GLOBAL PHARMA 360

News of Note

NOVO NORDISK JOINS UNICEF IN GLOBAL AND LOCAL EFFORTS TO END CHILDHOOD OBESITY

In a new three-year collaborative initiative to end childhood obesity the partners plan to do global research to share lessons and effective strategies to fight the disease, but they're also initiating on-the-ground efforts in Latin American and Caribbean countries with high prevalence.

For instance, in Mexico the two are piloting a breastfeeding program to encourage new mothers to adopt the practice. Breastfeeding has been shown to have positive health benefits for children, including making it less likely that they'll end up living with obesity.

Novo Nordisk's interest is tied to its research and treatments focused on Type 2 diabetes, which is linked to childhood obesity. Studies show childhood obesity is a strong risk factor for developing Type 2 diabetes.

PFIZER TO DEBUT PODCAST SERIES AROUND VACCINES, PROBING SCIENTIFIC, CULTURAL AND POLITICAL ISSUES

Pfizer's latest podcast is a documentary-style dive into vaccines. The eight-part series, called "The Antigen," launched in mid-December and tackles the scientific, cultural and political issues around vaccination.

Host Yasmeen Agosti, a pediatrician and global medical affairs lead for viral vaccines at Pfizer, interviews a variety of experts, beginning with the general introduction in Vaccines 101 and taking listeners around the world to look at the history of vaccines. Later episodes dive into the current hot topic of anti-vax or vaccine hesitancy, which the World Health Organization named as one of the top 10 threats to global health in 2019.

The audio series allows Pfizer to tell the longer story of vaccines, albeit broken up into smaller pieces that people can consume when and where they want. The expert guests include well-known organizations and executives such as the director HIV program at the Gates Foundation, Dr. Emilio Emini, and Save the Children U.S. President and Chief Operating Officer Janti Soeripto.

SANOFI, REGENERON UNCOUPLE ON LONG-STANDING DRUG PARTNERSHIP, SPLITTING UP PRALUENT, KEVZARA

After more than a decade of working together, Sanofi and Regeneron's drug partnership finally turned a profit recently on the back of strong sales of blockbuster Dupixent. Instead of staying the course, the couple is now reworking their arrangement.

The companies will restructure their 12-year-old partnership into a royalty-based agreement for PCSK9 med Praluent and rheumatoid arthritis medication Kevzara, with Regeneron taking over U.S. rights to the former and Sanofi snagging global rights to the latter.

The restructuring, however, won't affect the companies' 50-50 split on Dupixent, which hit $633 million in global sales. The reworked deal is expected to close in the first quarter of 2020.

"Economically, it makes sense," Sanofi CEO Paul Hudson said recently, arguing the new structure gives the drugmaker "agility" and frees it of joint product committees and joint decision-making on those drugs.

TRUMP ADMIN MOVES TO SCRAP BIOLOGICS EXCLUSIVITY IN TRADE DEAL—AND PHARMA IS NOT AMUSED

President Donald Trump has continually railed against global "freeloading" for pharmaceuticals, but his administration's latest move won't win any praise from drugmakers on that front.

In trade negotiations with Canada and Mexico, the Trump administration agreed to scrap biologics exclusivity provisions, allowing each country to set its own rules. And that, in turn, could open some big-selling brands up to earlier-than-expected biosimilar rivals, at least outside the U.S.

As it stands, the U.S. provides 12 years of exclusivity for biologics. The new USMCA trade pact was set to provide 10 years of protections across all three markets.

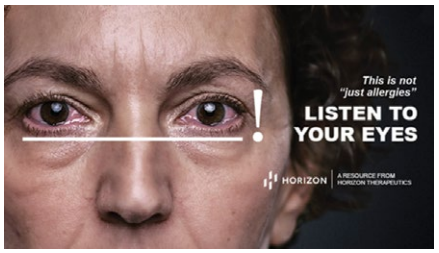
The decision means each country can regulate biologics exclusivity individually, which has drugmakers worried not only about Mexico and Canada, but about the precedent it sets for other trade pacts.

Pharma groups in the US aren't happy. BIO president Jim Greenwood said in a statement the decision "declares open season" on innovative pharma companies.

PhRMA head Stephen Ubl said the move puts "politics over patients," as it doesn't improve the affordability of medications for U.S. patients.

"The only winners today are foreign governments who want to steal American intellectual property and free-ride on America's global leadership in biopharmaceutical research and development," Ubl added.

HORIZON BUILDS COMMUNITY AROUND RARE THYROID EYE DISEASE



Horizon Therapeutics' latest awareness campaign"Listen to Your Eyes" was developed based on patient, physician and advocacy leader input. Through research and an ongoing patient council, Horizon found that not only is the disease unknown and misunderstood, but also that patients are underserved when it comes to education and information.

The campaign raises awareness of the need to see a specialist, such as an ophthalmologist or an oculoplastic surgeon, at the first sign of changes in the eyes, before the disease progresses to the point where the damage can become severe and permanent.

The work also includes social media pages for patients to share experiences based on feedback from many patients who told Horizon that the pain and disfigurement, along with the vision difficulties of TED, can lead to isolation, loneliness and depression.

FUJIFILM LIPOSOME PLANT READY TO DELIVER

Fujifilm has completed the first manufacturing facility in Japan to make drug-delivering liposomes to use for cancer fighting drugs it is developing. But the Japanese company is not keeping it all to itself. The plant also will make them for other drug developers.

The company said much of the manufacturing equipment and containment facilities installed in the liposome formulation facility are based on the technologies developed through its work producing sterile injectable formulations and even its photographic manufacturing.

Liposomes—nanoscale "bubbles" made of organic lipids already present in human cells—have proven effective in delivering active ingredients to cancer cells. Fuji has two immune checkpoint inhibitors in its phase 1 pipeline that will use them, but it says it also is researching their use in next-generation pharmaceuticals such as nucleic acid drugs and gene therapy drugs.

NOVARTIS, AFTER 5 BLOCKBUSTER NODS IN 2019, HOPES FOR 25 MORE IN THE COMING YEARS

The Swiss drugmaker is plotting 80 major drug submissions from 2020 to 2022 in the United States, Europe, Japan and China. Of that group, 25 could become new blockbuster meds or blockbuster label expansions for existing drugs. And Novartis is planning 50 submissions in China alone from 2019 to 2023.

In 2019, Novartis scored approvals for potential blockbusters in multiple sclerosis, spinal muscular atrophy gene therapy, breast cancer, wet AMD, and sickle cell disease.

Looking ahead, the company is planning new submissions in its core disease areas of oncology, neuroscience, ophthalmology, respiratory, CRM (cardiovascular, renal and metabolism), and IHD (immunology, hepatology and dermatology). The drugmaker has more than 160 projects in clinical development and more than 500 ongoing clinical trials.

It is also pouring resources into its cell, gene and radioligand therapy platforms: it has 16 clinical candidates across those technologies.

For existing medications, the company is eying 40 potential add-on indications, including seven for anti-inflammatory blockbuster Cosentyx alone. It is looking at broadening uses for Beovu, Piqray and Kisqali, among other drugs.

CHINA GIVES MERCK AND BMS COLD SHOULDER ON REIMBURSEMENT LIST AS PD-1 BATTLE ENTERS NEW PHASE

It's a familiar scene in the race onto China's national reimbursement list: Drugmakers cut prices by an average 60.7% to win coverage in the world's second-largest pharmaceutical market.

AbbVie, AstraZeneca, Bayer, Gilead Sciences, Johnson & Johnson, Novartis, Roche and Sanofi are among multinational pharma companies to have reached deals with the Chinese government to include their steeply discounted drugs in the country's insurance scheme over the next two years. Altogether, 52 Western-style drugs—versus traditional Chinese medicines—have a new place on the NRDL.

Industry watchers were waiting with bated breath for the negotiation outcome for the PD-1 class. As it turns out, only one drug, Tyvyt (sintilimab) from domestic firm Innovent Biologics and partner Eli Lilly, has won coverage after agreeing to slash prices by 64%. Merck & Co.'s Keytruda, Bristol-Myers Squibb's Opdivo and local firm Junshi Biosciences' Tuoyi failed to cut deals with the Chinese government.

The sole inclusion of Innovent's drug seems to imply that the pricing expectation from NHSA is pretty aggressive and that they fully understand the fierce competition in the market among the products.