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Bristol-Myers Squibb's Sprycel® tablets now approved for pediatric patients

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Bristol-Myers Squibb Company has 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.

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).

Jeffrey Jackson, development lead, hematology, Bristol-Myers Squibb said, "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. 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."

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.

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). 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.

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.

Stephen Hunger, lead study author, chief of the division of oncology and director of the Center for Childhood Cancer Research at Children's Hospital of Philadelphia said, "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. 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."

Acute lymphoblastic leukemia is characterized by chromosomal abnormalities and genetic alterations involved in the differentiation and proliferation of lymphoid precursor cells.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.

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.

Vickie Buenger, president of the Coalition Against Childhood Cancer (CAC2) said, "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. The availability of another option is a welcome step forward for those affected by this disease."

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