Background

In recent years, a number of bi- or multi-domain immune cell engaging modalities have been developed that enable the immune-mediated depletion of target cells to provide benefit in diseases like cancer.

These modalities are now increasingly used in other areas, e.g. infection or autoimmunity, to remove cells that drive disease pathology. Still, new cell engager formats are being sought to improve the effectiveness of target cell depletion and optimise general drug properties.

Given the variety of immune cells and cell engager formats available, it is crucial to have preclinical model systems that are capable of differentiating construct designs, based on depth and duration of efficacy, and highlight any toxicity flags such as cytokine release syndrome (CRS). It is of vital importance that any differences in efficacy observed can translate into human biology.

While such model systems have been established in oncology, they are not readily available in autoimmune research, and we are therefore seeking to either identify such a model or establish contacts with experts that can assist us in building one.

While our primary focus is developing a preclinical model to evaluate cell engaging modalities for autoimmune disease, we also welcome suggestions by potential collaborators on novel cell engager designs (particularly those that lead to improved activity in tissue).

What we're looking for

We are seeking to develop models for preclinical use that have predictive value for human disease outcomes, with a particular focus on inflammatory and autoimmune pathologies. This includes in vivo proof of concept (PoC) models, transgenic systems targeting key human receptors, and in vitro human-based cell systems. Our primary focus is on immune cells such as T-cells and NK-cells that drive these pathologies. However, we are also open to exploring models related to neutrophil and macrophage biology.

Solutions of interest include:

- Animal models with clear translational value, efficacy/safety endpoint
- Human systems to test redirection of immune cells towards target cells
- Novel cell engager design with scope for improved safety/efficacy.

Our must-have requirements are:

- Demonstrated utility of autoimmune/senescence model for testing of biologics and proven robustness of the model as shown by generation of reproducible dose-responses with test article(s)
- Evidence of translational value with data created in the model using drugs tested in human autoimmunity, with results reflecting different levels of efficacy observed in randomised clinical trials
- Research activities should have legal clearance for intellectual property rights (freedom to operate)

Our nice-to-have requirements are:

- Evidence of previous research experience in the study of cell engagers in translational models
- Availability of v-regions which are cross reactive towards key proteins of interest in non-human models
- Experience in cell engager design for the treatment of autoimmune diseases

What's out of scope:

- Techniques and modalities that lie outside the field of autoimmune research, e.g. tumour model

Acceptable technology readiness levels (TRL): Levels 3-6

1. Basic principles observed
2. Concept development
3. Experimental proof of concept
4. Validated in lab conditions
5. Validated in relevant environment
6. Demonstrated in relevant environment
7. Regulatory approval
8. Product in production
9. Product in market

What we can offer you

Eligible partnership models:

- **Sponsored research**
- **Licensing**
- **Co-development**
- **Material transfer**

Benefits:

Sponsored Research

Open to a range of potential funding options and models, including e.g. PhD studentships. Financial contribution to be determined based on individual projects and collaboration structure, with range of $50 - $200K, including a minimum of 50% indirect costs (financial support negotiable based on specific opportunities and partnerships).

Expertise

Established pharmaceutical company with proven success in drug development and approvals in the immunology and neurology therapeutic area. Partners will benefit from proven drug development expertise, with an assigned primary contact/sponsor to offer guidance, technical input and supporting the direction and translational needs of specific projects where relevant.

Tools and Technologies

A range of support activities available, including generating molecules (focus on antibody and small molecule modalities), bioinformatics analysis and support, in vivo models and target validation activities.

Please contact the University of South Florida Technology Transfer office representative for submission - Roisin McNally at rmcnally@usf.edu.