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SpeeDx receives FDA breakthrough designation for ResistancePlus®GC

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New diagnostic test enables antibiotic resistance testing and stewardship in gonorrhea treatment

Australia based SpeeDx Pty. Ltd. announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device designation for ResistancePlus® GC-expediting the path towards FDA clearance.

ResistancePlus® GC is the first commercially available molecular test providing ciprofloxacin susceptibility and resistance information to effectively treat the sexually transmitted infection (STI) N. gonorrhea.

It is already CE-marked and cleared by the Therapeutic Goods Association (TGA) for use across Europe, Australia and New Zealand. It detects both the sexually transmitted infection N. gonorrhea and sequences in the gyrA gene of the bacteria associated with susceptibility or resistance to ciprofloxacin, a previously used front-line antibiotic treatment.

Results from the test can be used to guide treatment decisions for gonorrhea infections, giving doctors and patients the option of using ciprofloxacin instead of ceftriaxone, one of the last remaining antibiotics available for multi-drug resistant infections.

Dr. Jeffrey Klausner, Professor of Medicine and Public Health at David Geffen School of Medicine and Fielding School of Public Health, University of California, Los Angeles said, “There is an urgent need for better diagnostics to address the problem of drug-resistant gonorrhea in the United States. Drug-resistant gonorrhea is an urgent public health problem.”

The FDA Breakthrough Devices Program is intended to help patients have more timely access to medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases by expediting their development, assessment, and review.

Colin Denver, SpeeDx CEO said, “We are very pleased that the FDA has recognised ResistancePlus GC as an important tool for the ongoing arms race against gonorrhea and rising antibiotic resistance. The results from our tests empower clinicians to make better informed treatment decisions, and we are passionate about the responsible use and stewardship of antibiotics to achieve the best possible patient outcomes.”

Ceftriaxone, a painful intramuscular injection, is the current front-line treatment for gonorrhea, however resistance has already been reported in Europe and Australia and experts are concerned that we may quickly run out of treatment options altogether.

Recent surveillance data indicates that in some regions up to 7 out of 10 infections could be effectively treated with a single, more convenient oral dose of ciprofloxacin if the susceptibility status is established prior to prescribing. The British Association of Sexual Health and HIV (BASHH) have recognised the importance of antibiotic stewardship in their recently updated gonorrhea management guidelines, preferring the use of ciprofloxacin over ceftriaxone if antibiotic susceptibility results are available prior to treatment.

“SpeeDx tests can help make antibiotic-resistance guided therapy a reality, giving doctors real time information to make smarter antibiotic treatment choices,” adds Dr. Klausner.

Besides developing antibiotic resistance testing for gonorrhea, SpeeDx is also conducting multi-site clinical trials for the ResistancePlus® MG test (not currently available for sale in the U.S.). The molecular test detects the rapidly rising STI Mycoplasma genitalium, also known as Mgen, along with genetic markers linked to antibiotic resistance. In recent years, Mgen prevalence has increased globally and developed high rates of resistance to the frontline antibiotic treatment, azithromycin.