Folate-Target Nanodevices To Activated Macrophages For Rheumatoid Arthritis

Fact Sheet

Project Information

FOLSMART
Grant agreement ID: 683356

Funded under
H2020-EU.2.1.2.2.
H2020-EU.2.1.2.5.
H2020-EU.2.1.2.
H2020-EU.2.1.2.3.

Overall budget
€ 4 993 833,75

EU contribution
€ 4 993 833,75

Coordinated by
ASSOCIACAO UNIVERSIDADE EMPRESA PARA DESENVOLVIMENTO TECMINHO
Portugal

Start date
1 January 2016

End date
31 December 2020

Objective

FOLSMART will bring to phase I clinical trials novel folate-based nanodevices (FBN) for the treatment of rheumatoid arthritis (RA). These nanodevices for folic acid (FA)-mediated targeting of activated macrophages showed improved clinical scores in a mouse model of RA when compared to methotrexate (MTX), first-line drug therapy for the treatment of RA. In this way, FBN will be benchmarked against this drug. MTX has significant associated toxicity and second-line biological therapies pose a great economic burden to hospital/public health systems. In parallel, nanodevices encapsulating Sulfasalazine (SSZ), will be tested. SSZ is a second line indication for
the treatment of RA, unresponsive to MTX or MTX-intolerant patients. Furthermore, FOLSMART proposes the optimization of mechanisms for the release of the drugs, through pH and temperature-sensitive nanodevices. Exploitation and business plans will be elaborated. In parallel, the initial economic evaluation of all proposed treatments will be performed to validate these claims.

Specific technological objectives of FOLSMART will be:

Good Manufacturing Practice (GMP) production of the FBN based therapies which have been positively bench-marked in the previous FP7 European project NANOFOL in comparison with the use of MTX in a RA mouse model:
- Liposomal MTX and SSZ with FA-“neck domain” peptide as targeting agent
- Nanoparticles from HSA-FA/MTX conjugates and SSZ
- Optimization of mechanisms of drug release and application to other fields

Pre-clinical development on RA models:
- Toxicology and pharmacokinetics, to determine tolerability and efficacy benefit in two animal models rat and dog, under Good Laboratory Practice (GLP) standards
- Genotoxicity and Carcinogenicity

Preparation for Phase I clinical trial of the best therapies bench marketed against MTX:
- Nanodevices with MTX and SSZ will offer improved tolerance and greater efficacy meaning that patients who do not do well on MTX will have cost-effective alternatives

Fields of science

Programme(s)

Topic(s)

Call for proposal

H2020-NMP-PILOTS-2015
## Funding Scheme

### Coordinator

**ASSOCIACAO UNIVERSIDADE EMPRESA PARA DESENVOLVIMENTO TECMINHO**

<table>
<thead>
<tr>
<th>Address</th>
<th>Activity type</th>
<th>EU contribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campus De Azurem</td>
<td>Other</td>
<td>€ 1 130 037,70</td>
</tr>
<tr>
<td>Universidade Do Minho</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4800 058 Guimaraes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Portugal</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Website  
Contact the organisation

### Participants (10)

#### SYNOVO GMBH

**Germany**

<table>
<thead>
<tr>
<th>EU contribution</th>
<th>Activity type</th>
</tr>
</thead>
<tbody>
<tr>
<td>€ 296 087,50</td>
<td>Private for-profit entities (excluding Higher or Secondary Education Establishments)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Address</th>
<th>Activity type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paul Ehrlich Str 15</td>
<td>Private for-profit entities (excluding Higher or Secondary Education Establishments)</td>
</tr>
<tr>
<td>72076 Tuebingen</td>
<td></td>
</tr>
</tbody>
</table>

Website  
Contact the organisation

#### UNIVERSITAET FUER BODENKULTUR WIEN

**Austria**

<table>
<thead>
<tr>
<th>EU contribution</th>
<th>Activity type</th>
</tr>
</thead>
<tbody>
<tr>
<td>€ 395 643,75</td>
<td>Higher or Secondary Education Establishments</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Address</th>
<th>Activity type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gregor Mendel Strasse 33</td>
<td>Higher or Secondary Education Establishments</td>
</tr>
<tr>
<td>1180 Wien</td>
<td></td>
</tr>
</tbody>
</table>

Website  
Contact the organisation

#### BLUECLINICAL - INVESTIGACAO E DESENVOLVIMENTO EM SAUDE LDA

**Portugal**

<table>
<thead>
<tr>
<th>EU contribution</th>
<th>Activity type</th>
</tr>
</thead>
<tbody>
<tr>
<td>€ 442 853,30</td>
<td></td>
</tr>
</tbody>
</table>

Website  
Contact the organisation
<table>
<thead>
<tr>
<th>Address</th>
<th>Activity type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avenida Villagarcia De Arosa 1919 1 4460 439 Motosinhos</td>
<td>Private for-profit entities (excluding Higher or Secondary Education Establishments)</td>
</tr>
<tr>
<td>MEDIZINISCHE UNIVERSITAET WIEN</td>
<td>Austria</td>
</tr>
<tr>
<td>EU contribution</td>
<td>€ 400 597,50</td>
</tr>
<tr>
<td>Address</td>
<td>Activity type</td>
</tr>
<tr>
<td>Spitalgasse 23 1090 Wien</td>
<td>Higher or Secondary Education Establishments</td>
</tr>
<tr>
<td>Website</td>
<td>Contact the organisation</td>
</tr>
<tr>
<td>INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM)</td>
<td>France</td>
</tr>
<tr>
<td>EU contribution</td>
<td>€ 484 487,50</td>
</tr>
<tr>
<td>Address</td>
<td>Activity type</td>
</tr>
<tr>
<td>101 Rue De Tolbiac 75654 Paris</td>
<td>Research Organisations</td>
</tr>
<tr>
<td>Website</td>
<td>Contact the organisation</td>
</tr>
<tr>
<td>INSTITUTO DE BIOLOGIA MOLECULAR E CELULAR - IBMC</td>
<td>Portugal</td>
</tr>
<tr>
<td>EU contribution</td>
<td>€ 432 911,25</td>
</tr>
<tr>
<td>Address</td>
<td>Activity type</td>
</tr>
<tr>
<td>Rua Do Campo Alegre 823 4150 180 Porto</td>
<td>Research Organisations</td>
</tr>
<tr>
<td>Website</td>
<td>Contact the organisation</td>
</tr>
<tr>
<td>GABO:MI GESELLSCHAFT FUR ABLAUFORGANISATION: MILLIARIUM MBH &amp; CO KG GAB O</td>
<td>Germany</td>
</tr>
</tbody>
</table>
EU contribution
€ 8,875

Address
Oskar Von Miller Ring 29
80333 München

Activity type
Private for-profit entities
(excluding Higher or Secondary Education Establishments)

Website
Contact the organisation

APPUT (VERONA) SRL
Italy
EU contribution
€ 653,240

Address
Via Alessandro Fleming 4
37135 Verona

Activity type
Private for-profit entities
(excluding Higher or Secondary Education Establishments)

Contact the organisation

BLUEPHARMA - INDUSTRIA FARMACEUTICAS
Portugal
EU contribution
€ 343,758,55

Address
São Martinho Do Bispo
3045 016 Coimbra

Activity type
Private for-profit entities
(excluding Higher or Secondary Education Establishments)

Contact the organisation

SOLFARCOS - SOLUÇÕES FARMACÊUTICAS E COSMÉTICAS LDA
Portugal
EU contribution
€ 405,341,70

Address
Rua Quinta Dos Orfaos Bloco A Loja 6
4710-453 Braga

Activity type
Private for-profit entities
(excluding Higher or Secondary Education Establishments)