



Press Release
September 27, 2022

Omixon Launches NanoTYPE™ RUO, a Multiplex Human Leukocyte Antigen Amplification kit compatible with Oxford Nanopore's MinION™ Platform and Enters into an Agreement with Oxford Nanopore Technologies

High resolution histocompatibility testing for urgent transplant cases made possible within five hours turnaround time



Budapest, Hungary, September 27, 2022. Omixon Biocomputing, Ltd announced today the launch of **NanoTYPE™ RUO**, a multiplex 11 loci human leukocyte antigen (HLA) amplification kit and the complementary NanoTYPER™ software compatible with Oxford Nanopore's MinION™ platform, enabling the fastest high-resolution HLA genotyping. Concurrently, Omixon announced that it has entered into a non-exclusive agreement with Oxford Nanopore Technologies that lifts the 48-hour data processing restriction for commercial software, allowing NanoTYPE™ users to deliver high-resolution HLA typing results to the clinic within four to five hours after receiving the sample.

NanoTYPE™ represents a remarkable advance in HLA typing. Laboratories can fully and unambiguously characterize the histocompatibility antigens at the protein coding level with significant impact before and after the transplant. Even though current next generation sequencing (NGS) technologies address most of the post-transplant needs of our Solid Organ Transplant programs, the current NGS technologies cannot deliver high resolution HLA typing at two-field level within several hours after an organ becomes available from a deceased donor. As such, we cannot perform matching at the epitope level between donor and recipient. Moreover, in the presence of anti-HLA antibodies we cannot match the antibody specificities to epitopes of the donor HLA. The NanoTYPE™ workflow, which allows HLA typing of a donor in the time frame of 5-6 hrs., addresses this unmet need in our community of transplant diagnostics.

"The ability to give a high resolution typing within 5 hours enables an unprecedented simplification of histocompatibility testing by going from HLA alleles to epitopes. The number of HLA alleles is in the tens of thousands, while the number of epitopes is only in the hundreds. This simplification can help to locate suitable donors faster for patients who already have pre-existing antibodies against certain HLA epitopes. Such high-risk patients die on the waiting lists in disproportionately higher numbers."

Prof. Ilias Doxiadis, former Managing Director of the Eurotransplant Reference Laboratory at the University Hospital Leiden and consultant for histocompatibility & immunogenetics at University Hospital Leipzig.

NanoType, also provides advantages over current NGS technologies because it does not require major investment in infrastructure, has a simple and fast protocol for the preparation of the sample before sequencing and data can be collected while the sample is sequenced. The advantage being that the sequencing run proceeds for as long as needed until enough data can be collected.

NanoTYPE was introduced as a prototype to selected laboratories in January 2021 and its genotyping performance was evaluated on more than 1000 samples in several laboratories worldwide by June 2022. Since then, customers ordered reagents to characterize over 1200 samples outside the evaluation study.

The meta-analysis of the individual datasets revealed an excellent concordance level with no phasing ambiguities. The results will be presented at the upcoming 48th Annual Meeting of the American Society for Histocompatibility and Immunogenetics next month.

In addition to 18 early access customers, Omixon has a supply agreement with the St Louis Hospital, part of the AP-HP in Paris. "Omixon customers have already tested the practical feasibility of using NanoTYPE in an urgent transplant setting alongside standard of care. NanoTYPE has the potential to fundamentally impact organ transplant outcomes, which is our stated goal" said Attila Berces, founder, and CEO at Omixon.



High resolution histocompatibility testing for urgent transplant cases made possible within five hours turnaround time.

ABOUT OMIXON

Omixon is a transplantation diagnostics company with customers in 25 countries, headquartered in Budapest, Hungary, with subsidiaries in Cambridge, MA and Utrecht, Netherlands. With core competences in bioinformatics, software engineering, molecular diagnostics, quality, and regulatory science. Omixon designs in vitro diagnostic products under ISO13485 to improve transplant outcomes. Omixon was the first company to enable unambiguous histocompatibility genetic testing - called HLA genotyping - on a next generation sequencing platform. Omixon recently introduced NanoTYPE, the first high resolution transplant compatibility test within five hours turnaround time on the Oxford Nanopore sequencing platform.

ABOUT OXFORD NANOPORE TECHNOLOGIES

Oxford Nanopore Technologies' goal is to bring the widest benefits to society through enabling the analysis of anything, by anyone, anywhere. The company has developed a new generation of nanopore-based sensing technology for real-time, high-performance, accessible, and scalable analysis of DNA and RNA. The technology is used in more than 120 countries to understand the biology of humans and diseases such as cancer, plants, animals, bacteria, viruses, and whole environments. Oxford Nanopore Technologies products are intended for molecular biology applications and are not intended for diagnostic purposes.

Forward-looking statements

This announcement contains certain forward-looking statements. Phrases such as "potential", "expect", "intend", "believe we can", "working to", "anticipate", "when validated", and similar expressions of a future or forward-looking nature should also be considered forward-looking statements. Forward-looking statements address our expected future business, and address matters that are, to different degrees, uncertain and may involve factors beyond our control.

INQUIRIES: sales@omixon.com