**Bristol-Myers Squibb’s Sprycel® (dasatinib) Tablets Now Approved in Combination with Chemotherapy in Certain Pediatric Patients with Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia**

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Corporate/Financial News  #ALL  #BMS  #cancer  #dasatinib  #oncology  #Sprycel  $BMY  Acute Lymphoblastic Leukemia  nurse  Oncology  patients  Ph+  Research  sprycel  Squibb  treatment  tumor

**Dateline City:**
PRINCETON, N.J.

- **Sprycel is the first and only second-generation tyrosine kinase inhibitor for pediatric patients for the treatment of newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia in combination with chemotherapy**

- **Approval marks second pediatric leukemia indication for Sprycel**

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced the U.S. Food and Drug Administration (FDA) has expanded the indication for Sprycel® (dasatinib) tablets to include the treatment of pediatric patients one year of age and older with newly diagnosed Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) in combination with chemotherapy.² Sprycel is the only second-generation tyrosine kinase inhibitor approved for this patient population. The approval, which was granted following priority review by the FDA, is based on data from the Phase 2 study, CA180-372 (NCT01460160).

“We recognize the urgency around developing and delivering therapies for children and young adults living with cancer, and today’s approval is an important example of our commitment to pediatric oncology,” said Jeffrey Jackson, Ph.D., development lead, hematology, Bristol-Myers Squibb. “Building on our previous indication for children with Ph+ chronic myeloid leukemia in chronic phase, we’re pleased to bring Sprycel tablets to a second type of pediatric leukemia. This approval will give physicians another treatment option to offer appropriate pediatric patients with Ph+ ALL.”

Sprycel is associated with the following Warnings and Precautions: myelosuppression, bleeding-related events, fluid retention, cardiovascular events, pulmonary arterial hypertension, QT prolongation, severe dermatologic reactions, tumor lysis syndrome, embryo-fetal toxicity and effects on growth and development in pediatric patients.³ Please see detailed Important Safety Information below.

The efficacy of Sprycel tablets in combination with chemotherapy was evaluated in a single cohort of the Phase 2, multicenter, single-arm CA180-372 study, which included 78 pediatric patients with newly diagnosed B-cell precursor Ph+ ALL.² At three years, the study demonstrated an event-free survival (EFS) binary rate of 64.1% (95% confidence interval [CI]: 52.4 to 74.7).³ Event-free survival is defined as the time from the start of Sprycel to lack of complete response at the end of the third high-risk block, relapse, secondary malignancy or death from any cause.

Of the 81 patients evaluated for safety, fatal adverse reactions occurred in three patients (4%), and eight (10%) experienced adverse reactions leading to treatment discontinuation, including fungal sepsis, hepatotoxicity of graft versus host disease, thrombocytopenia, CMV infection, pneumonia, nausea, enteritis and drug hypersensitivity.² The most common serious adverse reactions (incidence ≥10%) were pyrexia, febrile neutropenia, mucositis, diarrhea, sepsis, hypotension, infections (bacterial, viral and fungal), hypersensitivity, vomiting, renal insufficiency, abdominal pain and musculoskeletal pain.²

“As treatments have advanced in recent years, we’ve seen improvements in outcomes for pediatric patients with Ph+ ALL overall, but there remains a need for additional options,”³ said Stephen Hunger, MD, lead study author, chief of the division of oncology and director of the Center for Childhood Cancer Research at Children’s Hospital of Philadelphia. “The Phase 2 CA180-372 trial was particularly informative because it was designed to limit the use of cranial irradiation and stem cell transplant. In the study, Sprycel plus chemotherapy demonstrated a three-year event-free survival benefit. These results show that Sprycel is an effective medication for physicians to consider for children and adolescents with Ph+ ALL.”³,⁴

Acute lymphoblastic leukemia is characterized by chromosomal abnormalities and genetic alterations involved in the
differentiation and proliferation of lymphoid precursor cells.\textsuperscript{5} The most common childhood cancer in the United States, ALL represents 20\% of all cancers diagnosed in persons aged less than 20 years, or more than 3,000 new cases each year.\textsuperscript{6} Three percent of children who have ALL have the Ph+ subtype, which means they have a chromosome alteration that results in a specific mutation of the BCR-ABL gene.\textsuperscript{3}

“Coping with a pediatric cancer diagnosis, including searching for and identifying the right treatment regimen, can take a physical and emotional toll on patients and their families,” said Vickie Buenger, president of the Coalition Against Childhood Cancer (CAC2). “The availability of another option is a welcome step forward for those affected by this disease.”

In addition to this pediatric approval, Sprycel\textregistered is approved for use in children one year of age and older with Ph+ chronic myeloid leukemia (CML) in chronic phase (CP).\textsuperscript{1}

\textbf{About the Phase 2 CA180-372 Study}

In the CA180-372 trial, the 78 patients evaluated for efficacy in cohort 1 received Sprycel at a daily dose of 60 mg/m\textsuperscript{2} for up to 24 months, in combination with chemotherapy.\textsuperscript{1} The backbone chemotherapy regimen was the AIEOP-BFM ALL 2000 multi-agent chemotherapy protocol.\textsuperscript{1} Efficacy was established based on three-year EFS, defined as the time from the start of Sprycel\textregistered to lack of complete response at the end of the third high-risk block, relapse, secondary malignancy or death from any cause.\textsuperscript{2} The trial was designed such that patients with central nervous system 3 disease receive cranial irradiation.\textsuperscript{4} Patients were assigned to receive stem cell transplant (SCT) based on minimal residual disease if they were considered high-risk.\textsuperscript{4} Data from the CA180-372 trial were presented at the 2017 American Society of Hematology Annual Meeting.

The recommended starting dosage for Sprycel\textregistered in pediatric patients with Ph+ ALL is based on body weight.\textsuperscript{1} The recommended dose should be administered orally once daily, and the dose should be recalculated every three months based on changes in body weight, or more often if necessary.\textsuperscript{1} For pediatric patients with Ph+ ALL, Sprycel\textregistered/therapy should begin on or before day 15 of induction chemotherapy, when diagnosis is confirmed, and continue for two years.\textsuperscript{1}

Sprycel\textregistered tablets should not be crushed, cut or chewed.\textsuperscript{1} Tablets should be swallowed whole; however, there are additional administration considerations for pediatric patients who have difficulty swallowing tablets whole.\textsuperscript{1} Five patients with Ph+ ALL 2 to 10 years of age received at least one dose of Sprycel\textregistered/tablet dispersed in juice on Study CA180-372. The exposure for dispersed tablets was estimated to be 36\% lower as compared to intact tablets in pediatric patients. Due to the limited available clinical data, it is unclear whether dispersing Sprycel\textregistered/tablets significantly alters the safety and/or efficacy of Sprycel.

\textbf{Select Safety Profile for the CA180-372 Study}

In the CA180-372 study, 81 pediatric patients with Ph+ ALL received Sprycel\textregistered continuously in combination with chemotherapy.\textsuperscript{1} The median duration of therapy was 24 months (range 2 to 27 months).\textsuperscript{1}

Among these patients, the most common adverse reactions (reported in at least 20\% of patients) were mucositis (93\%), febrile neutropenia (86\%), pyrexia (85\%), diarrhea (84\%), nausea (84\%), vomiting (83\%), musculoskeletal pain (83\%), abdominal pain (78\%), cough (78\%), headache (77\%), rash (68\%), fatigue (59\%), constipation (57\%), hyperchromia (47\%), hypertension (47\%), edema (47\%), viral infection (40\%), hypotension (40\%), decreased appetite (38\%), hypersensitivity (36\%), upper respiratory tract infection (36\%), dyspnea (35\%), epistaxis (31\%), peripheral neuropathy (31\%), altered state of consciousness (30\%), fungal infection (30\%), pneumonia (excluding fungal) (28\%), pruritus (28\%), Clostridial infection (excluding sepsis) (25\%), urinary tract infection (24\%), bacteremia (excluding fungal) (22\%), erythema (22\%), chills (21\%), pleural effusion (21\%), sinusitis (21\%), dehydration (20\%), renal insufficiency (20\%) and visual impairment (20\%).\textsuperscript{1}

\textbf{INDICATIONS}

SPRYCEL\textsuperscript{®} (dasatinib) is indicated for the treatment of adult patients with:

- Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase
- Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib
- Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy

SPRYCEL\textsuperscript{®} is indicated for the treatment of pediatric patients 1 year of age and older with:

- Ph+ CML in chronic phase
- Newly diagnosed Ph+ ALL in combination with chemotherapy

SPRYCEL (100 mg) is a tablet.

\textbf{IMPORTANT SAFETY INFORMATION}

\textbf{Myelosuppression:}

Treatment with SPRYCEL\textsuperscript{®} is associated with severe (NCI CTCAE Grade 3/4) thrombocytopenia, neutropenia, and anemia, which occur earlier and more frequently in patients with advanced phase CML or Ph+ ALL than in patients with chronic phase CML. Myelosuppression was reported in patients with normal baseline laboratory values as well as in patients with pre-existing laboratory abnormalities.
In patients with chronic phase CML, perform complete blood counts (CBCs) every 2 weeks for 12 weeks, then every 3 months thereafter, or as clinically indicated.

In patients with advanced phase CML or Ph+ ALL, perform CBCs weekly for the first 2 months and then monthly thereafter, or as clinically indicated.

In pediatric patients with Ph+ ALL treated with SPRYCEL in combination with chemotherapy, perform CBCs prior to the start of each block of chemotherapy and as clinically indicated. During the consolidation blocks of chemotherapy, perform CBCs every 2 days until recovery.

Myelosuppression is generally reversible and usually managed by withholding SPRYCEL temporarily and/or dose reduction.

In clinical studies, myelosuppression may have also been managed by discontinuation of study therapy.

Hematopoietic growth factor has been used in patients with resistant myelosuppression.

**Bleeding-Related Events:**

SPRYCEL can cause serious and fatal bleeding. In all CML or Ph+ ALL clinical studies, Grade ≥3 central nervous system (CNS) hemorrhages, including fatalities, occurred in <1% of patients receiving SPRYCEL. The incidence of Grade 3/4 hemorrhage, occurred in 5.8% of adult patients and generally required treatment interruptions and transfusions. The incidence of Grade 5 hemorrhage occurred in 0.4% of adult patients. The most frequent site of hemorrhage was gastrointestinal.

- Most bleeding events in clinical studies were associated with severe thrombocytopenia.
- In addition to causing thrombocytopenia in human subjects, dasatinib caused platelet dysfunction in vitro.
- Concomitant medications that inhibit platelet function or anticoagulants may increase the risk of hemorrhage.

**Fluid Retention:**

SPRYCEL may cause fluid retention. After 5 years of follow-up in the adult randomized newly diagnosed chronic phase CML study (n=258), Grade 3/4 fluid retention was reported in 5% of patients, including 3% of patients with Grade 3/4 pleural effusion. In adult patients with newly diagnosed or imatinib resistant or intolerant chronic phase CML, grade 3/4 fluid retention occurred in 6% of patients treated with SPRYCEL at the recommended dose (n=548). In adult patients with advanced phase CML or Ph+ ALL treated with SPRYCEL at the recommended dose (n=304), grade 3/4 fluid retention was reported in 8% of patients, including grade 3/4 pleural effusion reported in 7% of patients. In pediatric patients with chronic phase CML, cases of Grade 1 or 2 fluid retention were reported in 10.3% of patients.

- Patients who develop symptoms of pleural effusion or other fluid retention, such as new or worsened dyspnea on exertion or at rest, pleuritic chest pain, or dry cough, should be evaluated promptly with a chest x-ray or additional diagnostic imaging as appropriate.
- Fluid retention events were typically managed by supportive care measures that may include diuretics or short courses of steroids.
- Severe pleural effusion may require thoracentesis and oxygen therapy.
- Consider dose reduction or treatment interruption.

**Cardiovascular Events:**

SPRYCEL can cause cardiac dysfunction. After 5 years of follow-up in the randomized newly diagnosed chronic phase CML trial in adults (n=258), the following cardiac adverse reactions occurred:

- Cardiac ischemic events (3.9% dasatinib vs 1.6% imatinib), cardiac related fluid retention (8.5% dasatinib vs 3.9% imatinib), and conduction system abnormalities, most commonly arrhythmia and palpitations (7.0% dasatinib vs 5.0% imatinib). Two cases (0.8%) of peripheral arterial occlusive disease occurred with imatinib and 2 (0.8%) transient ischemic attacks occurred with dasatinib.

Monitor patients for signs or symptoms consistent with cardiac dysfunction and treat appropriately.

**Pulmonary Arterial Hypertension (PAH):**

SPRYCEL may increase the risk of developing PAH in adult and pediatric patients, which may occur anytime after initiation, including after more than 1 year of treatment. Manifestations include dyspnea, fatigue, hypoxia, and fluid retention. PAH may be reversible on discontinuation of SPRYCEL.

- Evaluate patients for signs and symptoms of underlying cardiopulmonary disease prior to initiating SPRYCEL and during treatment. If PAH is confirmed, SPRYCEL should be permanently discontinued.

**QT Prolongation:**

SPRYCEL may increase the risk of prolongation of QTc in patients including those with hypokalemia or hypomagnesemia, patients with congenital long QT syndrome, patients taking antiarrhythmic medicines or other medicinal products that lead to QT prolongation, and cumulative high-dose anthracycline therapy.

- Correct hypokalemia or hypomagnesemia prior to and during SPRYCEL administration.

**Severe Dermatologic Reactions:**

Cases of severe mucocutaneous dermatologic reactions, including Stevens-Johnson syndrome and erythema multiforme, have been reported in patients treated with SPRYCEL.
Discontinue permanently in patients who experience a severe mucocutaneous reaction during treatment if no other etiology can be identified.

**Tumor Lysis Syndrome (TLS):**

TLS has been reported in patients with resistance to prior imatinib therapy, primarily in advanced phase disease.

- Due to potential for TLS, maintain adequate hydration, correct uric acid levels prior to initiating therapy with SPRYCEL, and monitor electrolyte levels.
- Patients with advanced stage disease and/or high tumor burden may be at increased risk and should be monitored more frequently.

**Embryo-Fetal Toxicity:**

Based on limited human data, SPRYCEL can cause fetal harm when administered to a pregnant woman. Hydrops fetalis, fetal leukopenia, and fetal thrombocytopenia have been reported with maternal exposure to SPRYCEL. Transplacental transfer of dasatinib has been measured in fetal plasma and amniotic fluid at concentrations comparable to those in maternal plasma.

- Advise females of reproductive potential to avoid pregnancy, which may include the use of effective contraception, during treatment with SPRYCEL and for 30 days after the final dose.

**Effects on Growth and Development in Pediatric Patients:**

In pediatric trials of SPRYCEL in chronic phase CML after at least 2 years of treatment, adverse reactions associated with bone growth and development were reported in 5 (5.2%) patients, one of which was severe in intensity (Growth Retardation Grade 3). These 5 cases included cases of epiphyses delayed fusion, osteopenia, growth retardation, and gynecomastia. Of these 5 cases, 1 case of osteopenia and 1 case of gynecomastia resolved during treatment.

Monitor bone growth and development in pediatric patients.

**Lactation:**

No data are available regarding the presence of dasatinib in human milk, the effects of the drug on the breastfed child, or the effects of the drug on milk production. However, dasatinib is present in the milk of lactating rats.

- Because of the potential for serious adverse reactions in nursing children from SPRYCEL, breastfeeding is not recommended during treatment with SPRYCEL and for 2 weeks after the final dose.

**Drug Interactions:**

**Effect of Other Drugs on Dasatinib**

- **Strong CYP3A4 inhibitors:** The coadministration with strong CYP3A inhibitors may increase dasatinib concentrations. Increased dasatinib concentrations may increase the risk of toxicity. Avoid concomitant use of strong CYP3A4 inhibitors. If concomitant administration of a strong CYP3A4 inhibitor cannot be avoided, consider a SPRYCEL dose reduction.
  - **Grapefruit juice** may increase plasma concentrations of SPRYCEL and should be avoided.

- **Strong CYP3A4 inducers:** The coadministration of SPRYCEL with strong CYP3A inducers may decrease dasatinib concentrations. Decreased dasatinib concentrations may reduce efficacy. Consider alternative drugs with less enzyme induction potential. If concomitant administration of a strong CYP3A4 inducer cannot be avoided, consider a SPRYCEL dose increase.
  - **St. John's wort** may decrease plasma concentrations of SPRYCEL and should be avoided.

- **Gastric Acid Reducing Agents:** The coadministration of SPRYCEL with a gastric acid reducing agent may decrease the concentrations of dasatinib. Decreased dasatinib concentrations may reduce efficacy.

Do not administer H2 antagonists or proton pump inhibitors with SPRYCEL. Consider the use of antacids in place of H2 antagonists or proton pump inhibitors. Administer the antacid at least 2 hours prior to or 2 hours after the dose of SPRYCEL. Avoid simultaneous administration of SPRYCEL with antacids.

**Adverse Reactions:**

The safety data reflects exposure to SPRYCEL administered as single-agent therapy at all doses tested in clinical studies (n=2809) including 324 adult patients with newly diagnosed chronic phase CML, 2388 adult patients with imatinib-resistant or -intolerant chronic or advanced phase CML or Ph+ ALL, and 97 pediatric patients with chronic phase CML.

The median duration of therapy in a total of 2712 SPRYCEL-treated adult patients was 19.2 months (range 0–93.2 months). Median duration of therapy in:

- 1618 adult patients with chronic phase CML was 29 months (range 0–92.9 months)
  - Median duration for 324 adult patients in the newly diagnosed chronic phase CML trial was approximately 60 months

- 1094 adult patients with advanced phase CML or Ph+ ALL was 6.2 months (range 0–93.2 months)

In two non-randomized trials in 97 pediatric patients with chronic phase CML (51 patients newly diagnosed and 46 patients resistant or intolerant to previous treatment with imatinib), the median duration of therapy was 51.1 months (range 1.9 to 99.6 months).

In a multicohort study of SPRYCEL administered continuously in combination with multiagent chemotherapy in 81 pediatric
patients with newly diagnosed Ph+ ALL, the median duration of therapy was 24 months (range 2 to 27 months).

In the newly diagnosed adult chronic phase CML trial, after a minimum of 60 months of follow-up, the cumulative discontinuation rate for 258 patients was 39%.

In the overall population of 2712 adult patients, 88% of patients experienced adverse reactions at some time, and 19% experienced adverse reactions leading to treatment discontinuation.

Among the 1618 adult patients with chronic phase CML, drug-related adverse reactions leading to discontinuation were reported in 329 (20.3%) patients.

- In the newly diagnosed chronic phase CML trial, drug was discontinued for adverse reactions in 16% of SPRYCEL-treated patients with a minimum of 60 months of follow-up

Among the 1094 patients with advanced phase CML or Ph+ ALL, drug-related adverse reactions leading to discontinuation were reported in 191 (17.5%) patients.

Among the 97 CML pediatric subjects, drug-related adverse reactions leading to discontinuation were reported in 1 patient (1%).

Patients ≥65 years are more likely to experience the commonly reported adverse reactions of fatigue, pleural effusion, diarrhea, dyspnea, cough, lower gastrointestinal hemorrhage, and appetite disturbance, and more likely to experience the less frequently reported adverse reactions of abdominal distention, dizziness, pericardial effusion, congestive heart failure, hypertension, pulmonary edema, and weight decrease, and should be monitored closely.

- In adult newly diagnosed chronic phase CML patients:
  - Drug-related serious adverse reactions (SARs) were reported for 16.7% of patients. Serious adverse reactions reported in ≥5% of patients included pleural effusion (5%)
  - Grade 3/4 laboratory abnormalities included neutropenia (29%), thrombocytopenia (22%), anemia (13%), hypophosphatemia (7%), hypocalcemia (4%), elevated bilirubin (1%), and elevated creatinine (1%)

- In adult patients resistant or intolerant to prior imatinib therapy:
  - Drug-related SARs were reported for 26.1% of SPRYCEL-treated patients treated at the recommended dose of 100 mg once daily in the randomized dose-optimization trial of patients with chronic phase CML resistant or intolerant to prior imatinib therapy. Serious adverse reactions reported in ≥5% of patients included pleural effusion (10%)
  - Grade 3/4 hematologic laboratory abnormalities in chronic phase CML patients resistant or intolerant to prior imatinib therapy who received SPRYCEL 100 mg once daily with a minimum follow up of 60 months included neutropenia (36%), thrombocytopenia (24%), and anemia (13%). Other grade 3/4 laboratory abnormalities included: hypophosphatemia (10%), and hypokalemia (2%)
  - Among chronic phase CML patients with resistance or intolerance to prior imatinib therapy, cumulative grade 3/4 cytopenias were similar at 2 and 5 years including: neutropenia (36% vs 36%), thrombocytopenia (23% vs 24%), and anemia (13% vs 13%)

  - Grade 3/4 elevations of transaminases or bilirubin and Grade 3/4 hypocalcemia, hypokalemia, and hypophosphatemia were reported in patients with all phases of CML
    - Elevations in transaminases or bilirubin were usually managed with dose reduction or interruption
    - Patients developing Grade 3/4 hypocalcemia during the course of SPRYCEL therapy often had recovery with oral calcium supplementation

- In pediatric subjects with Ph+ CML in chronic phase
  - Drug-related SARs were reported for 14.4% of pediatric patients
  - Adverse reactions associated with bone growth and development were reported in 5 (5.2%) of pediatric patients with chronic phase CML
  - In the pediatric studies, the rates of laboratory abnormalities were consistent with the known profile for laboratory parameters in adults

- In pediatric subjects with Ph+ ALL who were administered SPRYCEL in combination with multiagent chemotherapy
  - Fatal adverse reactions occurred in 3 patients (4%), all of which were due to infections
  - Eight patients (10%) experienced adverse reactions leading to treatment discontinuation
    - The most common serious adverse reactions (incidence ≥10%) were pyrexia, febrile neutropenia, mucositis, diarrhea, sepsis, hypotension, infections (bacterial, viral and fungal), hypersensitivity, vomiting, renal insufficiency, abdominal pain, and musculoskeletal pain
    - Grade 3/4 laboratory abnormalities (≥10%) included neutropenia (96%), thrombocytopenia (88%), anemia (82%), elevated SGPT (ALT) (47%), hypokalemia (40%), elevated SGOT (AST) (26%), hypocalcemia (19%), hypernatremia (19%), elevated bilirubin (11%), and hypophosphatemia (11%)

Most common adverse reactions (≥15%) in patients receiving SPRYCEL as single-agent therapy included myelosuppression, fluid retention events, diarrhea, headache, skin rash, hemorrhage, dyspnea, fatigue, nausea, and musculoskeletal pain.

Most common adverse reactions (≥30%) in pediatric patients receiving SPRYCEL in combination with chemotherapy included mucositis, febrile neutropenia, pyrexia, diarrhea, nausea, vomiting, musculoskeletal pain, abdominal pain, cough, headache, rash, fatigue, constipation, arhythmia, hypertension, edema, infections (bacterial, viral and fungal), hypotension, decreased appetite, hypersensitivity, dyspnea, epistaxis, peripheral neuropathy, and altered state of consciousness.
Please see full Prescribing Information.

SPRYCEL® is a trademark of Bristol-Myers Squibb Company.

About Sprycel

Sprycel first received FDA approval in 2006 for the treatment of adults with Ph+ CML in CP who are resistant or intolerant to prior therapy including imatinib. At that time, Sprycel was also approved for adults with Ph+ ALL who are resistant or intolerant to prior therapy. Sprycel is approved and marketed worldwide for these indications in more than 60 countries.

Sprycel is also an FDA-approved treatment for adults with newly diagnosed CP Ph+ CML, and in November 2017, Sprycel received FDA approval for the expanded indication for treatment in pediatric patients with CP Ph+ CML. The adult indication is approved in more than 50 countries.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit us at BMS.com or follow us on LinkedIn, Twitter, YouTube and Facebook.

Bristol-Myers Squibb Forward-Looking Statement

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 regarding the research, development and commercialization of pharmaceutical products. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on historical performance and current expectations and projections about our future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, and could cause our future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. No forward-looking statement can be guaranteed. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb’s business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb’s Annual Report on Form 10-K for the year ended December 31, 2017, as updated by our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. The forward-looking statements included in this document are made only as of the date of this document and except as otherwise required by federal securities law, Bristol-Myers Squibb undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise.

References


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#FDA approves $BMY therapy for certain pediatric patients with a type of acute lymphoblastic leukemia.