

Beware of Januvia: Merck's Diabetes Drug Contains Carcinogenic Potential, EU Warns

CE Noticias Financieras English

August 10, 2022 Wednesday

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Length: 316 words

Body

U.S. authorities found that **Merck & Co.**'s Januvia, a popular diabetes drug, is contaminated with a potential carcinogen.

An impurity called nitrosamine was found in some samples of the drug, which has the chemical name sitagliptin, the U.S. Food and Drug Administration (FDA) said Tuesday.

The agency said it was allowing **Merck** to continue selling sitagliptin-containing drugs with higher-than-allowed levels of nitrosamine to avoid shortages.

Merck confirmed in an email that it "recently detected a nitrosamine identified as NTTP in some lots of our sitagliptin-containing medicines." The company is working with health authorities around the world and has implemented additional quality controls to ensure that the drugs comply with the FDA's interim limits.

Merck confirmed that it found NTTP in three sitagliptin-containing drugs: Januvia, Janumet and Steglujan.

One of Merck's most lucrative drugs, at the mita

Januvia is **Merck's** third-biggest-selling drug with \$3.3 billion in sales last year, according to Bloomberg data. Janumet had revenues of nearly \$2 billion last year.

Sitagliptin, which is used to control high blood sugar levels in patients with type 2 diabetes, is one of a number of drugs found to be contaminated with nitrosamines since 2018. Another popular diabetes drug called metformin was among those affected, along with certain blood pressure pills and Chantix, Pfizer's smoking cessation drug.

Four years ago, pharmaceutical companies discovered that some blood pressure pills were contaminated with N-nitrosodimethylamine, or NDMA, which kicked off a multi-year review of commonly used drugs that uncovered several cases of contamination. It is likely that NDMA may increase the risk of cancer after prolonged exposure to levels detected in the drugs.

Merck shares fell as much as 1.9 percent following news of the FDA statement, but recovered to gain 1.2 percent by the close.

Load-Date: September 7, 2022

Merck says it obeys tax law despite probe by Senate

Financial Times (London, England)

August 8, 2022 Monday

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Section: NEWS; Pg. 5

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Byline: JAMIE SMYTH

Body

Drugmaker **Merck** has defended the company's approach to tax after a US congressional committee accused it of exploiting loopholes to avoid paying billions of dollars and blocking an inquiry into its practices.

Chief financial officer Caroline Litchfield said the company operated with the highest "ethics and integrity in absolutely everything we do" and was continuing to **co-operate** with the Senate finance committee's investigation.

Merck is one of several US-based multinational companies that have come under scrutiny from the committee, which is investigating how Big Pharma uses a combination of offshore subsidiaries, tax exemptions and legal loopholes to slash their tax bills.

In 2021, the company paid an effective tax rate of 11 per cent, almost half the US corporate tax rate of 21 per cent.

Almost half of its sales were generated in the US, according to company filings. "From a tax perspective, we operate and comply with not only the words of tax law but the spirit of tax law in each and every country in which we operate," Litchfield said in an interview.

Litchfield's comments follow blistering criticism of **Merck** last week from Democrat Ron Wyden, the Senate finance committee chair, who accused the company of stonewalling the committee's investigation into the tax policies of US pharmaceutical companies.

Merck had twice declined to provide information to the committee and is choosing to keep secret how much of its profits are reported by offshore subsidiaries for tax purposes, he said.

"There appears to be a substantial discrepancy between where **Merck** generates prescription drug sales and where **Merck** books profits from those drug sales for tax purposes," he added.

The committee is investigating how **Merck** structures sales of its blockbuster cancer drug Keytruda, which reached \$17.2bn last year, an increase of 19.5 per cent compared with 2020. It is examining why all profits generated from sale of Keytruda - including sales made to American buyers - are taxed in jurisdictions outside the US.

Merck says it obeys tax law despite probe by Senate

"Since **Merck** holds the intellectual property rights to Keytruda in the Netherlands and manufactures the drug entirely in Ireland, **Merck** is able to avoid billions of dollars of taxes on profits from sales in the US," said Wyden.

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Merck defends approach to taxes

The Irish Times

August 8, 2022 Monday

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Section: FINANCE; Pg. 12

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Body

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Chief financial officer Caroline Litchfield said the company operates with the highest "ethics and integrity in absolutely everything we do" and is continuing to **co**-operate with the Senate finance committee's investigation into its tax affairs.

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In 2021 the Kenilworth, New Jersey-based company paid an effective tax rate of 11 per cent in 2021, almost half the US corporate tax rate of 21 per cent. Almost half of its sales were generated in the United States, according to company filings.

"From a tax perspective we operate and comply with not only the words of tax law but the spirit of tax law in each and every country in which we operate," Ms Litchfield said in an interview. "I feel very strongly that what we do is the right thing."

Ms Litchfield's comments follow blistering criticism of **Merck** last week from Democrat Ron Wyden, the Senate finance committee chair, who accused the company of stonewalling the committee's investigation into the tax policies of US pharmaceutical companies.

Keep secret

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"Since **Merck** holds the intellectual property rights to Keytruda in the Netherlands and manufactures the drug entirely in Ireland, **Merck** is able to avoid billions of dollars of taxes on profits from Keytruda sales in the US," said Mr Wyden.

Merck defends approach to taxes

Tax experts say pharma companies are among the most prodigious users of aggressive tax strategies and have in the past deployed offshore schemes with colourful names, such as the "double Irish". - Copyright The Financial Times Limited 2022

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Common Diabetes Drug Januvia May Contain Traces of Carcinogen, FDA Says

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The Breeze: James Madison University

August 12, 2022 Friday

University Wire

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Section: NEWS; Pg. 1

Length: 332 words

Byline: Cara Murez

Body

FRIDAY, Aug. 12, 2022 (HealthDay News) - The popular diabetes drug Januvia may contain traces of a probable carcinogen, but patients should keep using the medication because it could be dangerous to stop taking it, the U.S. Food and Drug Administration announced this week.

Despite the discovery that Nitroso-STG-19 had been found in some samples of the drug, known generically as sitagliptin, "it could be dangerous for patients with this condition to stop taking their sitagliptin without first talking to their health care professional," the FDA explained in its alert.

Drug maker **Merck Co.** said it first detected the contamination and reported it to federal regulators, as it addresses the problem and works with health authorities around the world.

"We remain confident in the safety, efficacy and quality of our sitagliptin-containing medicines," the company said, the New York Times reported.

NTTP belongs to the nitrosamine class of compounds and some of these are classified as probable or possible human carcinogens based on laboratory tests, the FDA said. In recent years, these compounds have been found in a number of medications, including the heartburn medication Zantac, the antibiotic rifampin (used to treat tuberculosis and meningitis) and the smoking-cessation drug Chantix, the Times reported.

The FDA used information available on closely related nitrosamine compounds to calculate lifetime exposure limits for NTTP. At the maximum level the FDA is allowing under these circumstances, agency scientists determined that Januvia presents "minimal" additional cancer risk when compared to a lifetime of exposure to NTTP.

Januvia, which was first approved in 2006, is **Merck's** third most profitable drug, generating \$5 billion in annual revenue for the company, the Times reported.

More information

The U.S. National Library of Medicine has more on the medication sitagliptin.

SOURCE: U.S. Food and Drug Administration, news release, Aug. 9, 2022; New York Times

Was this page helpful?

Load-Date: August 12, 2022

Common Diabetes Drug Januvia May Contain Traces of Carcinogen, FDA Says Was this page helpful?

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AstraZeneca : EU Approves Lynparza For Early Breast Cancer

CE Noticias Financieras English

August 4, 2022 Thursday

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Body

AstraZeneca (AZN.L, AZN) and **Merck & Co** Inc.'s (MRK) Lynparza (olaparib) has been approved in the European Union as monotherapy or in combination with endocrine therapy for the adjuvant treatment of adult patients with germline BRCA1/2 mutations or gBRCAm, who have human epidermal growth factor receptor 2 (HER2)-negative high-risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy.

The approval by the European Commission was based on results from the OlympiA Phase III trial. In the trial, Lynparza demonstrated a statistically significant and clinically meaningful improvement in invasive disease-free survival (iDFS), reducing the risk of invasive breast cancer recurrences, new cancers, or death by 42% versus placebo.

Lynparza also demonstrated a statistically significant and clinically meaningful improvement in overall survival, reducing the risk of death by 32% versus placebo.

In March 2022, Lynparza was approved in the US for the treatment of gBRCAm, HER2-negative high-risk early breast cancer.

Lynparza is also approved in the US, EU, Japan, and many other countries for the treatment of patients with gBRCAm, HER2-negative, metastatic breast cancer previously treated with chemotherapy based on results from the OlympiAD Phase III trial. In the EU, this indication also includes patients with locally advanced breast cancer.

For More Such Health News, visit rttnews.com

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TotalEnergies Q2 profits double on soaring oil prices

Gulf Times

July 28, 2022 Thursday

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Length: 1756 words

Body

French energy giant TotalEnergies said yesterday its profits more than doubled in the second quarter on the surge in global oil and gas prices as a result of the war in Ukraine.

TotalEnergies said in a statement that its bottom-line net profit amounted to EUR5.7bn (\$5.8bn) in the period from April to June, compared with EUR2.2bn a year earlier.

Second-quarter sales were up 37% at EUR74.8bn.

"Russia's invasion of Ukraine continued to impact energy markets in the second quarter, with oil prices averaging more than \$110 per barrel, refining margins reaching record-high levels, and natural gas prices holding above oil partly in Europe and Asia," said chief executive Patrick Pouyanne.

"In this context, TotalEnergies responded by increasing energy output, thus contributing to energy security."

Runaway oil and gas prices are generating bumper profits across the sector.

British energy giant Shell also said on Thursday its bottom line increased five-fold in the second quarter.

In France, there is much debate on whether such windfall gains should be taxed.

Pfizer

Pfizer reported a jump in second-quarter profits yesterday behind a near doubling of revenues driven by sales of its Covid-19 vaccine and therapeutic drug Paxlovid.

The drugmaker raised some of its overall financial benchmarks, but maintained 2022 sales targets for its two Covid-19 products: \$32bn from the vaccine co-developed with German company BioNTech; and \$22bn from Paxlovid.

The total is equal to just over half of forecasted 2022 total revenues.

In the quarter ending June 30, profits were \$9.9bn, up 78% from the year-ago period following a 47% jump in revenues to \$27.7bn.

US officials last month approved emergency authorisation to Pfizer and Moderna for Covid-19 vaccines in under-five-year-olds, the final age group awaiting immunisation in most countries.

Pfizer is currently working on a Covid-19 Omicron vaccine booster candidate for the fall, assuming regulatory approval is granted, company officials said.

Revenues for the vaccine came in at \$8.8bn, up 13% from the year-ago period, while sales of Paxlovid were \$8.1bn - a big jump over the prior quarter following a five-fold growth in US utilisation.

Volkswagen

German auto giant Volkswagen said yesterday that it was able to overcome global economic headwinds and supply chain issues to put in a "robust" performance in the first six months of 2022.

TotalEnergies Q2 profits double on soaring oil prices

A week after Volkswagen announced that it would part ways with its chief executive Herbert Diess, the carmaker said it was "confident" for the second half of the year.

"Despite unprecedented global challenges, Volkswagen has demonstrated remarkable financial robustness," said chief financial officer Arno Antlitz.

"Despite all the caution in the face of the volatile market environment and geopolitical risks, we are confident that we can further accelerate the transformation of the group," Antlitz said.

VW said its net profit rose by 26% to EUR10.6bn (\$10.8bn) in the first six months, even if its bottom-line in the second quarter alone was hit by an accounting effect linked to hedging against fluctuations in raw material prices.

Underlying, or operating, profit rose by 16% to EUR13.2bn in the period from January to June.

"This was driven by strong performances from the premium and sport brand group," VW said.

First-half revenues were nearly stable at EUR132.3bn, but unit sales were down by 14% at four million vehicles, not least because of the worldwide shortage of semiconductors plaguing the industry.

Looking ahead, Volkswagen said it "confirms its outlook for 2022...as supply constraints ease."

The carmaker expected "the product mix to normalise in the second-half as the semi-conductor situation improves in combination with a strong order book," it said.

"A noticeable recovery of the monthly sales towards the end of second quarter additionally bodes well for second-half sales," it said.

Nevertheless, it was "still not possible to conclusively assess the specific effects of the war in Ukraine or effects of the Covid-19 pandemic on the Volkswagen group's business, on the global economy and growth in the industry in fiscal year 2022," VW cautioned.

Samsung Electronics

South Korean chip powerhouse Samsung Electronics said that second-quarter operating profits were up 12.18%, with record profits in its system semiconductor division despite global supply chain woes.

The company's "system semiconductor businesses... achieved a record high quarterly profit," Samsung said in a statement, adding it had both expanded its product line-up and increased the supply of chips to global customers.

"Earnings in the Memory Business improved both year-on-year and quarter-on-quarter as the Company focused on meeting solid demand for servers," Samsung said.

In June, the company became the first chipmaker in the world to mass-produce 3-nanometre microchips as it sought to match and eventually outpace Taiwan's TSMC in the race to manufacture the world's most advanced chips.

The new chips will be smaller, more powerful and efficient, and will be used in high-performance computing applications before being put into gadgets such as mobile phones.

The vast majority of the world's most advanced microchips are made by just two companies -- Samsung and TSMC -- both of which are running at full capacity to alleviate a global shortage.

Merck & Co

Merck & Co reported higher-than-expected second-quarter earnings and revenue on strong sales of its blockbuster cancer drug Keytruda.

The company said it earned \$4.74bn in the quarter, or \$1.87 a share, compared with \$1.55bn, or 61 cents a share, a year earlier.

Analysts on average had expected the company to earn \$1.70 a share, according to Refinitiv data.

Revenue in the quarter rose 28% from a year ago to \$14.6bn, topping the average Wall Street forecast of \$13.9bn.

Much of that beat came from sales of **Merck's** top-selling drug, the cancer immunotherapy Keytruda, which came in at \$5.3bn for the quarter, compared with analyst estimates of \$4.9bn.

On Wednesday, US Senator Ron Wyden, a Democrat, sent a letter to **Merck** suggesting the company had avoided billions of dollars of US taxes owed from Keytruda sales in recent years by booking all the profits from the treatment outside of the United States.

TotalEnergies Q2 profits double on soaring oil prices

Sales of **Merck's** Covid-19 antiviral treatment Lagevrio were \$1.2bn in the quarter, primarily from the UK and Japan.

Merck raised its full-year sales forecast to \$57.5bn to \$58.5bn from its previous outlook of \$56.9bn to \$58.1bn.

That includes a negative impact of roughly 3% due to the strong dollar.

Analysts had forecast 2022 sales of \$58.1bn, according to Refinitiv data.

ArcelorMittal

ArcelorMittal, the world's number-two steel maker, said that profits fell in the second quarter, weighed down by inflation and the war in Ukraine.

The group said in a statement its performance was "overshadowed by the outbreak of war in Ukraine, where we have steel and mining operations".

"Globally, the conflict is impacting growth and adding further inflationary pressure, which is spilling over into weakening of demand (for steel)," the group said.

In the second quarter, net profit eased by 2% to \$3.9bn.

But over the first half, ArcelorMittal's bottom line increased by 27% to \$8.0bn, primarily due to a strong performance in the first three months of the year.

ArcelorMittal said steel output fell by 18% to 14.6mn tonnes in the period from April to June.

Second-quarter sales, on the other hand, grew by 14.5% to just over EUR22bn, driven by an increase of some 30% in steel prices.

ArcelorMittal employs some 26,000 people in Ukraine and suspended its operation there when the war broke out.

But it said in May it would resume operations in Ukraine, even if only one of the three furnaces there has since restarted.

Looking ahead, chief executive Adity Mittal said that "despite the more uncertain global macro outlook", the business was "well positioned to effectively manage through the cycle".

Barclays

British bank Barclays said yesterday that profits tumbled on bad debt charges and litigation costs in the first half, and warned on the impact of surging inflation on customers.

Net profit sank to &#pound;2.5bn (\$3.0bn) in the six months to June, from &#pound;3.8bn a year earlier, Barclays said in a statement.

Total provisions and legal charges hit &#pound;1.8bn, 10 times higher than last time around.

Barclays booked a net charge of &#pound;600mn after selling more products to investors in the United States than it was allowed.

It also set aside &#pound;341mn for potential loan losses and warned over the impact of Britain's cost-of-living crisis - echoing remarks from rival UK lender Lloyds.

"We are alert to the pressure that the rising cost of living will have on our customers and colleagues," said Barclays chief executive CS Venkatakrishnan.

"We have a range of measures in place to help and are looking to do more."

Barclays forecast UK economic growth would slow, but said it was difficult to say if it would enter recession.

Earlier this week, the International Monetary Fund cut its UK economic outlook due to stalling global growth.

Shell

British energy giant Shell said yesterday that its net profit soared more than five-fold to \$18bn in the second quarter, fuelled by resurgent oil and gas prices, and rewarded shareholders with another bumper buyback.

The surge in profits in the three months to June was partially attributable to a reversal of \$4.3bn in impairments after the company raised its forecasts for the gas and oil market.

"We delivered strong financial results," said chief executive Ben van Beurden alongside the results statement.

The London-listed energy major announced a \$6bn share buyback programme, having already returned \$8.5bn to shareholders.

Van Beurden warned also that "with volatile energy markets, economic turbulence and the ongoing need for action to tackle climate change, 2022 continues to present challenges to consumers, to government, and to companies".

TotalEnergies Q2 profits double on soaring oil prices

Shell had rebounded into a \$3.4bn profit in second quarter of 2021 from a \$18.1bn loss in the same period of 2020 when it took a massive impairment charge on the Covid-ravaged oil market.

However, oil and gas prices have soared this year owing to the Ukraine war and after countries lifted pandemic lockdowns.

Gas prices, which sky-rocketed in March after Russia launched its invasion of Ukraine, are soaring once more this week after Moscow curbed crucial deliveries to Europe in recent days.

The world's energy majors are reaping the benefits of this year's surge in global oil and gas prices as a result of the war in Ukraine.

Load-Date: July 28, 2022

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Wall Street turns green after inflation data moderates bets on rate hikes

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August 10, 2022 Wednesday

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Length: 281 words

Body

The main stock indexes of the U.S. market are trading with strong gains on Wednesday. **Wall Street** advances boosted by lower-than-expected U.S. inflation data, which helps to moderate bets on sharp rate hikes.

The **Dow Jones** main index, composed of the shares of 30 industrial giants, rises 1.66% to 33,317.89 points. The **S&P 500**, the extended 500-component benchmark, gains 1.95% to a level of 4,202.78 points. The tech-heavy **Nasdaq** advances 2.52% to 12,808.77 points.

The U.S. **Consumer Price Index**

(CPI) rose 8.5% in July in its year-on-year rate, just after registering a 9.1% increase in June. A Reuters poll of analysts had forecast the figure at 8.7 percent.

The inflation reading moderates bets for future interest rate hikes by the **Federal Reserve**

(Fed), which has said it is willing to make strong adjustments to the price of money in order to achieve this, even if in the process it must slow down the economy's growth.

Stocks of large mega-cap technology companies, with valuations based on more forward-looking earnings, are the biggest beneficiaries today of a lower cost-to-growth outlook. **Apple** gains 1.77 percent and **Microsoft**, 2.33 percent. AAPL Chart by TradingView

"The Federal Reserve could take less aggressive measures at its next meeting and it is likely that we will start to see a recovery in the market and in the stock indexes," explained Eduardo Ramos, market analyst for the ATFX platform, in a note

Within the Dow Jones index, only one of its 30 stocks (**Merck&Co**) shows a moderate loss. In the gains, Salesforce.com shares stand out, with 3.46%, in addition to the aerospace company Boeing, with 3.29%, GoldmanSachs, with 3.21%.

Load-Date: September 7, 2022

NY stock markets close mixed, eyeing Nvidia result and on eve of CPI

CE Noticias Financieras English

August 8, 2022 Monday

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Length: 261 words

Body

New York stock markets closed without a single signal on Monday, tracking quarterly financial results. Downward adjustment in Nvidia's revenue forecast gave the company the worst unemployment on the Nasdaq in the session. The negotiations are still on the eve of the result of the consumer price index (CPI) of the United States, to be released on Wednesday, 10.

At the close, the Dow Jones rose 0.09% to 32,832.54 points, the S&P 500 fell 0.12% to 4,140.06 points, and the Nasdaq dropped 0.10% to 12,644.46 points.

Nvidia's shares fell 6.30% after the company revised down its revenue for the second quarter of fiscal 2023 from \$8.1 billion to \$6.7 billion in preliminary financial results released Monday. The company was the worst performer on the Nasdaq, while the technology sector, of which it is a member, led the decline in the S&P 500.

The Dow Jones, in turn, guaranteed an advance with a 2.33% rise in Walt Disney, which releases its latest balance sheet on Wednesday, followed by Dow Chemical Company (+1.28%) and **Merck & Co** (+1.24%). With an eye on the passage of the climate package in the US Senate and the push for electric vehicles, General Motors (+4.16%) and Ford (+3.14%) advanced.

The negotiations take place on the eve of the American CPI in July. The result of the economic indicator may consolidate expectations of a 75-basis point hike by the Federal Reserve (Fed, the US central bank) at the next monetary meeting in September, says Oxford Economics. With the robust labor market, as shown in the payroll report, the focus should be on inflation.

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Breast cancer drug boost for AstraZeneca

Mail on Sunday (London)

August 5, 2022 Friday

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Byline: Calum Muirhead

Body

ASTRAZENECA'S drug pipeline was boosted after European regulators cleared one of its cancer treatments.

The pharmaceutical giant's Lynparza drug has been approved by the European Commission to treat those suffering from a type of high-risk, early-stage breast cancer.

The approval followed data from a Phase III clinical trial published last June which showed Lynparza reduced the risk of death by 32pc.

The drug was approved for use on breast cancer patients in the US in March.

'Today's approval marks a new era of care in Europe for patients with an inherited form of breast cancer,' said Andrew Tutt, professor of oncology at the Institute of Cancer Research in London who led the clinical trial.

In Britain, around 11,500 die from breast cancer each year, according to Cancer Research UK. Approval in the EU will trigger a £62m payment to AstraZeneca from US pharma group **Merck & Co**, which it collaborated with to develop the treatment.

AstraZeneca shares edged up 0.5pc, or 58p, to 10720p following the news, further cementing its position as the most valuable company on the London stock market with a value of around £165bn. The EU approval provides yet another shot in the arm for the company's cancer drug pipeline following its £1.1bn purchase of US firm TeneoTwo last month, which gave it access to TNB-486, an early stage experimental treatment for a form of non-Hodgkin lymphoma, a type of blood cancer that can lead to tumours.

Enhertu, another of its cancer drugs which it developed alongside Japanese firm Daiichi Sankyo, has already been approved for use in the EU and the US for certain types of breast cancers.

Load-Date: August 5, 2022

Wall Street opens in green and the Dow Jones rises 0.55%.

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August 8, 2022 Monday

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Body

New York, Aug. 8. Wall Street opened Monday in green and its main indicator, the Dow Jones Industrials, gained 0.55%, starting the week on a positive note when the fear of a possible recession is still present among shareholders.

Ten minutes after the opening of the trading floor, the Dow Jones added 179 points to 32,936, while the S&P 500 gained 0.41% or 17 units to 4,163.75.

The Nasdaq composite index, which includes the main technology companies, was up 0.17% or 22 points, to 13,250.75.

A better-than-expected jobs report last Friday divided investors and analysts. Some expressed concern that the U.S. Federal Reserve (Fed) may continue to raise interest rates aggressively, while others questioned whether the country's economy might actually be in recession.

"Markets are still digesting Friday's jobs report. When you look at what's happening in the labor market, this doesn't look like a recession in the broad sense," Kiran Ganesh, multi-asset strategist at UBS, said in remarks picked up by The Wall Street Journal.

The key report this week will be U.S. inflation data for July to be released on Wednesday.

All sectors were in the green, with the biggest gains in non-core goods (1.9%), commodities (1.43%) and real estate (1.24%).

Among the 30 listed companies in the Dow Jones, the best performers were Walt Disney (2.15%), Boeing (1.87%) and American Express (1.77%), while the biggest losses were recorded by **Merck & Co** (-0.4%), Verizon (-0.38%) and Visa (-0.29%).

In other markets, Texas oil fell to 88.16 dollars per barrel, the yield on the 10-year US Treasury bond fell to 2.792 %, gold rose to 1,797.30 dollars per ounce and the dollar lost ground against the euro, with an exchange rate of 1.019. EFE

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