Drug Repositioning

Making the most of your drug development pipeline

In the current economic climate it is increasingly important to maximize the ROI of a developed drug product. Recent figures indicate that only 4% of development and launch costs are recouped for a single agent launched for a single indication and total development costs have doubled in the last 20 years to an average spend of $2.2billion (Bain Capital 2009).

Drug repositioning (the application of "old" drugs in "new" indications) is not a new strategy and there have been major success stories in this area (Pfizer's Viagra for example). Increasingly companies are looking to reposition already licensed products (and those in development for other indications) to help maintain productivity in times when discovery R&D budgets are limited.

Through the use of fresh functional human tissues, Biopta provides invaluable data to allow selection of drug candidates with the greatest likelihood of clinical success in new indications. While drug repositioning and the increasing use of the 505(b)(2) pathway may eliminate many of the development hurdles, the high risk financial outlay of a proof of concept clinical study may not be avoided. By utilizing efficacy models in human tissue drug developers can rapidly screen their compounds for effects in a variety of disease indications allowing key decisions to be made on real human data.

Drug repositioning

Many successes in repositioning have emerged following serendipitous observations in clinical trials or early preclinical work. At Biopta we can assist in the selection of new drug indications by testing your compound in specific human tissue models or by offering a general efficacy screen in a standard panel.

Galantamine

Galantamine (marketed under the names Nivalin, Razadyne, Razadyne ER and Reminyl) is an anticholinesterase used in the treatment of vascular dementia and Alzheimer's Disease. By virtue of its mechanism of action there are several areas in which this compound could be used. Using healthy human stomach from organ transplant donors we assessed the effects of galantamine on electrical field stimulation (EFS)-induced contractions.

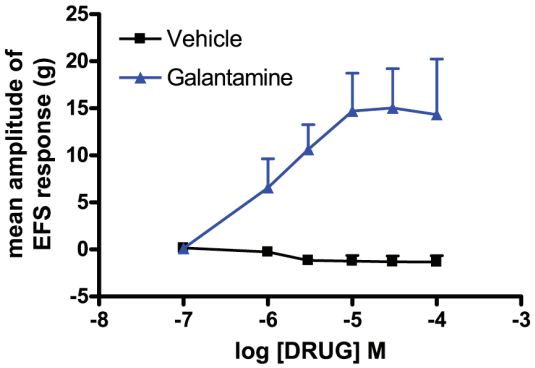

Figure 1. Effects of galantamine on EFS-induced contractions in healthy human gut tissue (n=3 patients)

By inhibiting the breakdown of acetylcholine in the stomach, galantamine caused a concentration dependent increase in the amplitude of EFS contraction. This action would increase gastric emptying demonstrating that galantamine could be useful in the treatment of gastroparesis.

Biopta offers a range of assays in many tissue types both healthy and diseased which can be utilized to investigate potential uses for your compound in addition to the primary indication.

Benefits of Human Tissue Testing for Repositioning Assets

- Improves decision-making processes for alternative clinical applications
- Strengthens repositioning NDAs by obtaining data in targeted patient populations
- Adds commercial value by generating human data prior to costly clinical trials

Inflammation	Vascular	Contractility	Permeability
Skin (dermatitis, psoriasis)	Coronary Artery (vasospasm)	Lung (asthma)	Gut (malabsorption)
Gut (irritable bowel syndrome, ulcerative colitis, Crohn's disease)	Resistance Artery (blood pressure)	Heart (heart failure)	Blood vessels (vascular permeability)
Lung (asthma, allergic responses)	Cerebral Artery (migraine)	Gut (all regions) (diarrhea, constipation)	Lung (cystic fibrosis)
		Bladder (overactive bladder, neurogenic bladder)	

Table 1. Examples of available efficacy assays in human tissue.

To discuss your repositioning projects in more detail please contact us at the address below.

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