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TC BioPharm and Sistemic announce collaboration to develop an innovative range of cancer-specific theranostic products.

With the aim of improving clinical outcome in cancer patients, TC BioPharm (TCB) and Sistemic will work together to develop a range of biomarkers designed to provide valuable information on individual patient responses to TCB's innovative cell therapy product.

Taking a 'personalised medicine approach, cancer patients will be screened with a suite of biomarkers which predict individual response to treatment, resulting in greater potential for stabilisation of disease. Biomarkers developed as part of this collaboration will allow 'bespoke' patient-specific treatments to be delivered on a 'case-by-case' basis, with each dose of therapeutic product optimised to provide the most efficacious outcome.

Leveraging Sistemic's proven expertise in the field of microRNA (miRNA) detection systems, the two companies aim to provide clinicians and patients with a unique treatment platform which combines innovative cell therapy with theranostic feedback. This pioneering approach will place TC BioPharm and Sistemic at the forefront of an exciting new treatment paradigm – 'precision medicine'.

TCB's technology uses patients' own immune cells grown in culture to target cancer, and has a safe history of use based on the treatment of numerous patients by Medinet in Japan. Further to scientific advice from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) which has provided a clear roadmap to clinical studies, the Company plans to treat the first cohort of patients during 2015, working alongside established cancer clinics in Glasgow, Southampton and Birmingham.

Sistemic is a development-stage biomedical company focused on the optimisation of tools for the analysis of miRNA and other non-coding RNAs for applications in the development of cell therapies and drug repositioning. Sistemic's patented and proprietary technology platforms provide a novel way to apply the information content of miRNA's to overcome key obstacles to creating clinically useful and cost effective cell therapies.

TC BioPharm's director of clinical and regulatory affairs Dr Keith Gillon said: *'biomarker-led therapy has benefit for both patients and clinicians alike – effectively increasing probability of selecting the treatment most likely to be effective in individual patients.'*

Jim Reid, Chairman and CEO of Sistemic added: *'Sistemic has pioneered the use of miRNA for cell characterisation and the development of potency assays for cell therapy products and works with the leading companies from all over the world. This collaboration moves the company into the development of precision medicine products which will guide therapeutic decisions and allow cost effective and efficacious use of these transformational treatments bringing real hope to many patients living with cancer. The right treatment to the right patient, at the right time and at the right cost is the focus of this collaboration'*

TCB's chief executive Dr Michael Leek summarised, *'this partnership between two complementary Scottish companies will herald the way for a new generation of cell-based cancer therapies which, when combined with companion products such as those being developed here, have significant potential to dramatically improve cancer patient quality of life'*



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TC BioPharm

Founded July 2013, TC BioPharm is a clinical development company with a cell-based product pipeline capable of treating a variety of disorders including cancer and severe viral infections. Headquartered in Edinburgh with a Clinical Manufacturing Facility in Glasgow, TC BioPharm's lead product is an autologous anti-cancer immunotherapy which involves expansion of naturally occurring, 'cancer-killing' T cells over several weeks, formulating a treatment for a wide-variety of different tumour types. The therapeutic approach has been implemented to successfully treat various tumour types including lung and gastric cancer, renal cell carcinoma, hepatocellular carcinoma, pancreatic cancer, acute myeloid leukaemia, multiple myeloma and acute lymphoblastic leukaemia. Phase II/III clinical studies are planned to commence in the UK during mid-2015.

Sistemic

Sistemic's primary business is focused on providing innovative microRNA-based problem-solving services and kit-based products to areas of unmet need within Pharmaceutical, Biotechnology and the Cell Therapy research, development and manufacture markets. MicroRNAs are seen as the master controllers of a cell and as such Sistemic believe that they are providing instructive information on effects on a whole cell or organism rather than an isolated pathway. This system approach means that the data produced is more indicative of the biology and more diagnostic of actual effect. Their extensive suite of tools for the Cell Therapy community includes SistemQC™ which is used to characterise cells including stem cells (Cell Identity, Purity, Potency, and Safety) as well as monitoring the QC of production. Furthermore, cell products in the later stages of clinical development benefit from SistemQC™ miRNA-based profiling approach in facilitating patient stratification and monitoring the response to the treatment. In addition, the drug development markets are served through a range of products which include SistemTOX™, SistemKB™ and SistemRNA™. Sistemic has a worldwide customer base and a strong intellectual property portfolio.

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