MedicalXpress

Merck seeks new OK for cancer drug, reorganization on track

January 12 2015, byLinda A. Johnson

Drugmaker Merck & Co. is ratcheting up its race with rival Bristol-Myers Squibb Co. for leadership in one of today's hottest research areas, immuno-oncology, which harnesses the immune system to fight cancer.

Merck said Monday that by midyear it will apply for approval of its melanoma drug, Keytruda, for fighting lung cancer. That's one of more than 30 cancer types for which the drug, designated a breakthrough therapy by the Food and Drug Administration, is being studied.

Merck, the world's fourth-largest drugmaker by revenue, issued the update ahead of an investor presentation late Monday.

Merck CEO Kenneth Frazier was to announce that Merck, based in Kenilworth, New Jersey, has more than 10 drugs in late-stage patient testing and is on track with cost-cutting and other changes in its latest restructuring program, announced in October 2013.

Merck said its reorganization has saved $2.5 billion in annual costs, compared with its 2012 level, partly from 2014 closures of its sprawling former headquarters in Whitehouse Station and a site in Summit, both in New Jersey. It sold its consumer health business to Bayer AG for $14 billion and decided to retain and build its veterinary medicine business.

Last year, Merck got seven new medicines improved, including tablets to gradually reduce grass and ragweed allergies and three medicines first in their class: blood thinner Zontivity, known chemically as vorapaxar;

Belsomra (suvorexant) for insomnia and Keytruda (pembrolizumab).

Keytruda, approved on Sept. 4 for treating advanced melanoma, is the first medication to get U.S. approval among the multiple immuno-oncology drugs in development. They mobilize the body's immune system to "uncloak" and attack cancer cells otherwise stay hidden, an approach that prolongs patient survival and has other advantages over older treatments.

Bristol-Myers has a similar drug, Opdivo, that the FDA approved on Dec. 22 for advanced melanoma, the deadly skin cancer. On Sunday, Bristol-Myers said it was stopping early a late-stage lung cancer study of Opdivo because it clearly increased survival compared to chemotherapy, the standard of care.

At least some analysts see Merck as having a slight edge in the race to get its drug approved ahead of Bristol's for the much bigger market of patients with non-small cell lung cancer, which includes 85 percent to 90 percent of all lung cancer cases. Lung cancer kills about 160,000 Americans a year, compared with just 10,000 for the smaller melanoma market.

Dr. Tim Anderson, an analyst with Bernstein Research, wrote Monday that initially Merck could end up with an approval for Keytruda that allowed its use in more than three times as many U.S. patients as Opdivo.

Both drugs are in a subset of immuno-oncology drugs called checkpoint inhibitors. With Merck and Bristol doing multiple studies on their medicines, and other companies rushing to catch up, it's too soon to tell which drug will dominate the category.

Besides Keytruda, the Merck drugs now in late testing—normally the

final stage of patient testing before seeking government approval—include three drugs for diabetes, two for infectious diseases, two vaccines and one drug each for Alzheimer's disease, hardening of the arteries, dust mite allergies, hepatitis C, osteoporosis and bladder cancer.

In trading Monday, Merck shares dipped 26 cents to $62.30, slightly less than the broader market decline. Bristol-Myers shares jumped $1.86, or 3.1 percent, to $62.18, then rose another 15 cents after hours.