

J&J expects 10-plus new drug applications by 2017

May 23 2013, by Linda A. Johnson

(AP)—Johnson & Johnson is developing what could eventually be game-changing treatments for depression and pain, and it's aiming to apply for approval of more than 10 new medicines by 2017, executives said Thursday during a review of the health care giant's medicine business.

The [depression drug](#), a chemical cousin of the powerful anesthetic ketamine, appears to bring relief from crippling depression in just a day—rather than the four to eight weeks needed for existing pills, which don't work for many patients.

The pain treatment, while in earlier stages of testing, is not addictive and could replace widely used—and abused—opioid painkillers such as Oxycontin that cause harsh side effects and many fatal overdoses.

J&J, which makes everything from baby shampoo and Tylenol to biologic drugs and medical devices, has seen its revenue rebound after a rare decline in 2009, thanks to a surge of 11 new medicines launched since then. Unlike most drugmakers, J&J is well past its worst stretch of its big prescription drugs losing patent protection and seeing their sales slashed by cheaper generic competition.

And now the company says it plans by 2017 to apply for approval of 11 new medicines in the U.S. and Europe, plus a polio vaccine for other parts of the world and 25 variations of existing drugs.

"Our focus is now on enhancing our pipeline to deliver the next wave of

growth," Joaquin Duato, one of two chairman of J&J's worldwide prescription drug business, told analysts and journalists at the daylong meeting.

Like its rivals, the company says it is focusing on conditions that lack adequate treatments, as well as expanding sales in emerging markets such as China and India.

J&J's 11 experimental drugs, now in mid- or late-stage patient testing, include a potential hepatitis C treatment being reviewed by regulators, a version of its Invega Sustenna schizophrenia shot designed to last three months, drugs for three types of cancer and new vaccines for flu and rabies.

Another of the 11 drugs is esketamine, which is chemically related to ketamine, an anesthetic sometimes abused at raves for the high and hallucinations it can produce.

J&J this year started mid-stage patient testing of an inhaled, low-dose version of esketamine for patients not helped by other antidepressants. Assuming it's approved, J&J is planning to have it administered in doctor's offices and clinics, but not distributed through pharmacies—to limit the potential for abuse, said Dr. Hussein Manji, head of neuroscience research.

He said J&J is also testing variations including a pill version and using esketamine to treat bipolar disorder, adding that doctors and government mental health experts have high hopes for what could be "the biggest breakthrough in psychiatry in 40 years."

That's needed because depression is one of the top causes of disability worldwide and leads to more than 38,000 suicides a year— just in the U.S. Current treatments only resolve depression in about a third of

patients.

The promising pain drug, fulranumab, is currently being tested in patients with osteoarthritis, the joint pains common in older folks from years of wear and tear, and in patients with pain from nerve damage caused by diabetes. It also could be tested for back or other pain types.

Manji said it could be a big advance over today's options. Those are mainly anti-inflammatory pain relievers such as naproxen that aren't always effective and addictive narcotic painkillers that are responsible for pill mills, crime rings and thousands of overdoses.

If approved, it could usher in a "post-opioid era," Manji said.

J&J said it's continuing research on multiple ways to attack Alzheimer's disease, and downplayed the failure last year of one drug it's been developing with Pfizer Inc.

Johnson & Johnson also is researching new treatments for heart disease, immune disorders and diabetes.

Executives noted the company's drug business is growing fastest among the top 10 drugmakers in the key markets of the U.S., Europe and Japan.

The 11 new products it's launched since 2009 brought in 17 percent of total pharmaceutical sales last year, up from 9 percent in 2011. Those products include Zytiga for prostate cancer, anti-clotting drug Xarelto, Incivo for hepatitis C and J&J's first diabetes treatment, Invokana.

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