ACN 010 126 708

ASX Release
17 October 2017

RHS releases validation data for NGS product PG-Seq™

Highlights

- RHS completes extensive validation of its Next Generation Sequencing product PG-Seq™
- PG-Seq™ enters clinical validation at external sites ahead of full commercial product launch

Adelaide, 17 October 2017: RHS Limited (ASX: RHS) ("RHS" or "the Company") is pleased to release the performance data for PG-Seq™, its complete Next Generation Sequencing solution for Pre-implantation Genetic Testing, at the Fertility Society of Australia meeting currently being held in Adelaide, South Australia.

Incorporating RHS' DOPlify™ whole genome amplification technology, NGS library preparation reagents and software, PG-Seq™ provides accurate and robust chromosome copy number detection. The application of the product is for the detection of aneuploidy, which is an incorrect number of chromosomes, in IVF embryos prior to transfer.

Based on almost 400 samples with known chromosome content, PG-Seq™ demonstrates whole chromosome aneuploidy detection accuracy of 98.4% for 5 cell samples and 95.8% for single cells. RHS has also tested smaller genetic changes and will soon be releasing this data.

RHS' validation of PG-Seq™ for Pre-implantation Genetic Screening (PGS) is by far the most extensive dataset released for any equivalent product. The release of RHS' cell line validation data coincides with the commencement of clinical validation at 2 selected independent clinical sites, each of which will generate comparative data from rebiopsied embryos that have previously been tested with VeriSeq.

PG-Seq™ includes all of the specific reagents needed for PGS. The kit has been optimized, validated, stability tested and a full quality control (QC) framework is in place. RHS is now finalising supplier agreements in preparation for full commercial launch and will supply PG-Seq™ under a targeted early access program prior to the official product launch in early 2018.

PG-Seq™ will be priced similarly to the cost per sample of Illumina's VeriSeq PGS product but is designed and validated to process 48 biopsies simultaneously, twice that of VeriSeq. The ability to double throughput with PG-Seq™ provides laboratory cost savings through work flow efficiencies with no additional equipment required.

RHS also expects significant interest in PG-Seq™ when data is released on non-invasive PGS using spent culture medium at this weeks' Fertility Society of Australia conference and the upcoming American Society for Reproductive Medicine conference in San Antonio at the end of this month. Optimised protocols have been developed jointly with the Monash IVF Group and the approach has already progressed to an early stage prospective clinical trial (see the joint media release; http://www.rhsc.com.au/news/monash-ivf-group-and-rhs-joint-media-release/).

PGS involving embryo biopsy requires considerable experience and skill. There are some reservations over possible embryo damage or stress due to the biopsy procedure, which has led to cautious uptake of PGS even in light of clinical evidence supporting its use, particularly for women of advanced maternal age.

There are approximately 2 million IVF cycles performed globally and RHS estimates that 10% use PGS. With an average of 3 embryos biopsied per cycle, this equates to a current addressable market of 600,000 tests per annum, valued conservatively at over $60M. There are a number of published clinical studies showing that aneuploidy rates increase dramatically in the IVF embryos of women 35 years of age and upwards. More than 61% of Australia and New Zealand's 76,309 IVF cycles initiated in 2015 were undertaken by women 35 years of age or older indicating strongly that the PGS market is still maturing. The introduction of non-invasive PGS using embryo culture medium is anticipated to significantly increase the global use of PGS.

With the release of these extensive validation results, PG-Seq™ is demonstrated as a highly accurate and competitive complete PGS solution. A summary of the PG-Seq™ validation study is available on the RHS website (http://www.rhsc.com.au/uploads/general/PG-Seq_full_validation_data.pdf) and full technical details will be released at the American Society of Reproductive Medicine meeting later this month.

The competitive advantages of PG-Seq™

- Higher throughput
    - PG-Seq™ can process 48 samples per run on the same Illumina MiSeq sequencer used for the Illumina VeriSeq 24 sample kit in approximately the same turnaround time. Market research has indicated that the sequencers are typically run overnight; hence the duration difference does not impact time to result.
- PGS+PGD (Preimplantation Genetic Screening + Preimplantation Genetic Diagnosis)
    - There is a capability to combine PG-Seq™ with RHS' patented Targeted Sequence Enrichment (TSE) on clinical genes of interest, such that both PGS & PGD can be processed from a single biopsy. This patented approach is novel in the IVF market and is applicable in a broad range of other markets including the genetic screening of circulating tumour cells.

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About RHS

RHS is a developer of advanced single cell genomic technologies focussed on improving health and research outcomes, based on deep technical experience in the field. DOPlify™ is a platform product for whole genome amplification (WGA) of single or small numbers of cells. DOPlify™ is applicable to the global Next Generation Sequencing (NGS) market. PG-Seq™, RHS' NGS workflow and EmbryoCellect®, RHS' microarray workflow, both incorporate DOPlify™ and have been specifically designed for the genetic screening of IVF embryos.

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Issued Capital
89.9 million shares
7.05 million options

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