Media Release

Challenges of ending drug-resistant tuberculosis (DRTB) the focus of Special Edition of the International Journal of Tuberculosis and Lung Disease (IJTLD)

Wednesday, 4th November, 2020 (Paris, France) – --Drug-resistant TB (DRTB) continues to be a public health threat and is one of the leading antimicrobial resistant infections globally. Worldwide in 2019, close to half a million people developed DRTB. However, only 38 per cent of people with DRTB started treatments and of those treated, only 57 per cent were treated successfully.

After decades of no new treatments and drugs for the treatment of DRTB, there have been a number of new drugs and regimens developed for the treatment of DRTB since 2012 when the new drug bedaquiline (BDQ) was registered for use.

Bedaquiline was the first new TB drug for nearly 50 years and the challenges facing policy makers and service providers in the global roll-out and scale up of the use of bedaquiline is the subject of a Special Edition of the ***International Journal of Tuberculosis and Lung Disease (IJTLD)*** being published in its October issue.

The approval of bedaquiline almost eight years ago by the US Food and Drug Administration (FDA) for use in treatment of multidrug-resistant tuberculosis (MDR-TB) in adults was considered a critical development and offered the first hope in decades for improving the outcomes for people with DRTB as well as decreasing the duration and toxic side effects of treatment. The registration of bedaquiline occurred as the true extent of DRTB in high burden countries such as China, India and Russia was becoming clear with evidence that drug resistant forms of TB was being directly spread, no longer confined to people who had been treated for TB in the past. The need for new, more effective treatments was greatly increased.

However, by 2015, only 1,000 individuals had received the new drug because of challenges around cost, procurement, and regulations. Those numbers have since improved - Johnson & Johnson stated earlier this year that it has provided some 210,000 people with bedaquiline since 2012 – but this is clearly insufficient with some four million having fallen ill to MDR-TB in the past eight years and other combination therapy regimes involving the other new drugs registered for the treatment of DRTB, pretomanid and delamanid, also experiencing a slow uptake.

“The United Nations has set a global target to end TB by 2030 - achieving that goal will necessarily require increasing access to all the present DRTB drugs and those that are in development now ,” said **Grania Brigden**, Director of the TB Department at the International Union Against Tuberculosis and Lung Disease (The Union), which is also the publisher of the IJTLD.

“Going forward, this new compilation of research can teach us some vital lessons around overcoming obstacles to the rolling out of DRTB drugs more effectively and ensuring everyone who needs them has access to them.”

The IJTLD Special Edition looks at ways to accelerate the global roll-out of bedaquiline and contains 16 articles and three editorials focused on the lessons learned from bedaquiline’ s early years.

Highlights of the Special Edition include:

- **Rutta** *et al* examine an innovative donation agreement between Janssen Therapeutics and the United States Agency of International Development (USAID). As part of that agreement, 105,000 courses of bedaquiline were provided over four years by Janssen and coupled with technical assistance to support countries in the scale-up efforts.

- **Edwards** *et al* and **Zabsonre** *et al* describe the critical role of this technical assistance in supporting implementation. Introducing a new drug within existing national TB programmes requires a multi-pronged effort to address policy change, train providers, monitor for drug safety and address side effects, manage drug supply and forecasting, and measure outcomes. While most countries experienced a slow start (taking on average 2 years to introduce access to bedaquiline for people with MDR-TB), Kyrgyzstan was able to achieve nationwide coverage in only 12 months.

- An in-depth look at two of the highest burden countries for rifampicin-resistant TB (RR-TB)—India and South Africa—is provided by **Sachdeva** *et al* and **Ndjeka** *et al*, respectively. Key to success in India was expedited regulatory approval and the generation of local patient safety and outcome data for policy makers. Perhaps no other country has demonstrated greater impact on bedaquiline policy than South Africa, which has undertaken an ambitious approach to MDR/RR-TB over the past decade through early adoption of new drugs, rapid diagnostics and decentralised models of care. As a result, South Africa has provided critical programmatic safety and efficacy data on bedaquiline use to inform global policy guidance.

- Safety and efficacy data from programmatic use are required for a range of settings. **Vambe** *et al* describe predictors of poor patient outcomes among a large cohort receiving treatment with bedaquiline and/or delamanid in Eswatini (formerly Swaziland). Combined use of both drugs and older age were associated with inferior outcomes, reflecting the importance of continued high-quality data collection, analysis and interpretation to inform treatment guidelines.

- This is emphasised in the endTB project, where **Seung** *et al* suggest that maintaining quality data requires significant resource inputs. In 2014, the WHO introduced processes for streamlining updates to WHO guidance on MDR/ RR-TB. Since this time, at least eight different updates and interim guidance documents that relate to the treatment of MDR/RR-TB have been released. These include a rapid communication that provides for the treatment of MDR/RR-TB with shorter (9–12 months) all-oral regimens in December 2019.

Helen Cox *et al* conclude in the opening editorial:

“As global recommendations are now rapidly changing, country TB programmes will also need to develop and maintain capacity to adapt national guidance much more rapidly. While many countries have successfully navigated changing guidance in HIV care provision, implementing similar innovative approaches to TB care have proven slower and more difficult.

“As other new safe and effective drugs for the treatment of people with MDR/RR-TB are identified, experiences from the bedaquiline introduction and scale-up in various countries will be crucial in informing and expediting this process.”

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About the International Union Against Tuberculosis and Lung Disease (The Union)

The Union was founded in 1920 and is the world’s first global health organisation. We are a global leader in ending TB, we fight the tobacco industry, and we solve key problems in treating major diseases. We use science to design the best treatments and policies for the most pressing public health challenges affecting people living in poverty around the world. The Union’s members, staff and consultants operate in more than 140 countries and embody our core values of accountability, independence, quality and solidarity.

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About the International Journal of Tuberculosis and Lung Disease (IJTLD)

The IJTLD is the official publication of The Union, and the leading peer-reviewed journal dedicated to lung health worldwide is the reference for clinical research and epidemiological studies on tuberculosis. It is also the only peer-reviewed journal dedicated to lung health worldwide, including articles on TB-HIV and non-tuberculosis related respiratory diseases such as asthma, acute respiratory infection, COPD, child lung health and the hazards of tobacco and pollution.