## Major international FDA-led study confirms CellOPTIQ® High Content Assay as the leading *in vitro* platform to assess cardiotoxicity in new drugs

Motherwell, Scotland, 27<sup>th</sup> September 2018 – <u>Clyde Biosciences</u>, the leader in cardiac cell function assessment, announced today that its proprietary CellOPTIQ® High Content Assay (HCA) outperformed other assay types in the global <u>CiPA</u> myocyte study designed to develop more accurate and comprehensive *in vitro* cardiac safety evaluation of new drugs.

CiPA (the 'Comprehensive *in vitro* Proarrhythmia Assay') is a global initiative begun by the US Food and Drug Association to address shortcomings in the assessment of proarrhythmic risk. Its recommendations may become a regulatory requirement for all investigatory new drugs. CiPA assessed cardiac toxicity in a panel of known high, medium and low risk drugs and the results were published in <u>Cell Reports Volume</u> 24, Issue 13, September 25<sup>th</sup> 2018.

Professor Godfrey Smith, CSO of Clyde Biosciences said 'We're delighted with these results. CiPA has been a major international undertaking across 10 sites, looking at 28 drugs with known risks of causing arrhythmias which can cause loss of consciousness and sudden death. The results clearly show that our CellOPTIQ® HCA delivered superior performance across all study drugs from low to high risk. CellOPTIQ® HCA was the only optical assay to meet the quality standards set by the CiPA initiative."

Clyde's serum-free approach provided consistent, accurate results across the 28 compounds including drugs such as dofetilide (high risk), bepridil (high risk) and verapamil (low risk). CellOPTIQ® was able to detect proarrythmic events (repolarisation prolongation) more consistently than the multi-electrode array (MEA) platform. Clyde Biosciences was the only site to detect arrhythmia-like events caused by high-risk compound bepridil at the expected concentration, and was the only site to measure expected QT-shortening from low-risk compound loratidine.

CellOPTIQ® HCA is a completely new type of cardiac cell function assay demonstrating clear, accurate assessment of the dose-dependent effect of any drug or combination of drugs. Unlike MEA techniques, the CiPA study found that CellOPTIQ® HCA was able to produce an unambiguous signal from arrhythmia-like events and categorise them by arrhythmia type. CellOPTIQ® HCA was also the only platform in the myocyte study capable of generating measurements of drug-induced action potential shape. Triangulation of the AP shape is a key predictor of proarrhythmic risk and the CellOPTIQ® HCA's platform is uniquely able to measure these changes and add predictive power to the assay.

CellOPTIQ® HCA is unique to Clyde Biosciences, and the only platform that can assess three variables – voltage, intra-cellular calcium and cardiac cell contraction – in a single experiment in the same cells with unrivalled accuracy, working on a wide range of cardiac cell types, for maximum flexibility. From its Glasgow headquarters, Clyde Biosciences works with global pharmaceutical and biotech companies to meet their drug testing needs.

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**Notes to Editors** 

## **About Clyde Biosciences**

Clyde Biosciences provides the gold standard in cardiac cell function assessment for pre-clinical pharmaceutical R&D, safety pharmacology and cardiac drug development. Clyde provides early identification of cardiotoxicity in small molecule drug candidates using its CellOPTIQ® HCA to boost its partners' chances of success.

Detecting small molecule cardiotoxicity late in the drug development process wastes time and money. Most seriously, it reduces the success rate in bringing new drug candidates through to clinical studies. CellOPTIQ HCA is a completely new type of cardiac cell function assay that guarantees clear, accurate assessment of the dose-dependent effects of any drug or combination of drugs.

Clyde Biosciences is trusted by world-leading biopharma companies and academic centres to deliver precise cardiac cell function assessment which can be used to determine drug efficacy and safety.