Inhalt

Internationale Nachrichten

1. EMA: Positives Votum für neue Präparate
Der Ausschuss für Humanarzneimittel der europäischen Arzneimittelagentur EMA hat kurz vor Weihnachten noch einige Zulassungsempfehlungen ausgesprochen. Diese betrifft unter anderem das Bedaquilin-haltige Präparat Sirturo®. Es sollte nach Ansicht der EMA-Experten im Rahmen einer Kombinationstherapie zur Behandlung bei multiresistenter Tuberkulose (MDR-TB) bei Erwachsenen zum Einsatz kommen. Wie wirkt Bedaquilin? Es hemmt die mykobakterielle ATP-Synthase und schneidet die Tuberkulose-Bakterien dadurch von ihrer Energieversorgung ab.
Source: Parmazeutische Zeitung, http://ow.ly/siOVL (Dezember 20, 2013)

2. Decentralisation of care reduces HIV and TB-related deaths, illness in Swaziland and Uganda
New studies from Eastern and Southern Africa add to mounting evidence that anti-retroviral therapy (ART) has a profound impact on reducing opportunistic infections, and that decentralised and integrated TB and HIV care increases use of services and ART uptake, thus bettering overall patient outcomes.
Source: aidsmap, http://ow.ly/skZjj (Dezember 19, 2013)

3. Global Drug Facility to expand MDR-TB drug stockpile with new UNITAID grant
Geneva - UNITAID's Executive Board has committed funding of US $14.9 million to the Stop TB Partnership's Global Drug Facility (GDF) to expand the Strategic Rotating Stockpile (SRS) for multidrug-resistant tuberculosis (MDR-TB) medicines.
The GDF stockpile aims to help halt the spread of MDR-TB by guaranteeing supply and improving delivery times of drugs. Countries will benefit from increased flexibility in drug supply as they take on the challenge of scaling up the management of MDR-TB. This support will be linked to the Global Fund Rapid Response Mechanism and GDF aims to move the SRS programme towards longer-term funding sources and a new operating model.
Source: Stop-TB Partnership, http://ow.ly/sl9vT (Dezember 13, 2013)

TB in Deutschland

1.ASV: Erstes Behandlungskonzept zur Tuberkulose
Erst kürzlich betonte der Gemeinsame Bundesausschuss, er wolle jetzt kontinuierlich Hinweise zur Konkretisierung des Indikationsspektrums der ambulanten spezialfachärztlichen Versorgung geben:

Am Donnerstag beschloss der GBA, dass für Tuberkulose künftig ein spezialfachärztliches Angebot geben soll. Damit sind jedoch noch nicht alle Fragen geklärt.
Tuberkulose ist die erste Erkrankung, für die es künftig ein spezialfachärztliches Behandlungsangebot geben soll. Das hat der Gemeinsame Bundesausschuss (GBA) am Donnerstag in Berlin beschlossen. Die entsprechende erste Anlage zur Richtlinie der ambulanten spezialfachärztlichen Versorgung (ASV) tritt voraussichtlich zum 1. April 2014 in Kraft.
Source: Ärzte Zeitung, http://ow.ly/siPgv (Dezember 20, 2013)

Forschung & Entwicklung

1. Clinical trials on child-friendly bedaquiline MDR-TB drug for children initiated
"Before the BPCA [Best Pharmaceuticals for Children Act] and the PREA [Paediatric Research Equity Act] became law, more than 80 per cent of the drugs approved [by FDA] for adult use were being used for children, even though the safety and effectiveness had not been established in the latter. Today that number has been reduced to about 50 per cent," a FDA blog post notes.
The effects of BPCA and PREA are already beginning to show. Janssen Pharmaceuticals, whose new drug (bedaquiline) was approved by the FDA last year for use in adults with MDR-TB disease, has already initiated steps to produce a paediatric version.
Source: The Hindu, http://ow.ly/skZJD (Dezember 19, 2013)

2. BCG vaccine more effective than previously thought
Bacillus Calmette Guérin (BCG) vaccine is included in the childhood vaccination programme of many countries, and is the only licensed vaccine against tuberculosis (TB). However, it has previously been thought to only be effective against the less common forms of the disease that occur away from the lungs. Its efficacy against pulmonary TB, found in the lungs and by far the greatest burden of TB, has varied widely depending on location, ranging from 0% in South India to 80% in the UK.
In order to better understand the reason behind this variability, researchers led by the London School of Hygiene & Tropical Medicine conducted a systematic review of global literature on all reported BCG trials across 10 medical electronic databases, looking at the factors affecting its level of protection against pulmonary TB.
The research shows for the first time that the BCG vaccine is actually highly protective against pulmonary TB in all parts of the world, including significant protection when administered in the tropics.
Source: London School of Hygiene & Tropical Medicine, http://ow.ly/sl9Xy (Dezember 16, 2013)

3. TB bacteria mask their identity to intrude into deeper regions of lungs
TB-causing bacteria appear to mask their identity to avoid recognition by infection-killing cells in the upper airways. The bacteria call up more permissive white blood cells in the deeper regions of the lungs and hitch a ride inside them to get into the host's body.
These findings are reported Dec. 16 in the advanced online edition of the journal *Nature*. The research was a collaboration between the University of Washington and the Seattle Biomedical Research Institute.
Source: University of Washington, http://ow.ly/sla8q (Dezember 19, 2013)

Publikationen

1. Ukraine anti-corruption report examines how HIV and TB drug procurement loopholes feed epidemics
Corruption, staged competition, abuse of commercial secrets, and speculations over the official status prevent Ukraine from overcoming the epidemics of HIV/AIDS and TB, both of which have threatened the country's national security.
The report can be downloaded here:
http://www.eatg.org/gallery/169528/Who%20Makes%20Money%20on%20Epidemics%20of%20HIV-AIDS%20and%20Tuberculosis%20in%20Ukraine.pdf
Source: Science Speaks, http://ow.ly/sl92x (Dezember 16, 2013)

2. Principles for designing future regimens for multidrug-resistant tuberculosis
Fewer than 20% of patients with multidrug-resistant (MDR) tuberculosis are receiving treatment and there is an urgent need to scale up treatment programmes. One of the biggest barriers to scale-up is the treatment regimen, which is lengthy, complex, ineffective, poorly tolerated and expensive. For the first time in over 50 years, new drugs have been developed specifically to treat tuberculosis, with bedaquiline and potentially delamanid expected to be available soon for treatment of MDR cases. However, if the new drugs are merely added to the current treatment regimen, the new regimen will be at least as lengthy, cumbersome and toxic as the existing one. There is an urgent need for strategy and evidence on how to maximize the potential of the new drugs to improve outcomes and shorten treatment.
Any future regimen should satisfy the following principles: (i) it should contain at least one new class of drug; (ii) it should be broadly applicable for use against MDR and XDR *Mycobacterium tuberculosis* complex strains; (iii) it should contain three to five effective drugs, each from a different drug class; (iv) it should have an exclusively oral delivery; (v) it should have a simple dosing schedule; (vi) it should have a good side-effect profile that allows limited monitoring; (vii) it should have a maximum duration of 6 months; and (viii) it should have minimal interaction with antiretroviral drugs. Here, we discuss and present the evidence underlying each principle.
Source: Bulletin of the World Health Organization, http://ow.ly/slbyd (Januar 2014)

3. Safety and availability of clofazimine in the treatment of multidrug and extensively drug-resistant tuberculosis: analysis of published guidance and meta-analysis of cohort studies
The Study is available here: http://bmjopen.bmj.com/content/4/1/e004143.full
Source: Stop-TB Partnership, http://www.stoptb.org/ (Januar 02, 2014)

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