# Regulatory approval of novel TB diagnostic in China granted to Oxford Vacmedix licensee Changzhou Biotech

*First regulatory approval worldwide for any application of the Recombinant Overlapping Peptide (ROP) technology*

**Oxford, UK – 25th April 2024**

Oxford Vacmedix (OVM), the UK-based biopharma company developing vaccines to treat cancer announced today that its licensee, Changzhou Biotech (CBI), has been granted regulatory approval in China for a novel diagnostic test for Tuberculosis (TB). The TB diagnostic test has been developed using the same ground-breaking ROP technology that OVM is using to develop vaccines to treat cancer. The approval of the TB diagnostic is the first regulatory approval worldwide for the ROP technology. CBI will manage all regulatory and manufacturing aspects of development and will work with partners to commercialise and distribute the test to hospitals in China. Under the terms of the license OVM will receive royalties on all sales of the kit with minimum royalties guaranteed and has access to all the clinical and testing data generated.

The regulatory approval for an ROP diagnostic further strengthens confidence in OVM's lead cancer vaccine OVM-200, being developed with the same technology. OVM-200 targets survivin, a protein overexpressed by cancer cells that allow unregulated growth and stimulates an immune response. The vaccine is in a Phase 1 trial in the UK which is focused on safety and on establishing an immune response in advanced cancer patients in three cancer indications – non small cell lung cancer, prostate cancer and ovarian cancer. Initial results from Phase 1a, the dose escalation part of the trial, showed very good safety and a strong immune response. Phase 1b to test the chosen dose in more patients is ongoing. The ROP technology is unique in being suitable for all HLAs (human leucocyte antigen). In addition, the technology promises minimally invasive, cost effective, efficacious therapy that can also extend and enhance the effect of immunotherapy.

Professor Shisong Jiang, Founder/CSO of OVM and CEO of CBI said "We are delighted to have regulatory approval for the TB diagnostic in China. TB is very widespread in China and an effective diagnostic test will be a big step forward in helping people receive the best treatment and care. Development has been challenging and I would like to recognize the great team effort that has overcome many barriers to win this approval."

William Finch, CEO of OVM said: "We are very pleased that our licensee Changzhou Biotech has reached this significant milestone. The development, manufacturing and clinical testing have all been completed and now the test can be commercialized in China. We look forward to CBI having success both with the TB diagnostic and with other diagnostic tests including the recently licensed diagnostic test for anti-microbial resistance.

**END**

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**Notes to Editor**

**About Oxford Vacmedix**

Oxford Vacmedix UK Ltd, based at the Oxford Science Park, UK, is a bio-pharma company that was spun out from the University of Oxford's Department of Oncology and is utilising the novel proprietary platform technology of recombinant overlapping peptides (ROPs) invented by Professor Shisong Jiang. ROPs have been validated as a technology to stimulate broad and strong T cell immunity therefore forming a good platform for therapeutic vaccines and diagnostics in cancer and infectious diseases.

The technology uses the novel, proprietary platform of ROPs to design and develop therapeutic cancer vaccines and diagnostics with the potential for increased efficacy, lower costs, simpler regulatory pathways and synergy when used in combination with other immune oncology (IO) agents. The company has extensive contacts and collaborations in China through Changzhou Bioscience Group (CBIG) that is using the ROP platform for diagnostics in both cancer and in infectious diseases.

OVM is developing two lead vaccines, OVM-100 and OVM-200, focusing on unmet clinical need. OVM-100 is an HPV vaccine targeted at cervical cancer, and OVM-200 represents a new type of vaccine utilising survivin to target solid tumours including prostate, ovarian and non-small cell lung cancer (NSCLC). Both vaccines will be tested as single agents and in combination with IO agents. OVM has a strong pipeline, with a diagnostic for anti-microbial resistance being tested and two other cancer vaccines is preclinical development.

OVM secured Series A investment from Dx&Vx (formerly Cancer ROP), a listed South Korean biotech company, and from existing shareholders in China in 2018. The company is currently seeking Series B funding to advance OVM-200 to Phase 2 and OVM-100 into Phase 1 trials, as monotherapy and also in combination. In addition, the option of using mRNA delivery with the ROP technology is also being explored.

For more information: http://www.oxfordvacmedix.com

**About Changzhou Nuijin Shisong Biotechnology Ltd**

Changzhou Niujin Shisong Biotechnology Company Ltd. (CBI) was founded in September 2012 to develop products and to further improve the technology based on Prof. Jiang's Recombinant Overlapping Peptides (ROP) technology developed in Oxford University. CBI holds an exclusive licence from OVM to develop diagnostic products for 4 indications from this platform technology for the greater China market. CBI has its own research and development laboratory in the Changzhou City, and it works closely with leading research institutions in China in product development. In the last 2 years, CBI has achieved break-through development of both HPV and Survivin therapeutic agents and has recently obtained regulatory approval for a diagnostic test for TB. The company is now looking for out-licensing or co-development opportunities for the commercial development of these products.

For more information: http://www.vacmedix.cn/en