



MHRA Licenses Novel Fc Silencing Technology from mAbsolve

Fully silent antibodies as true negative controls for in vitro and cell-based effector function assays

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The Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health and Social Care and [mAbsolve](#), developers of a novel Fc silencing variant, today announced a licensing deal for mAbsolve's Fc silencing technology. The agreement provides scientists at the MHRA's South Mimms Laboratories with access to the new STR Fc silencing platform for use in the development of biological reference materials including WHO international standards.

Fc-mediated immune effector activities are an important part of an antibody's natural function, but in many therapeutic antibodies these interactions are not desirable and can lead to catastrophic side effects. Many approaches to eliminate effector function have been developed, but all of them have limitations. The STR Fc silencing platform, developed by mAbsolve and described in a [recent PLOS One article](#), delivers one of the most truly silent Fc mutations described to date. The technology therefore has the potential to improve the safety and efficacy of therapeutic antibodies and Fc fusion proteins.

Assessment of Fc-effector functions associated with clinical efficacy or conversely, associated with unwanted inflammatory responses, is an essential part of the development and control of therapeutic antibodies and Fc fusion proteins. The availability of WHO reference reagents, allows the calibration of assays and traceability of bioactivity data, regardless of where or when the assay is performed. Under the terms of this license agreement, the MHRA will be able to develop and distribute reference reagents containing the STR mutations to support bioassays used to characterize the biological activity of biotherapeutic medicines at various stages of their lifecycle. Importantly, this will facilitate global harmonisation.

"As the number of biotherapeutic monoclonal products both approved and under development grows, it is important to develop tools to ensure consistency in the biological activity of different products. At the MHRA we are developing a panel of reference reagents with distinct Fc-domain characteristics as a benchmark for assays used to study Fc-binding activity." Dr. Sandra Prior, Principal Scientist in the Division of Therapeutic Reference Materials; Science, Research and Innovation; MHRA.

"mAbsolve is committed to improving the safety and effectiveness of therapeutic antibodies, and we strongly believe that STR technology can be of real benefit to a large proportion of antibody and Fc fusion proteins in development. Our STR mutations provide a truly silent Fc region and so we look forward to working with the MHRA to utilise this technology as a gold-standard negative control in Fc receptor binding assays." Dr. Geoff Hale; Chief Executive Officer at mAbsolve.

For more information, visit the [NIBSC](#) and [mAbsolve](#) websites.

About the MHRA

The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in the UK. The MHRA is responsible for making sure these products meet set



Medicines & Healthcare products Regulatory Agency



standards for safety, quality and effectiveness. The MHRA is an Executive Agency of the Department of Health and Social Care. www.gov.uk/mhra

National Institute for Biological Standards and Control (NIBSC) standards, from the MHRA, are available globally to support the quality, safety, and efficacy of biological medicines. The MHRA develops and produces over 90% of the WHO International Standards in use around the world. The MHRA also offers NIBSC contract and control testing services. www.nibsc.org

About mAbsolve Limited

mAbsolve founded in the UK by pioneers of therapeutic antibody development and engineering from both Oxford and Cambridge. We have experienced the clinical challenges caused by incomplete silencing of antibodies using LALA, aglycosylated or IgG4 variants. To address this, we have developed a best-in-class solution for silencing of antibody effector function. Visit www.mabsolve.com for more information.

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