

UNIVERSITY INVENTION DISCLOSURE FORM

Oct 2014

University Technology Transfer Office

1. Title of Invention Anti-Inflammatory Use of Autologous Adipose Stem Cells

Inventors:

Name	Home Address	Citizenship
1. Dr. Juan Grasa (on sabbatical leave from a Spanish university and working in the lab of Prof. Jones)	Spain	Spanish
2. Dr. Jianping Chen (visiting researcher on a 2 year sabbatical leave from Thompson & Thompson (USA)*)	Albany, New York (USA)	Chinese
3. Prof. Jones (University Professor)	University	Welsh

** Thompson & Thompson (T&T) is a global company active in the field of anti-inflammatory products, with interests in cellular therapies*

2. Has the invention been **publicly disclosed, publicly used, presented, published or offered for sale?**

When? No Circumstances: _____

3. Is the invention **going to be** publicly disclosed, publicly used, presented, published or offered for sale?

When? Yes Circumstances: Dr. Grasa plans to **announce** a Phase I/II trial in Spain and Wales **on 25 November 2014** to a **general audience** of interested clinicians and the wider medical community in order to recruit patients to the trial.

LET THE TTO KNOW WELL BEFORE ANY PRESENTATION, DISCLOSURE OR OFFER FOR SALE OF THE INVENTION.

4. **Background of the Invention:** (Brief description of background, including problems solved. Use additional sheets if needed)

Cells known as pre-adipocytes found in the body's fat reserves are the precursors of the adipocyte cells that make up the majority of the cells in adipose tissue. Their stem cell-like nature, i.e. the ability of these cells to develop or differentiate into various cell types has been known for some years, but **Dr. Grasa and Prof. Jones have noticed and studied an additional property of a subset of these cells, adipose stem cells (ASCs), which have anti-inflammatory effects.** Patients with chronic inflammatory conditions such as psoriasis, Crohn's disease, rheumatoid arthritis or ulcerative colitis often have no other option than to seek out expensive therapeutic antibody treatments such as Infliximab/Remicade, where and when they are available and can be afforded. These treatments are not only expensive (USD15-25K per year), but treatment can be long term, lasting several or many years. What is needed is a way to provide a more effective and shorter treatment that has correspondingly lower long-term costs because continued treatment is less necessary. ASCs occur naturally in numbers too low for use as an effective medicine, **in 100ml of liposuction material (fat tissue and other components) there are around 6000 cells. Dr. Grasa and Prof. Jones have found a way to extract and multiply (expand) the ASCs in cell culture to a number closer to 60 million cells,** enough for two separate treatments. **Together with Dr. Jianping Chen, they have found that this expansion of the cells also reduces their capacity to develop into other tissues, without diminishing their capability to modulate the immune system.**

5. **Describe the Invention:** (Describe the structure, function and all uses of the invention. Use sketches and/or additional attached sheets as necessary.)

Dr. Grasa and Prof. Jones have discovered that when ASCs are cultured in conditions that mimic inflammatory and anti-inflammatory conditions in the body, they release a factor called IDO. This **known molecule** has the capability of modulating the immune system by interacting with key signal molecules that the different cell types of the immune system use to co-ordinate their efforts, or in the case of some inflammatory diseases, over-react and cause problems. **Dr. Grasa and Prof. Jones have tested the effects of this IDO release** in animal models of **several inflammatory diseases** and found that with one or two doses of ASCs, the condition **can be brought under control in a majority of individual animals.**

The invention would be put to use in the following way in the clinic:

1. 100ml of fat tissue is obtained from the patient by liposuction (even slim people have spare fat in sufficient quantities).
2. This tissue is sent to a dedicated facility where ASCs are purified from this tissue.
3. The ASCs are subjected to a 6 week expansion programme with successive rounds of cell culture under cGMP conditions suitable for a medical product.
4. The ASCs are cleaned of culture materials and suspended in a storage solution (developed by the inventors) in glass vials with seals suitable for administering injections of the cells for

- shipment to the medic and use within two weeks, using refrigerated transport and storage.
5. As with the ASCs in every step of this process, the vials are labeled with barcodes that permit the identification of the patient to ensure that they receive their own cells back and not those of another patient (i.e. autologous cells are used, belonging to the same person).
 6. The cells are either injected directly into areas of chronic inflammation or are administered systemically and home-in on such areas.
 7. A second treatment is given 2-4 months after the first treatment.
 8. The patient is followed to see if additional cell expansion and treatment is required in the following years.

6. How is the invention new and non-obvious? Please list any prior references which may be relevant to your invention:

Whilst the **immunomodulatory effect of IDO was known for the last 10 years**, the ability of ASCs to produce IDO in response to inflamed conditions is a previously unobserved phenomenon, unapplied to any field of medicine. Furthermore, the process of expanding the cells has been developed by Dr. Grasa and Prof. Jones and increases **the factor of multiplication of the cells from 100x by known methods, to 10000x giving useful amounts of cells for treatment**. Additionally, **as noted by Dr. Jianping Chen, the expanded cells lose much or their ability to transform into other tissues after expansion**, but none of their anti-inflammatory properties. This could have important **product safety benefits** and has not been previously described.

Note: Where are the potential markets for the invention? Consider what regions/countries (other than Europe) where the University should seek to have patent protection. According to Global TrackMed, the **anti-inflammatory cell-therapy market** is anticipated to reach to **\$15 billion** by **2018**. We do not know **what fraction of this market will due to contribution from ASC approaches, but we suspect it is large**.

7. Sponsored research involved? NO _____ YES (Identify Sponsor) **T&T (partial)**
Submitted under their Employment or Consulting Agreement by the following inventors:

Signature	Date	Signature	Date
1.		3.	
2.		4.	

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