

Merck: New drugs pending approval or in late tests

May 6 2014, by Linda A. Johnson

Merck & Co. could get an impressive six new prescription medicines approved in the U.S. this year and will soon apply for regulatory approval of two others, company executives said Tuesday during a briefing on Merck's business.

In addition, Merck is running late-stage patient tests of promising experimental drugs for HIV and hepatitis C, and it's aiming to be a leader in a hot new area of <u>cancer research</u> called immuno-oncology. Merck and several rivals are trying to develop drugs that fight cancer essentially by stimulating the immune system to identify and attack cancer cells.

The news was overshadowed by the announcement that Merck, based in Whitehouse Station, New Jersey, has agreed to sell its consumer health business to Germany's Bayer AG for \$14.2 billion. Merck's Claritin allergy pills, Coppertone sun-care line, and Dr. Scholl's foot-care products will join Bayer aspirin, plus Aleve pain reliever, Alka-Seltzer and One-A-Day vitamins.

Since January, Merck has been considering options for its consumer and <u>animal health</u> businesses, which bring in about 4.5 percent and 8 percent of Merck revenue, respectively. Both units saw sales decline in the first quarter. On Tuesday, Merck said it will continue exploring ways "to augment its animal health business."

"For the right assets that complement and extend our business, at the



right price, we would be interested in buying assets" in animal health, CEO Kenneth Frazier told analysts and journalists gathered for the half-day presentation in Boston.

The Bayer deal will help Merck fund more research on its innovative—and more lucrative—<u>prescription drugs</u>. Focusing on science has long been Merck's mantra.

"The best way for us to drive value over the long term ... is through innovation," Frazier said. "That's why we must execute in our laboratories."

Amid the recent tidal wave of generic competition to drugs that once brought in billions each year, Merck and rivals are finding it harder to come up with drugs that are better or safer than older ones. It's become more common for heavily touted experimental drugs to run into problems after years of expensive testing, from dangerous cardiac or other side effects to just not working as hoped.

Merck had two medicines approved by the U.S. Food and Drug Administration in mid-April, both quick-dissolving immunotherapy tablets taken daily for months to gradually reduce seasonal allergies. Grasstek is for hay fever caused by grass pollens, while Ragwitek is for ragweed allergies.

The FDA currently is reviewing four others:

- —Zontivity, an anticlotting <u>drug</u> for preventing heart attacks and strokes.
- —V503, an updated version of Merck's vaccine Gardasil that protects against twice as many strains of cancer-causing human papilloma virus.
- —MK-3475, an advanced melanoma treatment, based on an antibody



and meant to stimulate the immune system.

—suvorexant, an insomnia treatment held up last year when the FDA said it wouldn't approve the drug until Merck did additional patient studies.

Merck said it expects later this year to apply for approval of two other drugs that both have been delayed over safety or efficacy concerns. Odanacatib is a new osteoporosis medicine—a category Merck pioneered with its Fosamax. The other drug is sugammadex, for reversing the effects of anesthesia after surgery.

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Citation: Merck: New drugs pending approval or in late tests (2014, May 6) retrieved 16 April 2024 from https://medicalxpress.com/news/2014-05-merck-drugs-pending-late.html

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