CHARITÉ/BIH-PARTNER WANTED!

Short profile

Name: Bioimmunate Tech. Ltd.

Medical field	Medical device
Product type	A Cell remover (column)
Growth stage	POC from MS blood patients (towards POC in animal model.)
Team	Sigalit Carmel, MD, PhD- CEO & Founder MD+ Ph.D. in immunology in the field of autoimmune diseases and the formation of autoimmune diseases from the Hebrew University. She worked as a general practitioner in the heart surgery intensive care unit at Tel Hashomer & Assuta Hospital and served as a biology and immunology lecturer at Sapir Academic College. Ronny Pinkus, PhD, MBA – CTO Over 27 years experience in CMC and Pharmaceutical manufacturing Joined Bioimmunate after several managerial roles at InterPharm, Merck-Serono, Teva Pharmaceutical industries, InSight Biopharmaceuticals, BiomX & Moebius Medical CMC Consulting for Sun Pharma, Biolight life sciences, Synvaccine, Rapo, Biondvax, Trobix, Tarius, MigVax, SciSparc, OphrX & Maolac Expert with manufacturing and analytics of recombinant proteins; biopharmaceuticals, food tech & medical device. GMP Scale up manufacturing >5 Kg purified Rec mAbs Dalit Hecht, PhD– VP R&D Over 25 years' experience in CMC and Preclinical development Joined Bioimmunate after several managerial roles at Amai Proteins LTD and InSight Biopharmaceuticals. A biotechnology expert researcher, experienced in product development, scale up and transfer from bench to pilot plant with a proven record of innovative R&D and Life Sciences solutions. Expert with manufacturing and analytics of recombinant proteins. Consulting for Bio analytics Click or tap here to enter text.

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Description of product:

Bioimmunate develops a unique product for the treatment of multiple sclerosis (MS) by filtering out the MS related cells from the body while recognizing, capturing and removing these specific cells for each patient, without side effects. The treatment is carried out only 2-3 times a year and stops the progression of the disease and will replace medications. The Technology of the product is based on recognition of HLA molecules that are able to recognize and capture specific T cells clones that are related to the myelin basic protein and other myelin peptides.

Desired project goal: *Please also elaborate on the primary outcome*

Cooperation with the Charité hospital will bring to the establishment of an observational clinical trial in Europe. It includes taking a swab examination from MS patients to do an HLA typing. This collaboration will enable establishment of knowledge of the exact HLA proteins that are involved with MS. Since there is a strong connection between the HLA B1501 and MS,(Apparently between 50-60% of MS patients carry this specific HLA) Bioimmunate is aimed is to reavel further HLA proteins that are connected to the disease in order to design an efficient therapy for MS. It is based on the fact that these HLA proteins represent specific T cell clones that are MS related. The recognition of these clones will enable their removal from the circulation. Such a removal will achieve a steady state in the progress of the disease and enable the body to regenerate the CNS especially when treted in newly diagnosed patients.

In conclusion,this observational clinical dtudy will enable Bioimmunate to design and express the axact HLA's that are involved in the disease in order to treat the patiens efficiently.

Desired project type: *Please also elaborate on the following points, if applicable: population, intervention, study design etc.*

Intervention: The observational clinical trial will perform an HLA typing in order to collect and characterized the data regarding the common HLA molecules among different MS patients according to their specific patern.

Study design: This is a non-interventional, exploratory, prospective, open, seven arms-controlled study.

Multiple Sclerosis, CIS, RIS, NMO, Anti-MOG patients or subjects free of MS and/or other autoimmune diseases that will be found eligible for

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one of the following study arms, will be invited to participate in the study:

Arm A. Newly diagnosed Multiple Sclerosis patients - 400 patients

Arm B. Known Multiple Sclerosis patients - 400 patients

Arm C. Subjects free of MS and/or other autoimmune diseases - 50 subjects

Arm D. CIS patients - 400 patients

Arm E. RIS patients - 400 patients

Arm F. NMO patients - 400 patients

Arm G. Anti-MOG patients – 400 patients

Primary and secondary endpoints

Primary Objective:

Establish a pilot database of MS patients, determining their HLA type and their unique MS related presented peptides repertoire.

Secondary Objective:

1. Based on the dataset accumulated, designing a unique biological probe, able to recognize and capture specific WBCs from patients' collected blood.

2. Quantify the specific disease related WBCs collected from each patient.

Visit 1:

Visit 1 is a screening visit in order to define the subject's background and eligibility according to inclusion/exclusion criteria, to assign the subject into one of the study arms and to assess the HLA typing.

Visit 2-25:

In accordance with the development stage at Bioimmunate, participants will be invited following visit 1 for additional visits . During these visits 2-25, a peripheral blood test will be taken in order to produce mononuclear cells for R&D purposes.

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