GLOBAL PHARMA 360

News of Note

NOVARTIS SIGNS COLLABORATION DEAL WITH TINY PARVUS FOR DIABETES NANOMEDICINE

Novartis, which has been busy with its CAR-T and NASH programs, recently moved on to diabetes after penning a new pact with virtual Canadian biotech Parvus Therapeutics to use its leading tech.

Novartis gets exclusive worldwide rights to use Parvus' Navacims nanomedicine tech, specifically for diabetes patients with Type 1 (T1D), and will take on the clinical and sales work for this program.

On its side, privately owned Parvus will be primarily in charge of the ongoing preclinical work for the T1D program and filing an IND with Novartis.

FDA HITS THE GROUND RUNNING WITH 12 FIRST-QUARTER 2017 DRUG APPROVALS

After a big slowdown in 2016, new Food and Drug Administration (FDA) drug approvals got off to a hot start in 2017.

With 12 new drugs approved in the first quarter, FDA approval action this year bested any since 2011. In recent years, the agency has signed off on between six and ten new drugs in the first quarter.

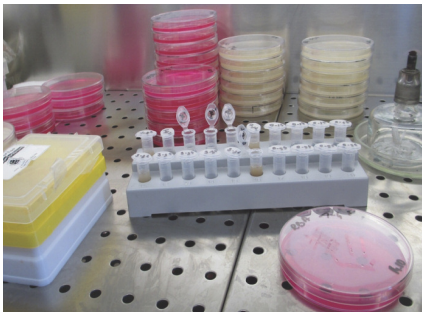
Notable approvals this year are Roche's multiple sclerosis med Ocrevus, and Sanofi and Regeneron's atopic dermatitis med Dupixent. The pharma giants will now put their formidable sales forces behind the products, which are expected to be the biggest launches this year.

GSK VACCINE R&D EXEC: GET TO WORK NOW ON THE NEXT EMERGING DISEASE OUTBREAK

Caught off guard by deadly outbreaks such as Ebola and Zika, experts now say the current process of developing vaccines for emerging diseases needs a shakeup. Here's what GlaxoSmithKline's US vaccine R&D head Ripley Ballou has in mind.

He said developing vaccines without a strong commercial case requires predictable, ongoing funding and a dedicated, permanent infrastructure. To make sure new immunizations can be brought online quickly, development should focus on platform technology, rather than disease-by-disease work.

Speaking about platform technology, he pointed out that scientists should ideally be able to "plug and play" different diseases to quickly create new vaccines in an emergency. That capability exists "today and is only going to get better," he said.



CHINA PHARMA POISED FOR EXPLOSIVE GROWTH

As drugmakers face growth challenges in the US and other developed countries, China is starting to look more enticing.

Already the second-largest pharma market in the world, pharma sales in China could pass $300 billion by 2020. That will happen as regulators in the country push to offer new drugs to sick patients who have traditionally not had access to the world's groundbreaking meds.

Recently, officials in China proposed a slate of changes to the country's drug approval process to speed foreign drug approvals by loosening testing rules. Traditionally, drugmakers have faced high barriers to entry in China centered around local drug testing. But with those laws set for a change, Big Pharma is taking notice.

Gilead, for one, hired a former Roche exec last fall to oversee hepatitis C drug launches in China. For its part, Pfizer started rebuilding a China sales team last fall on the heels of a new approval for its mega-blockbuster pneumococcal vaccine Prevnar 13.

Novartis recently won Chinese approvals for kidney cancer med Votrient and myelofibrosis med Jakavi, while Roche secured an approval for melanoma drug Zelboraf and AstraZeneca gained a nod for lung cancer therapy Tagrisso.

Of course, cost remains an issue in China, with more than 1.3 billion people living in the country and many of them with very low incomes. Government officials are continuously looking for ways to limit spending and drive costs down.

UK STARTS HANDING OUT £4.7B BOOST TO SCIENCE FUNDING

In the run-up to the United Kingdom's referendum on European Union membership, leaders from big pharmas, biotechs, academic groups, and regulatory agencies across the region warned repeatedly of the risks of Brexit.

Brexit will make it harder to hire staff from overseas, hinders cross-border collaboration, affects access to venture capital, and complicates regulations. But, buoyed by the attention of a government that sees life science research as a core strength, many people think industry-specific headwinds will be less severe than feared.

The United Kingdom has unveiled bioscience research investments facilitated by the government's commitment to provide more in R&D funding over the next five years. Officials at the Biotechnology and Biological Sciences Research Council (BBSRC) have awarded cash to projects tackling topics such as the role of epigenetics and the immune system in aging.

CHASING A BIG PAYDAY, NEW DRUGMAKERS SLIGHTLY FAVOUR SOLO LAUNCHES

To partner or not to partner on a new drug launch? The top-line stats offer a first set of clues: Average first-year sales for a partnered launch topped $17 million, compared with $13.1 million for drugs launched solo. For partnered meds, the average number of initial sales calls was far higher, at about 65,000 compared with 10,000 for solo launches.

Going solo may be a high-risk option, but it offers bigger rewards. Even with lower average sales, the solo route produced enough growth to power more companies to "medium-sized" — with first-year sales between $101 million and $500 million — than partnering did. One of those risks lies with payers. Companies that go solo have their products rejected for coverage half the time, compared with 32% for those that launched with a partner.

On the Trump Front

BRACE YOURSELF, TAX INVERSIONS COULD MAKE A COMEBACK

The US Treasury is set to review its recently introduced tax rules — and that means the crackdown that put an end to pharma's tax-inversion mania could be in for a change.

President Donald Trump has signed an executive order directing the agency to look over its newest tax regulations — specifically those enacted in 2016 and 2017 — and root out "things that are significant and create complexity and undue burdens," Treasury Secretary Steven Mnuchin said, as quoted by Bloomberg.

Only one round of new rules fell within that time frame — the round that scuttled the record-breaking Pfizer-Allergan merger — and inversions are "obviously one of the significant things and one of the things we would be looking at," Mnuchin said.

Pharma certainly would not mind if Treasury loosened the reins on inversions. Such deals allowed US companies to lower their tax rates by buying up tax-advantaged targets.

If inversions came back to life, the event would mark just one corporate-friendly move that pharma players are expecting from the Trump administration. CEOs across the sector have talked up the potential for US tax reform to free up overseas cash for buyouts.

TRUMP'S FDA CHOICE GOTTLIEB OFFERS SOLUTION TO CONFLICT-OF-INTEREST CLAIM

In a letter to the ethics head of the Department of Health and Human Services, Gottlieb has said he will recuse himself from any decisions on matters in which he has a financial interest, which includes a lengthy list of biopharma companies.

As a former FDA deputy commissioner and health policy expert, Gottlieb has the credentials for the job. However, he sits on the board of several small biopharma companies, is an advisor to GlaxoSmithKline and formerly Bristol-Myers Squibb. Add in his role as a partner at venture capital fund New Enterprise Associates and managing director of investment banking firm TR Winston & Co., and that gives him an interest in a host of small firms.

Those links have made some people uncomfortable, particularly in light of a recently published Wall Street Journal article that says Gottlieb earned millions of dollars from his industry-related activities in the last few years.

Adapted from FierceBiotech and FiercePharma.

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