	TODE20160420001

Details

Description

The German SME was founded out of the University of Mainz in 2004. Since then it is a service provider for research-based pharmaceutical companies, biotech companies, medical-biological research institutions and medical devices manufacturers.
The basic idea is using appropriate and high-quality animal models, accomplish facts and generate reproducible data. Professionals are forming a team that has extensive experience in animal husbandry and breeding, diagnostics, and pharmacology and pathology.

The core competencies of the company cover the fields of diagnostics of a complete health monitoring service for laboratory animals, the production of diagnostic monoclonal and polyclonal antibodies, and pharmaceutical and toxicological studies following the guidelines of good laboratory praxis (GLP).

The company is ready to offer the following tasks to clients within services agreements, on a "fee-for-service" basis. Participants of European research projects are welcome to outsource in-vivo studies by subcontracting.

Preclinical studies are performed in vivo according to standard methods or are developed according to the customers needs using tailor-made methods and models. A large animal unit and surgical facility enables a broad range of studies, such as implant, cardiovascular, neonatal and pharmacokinetic studies. The facility house allows keeping of up to 25 pigs.

The following services are offered in details:

1) Antibodies and assay development

The custom antibody services include peptide design, syntheses, labelling and conjugation, monoclonal and polyclonal antibody production, purification and immunoassay development. Antibody generation is carried out via:

• peptide immunisation
• DNA immunisation
• monoclonal antibodies in mouse and rat
• polyclonal antibodies in mouse, rat and guinea pig
• immunisation in genetically modified animals is possible according to S1 security prescriptions.

Tailor-made antibody based assays are developed, tested, evaluated and delivered as microplate based test systems for high throughput screening.

2) Preclinical research

The company conducts a wide variety of reproducible and comprehensible in vivo studies by using own laboratory animals according to the needs of the customers. The services include:
• toxicological studies according to GLP standard
• pharmacological studies
• pharmacokinetics
• transdermal tests in pigs
• medical device testing (including histology/X-ray or clinical chemistry)
• therapeutical studies
• tumor models

3) Diagnostics

Health monitoring of laboratory animals service following the recommendations of FELASA include:
• serological tests (ELISA)
• direct antigen test (RT-PCR/PCR)
• parasitology
• pathology (Histopathology)
• cytology
• microbiological tests (differentiation, antibiogramm)
• coagulation screening from blood samples
• clinical chemistry for different species (mice, rats, dogs, pigs).

4) Studies in a large animal unit

Implant Studies, e.g. oesophagal stents and implants, tracheal stents, urethral catheters;

Dermal Studies, e.g. wound dressing, wound healing, pharmacocompability, cardiovascular studies, heart catheters, blood vessel catheters and stents, ECG;

Neonatal studies, EEG;
Pharmacokinetic studies

Current and Potential Domain of Application:

• pharmaceutical Research and Development (oncology, neurogenerative diseases): in vivo preclinical testing
• chemical industry: in vivo toxicological testing (REACH)
• medical device testing, in vivo
• food microbiology

• husbandry of laboratorial animals
• development of antibody-based diagnostics

Advantages and Innovations

The companies' expertise in veterinary medicine and the facilities of keeping small and big laboratory animals enables them to offer an exceptional broad variety of pharmacological research services that are not very common for an SME.

In details the advantages for the clients and partners are:

•Essential in vivo research is realised in-house, and therefore ensures cost-effective service and a direct transfer.

Operating rooms for small and big animals

•Veterinary surgeon expertise allows animal health monitoring services within own research projects and also as external service not common in competitive offers.

•A large variety of pharmacological and biomedical research and development services is provided by using both standardised and tailor-made methods according to the customers' needs.

Stage of Development

Available for demonstration

IPR Status

Secret Know-how,Patents granted,Other

Profile Origin

Private (in-house) research

Keywords

Technology

06001005	Diagnostics, Diagnosis
06001013	Medical Technology / Biomedical Engineering
06002007	In vitro Testing, Trials
06002010	Toxicology
07001009	Veterinary Medicine

Market

05001001	Diagnostic services
05001002	In-vitro diagnostics
05001007	Other diagnostic
05002005	Other medical imaging
05009003	Animal health

NACE

A.01.4.5	Raising of sheep and goats
A.01.4.9	Raising of other animals
Q.86.9.0	Other human health activities

Network Contact

Issuing Partner

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Open for EOI : Yes

Dissemination

Send to Sector Group

Bio Chem Tech

Client

Type and Size of Organisation Behind the Profile

Industry SME 11-49

Year Established

2004

Turnover

1 - 10M

Already Engaged in Trans-National Cooperation

Yes

Experience Comments

Languages Spoken

English
German

Client Country

Germany

Partner Sought

Type and Role of Partner Sought

- Type of partner sought:
pharmaceutical industry and research organisations, biotechnology companies and research organisations, chemical industry, medical devices development.

- Specific area of activity of the partner:
The ideal partner should be active in drug or medical devices development, diagnostic development.

- Task to be performed by the partner sought:
The partners or clients may deliver:
targets for antibody development, lead substances for preclinical in vivo testing, chemical substances for in vivo toxicological testing.

Type and Size of Partner Sought

SME 11-50,University,R&D Institution,SME <10,>500 MNE,251-500,SME 51-250,>500

Type of Partnership Considered

Services agreement
Technical cooperation agreement
Research cooperation agreement

Attachments