Bayer

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Investor News 2019

The news contents can be obtained from our website www.investor.bayer.com

Date	News
December 10, 2019	**Bayer to significantly step-up its sustainability efforts** - 2030 target to be carbon neutral in own operations - Ambitious 2030 objectives for access to health and nutrition in low- and middle-income countries and underserved communities - Measurable sustainability targets to be incorporated into management compensation
November 29, 2019	**Bayer completes sale of Currenta stake to Macquarie Infrastructure and Real Assets** Further step in Bayer's efforts to sharpen focus on core business
November 25, 2019	Not intended for U.S. and UK Media **Bayer submits application to EMA for use of rivaroxaban in children with venous thromboembolism** - Adding treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children from birth to 17 years of age with confirmed VTE, including cerebral vein and sinus thrombosis - Submission based on results from phase 3 EINSTEIN-Jr. study showing convincing efficacy and safety profile for rivaroxaban in children with VTE - An oral liquid formulation of rivaroxaban that does not require injections and regular monitoring was developed to facilitate pediatric administration - Patent extension in Europe of six months will be applied for once the procedure is completed
November 18, 2019	Not intended for U.S. and UK Media **Phase III VICTORIA study with vericiguat in patients with worsening chronic heart failure meets primary endpoint** - Vericiguat reduced the risk of cardiovascular death or heart failure hospitalization versus placebo when given in combination with available heart failure therapies - Vericiguat is the first-in-class soluble guanylate cyclase stimulator being developed to treat patients with worsening chronic heart failure
November 07, 2019	NOT FOR DISTRIBUTION IN THE UNITED STATES OF AMERICA, AUSTRALIA, CANADA, SOUTH AFRICA OR JAPAN **Bayer refinances 1.75 billion euro hybrid bond** - New issue of two tranches with a non-call period of 5.5 and 8 years combined with a tender offer for Bayer's existing hybrid bond
November 04, 2019	**Bayer completes sale of Dr. Scholl's™ brand to Yellow Wood Partners**

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October 30, 2019	Third quarter of 2019 **Bayer: Encouraging business performance across all divisions - agreements signed to divest Currenta and Animal Health** - Group sales increase by 5.4 percent (Fx & portfolio adj.) to 9.830 billion euros - EBITDA before special items advances by 7.5 percent to 2.291 billion euros - Crop Science reports higher sales and substantial earnings growth - Pharmaceuticals increases sales - earnings decline due to one-time income in prior year - Consumer Health posts growth in sales (Fx & portfolio adj.) and earnings - Net income declines by 63.9 percent to 1.036 billion euros - substantial divestment gain included in prior year - Core earnings per share up by 6.4 percent to 1.16 euros - Group outlook confirmed and aligned to continuing operations
October 14, 2019	Not intended for U.S. and UK Media **U.S. FDA approves rivaroxaban to help prevent blood clots in acutely ill medical patients** - A new oral option for patients in the U.S. with acute medical illnesses at risk for thromboembolic complications who are not at high risk of bleeding - Rivaroxaban is the only non vitamin K antagonist oral anticoagulant (NOAC) approved in the U.S for the continuum of venous thromboembolism (VTE) care, from prevention and treatment of initial VTE through extended prevention of recurrent VTE
October 1, 2019	**Ertharin Cousin to become member of Bayer AG Supervisory Board** - International expert in the area of nutrition and agriculture - Cousin succeeds Thomas Ebeling, who stepped down at the end of September
September 28, 2019	Not intended for U.S. and UK Media - European Society for Medical Oncology (ESMO) Congress 2019 **Updated analysis for larotrectinib confirms high response rate and durable responses over three years in children and adults with TRK fusion cancer** - 79% overall response rate (ORR) in 153 evaluable adult and pediatric patients at time of new data cut off (February 19, 2019); results consistent with previous publications(1,2) - Similar ORR of 75% in patients with brain metastases(1), adding to the previously reported evidence for larotrectinib's activity in central nervous system (CNS) - Median progression free survival (mPFS) of 28.3 months and median overall survival (mOS) of more than three years (44.4 months) was achieved; median duration of response (mDOR) of nearly three years(1) - Largest dataset with longest follow-up of any TRK inhibitor illustrates favorable safety profile across ages and tumor types(1)
September 23, 2019	Not intended for U.S. and UK Media **Vitrakvi® (larotrectinib) receives first tumor-agnostic approval in EU** - Precision oncology treatment Vitrakvi® (larotrectinib) approved for the treatment of adults and children with locally advanced or metastatic solid tumors that have a rare genomic alteration called an NTRK gene fusion - Vitrakvi, which was exclusively designed to treat TRK fusion cancer, is the first therapy in the EU with a tumor-agnostic indication - Larotrectinib provides high response rates and durable responses in adults and children with TRK fusion cancer, including primary CNS tumors and brain metastases - In studies, larotrectinib demonstrated an overall response rate of 72% including 16% complete responses, with 75% of patients still on treatment after one year - Larotrectinib showed a favorable safety profile, with the majority of adverse events (AEs) being grade 1 or 2; only 3% of patients had to stop therapy due to treatment emergent AEs

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September 20, 2019	Not intended for U.S. and UK Media - European Society for Medical Oncology (ESMO) Congress 2019 **Bayer data at ESMO 2019 highlights innovation in cancer research** - New data for larotrectinib on durability of response in patients with TRK fusion cancer to be presented in a poster discussion on September 28 - Data from Bayer's prostate cancer franchise to be presented, including clinical relevance of drug-drug interactions in men with nmCRPC taking darolutamide and real-world data and pain evalutation data in men with mCRPC treated with radium 223 dichloride - New analyses from the Phase II study REGOBONE evaluating the efficacy and safety of regorafenib in patients with rare locally advanced or metastatic relapsed chondrosarcoma to be highlighted in an oral presentation on September 30
September 10, 2019	Changes to Board of Management structure as of January 1, 2020: **Bayer reduces size of Board of Management from seven to five members**
September 02, 2019	Not intended for U.S. and UK Media - New guidelines from the European Society of Cardiology (ESC): **Xarelto™ 2.5 mg plus aspirin recommended for patients at high risk of heart attacks, strokes and death due to chronic coronary syndromes** - Clinical practice guidelines from the European Society of Cardiology (ESC) recommend Xarelto vascular dose (2.5 mg twice daily) plus aspirin low dose once daily in the management of patients with chronic coronary syndromes (CCS) as well as for patients with diabetes and lower extremity arterial disease - New guidelines include a change in nomenclature from 'stable coronary artery disease' to 'chronic coronary syndromes' to better reflect the continuous high risk of heart attacks, strokes and death within this patient population
September 02, 2019	**Bayer completes sale of iconic Coppertone™ brand to Beiersdorf** Divestiture enables Bayer to focus on core OTC business
August 20, 2019	**Bayer to sell its Animal Health business unit to Elanco for 7.6 billion U.S. dollars** - Exit of Animal Health business completes the series of portfolio measures initiated by Bayer in November 2018 ahead of announced schedule - Enhances Bayer's focus as a global leader in life sciences
August 08, 2019	**Bayer acquires BlueRock Therapeutics to build leading position in cell therapy** - Implied total company value of up to USD 1 billion, inclusive of 40.8 percent stake currently held by Bayer - Initial focus in neurology, cardiology, and immunology with start of first clinical program in Parkinson's disease expected later this year - BlueRock Therapeutics to continue to operate as an independent company
August 06, 2019	**Bayer and LANXESS to sell their stakes in Currenta to Macquarie Infrastructure and Real Assets** Currenta valued with an attractive enterprise value of EUR 3.5 billion (100%)
July 31, 2019	Not intended for U.S. and UK Media **U.S. FDA approves darolutamide, a new treatment for men with non-metastatic castration-resistant prostate cancer** - Darolutamide was approved in the U.S. under the FDA Priority Review designation; approval granted three months ahead of target FDA action date - Approval based on Phase III ARAMIS trial evaluating the efficacy and safety of darolutamide plus androgen deprivation therapy (ADT) compared to placebo plus ADT

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July 30, 2019	Second quarter of 2019: **Bayer on track in operational business** - Group sales increase by 0.9 percent (Fx & portfolio adj.) to 11.485 billion euros - EBITDA before special items advances by 24.7 percent to 2.927 billion euros - Crop Science sees sales decline (Fx & portfolio adj. and pro forma) in challenging environment but posts substantial earnings growth due to acquired business - Pharmaceuticals posts higher sales and strong earnings growth - Consumer Health increases sales and earnings - Net income falls by 49.1 percent to 404 million euros, held back by special items for restructuring and impairments - Core earnings per share increase by 5.9 percent to 1.62 euros - Group outlook confirmed yet increasingly ambitious
July 26, 2019	Not intended for U.S. and UK Media **Bayer receives positive CHMP opinion for precision oncology treatment larotrectinib with first ever tumor-agnostic indication in Europe** - Recommendation for approval for the treatment of adults and children with locally advanced or metastatic solid tumors that have a rare genomic alteration called an NTRK gene fusion - Upon approval, larotrectinib would be the first therapy in Europe with a tumor agnostic indication - CHMP opinion is based on pooled data showing that larotrectinib provides high and durable responses in adult and pediatric patients with TRK fusion cancer, including CNS tumors - Larotrectinib showed a favorable safety profile, with the majority of adverse events being grade 1 or 2 - Final decision from the European Commission is anticipated within the next months
July 22, 2019	**Yellow Wood Partners to acquire iconic Dr. Scholl's™ brand from Bayer**
July 18, 2019	Not intended for U.S. and UK Media **Bayer, Bristol-Myers Squibb and Ono Pharmaceutical enter into a clinical collaboration agreement to investigate Stivarga® (regorafenib) and Opdivo® (nivolumab) as combination therapy in patients with colorectal cancer** - Combination of regorafenib and nivolumab vs. regorafenib alone to be evaluated in patients with micro-satellite stable metastatic colorectal cancer - Companies plan indication-seeking trial
July 08, 2019	Not intended for U.S. and UK Media - Important step towards improved treatment for children with venous thromboembolism **Rivaroxaban demonstrates strong efficacy and safety profile in phase III study in children with thromboembolism** - Phase III EINSTEIN-Jr. study in children concludes the largest pediatric thromboembolism program delivering results consistent with those in adults - Study shows a low risk of recurrent venous thromboembolism (VTE) in children treated with rivaroxaban compared with standard of care with low rates of bleeding - First phase III data on the use of a non-vitamin K oral anticoagulant (NOAC) in a large pediatric population - Study investigated a body weight-adjusted oral 20 mg equivalent dose of rivaroxaban for the prevention of recurrent VTE in children from birth to 17 years of age with confirmed VTE, including cerebral vein and sinus thrombosis
July 02, 2019	**LEO Pharma completes the acquisition of Bayer's prescription dermatology business**
July 01, 2019	**Century Therapeutics launches with USD 250M financing for induced pluripotent stem cells (iPSC) allogeneic cell therapy platform** - Created by Versant Ventures and partnered with Fujifilm to develop iPSC-derived adaptive and innate immune effector cell therapies - Leaps by Bayer leads investment round with USD 215 million commitment to develop next-generation immune oncology treatments
June 26, 2019	**Bayer Supervisory Board takes action to address the glyphosate litigation and welcomes the appointment of Ken Feinberg as mediator**

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June 21, 2019	Not intended for U.S. and UK Media **Bayer initiates Phase III trial of Aflibercept to prevent blindness in premature infants**
June 19, 2019	Not intended for U.S. and UK Media **Regorafenib to be tested in brain cancer patients in multi-arm cooperation trial** - GBM AGILE, an international platform trial sponsored by the Global Coalition for Adaptive Research (GCAR) to evaluate multiple therapies for patients with newly diagnosed and recurrent glioblastoma, is now open for enrollment in the US with regorafenib as the first treatment arm - Results from the Phase II REGOMA study (Lombardi G et al, Lancet Oncol, 2018) support further evaluation of regorafenib in patients with newly diagnosed and recurrent glioblastoma, the most aggressive form of brain cancer - Medical need remains high in glioblastoma as treatment options are limited and patient outcomes have remained largely unchanged over several decades
June 03, 2019	Not intended for U.S. and UK Media - Annual Meeting of the American Society of Clinical Oncology (ASCO) 2019: **New data on larotrectinib efficacy in patients with TRK fusion cancer and primary CNS tumors or brain metastases presented at ASCO 2019** - In five TRK fusion cancer patients with brain metastases across different tumor histologies, the overall response rate was 60%, with disease control achieved in all patients - In 14 adult and pediatric patients with TRK fusion cancer with primary central nervous system (CNS) tumors (including high grade gliomas), the overall response rate was 36% including two complete responses - 71% of evaluable patients with primary CNS tumors experienced disease control for 24 weeks or more - First prospective analysis of the activity of larotrectinib in patients with TRK fusion cancer and intracranial disease, including first data ever presented for a TRK inhibitor in adult primary CNS TRK fusion cancer
May 31, 2019	Not intended for U.S. and UK Media - 2019 American Society of Clinical Oncology (ASCO) Annual Meeting **Bayer's darolutamide plus androgen deprivation therapy (ADT) delays worsening of disease-related symptoms and maintains quality of life beyond end of study treatment compared to placebo plus ADT in men with non-metastatic castration-resistant prostate can** - Results of a new post-hoc analysis showed that treatment with darolutamide plus androgen deprivation therapy (ADT) delayed worsening of urinary and bowel symptoms versus placebo plus ADT - Exposure-adjusted incidences of treatment-emergent adverse events (TEAEs), including notably TEAEs associated with androgen receptor (AR) antagonists, were generally similar for darolutamide plus ADT compared to placebo plus ADT - Darolutamide plus ADT maintained quality of life in men with non-metastatic castration-resistant prostate cancer (nmCRPC) beyond end of study treatment with scores similar to placebo plus ADT - Analysis on quality of life related endpoints from pivotal Phase III ARAMIS trial presented at the American Society of Clinical Oncology (ASCO) Annual Meeting as an oral presentation on May 31, 2019 - Darolutamide is under Priority Review in the U.S., and has been filed in Europe, Japan and additional countries

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May 15, 2019	Not intended for U.S. and UK Media - Annual Meeting of the American Society of Clinical Oncology (ASCO) 2019 **New data for larotrectinib show overall response rates of 94% in children and 76% in adults with TRK fusion cancer; clinical benefit demonstrated in patients with primary central nervous system tumors and brain metastases** - In children with TRK fusion cancer (n=34), the overall response rate (ORR) was 94% and durable, with median duration of response (DOR) not reached - In adults with TRK fusion cancer (n=74), the ORR was 76% and durable, with median DOR not reached - In evaluable patients with brain metastases (n=5), ORR was 60% - Improvements in quality of life were shown with larotrectinib treatment in both children and adults - Majority of adverse events were grade 1 or 2, as reported in prior publications
May 13, 2019	**Bayer statement on jury's decision in California State Glyphosate Trial**
May 13, 2019	**Beiersdorf to acquire iconic Coppertone™ brand from Bayer** - Significant expansion of portfolio will advance Beiersdorf's leading position as sun care expert - Beiersdorf delivers first major acquisition under its new C.A.R.E.+ strategy - Divestiture enables Bayer to focus on core OTC business
May 13, 2019	Not intended for U.S. and UK Media - 2019 American Society of Clinical Oncology (ASCO) Annual Meeting: **Bayer to present new data at ASCO 2019 highlighting commitment to evolve cancer treatment paradigm** - Data from Bayer's growing oncology portfolio include new analyses on the company's precision oncology treatment larotrectinib, with two oral presentations in patients with solid tumors that harbor an NTRK gene fusion: one on expanded data in pediatric patients and the other one in patients with brain metastases or primary central nervous system tumors - First detailed presentation of quality of life data from the Phase III ARAMIS trial of the investigational androgen receptor antagonist darolutamide in patients with non metastatic castration-resistant prostate cancer - Oral presentation on investigational ATR inhibitor BAY 1895344 in patients with advanced solid tumors - Long-term data from patients with relapsed or refractory follicular lymphoma treated with copanlisib
April 29, 2019	Not intended for U.S. and UK Media **U.S. FDA accepts new drug application and grants priority review for darolutamide**
April 29, 2019	Not intended for U.S. and UK Media **Study reaffirms safety and efficacy profile of Xarelto™ for the prevention of stroke in patients with atrial fibrillation** - First results from RELOADED, an observational study in the EU, indicate that non vitamin-K oral anticoagulants (NOACs) like Xarelto provide a benefit in renal preservation over time when compared to the vitamin-K antagonist (VKA) phenprocoumon - The data from the comparative effectiveness study in Germany confirm an improved safety outcome and comparable effectiveness for Xarelto compared with phenprocoumon in patients with non-valvular atrial fibrillation (NVAF), including those with renal insufficiency(1)
April 27, 2019	After Annual Stockholders' Meeting votes to not ratify Board of Management's actions: **Bayer's Supervisory Board unanimously stands behind Board of Management**

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April 26, 2019	CEO Werner Baumann at the Annual Stockholders' Meeting of Bayer AG: **"We made great progress - both operationally and strategically"** - Bayer now the leader in agriculture - Lawsuits and first verdicts concerning glyphosate weigh on company - Sales and earnings increased in 2018 / Proposed dividend of 2.80 euros marks record payout by Bayer - Successful start to fiscal 2019 - outlook confirmed
April 25, 2019	First quarter of 2019: **Bayer: strong operational start to the year** - Group sales increase 4.1 percent (Fx & portfolio adj.) to 13.015 billion euros - EBITDA before special items advances by 44.6 percent to 4.188 billion euros - Crop Science posts substantial sales and earnings gains following the acquisition - Pharmaceuticals shows encouraging sales and earnings growth - Consumer Health below the prior-year quarter, full-year outlook confirmed - Net income declines as expected by 36.5 percent to 1.241 billion euros, held back by special items related to the acquisition and restructuring - Core earnings per share increase 13.8 percent to 2.55 euros - Business outlook for 2019 confirmed
March 27, 2019	**Bayer statement on jury's decision in phase two of California glyphosate trial**
March 25, 2019	**Bayer reaches settlement to resolve Xarelto™ litigation**
March 19, 2019	**Bayer statement on jury's decision in phase one of California glyphosate trial**
March 08, 2019	Not intended for U.S. and UK Media **Bayer submits European marketing authorization application for darolutamide** - Third submission for darolutamide in two weeks underscores Bayer's commitment to fill an unmet need for men with nmCRPC worldwide - Regulatory submission based on positive data from Phase III study ARAMIS
March 05, 2019	Not intended for U.S. and UK Media **Bayer submits darolutamide for marketing authorization in Japan** Regulatory submission based on positive data from Phase III ARAMIS study
February 27, 2019	Fiscal 2018: **Bayer increases sales and earnings - leader in agriculture after acquisition** - Group sales advance 4.5 percent (Fx & portfolio adj.) to 39.586 billion euros - EBITDA before special items increases by 2.8 percent to 9.547 billion euros, held back by currency effects of 457 million euros - Pharmaceuticals posts higher sales (Fx & portfolio adj.) and slightly lower earnings - Consumer Health: sales level with prior year (Fx & portfolio adj.), earnings decline - Crop Science reports sales gains, substantially higher earnings due to the acquisition, integration off to a strong start - Positive safety profile of glyphosate unchanged - Bayer vigorously defending itself against lawsuits - Net income at 1.695 billion euros, impacted by one-time effects - Core earnings per share at 5.94 euros, above expectations - Net financial debt at 35.679 billion euros, significantly better than expected - Bayer confirms 2019 Group outlook and 2022 targets
February 27, 2019	Not intended for U.S. and UK Media **Bayer completes rolling submission for darolutamide in U.S.**
February 26, 2019	Bayer proposes dividend for 2018 of 2.80 euros per share **Total dividend payment: record high of 2.611 billion euros**

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February 15, 2019	Not intended for U.S. and UK Media **Bayer exercised option to obtain full licensing rights for larotrectinib and BAY 2731954 (LOXO-195)** - Bayer exercised option under change-in-control clause in it's agreement with Loxo Oncology to obtain full licensing rights for the two TRK inhibitor agents - Bayer to be solely responsible for the global development and commercialization of both larotrectinib and BAY 2731954 (LOXO-195) - Co-Promotion in the U.S. to be converted into exclusive commercialization by Bayer - Larotrectinib was approved in November 2018 in the U.S. under the brand name VITRAKVI® as the first TRK inhibitor for patients with advanced solid tumors harboring an NTRK gene fusion; filings in Europe and other regions underway
February 14, 2019	Not intended for U.S. and UK Media - American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) 2019 **Bayer's darolutamide plus androgen deprivation therapy (ADT) significantly extends metastasis-free survival with a favorable safety profile compared to placebo plus ADT in non-metastatic castration-resistant prostate cancer** - Statistically significant improvement in metastasis-free survival (MFS), with a median MFS of 40.4 months with darolutamide plus androgen deprivation therapy (ADT) versus placebo plus ADT (18.4 months) - Positive trend in overall survival with a 29% reduction in risk of death at interim analysis (P=0.045) - Incidence of treatment-emergent adverse events was similar for darolutamide plus ADT and placebo plus ADT - Health-related quality of life was maintained - First results from the Phase III ARAMIS trial with the androgen receptor antagonist darolutamide were presented in an oral presentation at American Society of Clinical Oncology Genitourinary Cancers Symposium and simultaneously published in The New England Journal of Medicine
January 08, 2019	New predictive seed placement technology delivers strong results in 2018: **Bayer expands digital innovation pipeline at The Climate Corporation to bring breakthrough digital tools to more farmers**